2021 SAPA Annual Conference

Building a Healthier Future

Friday & Saturday
October 1 & 2, 2021
Virtual Conference

This year’s annual conference is co-organized with the
SAPA-DC Chapter

https://sapaweb.org
Greeting Message from the SAPA President

Dear SAPA members and friends,

On behalf of the Sino-American Pharmaceutical Professionals Association (SAPA), I cordially invite you to participate in the 2021 SAPA Annual Conference, to be held online due to the continued COVID-19 pandemic situation using Zoom webinar format from October 1 to 2, 2021.

The SAPA Annual Conference is a great platform for participants to share knowledge, wisdom, and viewpoints on important issues and current trends in academic research and pharma and biotech industries. Our events feature presentations and panel discussions by distinguished speakers and panelists from academia, industry, and regulatory authorities, to provide opportunities for scientific exchange, public health education, networking, career development, and business collaborations. Prior to pandemic this flagship event was usually held at the DoubleTree by Hilton Hotel and Conference Center, Somerset, New Jersey in the past several years, and each year attracted over 1,000 attendees. Due to continued pandemic situation and to ensure the safety of our speakers and participants, we have decided to host this year’s annual conference via virtual format again. Building on the past success and the convenience of the online event we got distinguished speakers and participants all over the world without geological restrictions.

The theme of this year's annual conference is “Building a Healthier Future”. This does not only showcase the ambition and mission of academic research, pharma and biotech industry, but also reflect our individual desire and organizational direction to further develop a stronger SAPA.

We are very grateful to have the team from SAPA-DC under the leadership of Charles Li to join force and actively participate this year's annual conference planning, a great example towards greater collaboration and realize our dream of OneSAPA.

This year's conference will cover diverse topics including the following:
- Plenary sessions featuring distinguished scholars and leaders to showcase the latest trend of the pharma development;
- Legal and Regulatory Issues, Challenges, and Opportunities in the Era of COVID-19;
- Public Health Challenges and Implications;
- Career Development Spotlight: “BE ON!”
- Frontiers in Drug Discovery and Development: From Academia to Industry;
- Healthcare Investment Trend and Transformative Deal Cases;
- Cross the Finish Line: Multiple Team Efforts in Drug Development at Clinical Stage;
- Challenges and Opportunities in Developing New Drugs and Treatment Modalities in CMC;
- Update and Advancement in Precision Medicine, Clinical Diagnostics and Medical Device.
It has been my honor and privilege to serve as the SAPA President in the past year. It was an awesome duty and responsibility, and it was also a great learning opportunity for me to have a much deeper understanding and appreciation of our beloved organization. I am incredibly grateful for the dedication, devotion, hard-work, guidance, and friendship of our leadership team and all the volunteers. Specifically, I would like to thank Dr. Baoguo Huang who has led the Board of Director and provided the much-needed guidance along the way, to Dr. Xiaodong Chen and Dr. Wansheng Jerry Liu from the SAPA President Office for your unforgettable trust and colleagueship, to all the Chapter Presidents for your close collaboration, to Dr. Xiucui and Dr. Tony Tong to step up and serve on the newly re-activated Advisory Committee, to all the Event Team Leaders, and to all the volunteers who had spent countless hours to make this another successful year during a very challenging climate. I also want to take this opportunity to thank all the strategic partners and corporate sponsors for your continued engagement and support along the way. To all the members and friends, thank you for being in this valuable community, and yes we can and will make it stronger.

Looking back, it has been a difficult year. The pandemic is not over yet, but we continued to push forward despite of the incredible challenges. What we have achieved didn’t come easily, but we had made substantial progresses. Not only we had hosted many impactful events, but also made transformative changes to the way we work to make it more efficient and effective. This is an important mindset and cultural shift to make our organization healthier and sustainable for years to come.

SAPA is quite unique and dear to many of us. With nearly 30 years of illustrious history, as an all-volunteer professional organization it has established itself as a trusted platform for many and continue to provide numerous opportunities for pharmaceutical professionals in different generations. Its impact is far beyond than many can imagine. We should be very proud on what we do.

Looking forward, I am confident and hopeful to see a much brighter future of SAPA under the new leadership, and I call you all to be part of it to make our dreams come true.

Together we can build a healthier tomorrow, for our profession and for our organization, also for each and every one of ourselves. I am looking forward to seeing you all virtually at the SAPA Annual Conference.

John Sun, PhD, MBA
SAPA President and 2021 SAPA Annual Conference Chair
Global Program Lead, Global Development Operations, Novartis
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# Program at a Glance

## Friday, October 1, 2021

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<tr>
<th>Time</th>
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<tr>
<td>1:00 pm – 3:05 pm</td>
<td>Plenary Session 1 (P1): <strong>Beyond the Trend and Landscape of New Drug Development: Breakthrough Discoveries and Technologies</strong></td>
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<td>3:05 pm – 4:00 pm</td>
<td>Sponsor Booths and Virtual Career Fair</td>
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<td>4:00 pm – 5:35 pm</td>
<td>Parallel Session A: <strong>Legal and Regulatory Issues, Challenges, and Opportunities in the Era of COVID-19</strong></td>
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<td>4:00 pm – 5:35 pm</td>
<td>Parallel Session B: <strong>Public Health Challenges and Implications</strong></td>
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<td>4:00 pm – 5:30 pm</td>
<td>Parallel Session C: <strong>Career Development Spotlight: “BE ON!”</strong></td>
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<td>9:00 pm – 10:00 pm</td>
<td>Parallel Session D: <strong>Virtual Reception and Happy Hour</strong></td>
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<td>9:00 am – 12:30 pm</td>
<td>Plenary Session 2 (P2): <strong>Collaborate and Innovate to Accelerate Development Process</strong></td>
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<td>12:30 pm – 1:30 pm</td>
<td>Sponsor Booths and Virtual Career Fair; Lunch and Learn</td>
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<td>1:30 pm – 5:00 pm</td>
<td>Parallel Session F: <strong>Frontiers in Drug Discovery and Development: From Academia to Industry</strong></td>
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<td>1:30 pm – 5:00 pm</td>
<td>Parallel Session G: <strong>Healthcare Investment Trends and Transformative Deal Cases</strong></td>
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<td>1:30 pm – 5:00 pm</td>
<td>Parallel Session H: <strong>Clinical Development, Data Sciences and Regulatory Affairs - Cross the Finish Line: Multiple Team Efforts in Drug Development at the Clinical Stage</strong></td>
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<tr>
<td>1:30 pm – 5:00 pm</td>
<td>Parallel Session I: <strong>Challenges and Opportunities in Developing New Drugs and Treatment Modalities in CMC</strong></td>
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<td>1:30 pm – 5:00 pm</td>
<td>Parallel Session J: <strong>Update and Advancement in Precision Medicine, Clinical Diagnostics and Medical Devices</strong></td>
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<td>5:00 pm – 6:00 pm</td>
<td>Parallel Session K: <strong>Interactive Network Breakout Sessions</strong></td>
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About SAPA

SAPA Mission

As a global organization, SAPA’s mission is:

- To promote the advancement of pharmaceutical science and biotechnology;
- To contribute to public health education;
- To promote entrepreneurship, healthcare investment and business cooperation;
- To foster the career growth of pharmaceutical professionals.

Introduction to SAPA

SAPA was founded in 1993 in the US as a non-profit organization and since then has grown rapidly and become one of the most active and well-recognized professional organizations in the US. SAPA is headquartered in the Greater New York area (NJ/NY/CT) with five US regional chapters (SAPA-NE in New England, SAPA-GP in Greater Philadelphia, SAPA-CT in Connecticut, SAPA-DC in Greater Washington DC area, and SAPA-MW in Midwest area), and one chapter in China. SAPA members are engaged in drug discovery, pre-clinical & clinical development, manufacturing, regulation, marketing, and distribution of pharmaceuticals and biotech therapeutic products. To fulfill its missions, each year SAPA and its regional chapters organize and sponsor many events including annual conferences, scientific symposia, seminars, workshops, and social activities both in the US and China. These events have been supported and sponsored by many organizations, including major pharmaceutical, biotech and CRO companies as well as many Bio-Parks and Development Zones in China.

SAPA Organization Structure

- **SAPA Board of Directors (BD):** BD Chair and BD Members including SAPA President and Immediate-Past-President. Setting up policies and regulations, nominating and approving SAPA officers, and guiding SAPA direction.

- **SAPA Executive Council (EC):** President, President-Elect, Immediate-Past-President, Vice Presidents, EC Members, and Standing Department Heads. Conducting SAPA daily operations, organizing SAPA events and activities.

- **SAPA Advisory Committee (AC):** Chaired by SAPA Immediate-Past-President and over 20 AC Members. Advising, guiding and supporting.

SAPA Locations

- **SAPA Headquarters:** New Jersey, USA
- **SAPA-CT (Connecticut Chapter):** Connecticut, USA
- **SAPA-DC (Greater Washington DC Chapter):** Greater Washington DC areas, USA
- **SAPA-GP (Greater Philadelphia Chapter):** Philadelphia and other Pennsylvania areas, USA
- **SAPA-MW (Mid-West Chapter):** Illinois and Indiana areas, USA
- **SAPA-NE (New England Chapter):** Boston and New England areas, USA
- **SAPA-China:** China

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### Executive Council (EC) Members (2020 – 2021)

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<td>Jiangchao Chen, PhD</td>
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<td>Long Chen, PhD</td>
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<td>Rong Cheng, MBA</td>
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<td>Yvonne Cheng</td>
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<td>Haifeng Cui, PhD</td>
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<td>Han Dai, PhD</td>
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<td>Wei Ding, PhD</td>
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<td>Helena Haixia Feng*</td>
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<td>Chenchao Gao, PhD</td>
<td>EC Member</td>
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<tr>
<td>Yong Guo, PhD, MBA*</td>
<td>EC Member</td>
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*Department Directors*

### Board of Directors (2019 – 2021)

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<td>Min Chen, PhD</td>
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<td>Weiguai Dai, PhD</td>
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<td>Amanda Fu, PhD</td>
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<td>Handan He, PhD</td>
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<td>Jun-Yan Hong, PhD</td>
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<td>Jiangbin (John) Hu, PhD</td>
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*Department Directors*
Advisory Committee Members (2021 – 2023)

Co-Chairs of the Advisory Committee: Xiu-Cai Liu, PhD, and Wei-Qin (Tony) Tong, PhD

Harry Chen, MD, PhD  Laura Hong, PhD  Mark Lin, PhD  Jingsong Wang, PhD
Li Chen, PhD  Junning Lee, PhD  Puchun Liu, PhD  Shifeng Wei, PhD
Jasmine Cui, PhD  Jian Li, PhD  Bingli Ma, MD  Li Yan, MD, PhD
Xin Du, PhD  Kechun Li, MBA  Young Shen, PhD  Yan Xia, PhD
Sean Fu, PhD,MBA  Xiaoling Li, PhD  Bin Shi, PhD  Lihu Yang, PhD
Daming Gou, PhD  Bo Liang, PhD, MBA  Li Shi, PhD  Dan Zhang, PhD
Frank Gan, PharmD  Guiqing Liang, PhD  Jin Wang, PhD  Zhongda Zhang, PhD

Former SAPA Presidents

Xiucai Liu, PhD  1993-94  Hancheng Zhang, PhD  2007-08
Guohua Zhang, PhD  1994-95  Mingde Xia, PhD  2008-09
Jun-Yan Hong, PhD  1995-96  Jisong Cui, PhD  2009-10
Bill S. Wei, PhD  1996-97  Jianji Wang, PhD  2010-11
Puchun Liu, PhD  1997-98  Baoguo Huang, PhD  2011-12
Junning Lee, PhD  1998-99  Handan He, PhD  2012-13
Lihu Yang, PhD  1999-00  Jiwen Chen, PhD  2013-14
Rick Z-X Xu, PhD  2000-01  Ning Yan, PhD  2014-15
Li Chen, PhD  2001-02  Weiguao Dai, PhD  2015-16
Jianzhong Guo, PhD  2002-03  Lei Tang, PhD  2016-17
Min Li, PhD  2003-04  Jian Liu, PhD  2017-18
John J. Hu, PhD  2004-05  Xiaole Shen, PhD  2018-19
Yusheng Wu, PhD  2005-06  Wansheng Jerry Liu, JD, PhD  2019-20
Charles Ying Wang, PhD  2006-07
## 2021 SAPA Annual Conference Organizing Committee

Conference Chair: John Sun, PhD, MBA  
Conference Co-Chair: Xiaodong Chen, PhD

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<td>Yunqi An, MS</td>
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<td>Charles Changhui Li, MS, MBA</td>
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<td>Jiajun Mei, PhD</td>
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<td>Yuting Pan, MS</td>
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Plenary Session 1 (P1): Beyond the Trend and Landscape of New Drug Development: Breakthrough Discoveries and Technologies

Session Moderators: John Sun, PhD, MBA, Xiaodong Chen, PhD, and Charles Li, MBA, MS

At this plenary session we will hear from world-renowned and authoritative scholars and leaders on the evolving landscape for new drug development and the trends of pharma R&D, and learn how to build a more diverse, equitable and inclusive future where everyone belongs. We will also learn the new advancement of the cutting-edge and innovative technology platforms into therapeutic applications across multiple areas.

1:00 – 1:05 pm
Opening Remarks
John Sun, PhD, MBA, SAPA President 2020-2021, Global Program Lead, Novartis

1:05 – 1:35 pm
Shishir Gadam, PhD, Vice President, Cell Therapy Manufacturing Science and Technology, Bristol Myers Squibb

Worldwide, approximately 720,000 people die from blood cancer every year, accounting for more than 7% of cancer deaths. Survival rates for most hematologic malignancies have improved overtime, due to the introduction of new and more effective treatments including autologous cell therapy treatments. Cell therapies are a relatively new type of biotherapeutic in the marketplace. As such, their commercial manufacture poses unique challenges in biomannufacturing that necessitate the need for new thinking and innovative solutions. One such unique challenge that cell therapies face is the variability in donated cells that form the starting material of the therapy; this greatly influences how one approaches the commercial manufacturing design and control strategy. This talk will share learnings related to the Chemistry, Manufacturing and Control (CMC) strategy from the first-generation autologous CAR-T and reflect on the aspirations of the future cell therapy manufacturing platforms.

1:35 – 2:05 pm
Carpe Diem: If Not Now, When? - Bio/Pharma and CROs Can Build a More Diverse, Equitable and Inclusive Future Where Everyone Belongs
Alberto Grignolo, PhD, Corporate Vice President, Parexel

Diversity, Equity and Inclusion are now in the mainstream of corporate consciousness but across Industries DEI inequities still abound. Pharma and Biotech have taken affirming public positions on DEI; in a number
of biopharma companies, women are better represented at all levels compared to other industries. But more work is needed to achieve greater parity. The pandemic has undeniably had a negative impact on many aspects of life, but it has also turbocharged the journey towards better health equity with more intentional and thoughtful listening to the voice of the patient and through more diverse and more decentralized clinical trials. In this moment in its history, the industry needs a highly motivated and productive workforce; this attitude can be fostered by work environments that promote diversity, equity, inclusiveness and true belonging. The mission of BioPharma provides powerful reasons to be proud to work here; in turn, the industry must ensure that ALL its workers feel valued, respected and supported. And we must never forget that the end goal of our efforts is benefit to the patient. Working together as allies in a diverse, equitable and inclusive environment will help ensure that this benefit is delivered.

2:05 – 2:35 pm
**SAPA Distinguished Achievement Awardee**
**The Evolving Landscape for New Drug Development: Trends in Pharmaceutical R&D**
Kenneth Kaitin, PhD, MS, Professor and Senior Fellow, Center for the Study of Drug Development, Tufts University School of Medicine

Over the past two decades, there has been an explosion in our understanding of the pathobiology and genetic determinants of many diseases for which there are currently few or no adequate treatments available. This growth in scientific knowledge has fueled a marked shift in the pharmaceutical industry toward the development of precision medicines, targeted therapies, and drugs to treat rare genetic disorders and other orphan diseases. Yet, the development of new pharmaceutical medicines remains a slow, expensive and risky process, and the shift to narrow-indication drugs comes with certain challenges.

This presentation will address the following:
- What are the current metrics on the time, cost and risk of new drug development?
- What are the factors that are leading companies to focus on narrow-indication therapies?
- What challenges are associated with this shift in focus?

2:35 – 3:05 pm
**SAPA Distinguished Achievement Awardee**
**Drug Discovery Innovation in 2021 and beyond: Speed to Clinic**
Litao Zhang, PhD, Global Head of Discovery Technology and Molecular pharmacology, Discovery Sciences, Janssen Research and Development

This talk will address the challenges in drug discovery and emerging innovative technology solutions that are being implemented across the industry. We will present cutting edge technology solutions and selected case studies to highlight the remarkable progress made by drug hunters to accelerate ideas to the clinic. We will also include transformational modalities to tackle undruggable targets to fuel the drug discovery pipelines.

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**Friday, October 1, 2021, 3:05 pm – 4:00 pm**

**Virtual Career Fair (CF): Sponsor Booths and Virtual Career Fair**

**Session Moderators:** Jack Wu, PhD, Yongle Pang, PhD, Tuochuan Dong, PhD, Aming Zhang, PhD, Stephen Xue, MS, Hongye Wei, MS, Zheng Chen, PhD, Jiajun Mei, PhD and Jian Wu, PhD

Many sponsors had hoped to meet the conference attendees in person at the Annual Conference when we originally planned to host this year’s Annual Conference at the DoubleTree Conference Center. Although we cannot do it in person this time, we are planning a series of virtual rooms to provide direct and interactive opportunities for the conference attendees to learn the newest developments and advancements of our sponsors. Several sponsors are seeking talents to join their teams so this is a great opportunity for the job candidates to find the next growth opportunity. Take a break between the sessions and visit these virtual rooms; serendipitous moments are waiting for you. We also encourage you to visit the SAPA Career Center for newly posted job opportunities:

[https://sapaweb.org/career-center/](https://sapaweb.org/career-center/)
3:05 – 4:00 pm

**Virtual Career Fair Main Lobby**

[Virtual Career Fair Main Lobby](https://us02web.zoom.us/j/84037016874?pwd=Yk92dHBlRnFCdW5uOS9tLmZXY8zUT09)

Meeting ID: 840 3701 6874
Passcode: sapa2021

**Aleon Pharma**

[https://us02web.zoom.us/j/9738508000?pwd=MmQ5NjdadWZRL0l0YnQ1OT9E9PRClVQT09](https://us02web.zoom.us/j/9738508000?pwd=MmQ5NjdadWZRL0l0YnQ1OT9E9PRClVQT09)

Meeting ID: 973 850 8000
Passcode: api5892

**Aucta Pharma**

[https://zoom.us/j/99344679401?pwd=eHF2QlhMME0rZkcxWmxGdWdFbnVLZz09](https://zoom.us/j/99344679401?pwd=eHF2QlhMME0rZkcxWmxGdWdFbnVLZz09)

**GemPharmatech LLC**

[https://us06web.zoom.us/j/86091997667](https://us06web.zoom.us/j/86091997667)

**GenScript**

[https://zoom.us/j/91856127103](https://zoom.us/j/91856127103)

**Hengrui**

3:05 - 3:30 pm

[https://us06web.zoom.us/j/3393054035?pwd=aGRJZ3RUTnBwY2qweFF1LzFrdFZz09](https://us06web.zoom.us/j/3393054035?pwd=aGRJZ3RUTnBwY2qweFF1LzFrdFZz09)

Meeting ID: 339 305 4035
Passcode: 398592

3:30 - 4:00 pm

[https://us06web.zoom.us/j/3393054035?pwd=aGRJZ3RUTnBwY2qweFF1LzFrdFZz09](https://us06web.zoom.us/j/3393054035?pwd=aGRJZ3RUTnBwY2qweFF1LzFrdFZz09)

Meeting ID: 339 305 4035
Passcode: 398592

4:00 - 4:30 pm

[https://us06web.zoom.us/j/3393054035?pwd=aGRJZ3RUTnBwY2qweFF1LzFrdFZz09](https://us06web.zoom.us/j/3393054035?pwd=aGRJZ3RUTnBwY2qweFF1LzFrdFZz09)

Meeting ID: 339 305 4035
Passcode: 398592

4:30 - 5:00 pm

[https://us06web.zoom.us/j/83073879855?pwd=bGY4blNnY1RWYk9vZCtGSUhva1ROZz09](https://us06web.zoom.us/j/83073879855?pwd=bGY4blNnY1RWYk9vZCtGSUhva1ROZz09)

Meeting ID: 830 7387 9855
Passcode: 492999

**Insilico Medicine**

[https://insilico.zoom.us/j/84680359665](https://insilico.zoom.us/j/84680359665)

**J-star**

[https://us02web.zoom.us/j/81984325648?pwd=V0VOOURZU05kRTITV1VMWVVc4dz09](https://us02web.zoom.us/j/81984325648?pwd=V0VOOURZU05kRTITV1VMWVVc4dz09)

Meeting ID: 819 8432 5648
Passcode: 316621
Session A: Legal and Regulatory Issues, Challenges, and Opportunities in the Era of COVID-19

Session Moderators: Wansheng Jerry Liu, JD, PhD, Li Feng, JD, PhD, and Xin Tao, JD, MS

Health care providers and life sciences companies, as well as government agencies, have been on the front lines fighting the pandemic. The pandemic has brought many challenges as well as opportunities. This panel from in-house legal departments and law firms will discuss practical challenges involving policy changes and applications at the practical and operational levels, opportunities such as new practice areas and new remote jobs, FDA regulatory issues in vaccine approvals, as well as legal issues relating to "returning to work"--in particular, legal considerations on vaccination mandates, disclosure requirements, and employer/employee’s rights and obligations, etc.--from health law and employment law perspectives.

4:00 – 4:05 pm  Opening Remarks
Wansheng Jerry Liu, JD, PhD, Partner and Chair of China Practice, Fox Rothschild LLP, President of SAPA, 2019-2020

4:05 – 4:25 pm  FDA Regulatory Issues in Fighting COVID-19
Michael N. Druckman, JD, Partner, Global Regulatory, Hogan Lovells LLP

In this session, former FDA lawyer Mike Druckman will discuss FDA regulatory and legal issues in fighting COVID-19, such as vaccine approval.

4:25 – 4:45 pm  COVID Policy Changes, Telecommuting and Communications in the Pandemic
Joanna Wu, PhD, JD, General Counsel, Biotech incubator

The pandemic has brought many challenges as well as opportunities. In terms of substantive law, in-house counsel needs to be updated continuously about policy changes and their interpretations to be able to advise their clients at the practical and operational level. In terms of practice, telecommuting has become the norm so time management as well as effectiveness of communication has become increasingly challenging. Both challenges also present opportunities - new practice areas, new remote jobs, etc.

4:45 – 5:05 pm  Practical Challenges and Strategies in Managing a Start-up in a Red-State During COVID
Jingxi Chu, JD, MS, Deputy General Counsel, Nanova, Inc.

Though many COVID control and prevention policies may pass legal muster, adapting a start-up company’s daily practice to them involves many compromises, frequent revisits, and lots of employee education.
Legal Considerations for the Return to Work
Elizabeth Litten, JD, Chief Privacy & HIPAA Compliance Officer, Corporate and Office of General Counsel Departments & Partner of Fox Rothschild LLP
Kenneth A. Rosenberg, JD, Partner, Labor and Employment, Fox Rothschild LLP

Despite the rise of virus variants that have extended the COVID-19 pandemic, a growing number of businesses nationwide are seeking to bring employees back to the workplace. Employers cite the need to service increased business activity, improve customer service and responsiveness, enhance employee supervision, rebuild corporate culture and values, boost creativity and morale, and address operational difficulties caused by remote work. However, their decision has been complicated by the rapidly spreading Delta variant, vaccine resistance and employees’ misgivings about returning to the office due to safety concerns and the convenience of working from home. Employers navigating this new reality face a variety of thorny questions and legal implications. Can employers ask workers about their vaccination status? Can they require employees to get vaccinated? What can they do if workers refuse to get the COVID-19 vaccine or balk at returning to the office? This program will address these and many other pressing legal issues facing employers today.

Friday, October 1, 2021, 4:00 pm – 5:35 pm

Session B: Public Health Challenges and Implications

Session Moderators: Yong Guo, PhD, MBA

The world is facing a challenging public health crisis brought about by COVID-19 pandemic. In addition to understanding the medical issues related to COVID-19, it is extremely important for the public to have a clear understanding of the public health issues. Public health and health policy experts will discuss issues and policies related to the current pandemic and as well as other public health concerns.

4:00 – 4:05 pm Opening Remarks
Yong Guo, PhD, MBA, Professor of Pharmaceutical Science, School of Pharmacy and Health Sciences, Fairleigh Dickinson University

4:05 – 4:35 pm COVID-19 Vaccines as a Public Health Issue
Margaret Fisher, MD, Special Advisor to the Commissioner of Health, New Jersey Department of Health

The COVID-19 pandemic is the pandemic of a lifetime for most of us. The pandemic has identified both strengths and weaknesses in the public health systems. Development of vaccines designed to finally control the pandemic was an epic achievement. Getting the vaccines delivered to people used every public health strategy imaginable. This presentation will review some of the challenges and successes from the viewpoint of a pediatric infectious disease specialist who joined the New Jersey Department of Health in October 2020.

4:35 – 5:05 pm The Ripple Effect: COVID-19’s Impact on Public Health Policy
Manan Shah, MBA, Vice President, Global Public Affairs | Assistant Professor, Public Health & Policy, LEO Pharma | Fairleigh Dickinson University

This presentation will look at health policy in the time of a global pandemic. The speaker will provide insights from both the pharmaceutical sector as well as from a public health perspective.

5:05 – 5:35 pm Professional Preparation in the Time of COVID: Pedagogical Challenges and Opportunities
Bojana Berić-Stojšić, MD, PhD, MA, Associate Professor and Program Director, MPH Program, School of Pharmacy & Health Sciences, Fairleigh Dickinson University

The purpose of this presentation is to review the current situation of professional preparation in public health, health promotion and education. How do we prepare our students for effective and meaningful practice of today and tomorrow? The discussion will focus on the barriers and opportunities that current situation presents to academic preparation; on the direction that we need to take and what resources are available to us at the moment.
At the completion of the presentation, participants will be able to:
1. Define public health and list reliable resources for effective teaching
2. Discuss pedagogical aspects of public health professional preparation
3. Identify challenges and opportunities to effective pedagogical practice

Friday, October 1, 2021, 4:00 pm – 5:30 pm

Session C: Career Development Spotlight: “BE ON!”

Session Moderators: John Sun, PhD, MBA and Brian Jiang, MS

4:00 – 5:30 pm

Anyone Can Learn How To “BE ON!”: Communicate, Present, Invest Yourself Like an Actor & Storyteller
Julie Campbell, MFA, Founder of Center Stage Connections

In the first 30 seconds of any interaction, people make a decision about whether they care about what you have to say and whether they will continue to listen.

Are you struggling with HOW to communicate more effectively with colleagues, clients, or management? You are invited to this spotlight session, with Julie Campbell of Center Stage Connections, where you will learn how to think of yourself as an actor on the business stage. In this interactive training, Julie shares tips, tools, and techniques from her 30+ years as a professional actor and storyteller. Come away with concrete strategies for more confidence, stronger presence and greater clarity in phone calls, meetings, and presentations. Choose to be wholly invested in your message and actions, and BE ON!

Friday, October 1, 2021, 9:00 pm – 10:00 pm

Session D: Virtual Job Fairs

Although we cannot hold the face-to-face reception because of the pandemic, networking happens everywhere! Grab your favorite drink and listen to our title sponsors introduce their latest technology and their job opportunities. Both of them are hiring, particularly in New Jersey. Don’t miss the happy hour!

9:00 – 10:00 pm

Virtual Room #D1: BeiGene 2021 SAPA Annual Conference Virtual Job Fair

Beigene is a biopharmaceutical company focused on developing molecularly targeted and immuno-oncology drug candidates for the treatment of cancer.

https://beigene.zoom.com/j/98041417186?pwd=WFRmemZoSsNkKzRtdH9p3UTNKh2Uudz09

- Meeting ID: 980 4141 7186
- Passcode: 66927329
9:00 – 10:00 pm
Virtual Room #D2: Porton 2021 SAPA Annual Conference
Virtual Job Fair

Porton Pharma Solutions Ltd. is a leading pharmaceutical CDMO in China, providing global pharmaceutical companies and drug institutions with customized R&D.
http://www.portonpharma.com

https://zoom.us/j/97080360298?pwd=NklLSmRwSXNBT1lhVW9NcFVqW
W5zUT09

- Meeting ID: 970 8036 0298
- Passcode: 886217
Plenary Session 2 (P2): Collaborate and Innovate to Accelerate Development Process

Session Moderators: John Sun, PhD, MBA, Xiaodong Chen, PhD, and Charles Li, MBA, MS

The unprecedented COVID-19 pandemic presented devastating human and economic costs since last year, yet it presented a rare opportunity for us to challenge the traditional ways we develop drugs. The new wave of digital disruption in healthcare also opened the new and exciting fields and forced us to think differently on modernization and transformation on how we conduct R&D in the future; it will be more data-driven and patient centered. Cross border and cross industry collaboration presented new prospects to accelerate the drug development process. After hearing the successful stories of our title sponsors, we are delighted to invite a panel of chief executives to share their views and predictions through their leadership lenses.

Other than the drug development process, this is also a good opportunity to discuss how to develop SAPA as an organization to a brighter and stronger future, acknowledge the contribution of our volunteers, and also unveil the new SAPA leadership team for the coming year.

9:00 – 9:10 am Opening Remarks
Xiaodong Chen, PhD, SAPA President, 2021-2022, Director of CMC Operations, Roivant Sciences

9:10 – 9:40 am A New Era for Biopharmaceutical Industry
Lai Wang, PhD, Global Head of R&D, BeiGene

9:40 – 10:10 am Contract Organizations: from Outsourcing Partner to Infrastructure in the Industry 4.0 Era
Nianfeng (Oliver) Ju, MBA, Chairman & CEO, Board office of Porton Pharma Solutions Ltd.

The presentation will discuss the history and future trends of the roles and key success factors of contract organizations in the evolving new ecosystem of the global pharmaceutical industry driven by technology and economics.

10:10 – 11:10 am CXO Forum: Through the Leadership Lens
John Sun, PhD, MBA, SAPA President 2020-2021, Global Program Lead, Novartis
Yiming Zhao, PhD, Staff Scientist, Regeneron Pharmaceuticals

Panelists:
• Dalvir Gill, PhD, CEO, TransCelerate Biopharma Inc.
• John Tsai, MD, Head of Global Drug Development and CMO, Novartis
• Scott Filosi, CEO of Hengrui USA & Hengrui Europe
• Jay Mei, PhD, Founder, Chairman & CEO, Antengene Corporation

The SAPA CXO Forum is a distinguished panel discussion as part of the planetary session “Collaborate and Innovate to Accelerate Development Process” on Saturday. It is a unique platform for idea exchange and deliberation around current and future challenges and opportunities in the pharmaceutical industry. This round table discussion featured renowned panelists who will discuss industry trends and provide insights into future growth and development. It will also provide strategy as portfolios continue to advance and evolve. Topics will include entrepreneurship, innovation, healthcare policy, regulatory reform,
financing in US and China, current challenges in recruitment and talent development. You will hear live stories, observations, and solutions including career advice from these successful and influential global chief executives and leaders.

11:10 am – 12:30 pm

**SAPA Membership Update: Service Awards and Election Results**

Yong Guo, PhD, MBA, Professor of Pharmaceutical Science, Fairleigh Dickinson University

Baoguo Huang, PhD, MBA, SAPA Chairman of the Board of Directors, Managing Director, SEQENS North America

Charles Li, MBA, MS, SAPA-DC President 2021-2023, VP of Business Development, Pharmaron Clinical - CR Medicon

Guiqing Liang, PhD, SAPA-NE President, Director and Fellow, DMPK, Vertex Pharmaceuticals

Xiaoyong Yang, PhD, SAPA-CT President, Professor at Yale University School of Medicine

John Sun, PhD, MBA, SAPA President, 2020-2021, Global Program Lead, Global Development Operations, Novartis

Xiaodong Chen, PhD, SAPA President, 2021-2022, Director of CMC Operations, Roivant Sciences

The SAPA presidents and senior leaders will present important update and report to the SAPA membership and community:

- Present the awardee of the SAPA 2021 Scholarship & Excellence in Education for Life Sciences.
- Showcase and highlight of Chapter events.
- Celebrate the volunteerism and present SAPA Service Excellence Awards and SAPA Special Recognition Awards.
- Share the main focus and plan for the coming year.
- Announce election results for the newly elected SAPA President-Elect and members of SAPA Executive Council.

Saturday, October 2, 2021, 12:30 pm – 1:30 pm

**Virtual Career Fair (CF): Sponsor Booths and Virtual Career Fair**

**Session Moderators:** Jack Wu, PhD, Yongle Pang, PhD, Tuochuan Dong, PhD, Aming Zhang, PhD, Stephen Xue, MS, Hongye Wei, MS, Zheng Chen, PhD, Jiajun Mei, PhD, and Jian Wu, PhD

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12:30 – 1:30 pm

**Virtual Career Fair Main Lobby**

[https://us02web.zoom.us/j/81406747748?pwd=T0JmYXJuUTBUUTJ1Q0xVQ0N3V0TUhDQT09](https://us02web.zoom.us/j/81406747748?pwd=T0JmYXJuUTBUUTJ1Q0xVQ0N3V0TUhDQT09)
Meeting ID: 814 0674 7748
Passcode: sapa2021

Aleon Pharma
https://us02web.zoom.us/j/9738508000?pwd=MmQ5NjdadWZRL0l0YnQ1Q9E9PRCIvQ0T9
Meeting ID: 973 850 8000
Passcode: api5892

Aucta Pharma
https://zoom.us/j/99344679401?pwd=eHF2QlhmMME0rZkcxWmxGdWfBNzLZz09

GemPharmatech LLC
https://us06web.zoom.us/j/98091997667

Genscript
https://zoom.us/j/91856127103

Insilico Medicine
https://insilico.zoom.us/j/84680359665

J-star
https://us02web.zoom.us/j/88063015428?pwd=cjBXQXFJODZpY1FVRkx4TDEvVlZ4QT09
Meeting ID: 880 6301 5428
Passcode: 316621

Pharmaron Clinical (CR Medicon)
https://us06web.zoom.us/j/86445632659?pwd=YWlICTUNybmRqVDh0REcxa1JKQmFXQT09
Meeting ID: 864 4563 2659
Passcode: 048097

Sino-Biologics
https://us06web.zoom.us/j/6373756501?pwd=UW0wUEcwZmM1BzUZUXUEowVHIRUT09
Meeting ID: 637 375 6501
Passcode: 3zxqGj

12:30 – 1:30 pm

Lunch and Learn

Preventing Bottlenecks in Therapeutic Antibody Discovery with Humanized Immunoglobulin Mice and Single-Cell Screening Technology
Qingcong Lin, PhD, CEO, Biocytogen Boston Corporation

Join from here:
https://biocytogen.zoom.us/webinar/register/WN_qfEr4JLAS8ujMi9ljFpzIA

The most favorable therapeutic antibodies will exhibit excellent developability properties and low immunogenicity. Human antibodies that are generated from immunoglobulin transgenic mice undergo in vivo natural selection, and the antibody-secreting B cells progress through affinity maturation. These properties have been proven to be clinically beneficial, as an increasing number of FDA-approved antibody therapeutics have been derived from humanized antibody mice.

Biocytogen’s RenMab mouse platform was engineered by our gene editing experts to contain the full complement of human V(D) and J genes in situ, including the surrounding non-coding regions, making the platform the most human-like to date. RenMab antibodies carry a full human heavy chain and kappa light chain repertoire and have been proven to be a robust human antibody discovery engine.
second-generation model, RenLite, carries the full heavy chain repertoire paired with a common light chain gene, which is specifically designed to eliminate the heavy and light chain mispairing that commonly occurs during bispecific/multispecific antibody discovery. RenMab and RenLite mice generate robust immune responses and produce antibodies with binding affinity in the subnanomolar range. Both RenMab and RenLite mice can be further genetically modified by knocking out specific target genes to break immune tolerance and elicit strong responses for challenging or highly homologous targets. Along with the establishment of an extensive library of RenMice for therapeutic antibody discovery, Biocytogen has developed an integrated service platform to discover and validate new therapeutics using advanced single-cell screening technology and humanized mouse models for therapeutic targets.

Saturday, October 2, 2021, 1:30 pm – 5:00 pm

Session F: Frontiers in Drug Discovery and Development: From Academia to Industry

Session Moderators: Dexi Yang, PhD, Jian Wu, PhD and Deyi Zhang, PhD

The COVID-19 pandemic is reshaping the frontiers of drug discovery and development. In this session, we invited speakers from both academia and biopharma to talk about the most advanced technologies for discovering future therapeutic agents. New modalities such as ADC and PROTAC showing great promise in clinical development on challenging targets will be discussed. In addition, directed evolution applied in the fast development of monopiravir and islatravir (antiviral drugs for Covid-19 and HIV) will also be covered. Furthermore, drug discovery practices in the academia that has always been the birthplace of new technologies, will also be included.

1:30 – 1:35 pm  Opening Remarks
Dexi Yang, PhD, Associate Principal Scientist, Merck & Co., Inc.

1:35 – 2:15 pm  Accelerating Drug Discovery and Development through Innovation in Chemistry
Jingjun Yin, PhD, Executive Director, Process Research & Development, Merck & Co., Inc.

"Medicine is for the patient," and it's increasingly important to bring medicine to the patient in need faster. At Merck, Process Research & Development plays a critical role in accelerating the drug discovery and development timeline through innovation in chemistry. As demonstrated in the development of HCV inhibitors elbasvir and ruzasvir, we quickly discovered a novel Pd-catalyzed asymmetric C-N cyclization reaction and developed the manufacturing process to enable the highly accelerated program timeline. Other examples of innovation on critical path featuring biocatalysis and photo-flow will also be briefly discussed.

2:15 – 2:55 pm  Synthesis and Evaluation of Arimetamycin A and Novel Anthracycline Chemotherapeutics
Steven Townsend, PhD, Associate Professor of Chemistry, Vanderbilt University

This presentation will discuss the synthesis of novel anthracycline hybrids - with the goal of increasing cytotoxicity and lowering cardio toxicity for this class of chemotherapeutics.

2:55 – 3:10 pm  Coffee Break

Sponsor presentation by GemPharmatech
Zhiying Li, PhD, Director, Life Science and Technology, GemPharmatech
3:10 – 3:45 pm  
**Targeted Protein Degradation in Oncology and Beyond**  
Haojing Rong, PhD, Vice President, Preclinical Development, Kymera Therapeutics  

The talk will introduce Kymera, a company that is dedicated to discover and develop targeted protein degradation to transformative new medicines, and two key programs of the company: KT-474 is an IRAK4 degrader, which is currently in clinic for auto-immune indication. Another one is a potent and selective degrader of STAT3, which is a classical undruggable target with potential in both oncology and immunology indications.

3:45 – 4:20 pm  
**Targeting BCL-X L: From Small Molecule Inhibitor to Antibody-Drug Conjugate (ADC) Clinical Candidate**  
Zhi-Fu Tao, PhD, Principal Research Scientist II, Oncology Discovery, Abbvie Inc.  

BCL-X L, an anti-apoptotic member of the BCL-2 family of proteins, drives tumor survival and maintenance and thus represents a key target for cancer treatment. The discovery of generations of small molecule BCL-X L inhibitors and a BCL-X L antibody drug conjugate (ADC) clinical candidate will be discussed in this talk.

4:20 – 5:00 pm  
**Applications of PROTACs to Overcome Resistance in Targeted Therapies and Immunotherapies**  
Jin Wang, PhD, Michael E. DeBakey, M.D., Professor in Pharmacology, Department of Pharmacology and Chemical Biology at Baylor College of Medicine Campbell  

PROTACs are a novel therapeutics modality to inhibit the scaffolding functions of proteins. I will discuss our work on the first reversible covalent PROTAC targeting Bruton’s Tyrosine Kinase (BTK) (Nature Communications 2020). Serendipitously, we discovered that cyano-acrylamide-based reversible covalent chemistry can significantly enhance the intracellular accumulation and target engagement of PROTACs and developed RC-1 as a reversible covalent BTK PROTAC with a high target occupancy as its corresponding kinase inhibitor and effectiveness as a dual functional inhibitor and degrader, providing a novel mechanism-of-action for PROTACs. Additionally, I will present our recent work on a novel PROTAC to boost antitumor immunities of cancer immunotherapies. One common feature for immune checkpoint blockades (ICBs), activated cytotoxic T cells, CAR-T and CAR NK cells is that they all kill cancer cells through granule exocytosis and death ligands to activate programmed cell death. However, cancer cells that are insensitive to these programmed death mechanisms will evade killing mediated by the antitumor immunity. We developed a novel PROTAC that can synergize with anti-PD1 to trigger immunogenic cell death and significantly inhibit tumor growth in an immunotherapy insensitive B16F10 mouse melanoma mouse model.

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**Saturday, October 2, 2021, 1:30 pm – 5:00 pm**

**Session G: Healthcare Investment Trend and Transformative Deal Cases**

**Session Moderators:** Xiaodong Chen, PhD, Jack Wu, PhD, Stephen Xue, MS, and James Early

Healthcare companies around the world are witnessing a record high in healthcare funding and deal activities this year. In the first seven months of 2021, global healthcare venture funding reached $63.5 billion across 3,086 deals, according to Crunchbase. With the pandemic accelerating many aspects of the healthcare industry, investment and business development are potentially moving faster than ever before.

The SAPA Investment and Business Development session is an excellent platform for participants to hear from and connect with global pharma leaders, investors, and cutting-edge growth companies on investing and business development topics. The agenda includes featured guest speakers discussing global healthcare investment trends and transformative business development cases. Broad topics will be covered.
in a panel discussion afterwards. Come and join us to navigate the ever-shifting healthcare investment and business development landscape.

1:30 – 1:35 pm  **Opening Remarks**  
Xiaodong Chen, PhD, Director of CMC Operations, Roivant Sciences  
Jack Wu, PhD, Head of Global Business Development, Search & Evaluation, Antengene

1:35 – 2:05 pm  **Embracing the Changing World with Innovation**  
Jonathan Liu, PhD, DVM, Chief Executive, Bio-Island Initiative & Chairman of the Board, BeiGene Guangzhou Biologics, Ltd. Co.

1. Chinese biotech industry is changing rapidly. BeiGene is innovating a way to innovate.  
2. This new way of innovation addresses a flaw and a bottleneck in Biotech development in China.  
3. BeiGene Innovation Center creates an ecosystem that leads Chinese biotech transformation.

2:05 – 2:35 pm  **Immunology, Even Hotter for Business Development**  
John Wang, PhD, Head of External Innovation, Immunology, Eli Lilly

Based on various Market Research reports (e.g. Future Wise, Fortune Business Insight etc.), the global immunology market is projected to grow from $92.00 billion in 2021 to $158.69 billion in 2028 at a CAGR of 8.1% in forecast period, 2021-2028. The anti-TNF drug Humira has already made history in pharmaceutical industry regarding its usefulness in treating inflammatory and autoimmune diseases and its annual sales record. In 2020, its global sales reached $20.39 billion (Fierce Pharma). Humira (adalimumab) was actually acquired by Business Development effort. The molecule was originally developed through a joint venture between Cambridge Antibody Technology and BASF in the UK. In 2000, Abbott acquired the pharmaceutical segment of the German chemical company, BASF, for $6.9 billion. There have been a number of billion dollar deals in Immunology area recently. However, despite its success, Humira is not the answer to every inflammatory and/or autoimmune disease. The research & development activities in immunology area are very active, driven by both unmet needs and rapid progress in science and technology. Immunology Business Development and Licensing will leverage the collective efforts from industry and academic institutes to bring innovative medicines to patients, which is getting more competitive and "hotter".

2:35 – 3:05 pm  **Partnering to Speed Transformational Medicines to Patients**  
Fang Zhang, PhD, Executive Director, China Business Development, Bristol Myers Squibb

This presentation will provide an overview of BMS as a leading patient-focused biopharmaceutical company with a focus on BMS’ China ambition and how we envision to leverage external opportunities to support our aspiration in China.

3:05 – 3:15 pm  **Coffee Break**

3:15 – 3:45 pm  **Current Investment Trends between the US and China**  
Chong Xu, PhD, MBA, Partner, F-Prime Capital Partners

Key trends, challenges and opportunities in life sciences investing in the US and China.

3:45 – 4:45 pm  **Q&A and Panel Discussion**  
Moderator: James Early, Managing Partner, Tamarack Advisory

Panelists:
- John Wang, PhD, Head of External Innovation, Immunology, Eli Lilly  
- Chong Xu, PhD, MBA, Partner, F-Prime Capital Partners  
- Vincent Xiang, PhD, Founding Managing Partner, 7GBioVentures  

4:45 – 5:00 pm  **Closing Remarks**  
Stephen Xue, MS, Director of Operation, Chipscreen Bioscience (US) Ltd
Saturday, October 2, 2021, 1:30 pm – 5:00 pm

Session H: Clinical Development, Data Sciences and Regulatory Affairs - Cross the Finish Line: Multiple Team Efforts in Drug Development at Clinical Stage

Session Moderators: Jerry J. Li, PhD, Charles Li, MBA, MS, Li Wan, PhD, and Yulan Zhang, MS

Drug development process is long and costly. Very small fraction of drug candidates can make to clinical stage. Even fewer of them can achieve positive outcome in a registration clinical trial that can be filed with regulatory health authorities for approval. Stake is high. It often can make or break a company. Vigorous study design, effective communication and close collaboration are critical to bring drug to cross the finish line for patient’s treatment.

1:30 – 1:35 pm Opening Remarks
Jerry J. Li, PhD, Director, Biostatistics, Programming and Data Management (BDM), Daiichi Sankyo, Inc.

1:35 – 2:05 pm Fruition of a Vision: Clinical Development of Trastuzumab Deruxtecan (T-DXd)
Caleb Lee, MD, PhD, Senior Director, Global Oncology Clinical Development, Daiichi Sankyo

The development of a drug from IND to market typically takes 10-15 years. In 2016, Daiichi Sankyo launched a 5-year plan to focus clinical development on oncology, with trastuzumab deruxtecan (T-DXd, DS-8201a) selected as a lead compound. T-DXd is an antibody-drug conjugate consisting of a humanized anti-HER2 monoclonal antibody linked to a topoisomerase I inhibitor payload through a tetrapeptide-based cleavable linker designed to improve upon then current ADC technology. Early results from the DS8201-A-J101 Ph1 trial led to acceleration of Ph2 and Ph3 trials. The Ph2 DESTINY-Breast01 trial demonstrated that T-DXd has durable antitumor activity in heavily pretreated patients with HER2-positive metastatic breast cancer, and led to accelerated approval in the US in Dec 2019 for the treatment of patients with HER2-positive metastatic breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting. DESTINY-Breast03, the first randomized phase 3 clinical trial recently reported positive results for trastuzumab deruxtecan, demonstrating a highly statistically significant and clinically meaningful improvement in PFS for patients with HER2-positive metastatic breast cancer that progressed on or after trastuzumab plus taxane. Results from each of these trials will be presented in the context of past and future development of T-DXd.

2:05 – 2:35 pm Statistical Fallacies in Clinical Research – Science to the Rescue Where Intuition Fails
Yue Shentu, PhD, Distinguished Scientist (Executive Director), BARDS, Global Clinical Development, Merck

Should we be concerned that 40% of hospitalized COVID patients in UK were vaccinated? A randomized controlled study showed an imbalance in baseline covariates. How should we interpret its result? A subgroup with promising treatment effect was found in a retrospective analysis of a failed Phase III trial. Should we follow up with a new study in this subgroup? In this presentation we will discuss some common statistical fallacies related to these questions and discuss the role of statistics and causal inference in clinical trials.
Clinical Considerations for Gene Therapy - Regulatory Perspectives
Ke Liu, MD, PhD, Senior Vice President, Head of Regulatory Affairs & Strategy, Sana Biotech, Inc.

The number of gene therapy clinical studies and submissions has been increasing exponentially. The growth in this area has led to a number of US FDA approvals. However, many challenges exist in the development and approval for such innovative therapies. This presentation discusses the lessons learned from US FDA approvals and the landscape of gene therapy trials. In addition, unique aspects of clinical considerations for early-phase trials for cell and gene therapies are also discussed.

Clinical Development in Rare Diseases: Opportunities and Challenges
Patricia Keegan, MD, Chief Medical Officer, TopAlliance Biosciences, Inc.

The development of new treatments for rare diseases, particularly rare cancers, offer significant opportunities in addressing unmet medical needs and advancing medical innovations globally and within specific regions of the world. Effective treatments are often lacking or suboptimal such that demand for new treatment options is pressing and leads to rapid enrollment in less complex (single arm) clinical trials. Additionally, regulatory authorities in the U.S. offer financial incentives for clinical development in rare diseases and expedited development programs for serious and life-threatening rare diseases. Challenges include 1) adequate accrual of patients to clinical trials, which generally require global programs where accrual may be driven by regions with the highest prevalence; 2) small sample sizes that may present challenges in the risk:benefit assessment of new drugs; 3) limited characterization of the safety profile of new drugs; and 4) limited evaluation of treatment effects across diverse populations. Addressing these challenges requires flexibility on the part of the pharmaceutical industry and regulatory agencies with regard to trial designs, such as use of external controls and/or other data sources to characterize the risks and benefits of drugs in rare diseases.

Q&A and Panel Discussion
Charles Li, MBA, MS, VP of Business Development, Pharmaron Clinical - CR Medicon
Li Wan, PhD, Senior VP, Head of Regulatory Affairs, GeneQuantum Healthcare (Suzhou) Co., Ltd.

Networking Session

Saturday, October 2, 2021, 1:30 pm – 5:00 pm

Session I: Challenges and Opportunities in Developing New Drugs and Treatment Modalities in CMC

Session Moderators: Yong Guo, PhD, MBA, Zheng Chen, PhD, and Eric Rong

New treatment options, more complex small molecules and modalities such as antibody-drug conjugates (ADC), gene and cell therapy provide new challenges in the CMC area in terms of developing manufacturing processes and ensuring the quality of new drug products. There is also a growing need for CMC to focus on patient-centric product design and implement appropriate delivery technologies to speed up "product-to-trial/market" time. In this session, experts in product development, manufacturing and quality will discuss the challenges and opportunities in API development, patient-centric product development and pharmaceutical quality. CMC scientists in analytical, pharmaceutical, and manufacturing development can all benefit from in-depth understanding of these challenges and start looking for new opportunities.

Opening Remarks
Yong Guo, PhD, MBA, Professor of Pharmaceutical Science, Fairleigh Dickinson University
1:35 – 2:10 pm  **Evolving Role of Pharmaceutical Science & Technology to Meet the Needs of Emerging Modalities**  
**Rao V. Mantri, PhD, MBA**, Vice President and Head, Drug Product Development, Bristol Myers Squibb

The emerging drug candidates and modalities landscape is evolving rapidly in both complexity of traditional candidates such as small molecules, monoclonal antibodies but also novel modalities engineered proteins, conjugates and nucleic acid therapeutics. The other macrotrends in the industry related to patient-centricity, pace of technological innovations, regulatory landscape leading to expectations of delivering drug products with quality and robustness embedded in them while maintaining speed to patient. The presentation will describe the importance of a) defining the quality target product profile which forms the basis for design and defines product attributes b) seamless connectivity between discovery and development to enable ‘druggable’ space and identify drug delivery approaches earlier in the value chain c) proactive risk characterization and mitigation underpinned by mechanistic understanding d) application of predictive modeling, emerging data science tools & closer partnership between development & manufacturing to enable speed and robustness and e) opportunities to leverage cross-industry pre-competitive collaborations to enhance innovation.

2:10 – 2:45 pm  **What Went Wrong with Anticancer NanoMedicine Design and How to Make It Right**  
**Duxin Sun, PhD**, Charles Walgreen Jr. Professor of Pharmacy and Pharmaceutical Sciences, College of Pharmacy, University of Michigan

The three design criteria of anticancer nanomedicines to improve anticancer efficacy and to reduce toxicity have been debated for decades. Although these criteria have repeatedly been confirmed in xenograft cancers, the majority of anticancer nanomedicines have failed to improve clinical efficacy, while the clinical efficacies/safeties of successful nanomedicines are inconsistent with these design criteria. First, the debate over tumor EPR may have mixed two different questions and missed more clinically relevant comparisons for nanomedicines versus free drugs. When tumors are compared with normal tissues, tumor EPR has been confirmed in both xenograft tumors and human cancers. However, nanomedicines may not enhance drug accumulation in human tumors compared with free drugs. Second, long-circulation nanomedicine should not be used as a universal design criterion because it does not further improve tumor accumulation by tumor EPR in human patients nor universally reduce distribution in normal organs. In contrast, nanomedicines change the drug tissue distribution to alter anticancer efficacy/safety. Third, a universal nanodelivery platform for different drugs is not feasible. Rather, drug-specific nanodelivery systems are required to overcome the intrinsic shortcomings of delivered drugs, which are determined by the physicochemical, pharmacokinetic, and pharmacodynamic properties of the delivered drugs and nanocarriers to improve their efficacy/safety.

2:45 – 3:00 pm  **Coffee Break**

3:00 – 3:35 pm  **Drug GMPs and CAR-T Therapies**  
**Daniel J. Roberts**, Senior Specialist, Pharmaceutical and Biotechnology Practice, Hogan Lovells

The Federal Food, Drug, and Cosmetic Act (FD&C Act) provides that FDA may approve a new drug application (NDA) or an abbreviated new drug application (ANDA) if, among other requirements, the methods used in, and the facilities and controls used for, the manufacture, processing, packing, and testing of the drug are found adequate to ensure and preserve its identity, strength, quality, and purity. This presentation will discuss Drug GMPs and CAR-T Therapies as well as FDA pre-approval inspections for CAR-T Therapies.

3:35 – 4:10 pm  **Development Efficiency and Innovation at the API-Drug Product Interface**  
**San Kiang, PhD**, Chief Technology Officer, J-star / Porton

Currently in almost all pharma companies, the development of API crystallization processes and drug product formulation and process are carried out separately. These development scientists are separated by organization, geographic location and by skill sets. There is efficiency and quality to be gained by pooling these resources together so that DP design and development can be done contemporaneously and not in sequence as is the case in our current practice.
From a technology point of view, this work process change can use co-processing approaches. In this technology excipients and API are combined during, before or after crystallization. Some of the newest technologies in this area will be illustrated.

4:10 – 5:00 pm  **Networking Session**

**Saturday, October 2, 2021, 1:30 pm – 5:15 pm**

**Session J: Update and Advancement in Precision Medicine, Clinical Diagnostics and Medical Device**

**Session Moderators:** Wei Ding, PhD, Yongmei Li, PhD, and Kai Ying, PhD

**Precision medicine, clinical diagnosis and medical device are important aspects of patient care in addition to pharmaceutical treatment. The advances in diagnostic tools have enabled the identification of therapeutic strategies more accurately for patients than ever. Medical devices are also essential in improving patient’s health and quality of life. Our program will bring together experts in the field to share their knowledge and showcase cutting edge technologies in the field of precision medicine, clinical diagnosis and medical device.**

1:30 – 1:35 pm  **Opening Remarks**
**Wei Ding, PhD, Head, Bioformatics/R&D, Admera Health**

1:35 – 2:10 pm  **On the Basis of Drug-Device Co-Development - A Device Perspective**
**Yaji Xu, PhD, Senior Staff Biostatistician, Biostatistics, Illumina**

**Precision medicine, particularly, applications in drug-diagnostic device co-development are becoming increasingly prominent. Usually, a well-characterized market-ready companion diagnostic (CDx) assay is desired for patient enrollment in device drug pivotal clinical trial(s) so that CDx clinical performance can be demonstrated from the single trial directly. However, such study design may be difficult or impractical in reality. For instance, a clinical trial assay (CTA) instead of CDx is used for patient enrollment to meet the trial timeline. Hence, a bridging study needs to be conducted subsequently to estimate the efficacy of the drug in the population defined by CDx. In this talk, I will present the general framework for validating CDx devices, with an emphasis on the studies to demonstrate CDx clinical performance. Particularly, some practical issues and challenges in conducting CDx clinical validation studies will also be discussed in this presentation.**

2:10 – 2:45 pm  **Advanced Biobanking: Learn How to Harness the Potential of Biobanks from IBX**
**Mike Sheldon, PhD, Senior Director, Scientific Affairs, Infinity BiologiX**

The 1990’s ushered in the era of “big science” involving large scale studies utilizing biosamples aimed at understanding the etiology and progression of human disease. The NIH National Institute of Mental Health was a leader in recognizing that the data emerging from big science initiatives must be the product of a process that maintains the highest standards of quality in all phases from the recruitment of study participants to the generation and analysis of data. This process, by necessity, includes sample collection logistics, processing, quality control, controlled storage and global distribution to disseminate materials to investigators worldwide. RUCDR Infinite Biologics was established as a biobank built by scientists for scientists with this mission at its core and grew into the world’s largest academically based biobank, maintaining the repositories of several agencies of the NIH and numerous clients. In 2020 RUCDR Infinite Biologics became Infinity BiologiX (IBX). While the name changed, the core mission did not. This presentation will focus on the efforts of IBX to continue to support its expanding commercial and academic client base in the 21st Century by offering a range of cutting-edge services that is constantly evolving with the times.
2:45 – 3:20 pm **Canfield Digital Imaging and Analysis**
*Heather Haselmann*, Director Business Development, Canfield Scientific, Inc.

Canfield Scientific, Inc. is the global leader in imaging systems, services and products for scientific research and healthcare applications, including the pharmaceutical, biotechnology, cosmetics, medical and skin care industries. Their Clinical Services Team specialize in photographic documentation to help demonstrate drug efficacy in clinical drug trials worldwide. Canfield pioneered the use of specialized devices in medical photography and has developed a wide range of innovative solutions for research and practice. Their patented technology includes multi-spectral and multi-modal 2D and 3D image capture systems, digital asset management, aesthetic simulation, and applications for detection, measurement and analysis for various skin conditions. These technologies have contributed to the development of numerous treatments and procedures and has significantly advanced the use of optical imaging in both clinical research and practice.

3:20 – 3:30 pm **Coffee Break**

3:30 – 4:05 pm **Todos Medical Covid Antiviral and Cancer Diagnostics**
*Gerald Commissiong*, CEO of Todos Medical

Todos Medical Ltd. is a developer and distributor of medical diagnostics addressing cancers, Alzheimer’s Disease and viruses, as well as a provider of Covid-19 testing supplies and automation solutions, and a developer and distributor of immune support products and antivirals that target the inhibition of 3CL protease for the treatment of Covid-19.

4:05 – 4:40 pm **In Vivo Antigen Discoveries Translated into Development of Therapeutic Human Antibodies for Treatment of Microbial Infections**
*Janos Luka*, PhD, CSO, Danuvius Biosciences, LLC

The most vital step in development of diagnostic assays and therapeutic antibodies is to identify the key antigens and epitopes targeted by immune responses. To achieve this, mouse hybridoma library from twenty-five gram-positive/negative bacteria was developed by immunizing naïve mice with serum from infected animals. The pools of antibodies present in these libraries were used to identify antigens in infected animals, and serum from infected patients. Antibodies were also identified as potential candidates for clinical diagnosis and therapeutic use. To develop fully human antibodies for therapy, human sera from previously infected patients were screened for presence of antibodies against antigens where the corresponding mouse monoclonal antibodies were effective in in vitro or in vivo functional assays. Human monoclonal antibodies were identified from the antibody library established from these individuals and are evaluated in vivo and in vitro for their ability to prevent and/or treat Multi Drug Resistant infections. The described mouse and human hybridoma library approach has significant advantages over other methods due because they can be quickly screened for diagnostic assay developments and therapeutics. In addition our procedure allowed us to develop rapid diagnostic assays for bacterial infections which can differentiate between infection and colonialization.

4:40 – 5:15 pm **How Startups are Accelerating Diagnostic + Therapeutic MedTech Stack**
*Annamarie Saarinen*, MA, Co-founder, CEO, Bloom Standard (HKSTP Inbubio)

Small, nimble early stage innovators are tackling unmet needs in underserved clinical ecosystems - including pediatrics and rare diseases. These teams are often multidisciplinary and focused on how best to integrate with public health priorities, clinical infrastructure, referral patterns, and accessible treatments/therapies. This approach creates a “medtech stack” - from screening to diagnostics to patient flow and precision pharma and biotech therapies - that can best serve patients and those treating them throughout the care continuum.
Saturday, October 2, 2021, 5:00 pm – 6:00 pm

Session K: Interactive Network Breakout Sessions

These interactive network sessions have become popular fixtures of the SAPA events. After the formal sessions, these are great opportunity to ask additional questions to the presenters and panelists, exchange ideas, and to build and expand personal and professional network. SAPA is a great platform to learn new scientific advancement and technologies, and also to make new friends connections. These are informal sessions to all participants to get to know each other, after a long day of the events. So come and turn on your video camera and microphone, and to open up and speak up. We looking forward to seeing you all.

Logistically, these interactive sessions are the continuations of the five afternoon parallel sessions (for example, K1 is the continuation of “Session F: Frontiers in Drug Discovery and Development: From Academia to Industry”, etc. You don’t need to switch your zoom links. For detailed information, please refer to the conference event page for details).

• Virtual Room #K1: Drug Discovery and Early Development
• Virtual Room #K2: Healthcare Investment and Business Development
• Virtual Room #K3: Clinical Development, Data Sciences and Regulatory Affairs
• Virtual Room #K4: CMC and Quality
• Virtual Room #K5: Precision Medicine, Clinical Diagnostics, and Medical Device
Bojana Berić-Stošić, MD, PhD, MA
Associate Professor and Program Director, MPH Program, School of Pharmacy & Health Sciences, Fairleigh Dickinson University

Dr. Bojana Beric-Stojsic is Director, MPH Program and Associate Professor of Public Health at the School of Pharmacy & Health Sciences, Fairleigh Dickinson University. She has been teaching health promotion and public health at universities in New Jersey, New York and her native Balkans (Serbia) for over 25 years. As Doctor of Medicine (MD) with Master of Arts (MA) and Doctor of Philosophy (PhD) in Health Education. Dr. Berić’s scholarship includes pedagogy in health promotion, Interprofessional Education (IPE), preparation of public health workforce and global and international health issues, with particular interest in social justice and rights of children. She has been active in professional associations at the state, national, and international levels, serving two terms as President of New Jersey SOPHE (Society for Public Health Education), serving as Regional Vice President of IUHPE/NARO (International Union for Health Promotion and Education/North American Regional Office) 2016-2019 term, and representing both national SOPHE and IUHPE/NARO at the United Nations since 2010.

Julie Campbell, MFA
Founder of Center Stage Connections

Julie Campbell is the Founder of Center Stage Connections (CSC). In May 2019 she founded CSC to help leaders and professionals to meet their communication goals. CSC offers virtual workshops and webinars that deepen employee engagement and meet the challenge of creating shared memorable connections with clients and colleagues, despite not being in the same physical space. Julie has a Master of Fine Arts (MFA) in acting from the University of Washington, and has played many leading and supporting roles in several film, TV, and stage shows. Julie has been an actor, writer and storyteller for 30+ years.

Jingxi Chu, JD, MS
Deputy General Counsel, Nanova, Inc.

Jingxi Chu is currently the Director of IP Affairs & Deputy General Counsel in Nanova, Inc., a bio-tech start-up, where her in-house practice areas cover both the IP and various corporate laws. Chu received her Chemistry BS degree in Peking University (1990), MS degree in Organic Chemistry in UIUC (1993), and JD from the University of Tennessee College of Law (2001). Before her law school, Chu worked as a medicinal chemist in Bayer Co. and National Cancer Institutes. Chu practiced law in Bass, Berry & Sims (Nashville, TN) and Oak Ridge National Lab (Oak Ridge, TN) and was the IP Portfolio Manager in University of Missouri System (Columbia, MO), before joining Nanova, Inc., in 2016.

Gerald Commissiong
CEO of Todos Medical

Mr. Commissiong serves as Chief Executive Officer and a member of the Board of Directors of Todos Medical. He has over ten years of experience in therapeutic and diagnostic development, including all aspects of product licensing, research collaborations, and go-to-market strategies. He is the former CEO and co-founder of Amarantus Bioscience, a company that developed LymPro, an Alzheimer’s disease entity currently in advanced development by Todos Medical. Mr. Commissiong has raised over $70 million in research capital to forward numerous scientific development programs, including those currently underway at Todos. He is a former professional football player for the Calgary Stampeders of the Canadian Football League who received a Bachelor of Science degree in Management Science and Engineering with a focus in Financial Decisions from Stanford University.

Michael N. Druckman, JD
Partner, Global Regulatory, Hogan Lovells LLP

Mike Druckman leverages his prior experience at the FDA – and what he has learned since then while extricating companies from regulatory problems – to anticipate and prevent life science clients from getting into trouble in the first place. Mike chairs Hogan Lovells’s Cell, Tissue, and Gene Therapies Working Group, a cross-disciplinary team that advises companies in this emerging space on the evolving regulatory and business challenges they face. Mike and the team work closely with companies developing stem cells, cord blood, placental tissues, gene therapies, proteins, and other cellular products to help people with serious health problems.
Scott Filosi
CEO of Hengrui USA & Hengrui Europe

Scott is responsible for Hengrui’s businesses in the United States and Europe. Scott is an outstanding business leader with over 25 years of successful pharmaceutical leadership experience across multiple therapeutic areas including oncology, immunology, neuroscience, rare diseases, targeted therapies and specialty pharmaceuticals. He has extensive experience in end-to-end commercial and other areas, including sales, marketing, operations, access, patient services and country managing director both in the U.S. and globally. Scott is joining Hengrui from Merck KGaA, EMD Serono where he served as Chief Commercial Officer for the US where his teams successfully launched multiple new medicines. Scott, who received his bachelor’s degree from Fitchburg State University in Massachusetts, held positions of increasing responsibility at Johnson & Johnson, Boehringer Ingelheim and UCB from 1993 to 2005 before joining Merck KGaA where he led Global Market Access and served as Chief Commercial Officer.

Margaret Fisher, MD
Special Advisor to the Commissioner of Health, New Jersey Department of Health

Dr. Fisher received her undergraduate education at Susquehanna University, Selinsgrove, PA, and her medical degree from the University of California at Los Angeles School of Medicine. She completed her Pediatric Residency and Fellowship Training in Pediatric Infectious Diseases at St. Christopher’s Hospital for Children, Philadelphia. She joined the NJ Department of Health as a Special Advisor to the Commissioner of Health in October 2020. She is the Medical Director of Clinical and Academic Excellence at Monmouth Medical Center and Clinical Professor of Pediatrics, Rutgers Robert Wood Johnson School of Medicine. Dr. Fisher’s academic activities have included frequent Continuing Medical Education programs locally, regionally, nationally, and internationally, participation in the American Academy of Pediatrics (AAP) Committee on Infectious Diseases (Red Book), AAP Committee on Continuing Medical Education, Disaster Preparedness Advisory Council, and Co-Chair of the CDC-AAP Global Immunization Collaboration, Strengthening Capacity for Global Pediatric Immunization Champions, and service as an elected member of the Board of the AAP. Dr. Fisher represented the AAP in the development of CDC guidelines for smallpox, anthrax, botulism and Zika virus. She has multiple published articles, book chapters, audiotapes and one book.

Shishir Gadam, PhD
Vice President, Cell Therapy Manufacturing Science and Technology, Bristol Myers Squibb

Dr. Shishir Gadam is currently a Vice President of Cell Therapy Global Manufacturing Science and Technology at BMS. He was previously at Genentech/Roche where he held various global leadership roles in Biologics Technical Development and Operations. Shishir brings strong leadership and a wealth of experience in biologics development, tech transfer, factory start-up, and manufacturing. Prior to joining Genentech, Shishir worked at Merck, in West Point, PA, on vaccine bioprocess development and biologics clinical manufacturing. He has a Ph.D. in Chemical Engineering from Rensselaer Polytechnic Institute, Troy, NY, an M.S. in Chemical Engineering from West Virginia University in Morgantown, WV, and a B.S. in Chemical Engineering from Indian Institute of Chemical Technology, Mumbai. In 2017, Shishir was inducted to American Institute for Medical and Biological Engineering (AIMBE) College of Fellows for his outstanding contributions to developing, scaling-up, designing and starting-up manufacturing processes and facilities, and defining product technology lifecycle strategies for biologics.

Dalvir Gill, PhD
CEO, TransCelerate Biopharma Inc.

Dr. Dalvir Gill is the Chief Executive Officer of TransCelerate and serves on its Board of Directors. Dr. Gill has more than 25 years of drug development experience. Prior to his appointment as CEO of TransCelerate in December 2012, Dr. Gill was the President of Phase II-IV Drug Development at PharmaNet-III, an international contract research organization. In this role, he was responsible for a global business spanning nearly 40 countries and had P&L responsibility for all operational departments and business development. Dr. Gill earned his BSc in Applied Biology from the University of Her福德shire and his PhD in Pathobiology from the Royal Free Hospital School of Medicine, University of London. He also holds a diploma in the health economics of pharmaceuticals from the executive program of the Stockholm School of Economics. Dr. Gill has presented his research and spoken at numerous conferences, and has authored more than 30 scientific publications. He also is an elected fellow of the Royal Society of Medicine.

Alber1o Grignolo, PhD
Corporate Vice President, Parexel

Dr. Alberto Grignolo is a Corporate Vice President at Parexel Regulatory & Access with over 39 years of experience as a regulatory and drug development professional and corporate executive; including 29 years as a Parexel consultant to pharmaceutical and biotechnology companies. He established the firm’s Japan Consulting Services during a two-year assignment in Tokyo. He is the Executive Sponsor of drug development programs on behalf of selected clients of Parexel. He participates actively in Parexel’s Diversity, Equity and Inclusion initiatives and in corporate efforts to promote and maintain a patient-focused culture and excellent customer service. A native European who has also lived in Latin America and Japan and speaks four languages, Dr. Grignolo has been a frequent Speaker, Program Chair, Session Chair or Instructor at more than 120 international conferences, seminars, workshops and courses on Drug Development and Regulatory Affairs and has published more than 60 professional and scientific articles. He is the Editor-in-Chief of DIA Global Forum online magazine, received DIA’s Global Inspire Award (Global Connector) in 2015 and was named a Fellow of DIA in 2017.

Heather Haselmann
Director Business Development, Canfield Scientific, Inc.

Heather Haselmann is the Director of Business Development for Canfield Scientific’s Clinical division, the global leader for imaging systems and services, a role she has held since 2018. Prior to that, she was the Associate Director of Business Development, since 2015. In Business Development, Heather has extensive knowledge of the industry which covers Dermatology, from hair growth to onychomycosis and changes to the skin, Aesthetics, Body contouring, Oncology and rare diseases related to skin. From 2005 to 2015, Heather worked in Clinical Service Project
Management in a series of increasing responsibility, including the FDA audit team. Her roles included directed project management of studies, documentation of imaging methodology, image reviews and image transfers to client sites. She additionally worked as a mentor to project managers to build their skills, and worked with business teams attending tradeshows on the client facing side, ultimately leading to her position in BD. Prior to Canfield, Heather was a sales manager at Qwest Communications, a former Telco and Baby Bell, and before that she was a team leader in Americorps NCCC. Heather is graduate of The College of NJ (TCNJ).

Nianfeng (Oliver) Ju, MBA
Chairman & CEO, board office of Porter Pharma Solutions Ltd.

Nianfeng Ju graduated from Department of Chemistry of Sichuan University and Class President of Cheung Kong Graduate School of Business, formerly served as the Manager of AkzoNobel China. In 2005, he co-founded Porter Pharma Solutions which was listed on the Shenzhen Stock Exchange in 2014. In 2020, Porter officially launched the Genes&Cell Therapy and the Drug Product CDMO platforms which integrate with API CDMO platform to provide global pharmaceutical and Biotech companies with excellent End-to-End CDMO services.

Kenneth Kaitin, PhD, MS
Professor and Senior Fellow, Center for the Study of Drug Development, Tufts University School of Medicine

Dr. Kenneth Kaitin is Professor and Senior Fellow at the Tufts Center for the Study of Drug Development at Tufts University. He previously served as CSDD’s Director for 23 years. He is also Advisory Professor at Shanghai Medical College at Fudan University and serves on the faculty of the European Center for Pharmaceutical Medicine at the University of Basel. Dr. Kaitin is an internationally recognized authority on drug development science and policy. He consults and speaks on global trends in pharmaceutical development and regulation, and he has provided public testimony before the U.S. Congress. A former President of the Drug Information Association, Dr. Kaitin recently served as Editor-in-Chief of Expert Review of Clinical Pharmacology, and as a consultant to the U.S. Department of Defense on bioterror countermeasures. In 2011, he received the Dr. Louis M. Sherwood Award, granted by the Academy of Pharmaceutical Physicians and Investigators, and in 2020 he was named Global Fellow in Medicines Development by the International Federation of Pharmaceutical Physicians. Dr. Kaitin is a director on the boards of Curis, Inc. (NASDAQ: CRIS), Bio-Tree Systems, Inc., and QCDx LLC. He earned his BS from Cornell University and MS and PhD in pharmacology from the University of Rochester.

San Kiang, PhD
Chief Technology Officer, J-star/Porton

As a Research Professor at Rutgers University, I worked on research projects in the Engineering Research Center for Structured Organic Particles and the Chemical Engineering Department. Research focus is on continuous manufacturing (CM) and particle engineering. More specifically how the material properties of API can be engineered and how these properties affect CM equipment train and drug product performance. Thirty-five years of pharmaceutical development and technology transfer experience in Bristol Myers Squibb covering both Active Pharmaceutical Ingredient (API) and Drug Product (DP) areas. PhD chemical engineer with experience in directing multi-disciplinary teams in pharmaceutical, chemical, and biochemical development and manufacture. Directed and/or participated in 11 NDA projects that were eventually commercialized. Successfully participated in one of the first QbD NDA filings. In this filing, led the use of risk assessment and process modeling with emphasis on fundamental mechanistic understanding for drug development. Well recognized expert in crystallization, particle engineering, reaction engineering, continuous processing (both DP and API), as well as the design of pharmaceutical composite materials through co-processing.

Caleb Lee, PhD, MD
Senior Director, Global Oncology Clinical Development, Daiichi Sankyo

Dr. Caleb Lee is a senior medical director at Daiichi Sankyo, Inc where he has been involved in the clinical development of trastuzumab deruxtecan (T-DXd) since July 2016. Prior to DSI, Caleb received his BA at Harvard University followed by an MD/PhD from the Tufts University School of Medicine. He then finished his medical residency and hematology/oncology fellowship at the Icahn School of Medicine at Mount Sinai. After some additional years in basic science research, he transitioned to DSI initially as the global clinical lead for T-DXd.

Patricia Keegan, MD
Chief Medical Officer, TopAlliance Biosciences, Inc.

Dr. Patricia Keegan, has served as the Chief Medical Officer and Senior Vice President for Medical Science at TopAlliance Biosciences, Inc., a subsidiary of Shanghai Junshi Biosciences. Prior to joining TopAlliance Biosciences, Inc. since August 2020. Prior to joining TopAlliance, Dr. Keegan held multiple positions at the U.S. Food and Drug Administration over 30 years. Her most recent position was Acting Associate Director of Medical Policy Oncology Center for Excellence (OCE), Office of the commissioner; as well as 16 years as the Division Director of Oncology Products; 4 years as Deputy Director Division of Clinical Trial Design and Analysis; and 8 years as Chief and Medical officer at Oncology Branch. Prior to joining FDA, Dr. Keegan was a Clinical Assistant Professor of Medicine in Hematology and Medical Oncology at University of North Carolina at Chapel Hill. Dr. Keegan received her Bachelor of Science in Biology from University of Illinois Champaign-Urbana. She earned her medical degree from Loyola University Stritch School of Medicine, where she also completed a residency in internal medicine and completed a fellowship in medical oncology at Roswell Park Memorial Institute, Buffalo, New York.

Elizabeth Litten, JD
Chief Privacy & HIPAA Compliance Officer, Corporate and Office of General Counsel Departments & Partner of Fox Rothschild LLP

Named one of New Jersey’s leading health care attorneys by Chambers USA, Elizabeth serves as national and regional counsel to a wide range of health care related entities including hospital systems, health care facilities, regulated and self-funded health plans, and health care technology companies. With more than 25 years of experience in the industry, she is known nationally as a go-to source for insight on health care law and regulation.
Jonathan Liu, PhD, DVM  
Chief Executive, Bio-Island Initiative & Chairman of the Board, BeiGene Guangzhou Biologics, Ltd. Co.

Dr. Jonathan Liu is CEO of BeiGene Bio-Island Innovation Center, Chairman of the Board and General Manager of BeiGene Biologics, Co., Ltd., also serves as Managing Director of BeiGene China BioVentures. He is responsible for establishing BeiGene Innovation Center and BeiGene BioVenture Fund. Prior to joining BeiGene Prior to joining BeiGene he headed Johnson and Johnson China Pharmaceutical Development and Manufacturing Sciences organization to develop biologics, small molecule drugs and vaccines. Before Johnson and Johnson Dr. Liu spent more than 20 years in the industry and had led many drug development projects in discovery, CMC, manufacturing and product registration, contributing to the successful launch, clinical studies and/or other major milestones for ReFacto®, BENEFIX®, FluMist®, ACAM2000® and 20 other drug products in Pfizer, Sanofi, AstraZeneca and China Novartis. He is a co-author of Quality by Design for Vaccine, a white paper to the U.S. FDA on behalf of the vaccine industry. He has authored or co-authored prolifically, including more than 150 scientific publications and more than 20 inventions patented in the U.S., Europe, and other countries. He has been a senior advisor or a board member of various biotech companies, investment firms, government agencies, trade organizations and scientific journal review committees.

Ke Liu, MD, PhD  
Senior Vice President, Head of Regulatory Affairs & Strategy, Sana Biotech, Inc.

Dr. Ke Liu has more than 20 years of experience and expertise in oncology, cell and gene therapy, including basic, translational, clinical research, drug development, and regulation. Before joining Sana in December 2020, Dr. Liu spent more than 17 years working at the U.S. Food and Drug Administration (FDA), including the Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Oncology Center of Excellence (OCE), most recently serving as OCE Associate Director for Cell and Gene Therapy, and Chief of Oncology Branch in CBER’s Office of Tissues and Advanced Therapies. He oversaw the clinical evaluation and approval of many innovative cancer therapeutics with curative potential [e.g., chimeric antigen receptor (CAR) T cells, T-cell receptor (TCR)-modified T cells, genome-edited products, neoantigen-based therapies, adoptive T cell therapies, oncolytic viral therapy, dendritic cell therapy, and combinations of these immune-oncologic therapeutics with checkpoint inhibitors and other agents]. He had received many awards, such as FDA honor award for FDA Guidance writing and reviews for new drug / biologic applications as well as mentoring award.

Janos Luka, PhD  
CSO, Danuvisu Biosciences, LLC

Dr. Janos Luka received his Ph.D. degree in Virology from Karolinska Institute, in Stockholm, Sweden in 1981. He did his postdoctoral work at Mayo clinic in Rochester, Minnesota on lymphotropic Herpesviruses including EBV and HHV-6, and HHV-7. He was Associate Professor at University of Nebraska Medical Center Department of Pathology and Microbiology from 1989 to 1993. He established an infectious disease diagnostic laboratory at Eastern Virginia Medical School where he was Associate Professor at the Department of Pathology from 1993 until 2003. In 2003 Dr. Luka left the Academics and was director of Proteomics at various companies until 2011. From 2011 until 2018 he was contract Scientist at the Walter Reed Army Research Institute, to identify and develop diagnostic assays to combat wound Infections. He received several SBIR and infectious disease grants, and published over one hundred peer- reviewed papers, several book chapters and patents. He was co-owner of BioWorld Consulting Laboratories between 2005 and 2018 then he founded Danuvis Biosciences, LLC, where he is CSO. At present the company discovering and developing monoclonal antibodies for treatment, and for rapid diagnostic assays to recognize microbial infections.

Rao V. Mantri, PhD, MBA  
Vice President and Head, Drug Product Development, Bristol Myers Squibb

Rao V. Mantri is a purpose-driven healthcare executive with 21 years of experience in product development, including small molecules, biologics, nucleic acid therapeutics & drug-device combination products. As Vice President and Head of Drug Product Development at Bristol Myers Squibb (BMS), Rao was responsible for development of BMS’ drug product portfolio and delivering solutions to address drug delivery challenges for different molecular modalities. Since joining BMS in 2000, he has held positions of increasing responsibility in design, development and technology transfer of small molecules and biologics drug products. He has broad experience in discovery support, formulation development, process engineering, materials science, analytical sciences, combination & digitally-connected products. Rao served on Industrial Expert Leadership committees at USP & IQ. Rao has a wide-ranging list of professional service contributions, awards and recognitions, keynote lectures, publications, book chapters, patents, and applications. Rao is a co-editor of “Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice”. Rao holds B. Tech. from Osmania University, India, M.S. in Chemical Engineering, M.S. & Ph.D. (honors) in Pharmaceutical Chemistry from The University of Kansas and Executive MBA from MIT Sloan School of Management.

Jay Mei, PhD  
Founder, Chairman & CEO, Antengene Corporation

Dr. Jay Mei has over 25 years of experience in clinical R&D of oncology therapeutics globally. He has published over 70 publications and is the co-inventor of multiple patents. In the 1990s, Dr. Mei dedicated himself to extensive cancer research at the National Cancer Institute in the U.S. In 2001, Dr. Mei joined as a Principal Scientist in the oncology team in the drug discovery division and Associate Director in clinical development at J&J. From 2006, Dr. Mei worked as a Senior Director/Global Clinical Program Head at Novartis Oncology. From 2008 to 2017, he served as Executive Director of the clinical development at Celgene, as one of the leading members in the clinical development of multiple blockbuster drugs that represent the most significant part of Celgene’s portfolio, including some significant oncology therapies worldwide, such as REVLMID®, POMALYST®, and IDHIFA®. Dr. Mei has been leading the management of Antengene since its inception in April 2017, and also currently holds adjunct professorship at the Baruch S. Blumberg Institute.
Daniel J. Roberts
Senior Specialist, Pharmaceutical and Biotechnology Practice, Hogan Lovells

Daniel J. Roberts, Senior Specialist Pharmaceutical and Biotechnology Practice, has over 19 years of government regulatory and pharmaceutical/biopharmaceutical industry experience. He was a United States FDA investigator for 8 years including 2 years overseas as the primary point of contact for conducting pharmaceutical inspections at the FDA India Office located at the United States Embassy in New Delhi, India. As an investigator, Mr. Roberts conducted Pre-Approval Inspections (PAIs) and for-cause investigations and inspections of pharmaceutical manufacturers of human and veterinary sterile and non-sterile finished dosage forms and APIs worldwide. During his tenure at the Agency, he conducted over 100 pharmaceutical inspections as a lead investigator. Significant compliance actions including 24 Warning Letters and Untitled Letters as well as 5 Import Alerts were issued because of the inspections that Mr. Roberts has conducted. Mr. Roberts was also the lead investigator for the first biosimilar inspection conducted by FDA in India. As a Senior Specialist at Hogan Lovells, Mr. Roberts successfully guides domestic and international clients in the preparation for and management of successful U.S. FDA pre-approval inspections and systems based inspections.

Haojing Rong, PhD
Vice President, Preclinical Development, Kymera Therapeutics

Haojing Rong earned her Ph.D. in Pharmaceutical Science at Ghent University in Belgium. Prior to joining Kymera in 2018, Haojing worked at Amgen, Merck, Amira Pharmaceuticals, Pfizer, and Shire. Haojing’s interest and expertise include ADME and toxicology integration for both small molecule and biotherapeutics, prediction of human pharmacokinetics, drug interactions using modelling and simulation, and applying integrated PK/PD modelling approach for efficacy and safety in drug development.

Kenneth A. Rosenberg, JD
Partner, Labor and Employment, Fox Rothschild LLP

Ken provides clients with creative and practical solutions to resolve their labor and employment issues efficiently. He leads Fox Rothschild’s Affirmative Action/OFCPP practice. Ken represents employers nationally in both union and non-union contexts. He works closely with business owners, human resource professionals and in-house counsel to ensure they are complying with the myriad of complex workplace-related rules mandated by federal and state law. As head of the firm’s AAP/OFCPP practice, Ken assists federal and state contractors: comply with the myriad of complex workplace-related rules mandated by federal and state law. Ken also assists his clients in developing and implementing employee handbooks, personnel policies and procedures, and employment and severance agreements. He further provides day-to-day counseling and training to his clients in connection with all federal, state and local laws that impact the employment relationship including, but not limited to, disciplinary, leave and accommodation, wage and hour issues. Ken aggressively defends his clients against claims of discrimination, harassment and retaliation. Ken obtained his J.D. from Albany Law School.

Annamarie Saarinen, MA
Co-founder, CEO, Bloom Standard (HKSTP Inubio)

Ms. Saarinen is a Humphrey Policy Fellow and co-founder of both the Newborn Foundation and Bloom Standard, a social impact innovation lab developing medical technologies for children in resource poor settings. Her own baby was diagnosed with critical heart defects at 3 days old, driving her focus on developing policies, programs and technologies to improve early diagnosis, health outcomes and access to care for children. She is recognized for spearheading the U.S. effort to become the first nation to implement universal newborn heart screening. To date, 40 million newborns have been screened as part of implementation in all 50 U.S. states with pilots and programs having been implemented in an additional 60 international countries. Ms. Saarinen was appointed by the U.S. Secretary of Health and Human Services to the federal Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) and has drafted more than 40 pieces of health legislation, authored more than 200 policy briefings of early diagnostics for health equity and access to care. Ms. Saarinen serves on the board of the Ped Device Innovation Consortium, Every Breath Counts Coalition, Medical Alley, the WHO Medical Device Technical Series workgroup, the WHO Research Network on COVID-19 in Children.

Manan Shah, MBA
Vice President, Global Public Affairs | Assistant Professor, Public Health & Policy, LEO Pharma | Fairleigh Dickinson University

Manan Shah is the Vice President and Head of Global Public Affairs for LEO Pharma, a Danish-based multinational healthcare company focused on medical dermatology. For nearly 15 years, Manan has worked in various global and US positions focused on policy, public affairs, communications and advocacy within the biotech and pharmaceutical sectors in numerous disease states including diabetes, hemophilia, multiple sclerosis, obesity, and medical dermatology. He has designed and current teaches numerous courses in health policy at Fairleigh Dickinson University’s Master of Public Health program including: Public Health Management and Policy, Politics & Public Health, Economic and Social Determinants of Health Policy, and Mental Health Advocacy. Manan has a Master’s in Public Affairs and Politics from Rutgers University, an MBA from the University of Illinois-Urbana Champaign, and undergraduate degrees from American University.

Mike Sheldon, PhD
Senior Director, Scientific Affairs, Infinity BiologiX

Dr. Sheldon received his B.A. from Cornell University in 1983 and a Ph.D. from SUNY at Stony Brook in 1993. After joining the faculty in Genetics at Rutgers University in 2007, he has served as Senior Director of Sample Processing Services at RUCDR INFINITE Biologics®, with operational oversight of all sample processing including isolation of primary cells from blood and other tissues, creation of cell lines, extraction and quality control of nucleic acids and storage and global distribution of biomaterials. All the sample processing workflows at INFINITE are designed to ensure consistent and superior quality standards within a state-of-
the art automation infrastructure that provides high throughput sample management and analysis for DNA, RNA and protein-based technologies to hundreds of labs globally. When RUCDR Infinite Biologics became Infinity Biologix (IBX) in 2020, he founded the IBX Scientific Affairs department with the mission to play a strategic role in the advancement of a number of company goals, including providing expert technical resources to potential and existing clients, discovery and adoption of new fields and associated technologies and the coordination of outreach initiatives designed to enhance the public profile of the company. Dr. Sheldon also serves as Director of the IBX CAP Biorepository.

Yue Shentu, PhD
Distinguished Scientist (Executive Director), BARDS, Global Clinical Development, Merck

Dr. Yue Shentu is a clinical biostatistician at Merck & Co. He graduated from Rutgers, State University of New Jersey with a Ph.D. degree in Biostatistics. Yue has 15 years of industry experience in metabolic and oncology drug development. He is currently the methodology lead for the late development oncology statistics group at Merck.

Duxin Sun, PhD
Charles Waigreen Jr. Professor of Pharmacy and Pharmaceutical Sciences, College of Pharmacy, University of Michigan

Dr. Duxin Sun serves as the Director of Pharmacokinetics (PK) Core. Dr. Sun also has joint appointment in the Clinical Biology program, the Interdisciplinary Medicinal Chemistry program, and University of Michigan’s Comprehensive Cancer Center. Dr. Sun’s research interests focus on drug discovery, nanomedicine and pharmacokinetics. Dr. Sun has published more than 240 papers, mentored 35 PhD students and 40 postdoctoral fellows/visiting scientists. Dr. Sun is a Fellow of American Association of Pharmaceutical Scientists (AAPS) and has served as chair of the PPB (Physical Pharmacy and Biopharmaceutics) in AAPS. Dr. Sun served on FDA Pharmaceutical Science and Clinical Pharmacology Advisory Committee. Dr. Sun has served on study sections for NIH, FDA, Cancer Research UK, French National Research Agency, and Italian Ministry of Health.

Zhi-Fu Tao, PhD
Principal Research Scientist II, Oncology Discovery, Abbvie Inc.

Dr. Zhi-Fu Tao is a principal scientist II and chemistry team leader in Abbvie Oncology Discovery. Dr. Tao is an experienced drug-hunter with proven track record. Throughout his career, Dr. Tao has played a key role in the invention of multiple small molecule and antibody drug conjugate clinical candidates; these include Venetoclax, which was first approved by the FDA in 2016 for treatment of RR CLL patients, as well as ABBV-167, ABBV-984, ABBV-467, ABBV-155, ABBV-637 and ABBV-1013. In 2021, Dr. Tao received the Heroes of Chemistry Award from the American Chemical Society, one of the highest honors the ACS gives to industrial chemists. Dr. Tao is an author of over 60 peer-reviewed publications, an inventor on over 30 issued US patents and a reviewer for more than 20 scientific journals. Dr. Tao has been invited to speak at numerous prestigious academic institutions and conferences, including AACR Annual Meeting and Gordon Research Conference.

Dr. Tao earned his Ph.D. in organic chemistry from East China University of Science and Technology and post-doctoral training in biochemistry at Tokyo Medical and Dental University and the University of Virginia.

Steven Townsend, PhD
Associate Professor of Chemistry, Vanderbilt University

Dr. Steven Townsend was born and raised in Detroit and completed his undergraduate education at Oakland University where he completed 4 years of research working on the synthesis of nucleoside radical precursors with Prof. Amanda Bryant Friedrich. From there he matriculated to Vanderbilt University where he completed an education in small molecule total synthesis, working on the total synthesis of bielschowskysin (also known as BSK) under the mentorship of Prof. Gary Sulikowski. There, Steve was a UNCF-Merck predoctoral fellow. Steve completed his education at memorial sloan kettering and Columbia University with Prof. Sam Danishefsky, where he worked on the total synthesis of erythropoietin, peptide ligation, and Diels-Alder methodology. Since 2014, Steve has established his independent program at Vanderbilt University where his group leverages organic chemistry to address problems in human health, particularly in the areas of human milk science, antimicrobial agents, and chemotherapeutics. Steve’s team has been honored with a number of awards, including most recently, the Sloan research fellowship, the Camille Dreyfus Teacher Scholar Award, The David Gin New Investigator Award from the ACS, the Ruth Kirstein Award for Excellence in Human Milk Science, and the C&E News Talented 12.

John Tsai, MD
Head of Global Drug Development and CMO, Novartis

As Head of Global Drug Development and Chief Medical Officer for Novartis, John Tsai is responsible for one of the strongest pipelines in the industry, with more than 160 projects in clinical development and over 500 ongoing clinical trials targeting around 50 diseases. Since taking up his role in 2018, John has led the US approval of more than 10 new medicines and multiple approvals in other markets, including several based on advanced therapeutic platforms such as cell and gene therapy.

John draws on more than two decades of experience in the pharmaceutical industry. He trained as an electrical engineer before qualifying as a physician, giving him a unique combination of skills. He is passionate about the potential to apply technologies such as artificial intelligence and data science to the challenge of developing new medicines, and has led a number of initiatives to simplify and streamline the Novartis drug development engine.

Born in Taiwan and fluent in Mandarin, John grew up in the US and has lived in Europe with his family for five of the last eight years. Having exposure to diverse cultures has enabled him to understand and provide different perspectives on drug development.

Jin Wang, PhD
Michael E. DeBakey, M.D., Professor in Pharmacology, Department of Pharmacology and Chemical Biology at Baylor College of Medicine Campbell

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John Wang, PhD  
Head of External Innovation, Immunology, Eli Lilly

Dr. John Wang is currently the Head of Eli Lilly Immunology External Innovation. His major responsibilities include establishing Immunology External Innovation strategy, leading global Search & Evaluation team to assess the Scientific and Consumer landscape to align external opportunities to R&D and Franchises, identifying gaps and developing recommendations, collaborating with internal stakeholders to develop a R&D and Consumer strategy for autoimmune and inflammatory diseases. Under his leadership as Head of Eli Lilly Immunology External Innovation, and with his proactive approach, Eli Lilly acquired Demira in January 2020 for $1.1 Billion cash, the largest acquisition deal in Lilly Immunology history. Prior to joining Lilly, John worked at Merck Business Development & Licensing and Corporate Development and Sanofi External Innovation group. John started his pharma career as a Principal Research Scientist at Wyeth Research (Pfizer) in 1996 and has become a seasoned pharma business development professional. He holds a PhD in Pharmacology from St. George’s Hospital Medical School, University of London, UK, a MS in Pharmacology from Nanjing Agri. University and DVM from Qingdao Agri. University. He has published nearly 30 peer reviewed journal articles and reviews.

Lai Wang, PhD  
Global Head of R&D, BeiGene

Dr. Lai Wang joined BeiGene in the early days of the company, 2011. His role has changed over the years within the organization, initially heading the biomarker and in vivo pharmacology groups. In 2013, he supported the clinical programs in the role of clinical biomarkers and translational research. In 2016, he was appointed as the head of China development, responsible for the clinical development in Asian-pacific region. Shortly afterwards Dr. Wang is leading the global research, clinical operation, statistics and data science & APAC clinical development team at BeiGene. Currently Dr. Wang is taking role of Global Head of R&D. Prior to joining BeiGene, Dr. Wang was the director of research at Joyant Pharmaceuticals, a biotech company based in Dallas, Texas. Dr. Wang received his B.S. from Fudan University and Ph.D. from University of Texas Health Science Center at San Antonio, and had post-doc training with Dr. Xiaodong Wang at Howard Hughes Medical Institute. Dr. Wang had over 20 years of experience in oncology field and over 10 years of experience in pharmaceutical industry on both research and development.

Joanna Wu, PhD, JD  
General Counsel, Biotech incubator

Dr. Joanna Wu has served as in house counsel for several life sciences companies. She started her legal career with the law firm of Ropes and Gray in Boston. She has a JD from UC Berkeley and a PhD from University of Virginia.

Vincent Xiang, PhD, MBA  
Founding Managing Partner, 7G BioVentures

Prior to founding 7G BioVentures, Dr. Vincent Xiang was a managing director and Head of Global BioVenture at Hillhouse Capital. Prior to that, he was a partner at 6 Dimensions Capital. He has over 20 years of experience in the life sciences industries in the U.S. and China. From 2013 to 2016, Dr. Xiang was Managing Director and Head of international investments & business development at Humanwell Healthcare Group (600079.SH), which has $1.3B/year in revenue in 2015. He led the $550M acquisition of US Epic Pharma, the largest M&A ever done by a Chinese healthcare firm. Prior to that, he worked as Managing Director of Burnell Life Science Venture Capital Fund, scouting first in class assets. From 2004 to 2012, Dr. Xiang was Portfolio Manager/Analyst at Franklin Templeton, investing in global life science companies at all stages. Previously, he was Vice President of business development at Genycous, a US biotech start-up. He was also Director of venture investment at Acacia Research, Associate at BioAdvance (a healthcare Angel fund), and Irvington Fellow at Skirball Center and licensed his patented technology to Millennium Pharmaceutical for royalty payments. Dr. Xiang began his career at Sinopharm in China. Dr. Xiang received his Ph.D. in molecular biology from University at Stony Brook, MBA from the Wharton School, and B.S. in Immunology and Microbiology from Fudan University. He is a founding member of BayHelix Group, founders and board members of two life science startups.

Chong Xu, PhD, MBA  
Partner, F-Prime Capital Partners

Chong is a Partner at F-Prime Capital. He focuses primarily on biopharmaceutical and medical technology sectors and works closely with the Eight Roads Ventures Asia team to manage portfolio companies and new investment opportunities in China. Prior to joining F-Prime in 2015, Chong was a consultant in McKinsey and Company’s Boston office, a hedge fund healthcare equity analyst with Massif Partners and Affirmed Healthcare, and a researcher focusing on developmental neurobiology at Temasek Life Sciences Laboratory in Singapore. Chong holds a Ph.D. in Cell Biology from University of Virginia and a MBA from Darden School of Business, University of Virginia. He received his B.S. in biology from Zhejiang University, China.

Yaji Xu, PhD  
Senior Staff Biostatistician, Biostatistics, Illumina

Dr. Yaji Xu is a statistician currently working at Illumina. His areas of expertise are applications of statistics to the design and analysis of studies evaluating in-vitro diagnostic devices (IVDs), with particular emphasis on devices/assays related to molecular genetics and pathology for precision medicine.
was a mathematical statistician in the Division of Biostatistics at the FDA Center for Devices and Radiological Health before joining Illumina. During his tenure at FDA, he participated in the regulatory review and authorizations on numerous CDx and tumor profiling assays such as the first NGS-based CDx oncology panel, and the first and the second NGS-based liquid biopsy oncology panels. He was a recipient of FDA Group Recognition Award and FDA Commissioner’s Special Citation Award. Dr. Xu was trained at the University of Texas and Yale University. He is also an adjunct professor in the Department of Statistics at the George Washington University in Washington, DC.

### Jingjun Yin, PhD
**Executive Director, Process Research & Development, Merck & Co., Inc.**

Dr. Jingjun (JJ) Yin obtained his B.S. degree from the University of Science and Technology of China and his Ph.D. degree with Prof. Lanny at Emory University. After a postdoctoral fellowship with Prof. Stephen Buchwald at MIT, JJ started at Merck Process Chemistry in Rahway, NJ in 2001. He has worked broadly across the Process Chemistry, Discovery Process Chemistry, and Enabling Technologies, and External Capabilities groups in Small Molecule Process Research & Development. He is now Executive Director and head of the External Capabilities group that works with strategic partners to support small molecule programs across the Merck pipeline. JJ has over 60 publications and patents.

### Fang Zhang, PhD
**Executive Director, China Business Development, Bristol Myers Squibb**

Fang Zhang is the Executive Director at Bristol Myers Squibb leading business development for the China market. She joined BMS in 2015 and has taken increasing responsibilities in the Business Development group including 5 years of experience in global Oncology Search & Evaluation. Fang received her Ph.D. degree in Bioengineering from the Georgia Institute of Technology and her M.B.A. degree from the Tepper School of Business at Carnegie Mellon University. Prior to earning her M.B.A., Fang worked as a postdoctoral research fellow at University of Pittsburgh where she conducted cancer drug discovery research.

### Litao Zhang, PhD
**Global Head of Discovery Technology and Molecular pharmacology, Discovery Sciences, Janssen Research and Development**

As DTMP head, Dr. Litao Zhang is responsible for leading a global team and working in close partnerships across Janssen JRD. Her team is actively applying advanced technology platforms such as Protein Degradation, DNA-encoded Library, Peptide Platform, Chemical Biology, Functional Genomics and Proteomics, Receptor Pharmacology, Biosignature, High Dimensional Pharmacology, Single Cell Omics, High Content Image, Cryo-EM and AI/ML to enable multimodality drug discovery from concept to NME across all therapeutic areas at Janssen. Prior to joining Janssen, Litao was Vice President of Leads Discovery & Optimization, Discovery Genomics & Proteomics and Biologic Discovery at Bristol-Myers Squibb. Her teams contributed to four commercially launched drugs: SPRYCEL®, FARXIGA®, DAKLINZA®, and ELIQUIS®. As a strong supporter of diversity & inclusion, she played a formative role in the launch of a company-wide employee resource group with the vision to enhance female business impact through the creation of a powerfully diverse and globally inclusive workplace.

### Lili Zheng, MS
**International Tax Partner | Deputy Managing Partner, Chinese Services Group, Deloitte**

Lili is a senior US international tax partner with more than 30 years of experience in the field. She currently serves as the Deloitte’s Asia Pacific Cross-Border Services Leader and Deputy Managing Partner of Deloitte US Chinese Services Group. She has substantial experience in cross-border tax planning and is responsible for Deloitte’s overall cross-functional services to MNCs investing Asia as well as Chinese & Asian clients investing in the US. Leveraging on her extensive experience in Deloitte offices in San Francisco, Tokyo, Beijing, San Jose and Hong Kong, Lili provides practical and implementable solutions to multinational companies on their cross-border investment structuring, IP planning, JV planning, M&A, entry and exit strategies. She is a trusted advisor with substantial experience in advising PE/VC funds and their portfolio companies in IPO positioning & restructuring to access different capital markets in the US, Hong Kong, Mainland China, and Taiwan. Fluent in Mandarin and Cantonese, she has a deep understanding of the unique considerations of companies from Asia Pacific on their cross-broader greenfield investments in the US and related supply chain impacts in various industries including but not limited to life sciences and healthcare, technology, financial services and manufacturing.

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Biographies of Session Moderators

**Xiaodong Chen**, PhD  
Director of CMC Operations, Roivant Sciences

Xiaodong is the Director of Chemistry, Manufacturing, and Control (CMC) Operations at Roivant Sciences where he is leading product development including technical due diligence on assets of interest and strategy development and execution of pharmaceutical development activities throughout the development and commercialization for both biologics and small molecule drugs. Prior to joining Roivant, Xiaodong was a Drug Product Development Team Leader and Senior Principal Scientist at Bristol Myers Squibb where he had led multiple matrix teams and participated in successful FDA filings. Xiaodong is actively involved in the scientific community. He has co-authored two book chapters, over a dozen peer-reviewed publications and numerous conference abstracts, as well as having chaired a number of national and international conference sessions. Xiaodong is on the Editorial Advisory Board of Journal of Pharmaceutical Sciences and invited reviewers for NIH contract proposals and scientific journals. Xiaodong received his Ph.D. from the Ohio State University.

**Zheng Chen**, PhD  
Associate Scientific Director, CPD Development Engineering, Bristol Myers Squibb

Zheng Chen is a cross-functional team and project lead in small molecule CMC development. She is currently an Associate Scientific Director in the development engineering group of Bristol Myers Squibb (BMS). Over her 15 years’ career in the pharmaceutical industry, Zheng has contributed, managed, and led the development of numerous small molecule assets in various phases, spanning from pre-clinical through post-marketing. Prior to BMS, she had held various roles with increasing responsibilities at Eli Lilly, Merck, J-Star Research and Celgene. With BMS, she contributed to several mid to late phase projects, including being a key member of ZEPOSIA® drug substance team for filing and continuously contributes to both ZEPOSIA® and ONJURE® LCM and leads project team to deliver new treatment options to patients. Zheng received her Ph.D. in Chemical Engineering from the University of Michigan, and both MS and BS from Tsinghua University, majored in Material Science and Polymer Science & Chemical Engineering.

**Wei Ding**, PhD  
Head, Bioinformatics/R&D, Admera Health

Dr. Wei Ding has over 20 years’ health care industry and academia experience, including the cancer research, precision medicine and translational research. Prior to Admera, Dr. Ding worked as the clinical genomics lead at Mount Sinai from 2014 to 2016. Prior to Mount Sinai, he was the Principal Scientist at Schering Plough then Merck from 1999 to 2013. He was also an adjunct professor at Kean University. Dr. Ding has published over 40 peer reviewed papers, patents and patent applications.

**Tuochuan Dong**, PhD  
Manager, Business & Operations, Avotres Inc

Tuochuan Dong works at Avotres Inc. as Manager, Business & Operations. He has worked for 7 years at Novartis Oncology as a biostatistician. He holds a PhD in Biostatistics from SUNY Buffalo, and a bachelor degree of Mathematics and Statistics from Peking University. Tuochuan is also a wechat blogger on the history of the pharmaceutical industry.

**James Early**  
Managing Partner, Tamarack Advisory

James Early is managing partner of Tamarack Advisory, which facilitates cross-border investment between the US and China. James has more than 20 years of experience in institutional finance, and has served on the advisory boards of several cross-border private equity companies. Bringing better medicine to China is James’ passion. He is a member of the Wall Street Fintech Club, Mensa, and is an EC member of SAPA-DC, and often appears as a guest on CCTV, Phoenix TV, CNN, BBC, CNBC, The Wall Street Journal and other international media.

**Li Feng**, PhD, JD  
Partner, Finnegan

Dr. Li Feng is a partner at Finnegan’s Washington D.C. office. She holds BS and MS degrees from Peking University, and PhD and JD degrees from the University of Utah. Dr. Feng practices patent litigation before U.S. district courts, post-grant proceedings before the Patent Trial the U.S.
Jerry J. Li, PhD  
Director, Biostatistics, Programming and Data Management (BDM), Daichi Sankyo, Inc.

Dr. Li has been working on clinical trials from Phase 1b to 4 with focus on Phase 2 and 3 studies. Dr. Li received his Ph.D. degree in Statistics from University of Maryland, College Park. He joined Merck in 2013 following working at the U.S. FDA. At Daichi Sankyo and Merck Dr. Li has been closely involved in clinical trial design, statistical analysis and reporting and authoring filing documents submitted to regulatory agencies worldwide. His clinical development expertise covers multiple indications in oncology, immunology, infectious diseases, and neurosciences. He also holds an advanced degree in molecular cell biology. Dr. Li has been a member of Executive Council of Sino-American Pharmaceutical Professionals Association Headquarters (SAPA-HQ) since 2016. He has successfully co-chaired SAPA Scientific Symposium in 2019, and co-chaired sessions including Clinical Development, Biostatistics and Data Sciences, Market Access and Health Economics at SAPA signature events.

Yongmei Li, PhD  
CEO, AvanBio Inc.

Dr. Yongmei Li is the CEO of AvanBio Inc., which focuses on the development of nano-scale superparamagnetic bead products and their applications in molecular diagnosis and protein analysis. Prior to her entrepreneurial journey, Yongmei had ten years of experience working at Boehringer Ingelheim Pharmaceuticals, Inc. As Senior Principal Scientist, she led a group of scientists in drug metabolism and pharmacokinetics in support of new drug development and was involved in global regulatory submissions. Yongmei Li holds a Ph.D. degree in Pharmacognosy (Natural Product Chemistry) from School of Pharmacy at University of Illinois, a MS degree and a BS degree in Pharmacy from West China University of Medical Sciences. As part of professional and community service, she served as a BD (Board of Directors) member of SAPA from 2017 to present, the President of SAPA-Connecticut from 2015 to 2016, Vice-principal of Huaxia Chinese School at Connecticut from 2012 to 2015, and the President of Western Connecticut Chinese Association in 2006.

Wansheng Jerry Liu, PhD, JD  
Partner and Chair of China Practice, Fox Rothschild LLP

Jerry practices in wide areas of intellectual property and corporate laws, including patent and trademark prosecution, litigation and opinions, contract review, formation of business entities, etc. He serves clients from individuals and start-up companies to Fortune 500 companies, including assisting a number of major Chinese pharmaceutical companies in IP protection and conducting business in the U.S., and has handled due diligence for investment, M&A and licensing deals valued from multi-million to multi-billion dollars. Prior to law practice, Jerry worked as a Senior Research Investigator in process development at Bristol Myers Squibb Company. He obtained Ph.D. in Organic Chemistry with Professor Sir Derek H. R. Barton (Nobel Prize, 1969) from Texas A&M University, J.D. from Rutgers University School of Law, and B.S./M.S. in Chemistry/Polymer Science from University of Science and Technology of China (USTC). Besides SAPA President in 2019-2020 and Editor-in-Chief of Rutgers Law Record in law school, Jerry is serving as Co-Chair of the CNIPA Committee of the New York Intellectual Property Law Association (NYIPLA) and General Counsel
Dr. Jiajun Mei is current working as Associate Director, Regulatory Affairs and CMC lead for Aleon Pharma International. He establishes the CMC function of Aleon and has contributed to over 50 INDs, including small molecular drugs, monoclonal antibodies, biosimilars, cell and gene therapies, etc. He also has extensive experiences on having meetings with the FDA. Before joining Aleon, Dr. Mei was a postdoc researcher at Princeton University. He received his Ph.D. degree in Chemistry from University of Virginia and B.S. degree form Peking University. Dr. Mei volunteers in the SAPA Investment Forum, Business development and Logistic teams. Dr. Mei is also a certified personal trainer and founder of the Dr. Mei Fitness Club. He also leads the Aleon employees to train 5 times per week in his “Fitness from Office/Home” program.

Yongle Pang, PhD
Discovery DM PK Bioanalyst, GSK

Dr. Pang is currently a bioanalyst in the discovery DM PK department at GSK (PA, USA). His job duty includes the design and delivery of fit-for-purpose bioanalytical data to support early discovery in vivo and in vitro projects. Before joining GSK, he was a staff scientist in the regulated bioanalysis department at Covance (WI, USA). He was responsible for method development and method validation for a variety of drug candidates. Dr. Pang is a graduate of Michigan State University (Ph.D. in Chemistry, MI, USA), where he developed enzyme-containing membranes for rapid monoclonal antibody digestion prior to mass spectrometry analysis. He has extensive experience in LC/MS-based small molecule and large molecule bioanalysis in the GLP and non-GLP settings. He has a great passion for bioanalysis and contributes to various peer-reviewed publications. He is also an active reviewer for journals in the analytical chemistry area.

Eric Rong
President, Praxgen Pharmaceuticals

Eric Rong is President, Praxgen Pharmaceuticals with more than 30 years of pharmaceutical industry experience in drug discovery, product development, leadership, technical transfer, manufacturing & packaging, project management, CMO, API, validation, regulatory affairs, ANDA, portfolio selection, company set up and operation, business development and product launch with solid dosage, semi-solid dosage, sterile injectables and ophthalmic suspension and ointment products. Prior to joining Sungene, he was President and CEO of Klus Pharma, the US subsidiary of Kelun Pharmaceutical, one of Top 10 pharmaceutical companies in China. Prior to Klus Pharma, he was the head of Formulation & Microbiology, R&D at Akorn Inc, a pharmaceutical company specializing in ophthalmic and injectable products. Prior to Akorn, he previously worked in various leadership and technical positions at Aventis, Pfizer, Patheon and Novartis. He led his team to submit more than 80 ANDAs to FDA successfully and led and involved more than 20 different dosage form under different phase new product research and development. He received his life science degree from Peking University.

John Sun, PhD, MBA
Global Program Lead, Clinical Technology and Innovation, Global Drug Development, Novartis; President of SAPA 2020-2021

John is an inspirational leader and a seasoned professional in the pharmaceutical industry, and also a passionate practitioner and advocate for career development. Currently he is a Global Program Lead at Novartis, and had served as Global Analytics Project Manager and Global Program Team Director in different franchises and development units. Before Novartis, John held positions with increased R&D responsibilities from Whitehall-Robins, Kos Pharmaceuticals, Schering-Plough, and Sanofi-Aventis. Over the years, John has actively volunteered in various professional organizations, served as Chair of Project Management Community in Drug Information Association (DIA), President and Career Lead at Sino-American Pharmaceutical Professionals Association (SAPA), Chair of Chinese Culture Community, President of Novartis Toastmasters Club and Area Director of Toastmasters International at District 83. John had presented in various domestic and international symposia on project management, drug development, and career development. John obtained his PhD in pharmaceutics from Virginia Commonwealth University, MBA from Rutgers University, and BMEd from Beijing University of Traditional Chinese Medicine. John is a certified Project Management Professional (PMP), trained in black-belt for lean six-sigma, and a Distinguished Toastmaster (DTM).

Xin Tao, JD, MS
Senior Associate, Global Regulatory, Hogan Lovells LLP

Xin Tao’s previous work experience as a research biochemist informs his science-based food and drug law practices. His unique ability in understanding and interpreting the complex scientific issues as they relate to the governing legal and regulatory requirements helps clients with all phases of product development, manufacturing, and marketing. His practice focuses on novel food and drug applications that require U.S. Food and Drug Administration (FDA) review and FDA Current Good Manufacturing Practices (cGMP) compliance for foods, dietary supplements, and pharmaceuticals.

Li Wan, PhD
Senior VP, Head of Regulatory Affairs, GeneQuantum Healthcare (Suzhou) Co., Ltd.

Dr. Li Wan has over fifteen years of industry experience in the clinical development and regulatory affairs for innovative small molecule and biological oncology, CNS and ophthalmic products. He is currently the Senior VP, Head of Regulatory Affairs at GeneQuantum Healthcare and Head of Regulatory Affairs Department at SAPA. Before joining GeneQuantum Healthcare, Dr. Li Wan was the Vice President and Head of Global Regulatory Affairs at Alphamab Oncology and Lyue Pharma. Prior to Lyue, he worked in the world-renowned big pharmaceutical companies including Pfizer and Novartis. He has successfully led many global IND/CTA/nda/bla submissions and obtained approvals in the US, EU, and China etc. He is a well known expert in global regulatory affairs and has been an invited speaker at many professional organizations and conferences. Dr. Wan holds a doctoral degree in Pharmaceutical Science from Rutgers University.
and is a certified regulatory affairs professional by the Regulatory Affairs Professional Society, USA.

**Hongye Wei, MS**  
Consultant, Precision Group

Hongye is a consultant at a healthcare company. She has dual degree in statistics and pharmacology.

**Jack Wu, PhD**  
Head of Global Business Development, Search & Evaluation, Antengene

Dr. Wu is the Head of Global Business Development, Search & Evaluation at Antengene, leading the business development efforts in search and evaluation, due diligence, and execution of preclinical through clinical stage to commercial business development opportunities in hematology & oncology. Previously, he was the US Head of Business Development at Adlai Nortye USA Inc., a clinical stage biopharmaceutical company. He was responsible for search & evaluation and deal transaction of business development opportunities. In addition, he managed the partnerships with Eisai and Merck. Before Adlai Nortye, he was the Manager of Commercial Partnerships at ATCC, one of the world largest biological resources centers. He was responsible for prospecting and developing new commercial and strategic partnership opportunities through engagements with external partners, contract term negotiations and preparations for major commercial transactions and agreements with business-to-business partners and other commercial customers. Prior to joining ATCC, Dr. Wu worked as the Sales & Marketing Manager of Discovery Biology Business Unit at GenScript USA. He led the global commercial team including marketing, sales, and customer care to support pharmaceutical and biotech clients’ Drug Discovery needs.

**Jian Wu, PhD**  
Senior Director of Medicinal Chemistry, Huahai US Pharmaceutical R&D Institute

Jian has been a Senior Director of Medicinal Chemistry at Huahai US Pharmaceutical R&D Institute in Somerset, NJ since July 2020. He is responsible for developing medicinal chemistry strategies, leading drug discovery team and managing research collaborations in different therapeutic areas. Prior to that, Jian was a Director of R&D at Progena in Malvern, PA, leading drug discovery team on ubiquitin ligase, debiquitination and PROTAC programs. During his 10-year tenure at Progena, he initiated and established numerous research collaborations with prestigious academic institutions and pharmaceutical companies. He has been invited to speak at ACS national meetings in 2016, 2017 and 2018. Jian received his BS degree in Medicinal Chemistry from China Pharmaceutical University in 2000 and Ph.D. degree in Organic Chemistry from Wayne State University in 2006. He conducted postdoctoral research with Prof. Jeffrey Bode at University of Pennsylvania (2007-2009). Jian has been actively involved in SAPA activities since 2019, and he is one of the key organizers of the 2021 Scientific Symposium.

**Jun (Stephen) Xue, MS**  
Director of Operation, Chipscreen Bioscience (US) Ltd.

Jun (Stephen) Xue is Director of Operation, as the first employee at Chipscreen Bioscience (US) Ltd. My main responsibilities include daily management and operation of the US branch, Chipscreen Biosciences (US) Ltd., a fully own subsidiary of Shenzhen Chipscreen Biosciences Co. Ltd. (688321.SH), staff recruitment, coordination with clinical development and business development affairs in US with external and internal departments. Jun has over 18 years of intensive pharmaceutical industry experience and has worked for many major pharmaceutical companies, including Roche, Sanofi, BMS, Celgene, Galderna, Eli Lilly, and Amicus. He has participated and supported several FDA NDA and European MAA submissions in various therapeutic areas, including immunology, oncology, dermatology, diabetes, and cardiovascular disease. Before coming to the USA, Jun was one of the first generations of Merck China employees working in sales and marketing. Stephen holds a Master of Science degree in Computer Science (minor in Statistics) and a bachelor’s degree in Biochemistry.

**Dexi Yang, PhD**  
Associate Principal Scientist, Merck

Dr. Dexi Yang is currently an associate principal scientist in discovery chemistry at Merck KW site. He graduated from D.I.I. in Nanjing University, and later received his Ph.D. in Organic Chemistry from The Ohio State University in 2008, where he worked on the total synthesis of chapparrone and polyandranes in Prof. David J. Hart's group. In 2009, he joined Prof. Glenn C. Micalizio’s group at The Scripps Research Institute in Florida as postdoctoral researcher and completed the total synthesis of alkaloid (-)-205B. After working at Dartmouth College for 1 year, he joined Merck in 2014 as a medicinal chemist in Kenilworth, NJ. He has designed and synthesized many drug candidates, mainly in the areas of infectious disease, cardiovascular and CNS, and three compounds are in preclinical or clinical stages. He has co-authored more than 20 publications and 8 patents. Dr. Yang also has an expertise in portrait and theater photography and has been the main photographer for SAPA and many events in NJPAC, Lincoln center and Carnegie Hall.

**Kai Ying, PhD**  
Director of Bioinformatics, Columbia University Medical School

Dr. Kai Ying currently is the director of Bioinformatics in Precision Genomics Laboratory, Columbia University Irving Medical Center. He got his PhD in Iowa State University in genetics and genomics, has Post-Doctoral training in NIH and works as a senior scientist at the Mount Sinai Medical School / Sema4 genomics. Dr. Ying has many years of experience in areas of cancer genomics, clinic genetics and molecular diagnostic, successfully leading the development informatics system of several NGS based clinic genetics diagnostic tests and approved/certified by CLIA, CAP and New York Department of Health.

**Aming Zhang, PhD**  
Manager, CMC-Analytical, GSK

Aming Zhang is currently a Biopharmaceutical Manager in CMC Analytical (CMCA) at GSK. His
Main responsibilities include leading a dynamic team to develop and apply cutting-edge analytical technologies to support biologic product characterization, process development and other CMC related activities throughout different stages of development. Prior to joining GSK, Dr. Zhang also worked for several other leading biotechnology and biopharmaceutical companies including Regeneron Pharmaceuticals, GSK and Amgen (Postdoc training). Dr. Zhang has also been a long-time volunteer and executive member of SAPA since 2012, and currently co-chairs the membership department at SAPA-HQ. He received his PhD in Chemical Engineering from University of Virginia in 2011, and B.S. from Zhejiang University.

**Deyi Zhang, PhD**
Manager, External Innovation and Collaborations, Hansoh Bio LLC

Over ten years experiences on cancer therapy. Especially focus on mAb immunotherapy for solid tumor, protein degradation induced by PROTAC in hematological malignancies. Study and analysis technology trend and pipelines development of different companies, seek cooperation opportunity with external organizations.

**Yulan Zhang, MS**
Associate, Health Economics & Outcome Research, KMK Consulting Inc.

Yulan is a healthcare consultant specialized in Health Economics & Outcomes Research and experienced in real-world data analytics. Yulan advises clients on HEOR protocol design and data analysis to evaluate products’ real-world efficacy and safety and to inform provider and payer strategies. Yulan led analysis for landscape assessment and outcomes-based contracts to provide evidence and insights for the negotiation of product tier and contract pricing. Recently, Yulan is in charge of drug safety evaluation to address issues with real world adverse event reporting of newly launched drugs. Exploration of drug launching strategy and Oncology HEOR are her next steps. Yulan holds an Master’s Degree in Biostatistics from Columbia University Mailman School of Public Health and a Bachelor’s Degree in Biochemistry & Cell Biology and Management Science from University of California San Diego.

**Yiming Zhao, PhD**
Staff Scientist, Regeneron Pharmaceuticals

Yiming Zhao received his B.Sc. in China, M.Sc. in Finland, and Ph.D. in the Netherlands in 2013. After that, he moved to the U.S. and worked as a Postdoctoral Fellow at Mount Sinai Medical School and Memorial Sloan Kettering Cancer Center. He has published more than 25 peer-reviewed journal articles including high-profile journals, and received Pathway to Independence Award (K99/R00) form NIH. In 2017, he decided to apply his passion for science to biopharmaceutical industry, and joined Regeneron Pharmaceuticals as a Formulation Scientist. He is currently working on developing large molecule formulations and innovative biologics formulations. In the industry, he continues to apply his scientific understanding and problem-solving skills to advancing new technologies, which has already led to multiple patent applications. He serves in SAPA as lead of Communication.
SAPA Service Excellence Award

The following individuals have been selected by the President Office and Executive Council as the winners of SAPA Excellent Service Awards:

- **SAPA Presidential Service Excellence Award**
  Wansheng Jerry Liu

- **SAPA Service Excellence Award**
  Vince Deng, Chenchao Gao, Yong Guo, Andy Han, Jiangbin (John) Hu, Changhui (Charles) Li, Yanming (Brian) Jiang, Guiqing Liang, Fang Shen, Xiaowen Wang, Jack Wu, Jun (Stephen) Xue, Xiaoyong Yang, Dexi Yang, Yulan Zhang, and Yiming Zhao

- **SAPA Special Recognition Award**
  Bob Ai, Yunqi An, Jiangchao Chen, Shuhui Chen, Zheng Chen, Gang Cheng, Yvonne Cheng, Lan Deng, Wei Ding, Tuochuan Dong, Helena Feng, Iris Gao, Hanxin Gao, Guanhua He, Lisa Huang, Lin Huang, May Huang, Zosia Jiang, Jerry J. Li, Xue (Tina) Liang, Xiaolan Liu, Jiajun Mei, Pan Pan, Yuting Pan, Yongle Pang, Eric Rong, Junchun (Cathy) Tang, Li Wan, Shaonan Wang, Hongyei Wei, Zhe Wu, Jian Wu, Di Wu, Aiguo Xu, Muyun Xu, Xiaojiao Xue, Wah Yan, Guangyao Yang, Tianyi Yang, and Aming Zhang

- **SAPA-China Service Excellence Award**
  Amanda Fu, Xiucui Liu, and Julia Zhang

- **SAPA-CT Service Excellence Award**
  Yifan Bao, Yiting Xu, Sisi Yang, Jinqi Zhan, and Chao Zheng

- **SAPA-DC Service Excellence Award**
  Rong Cheng, Yu Ding, James Early, Victor Liang, Feng Liu, Xin Tao, Mia Terwilliger, Chen Wang, Daozhan Yu, and Deyi Zhang

- **SAPA-GP Service Excellence Award**
  David Cragin, Cindy Guo, Ruixin (Rachel) Hao, Sheng Hu, Hui Wang, Sherry Wang, Xin Xin, Saisi Xue, Yang Yuan, and Xinjun Zhang

- **SAPA-MW Service Excellence Award**
  Qian Chen, Jingdong Qin, and Mufeng Wu

- **SAPA-NE Service Excellence Award**
  Joyce Chen, Yu Chen, Huijuan Li, Kejie Li, Dong Yang, Tracy Zhang, Yudan Zhang, and Chao Zheng
2021 SAPA Scholarship and Excellence in Education for Life Sciences

The SAPA Scholarship and Excellence in Education Program was established in 1999. The Scholarship is dedicated to recognize and support excellence on the part of outstanding high school students, and to encourage the finest high school graduates in the US to develop careers in Life Sciences. Each scholarship awards a one-time fund of $1,000 towards tuition payment.

Jason Ding

Jason Ding is a 2021 graduate of Mountain Lakes High School in Mountain Lakes, New Jersey. He completed 16 AP courses and maintained an excellent academic record graduating as the class valedictorian. Jason was very involved at his high school activities, being Student Body President, Debate Team Captain, and Key Club President to select a few. He has also done extensive biomedical research, interning at Mount Sinai Hospital and Memorial Sloan Kettering Cancer Center. His research on tumor mutation burdens in summer 2020 was published in Journal for Immunotherapy of Cancer and presented at various conferences. He also founded his own 501(c)(3) nonprofit organization in 2019. Jason enjoys playing the piano in his free time - a hobby that has earned him multiple awards at Carnegie Hall. Jason is currently a freshman studying molecular biology at Princeton University.
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Visit SAPA career center for job opportunities: https://sapaweb.org/career-center/
BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide.

BeiGene markets three internally developed medicines: BTK inhibitor BRUKINSA, anti-PD-1 antibody tisleltuzumab, and PARP inhibitor pamiparib. BRUKINSA is available in the United States, China, Canada, and additional international markets; tisleltuzumab and pamiparib are available in China. In November 2019, BRUKINSA became the first cancer drug approved by the U.S. Food and Drug Administration based on clinical trials run in China when it received accelerated approval to treat mantle cell lymphoma.

BeiGene Oncology

BeiGene is committed to advancing best- and first-in-class clinical candidates internally or with like-minded partners to develop impactful and affordable medicines for patients across the globe. We are dedicated to advancing more than 95 clinical trials involving more than 13,000 patients and healthy volunteers. Our expansive portfolio is directed by a predominantly internalized clinical development team supporting trials in more than 40 countries. Hematology-oncology and solid tumor targeted therapies and immuno-oncology are key focus areas for the Company, with both mono- and combination therapies prioritized in our research and development.

BeiGene also partners with innovative companies who share our goal of developing therapies to address global health needs. We commercialize a range of oncology medicines in China licensed from Amgen and Bristol Myers Squibb. We also plan to address greater areas of unmet need globally through our collaborations including with Amgen, Bio-Thera, EUSA Pharma, Mirati Therapeutics, Seagen, and Zymeworks. BeiGene has also entered into a collaboration with Novartis granting Novartis rights to develop, manufacture, and commercialize tisleltuzumab in North America, Europe, and Japan.

### BeiGene at a glance

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<th>CEO</th>
<th>Industry Collaborations:</th>
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<th>Main Offices:</th>
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<table>
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<td>23 across 5 Continents</td>
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### Our World-Class R&D Engine

- Internally Discovered Molecules to the Clinic in First 10 Years: 11
- Preclinical Programs Ongoing: 50+
- Internally Discovered Approved Medicines: 3
- Late-Stage Programs: 3
- Phase 3 or Potentially Registration-Enabling Trials: 30+

As of September 2021

To learn more about BeiGene, please visit [www.beigene.com](http://www.beigene.com) and follow us on Twitter at @BeiGeneGlobal.
**BEIGENE BIOISLAND INNOVATION CENTER**  
An ecosystem designed to accelerate innovations by empowering scientists and entrepreneurs

BeiGene, a global, science-driven biotechnology company, sees that innovations are fundamental to creating patient value. We brought three internally developed medicines to market in our first decade and are now advancing a broad and deep portfolio.

BeiGene continues to believe there are tremendous opportunities for medical innovation through early research and scientific discovery, and values great ideas and talent coming from anywhere. With the goal of empowering scientists and entrepreneurs to accelerate their innovations, BeiGene is launching an **Innovation Center at Biosiland Guangzhou**, a biotech hub within the vibrant entrepreneurial ecosystem of China's Greater Bay Area.

**BeiGene Biosiland Innovation Center** features fully outfitted R&D infrastructure that is designed to enable innovators to focus on science and turn their ideas into reality quickly and efficiently. The 11-story, 430,000-square-foot building is envisioned to be home to >30 early-stage companies. Scientists and entrepreneurs at Biosiland Innovation Center are expected to be able to leverage fully integrated research capabilities and have potential access to funding as well as BeiGene experts with a history of success in scientific excellence, efficient clinical development, state-of-the-art manufacturing, and global commercialization.

Are you entrepreneurial scientists with innovative ideas or early-stage startups interested in learning more about BeiGene’s Biosiland Innovation Center? Contact our team at Biosiland@BeiGene.com.
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Highly Potent

SFC

Biocatalysis

Milling

Metal Catalysis

Flow Chemistry

Pharmaceutical Crystallization

Process Research Service

more...

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API CDMO: porton@porton.cn
Drug Product CDMO: DDS.inquiry@porton.cn
Gene & Cell Therapy CDMO: BD.SZ@portonbio.com

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Tuesday, October 26, 2021
3:30-5:30 pm EDT

Join us for an exciting session with our recruitment team, leadership and representative from our PAN Asian Network People and Business Resource Group. Learn more about current job openings in BMS China, Cell Therapy, and Product Development.

Our PAN Asian Network drives business results worldwide by promoting a workplace environment that fully values the contributions of Asian employees and helps the organization deepen the understanding of Asian patients, customers and other stakeholders.

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Jing Yang
Lead, PAN Asian Network
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Production of cell and gene therapies (CGT) is costly, intricate, and high-risk; in part, because most supply chain and manufacturing processes involve multiple stakeholders and facilities, coupled with variant CGT life cycles and patient journeys. Likewise, launching a CGT is hard! As future commercial launches become more prevalent, challenges will only be amplified. Join Deloitte and other industry leaders navigating the complexities of NextGen Therapies and how processes can be optimized to make things simple.

Learn more: www.deloitte.com/us/cell-and-gene-therapy

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GemPharmatech TM

Contributes to Accelerating Drug Discovery and Preclinical R&D in the US. GemPharmatech, Co., Ltd. (GPT) is a leading provider of animal models and preclinical services, especially in the development of humanized animal models for the global preclinical R&D communities. Its global headquarters is in Nanjing, China. The company has opened new operations in the United States to house more than 6,000 research mouse models. GPT specializes in generating mouse models using innovative gene-editing technologies, with a large collection of conditional knockout (cKO), knockout (KO), humanized, immunodeficient, and germfree mice. GPT provides a one-stop service in custom model generation, custom breeding, cryopreservation and rederivation, phenotyping, and pharmacology services, including drug efficacy testing and safety evaluation. The company has developed one of the world’s largest collections of over 17,000 different genetically engineered mouse strains.

Ready to ship from Boston

• 17 humanized immune checkpoint strains (PD1, PDL1, CTLA4, CD137, CD73, LG3, OK40, TIGIT, TIM3 on both B6 and BALB/c genetic backgrounds)
• 3 severe immunodeficient strains: NCG-hiL15, NCG-CAG-tomato, NCG-X (capable of engraftment without irradiation)
• 2 humanized ACE2 strains: B6hACE2 (T037659) and BALB/c-hACE2 (T037915)
• 1 strain of Alzheimer’s disease: 4xFAD
• 1 strain of autoimmune disease: DBA1-hiL17A

Knockout All Project (KOAP)

• Generating knockout and conditional knockout mouse strains for all 23,000 protein-coding genes in the mouse genome.
• Over 16,000 available cKO/KO mouse strains, with more currently in development.
• If a strain is not yet available, one can be created in as fast as 3 to 6 months.

192 Cre Strains, and Growing

• Cre driver strains, including inducible Cre-ERT2 strains, to complement our large library of over 7,000 conditional knockout mice.
• 16 Cre-ox strains available to add another level of cell-type specificity to Cre-loxP expression.
• In-house validation to ensure appropriate expression in the expected tissues

Building Mouse Models for Rare Diseases

Funds more than 85% of the cost associated with GEMM construction

In 2021, GemPharmatech continues to call for applications for “The GEMMs for Rare Disease Research Initiative” to promote the research and novel therapeutic development for the treatment of rare diseases.

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Nanjing 210061, P.R. China

Online
sales@gempharmatech.us
http://gempharmatech.us
Why We Invent
AT MERCK, WE ARE INVENTING FOR LIFE.

We are taking on many of the world’s most challenging diseases because the world still needs cures for cancer, Alzheimer’s disease, HIV, and so many other causes of widespread suffering in people and animals.

We invent to help people go on, unburdened, to experience, create and live their best lives.

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About Aleon Pharma International, Inc.

Aleon Pharma International, Inc. (Aleon) is a global, one stop, full service regulatory affairs consulting firm dedicated to accelerating & strengthening the novel drug development programs of sponsors. Aleon was founded in 2010, and for over a decade, we have provided high quality regulatory support to innovative sponsor companies.

With teams based in New Jersey, US; Suzhou, China; and Amsterdam, Netherlands, we are committed to helping accelerate the development of life-changing treatments by providing high-quality regulatory affairs services in the US, China, and Europe.

Aleon is a very rewarding and exciting place to work!

- Inc.’s 2021 Best Workplaces Honoree.
- Inc.’s 2020 Best Workplaces: Ranked national top 5% for employee engagement.
- 2018 Outstanding Employer Award (1 out of the 3 winners) by New Jersey Business & Industry Association.

We welcome the opportunity to introduce Aleon to you. Let’s start the conversation today!
Focus on Patient Centric Innovation

About Asclelis
Asclelis is an innovative R&D driven biotech listed on Hong Kong Stock Exchange (Asclelis, 1672.HK). Asclelis is committed to developing and commercializing innovative drugs for treatment of viral hepatitis, NASH and HIV/AIDS, for unmet medical needs in China and globally. Led by a management team with strong expertise and a proven track record, Asclelis has developed into a fully integrated platform covering the entire value chain from discovery and development to manufacturing and commercialization. Asclelis has three marketed products and eleven R&D pipeline drug candidates (seven of them developed in house). 1. Viral hepatitis: (i) marketed all oral HCV regimen of Asclevir® and Ganovo® combination (RDV/DNV regimen and ASC18 fixed dose combination (FDC), (ii) marketed Pegasyss® for HBV clinical cure; (iii) breakthrough therapies for HBV clinical cure. 2. NASH: global development of novel drug candidates against three different targets – FASN, THR-beta and FXR. 3. HIV/AIDS: ASC09F under development for FDC treatment of HIV targeting protease.

https://www.asclelis.com
A Global Branded 505b2 Company with Robust Pipeline

Company Name: Aucta Pharmaceuticals, Inc.
Aucta is a company of creation of better product of proven molecule.

Industry: Pharmaceuticals

Number of Employees: 90 (40/US, 50/China)

Vision: Aucta aims to become a significant specialty pharma player in U.S. and China

Strategy: Our corporate strategy is to focus on proven molecule, use 505(b)(2) regulatory pathway, through innovation, creating new therapeutics, with lower scientific risk and meet unmet medical needs in attractive market segment.

Mission: Improve delivery for better medicine.

Business Description: Aucta Pharmaceuticals is a new drug product development company focusing on branded 505b2 new product development. Aucta adopts a branded generic hybrid model, generating both near term product revenue and mid/long term investment return, it aims to become a significant specialty pharma player in the U.S. and China marketplace. We focus on improved dosage form for patients with a therapeutic focus in Pediatrics, CNS, Topical and other complex dosage forms.

Robust Pipeline:
On U.S. front, Aucta has two approved ANDA products that were launched in 2018 and 2021. We also submitted our first 505b2 NDA product (epilepsy) with US FDA and is expected to be launched in 2022. A few ANDAs are currently under review by FDA, and more to be submitted 2022.

On China front, we have one approved product ready to launch (infantile spasm), and we have multiple programs undergoing MAA applications with NMPA and a robust CNS and pediatric portfolio in development.

There are multiple development programs undergoing Ph2 pivotal clinical trials, one of which is an orphan drug product (FDA designated), others are innovative in nature as the only treatment available in the marketplace.

Company Background:
The company was founded in 2012. Aucta has operations in both New Jersey, US and Shanghai, China. Aucta’s Lingang commercial site in China will be ready in 2022

Products/Partners:
The company is at an inflection point of transition from R&D to commercial company. The company has entered into multiple out-licensing agreements with reputable companies both in U.S. and China over the last few years.

Technologies:
Aucta has developed distinct technology platforms in Pediatrics and Special dosage forms.
BF Innovation Inc. (BFI) is a wholly-owned subsidiary of Bright Future Pharmaceutical Laboratories Ltd. in New York, United States. BFI focuses on research and development of prescription pharmaceuticals, technology transfer and scale-up of these pharmaceuticals to its partners and third party CMOs (contract manufacturing organizations). BFI is poised to foster novel collaborations that can lead to significant advances in helping people to better future.

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https://bfinnovation.net
About CR Medicon

High Quality Drug & Medical Devices Development in the U.S and China

We are a fast-growing, innovative Contract Research Organization (CRO) dedicated to providing high-quality clinical development services globally. With 700 staff, we are a full-service platform in China with a dedicated biometrics service platform in US. Our team is led by industry veterans with 15-25 years of experience. We have adopted Medidata technology platform globally, accredited in many Medidata products including Rave/Balance/CTMS/eTMF. Our team is highly proficient in CDISC implementation including CDISC CDASH/SDTM/ADaM. We can help you to make sure the same set of global standards and quality is implemented, meeting the requirements of both US FDA and China NMPA. If you are thinking about expanding your drugs or devices into China market, or if you are evaluating a biometrics CRO that can provide high quality services yet at the same time can be flexible enough, CR Medicon is your best choice.

Data Management & Biometrics Services in the U.S
We have a large Data Management and Biostatistics team with hundreds of successful study and submission experience in US and China. Our team is led by industry veterans with 15-20 years of experience. We use Medidata system for all of our US studies and about 75% of our China studies. Most of our studies are implemented using CDISC standards. Our biometrics team is ready to help you to conduct studies meeting international data and reporting standards no matter they are run in US or China.

- Case Report Form (CRF, eCRF) design
- Randomized trial and drug supply system design
- Database design, build, test and maintain
- Double data entry and comparison of paper-form data
- Data verification and validation management
- Medical coding
- SAE reconciliation
- External data reconciliation
- Sample size calculation
- Protocol development
- Statistical methodology development
- Statistical Analysis Plan (SAP) and mock up shells development
- Randomized schedule development and randomization list generation
- Development of Study Data Tabulation Model (SDTM) datasets
- Development of Analysis Datasets (ADaM)
- Creation of Tables, Listings, and Figures (TLF)
- Interim analysis
- Data Monitoring Committee (DMC) related statistical activities
- Integrated Summaries of Safety and Efficacy (ISS/ISE)
- Annual or periodic safety reporting
- Quality assurance and data management audit

Visit us: https://en.crmedicon.com  Email: biz@crmedicon.com
We are proud to support SAPA and wish great success with the 2021 SAPA Annual Conference.

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How has Fox Rothschild grown to 950 lawyers?

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Fox Rothschild LLP
ATTORNEYS AT LAW

950 attorneys nationwide

Wansheng Jerry Liu, Ph.D., J.D.
Partner & Chair of China Practice
SAPA President 2019-2020
609.844.3037 | wliu@foxrothschild.com
Hengrui Pharma

Jiangsu Hengrui Pharmaceuticals Co., Ltd. (“Hengrui Pharma”) is a publicly listed and a leading biopharma with headquarter in China. Founded in 1970, it has about 28,000 employees with therapeutic areas covering oncology, anesthesiology & analgesics, autoimmune, and metabolic & cardiovascular.

Key Facts:
- ~$70 billion Market Capitalization
- $768 million R&D Investment in 2020
- 7 New Molecular Entities Approved in China
- 220+ Clinical Trials Ongoing Worldwide

![Graph showing annual revenue and net profit from 2006 to 2013, with CAGR of 24% and annual revenue > $4.26 billion in 2020.]

Patient Centric

INNOVATION

GLOBALIZATION

TALENT

15 R&D centers globally, with more than 4,700 R&D Staff

Join Our Team:
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- Hengrui USA Website: [https://www.hengruius.com/careers.html](https://www.hengruius.com/careers.html)
- Eternity Bioscience, Inc Website: [https://www.eternitybioscience.com/openings.html](https://www.eternitybioscience.com/openings.html)

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Dedicated to Health

HighTide Therapeutics Inc. is a clinical-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutics for non-viral chronic liver diseases, gastrointestinal diseases and metabolic disorders, with a focus on areas of high unmet medical need and lack of effective treatment options.

The lead product candidate, HTD1801, an ionic salt of berberine and ursodeoxycholic acid, is a first-in-class drug new molecular entity. It has received Fast Track designation from the U.S. FDA for both NASH and PSC, as well as Orphan Drug designation for PSC.

For more information, please visit our website:
www.hightidedtx.com
ABOUT INNOCARE

INNOCARE PHARMA (HKG: 0666) IS A CLINICAL STAGE BIOPHARMACEUTICAL COMPANY COMMITTED TO DISCOVERING, DEVELOPING, AND COMMERCIALIZING FIRST-IN-CLASS AND/OR BEST-IN-CLASS DRUGS FOR THE TREATMENT OF CANCER AND AUTOIMMUNE DISEASES WITH UNMET MEDICAL NEEDS WORLDWIDE. INNOCARE HAS BUILT A ROBUST PIPELINE, INCLUDING ONE ASSET WITH TWO NDAs SUBMITTED, ACCEPTED AND GRANTED PRIORITY REVIEW BY THE NFDA, THREE OTHER ASSETS IN PHASE II/III TRIALS AND SEVERAL OTHERS AT THE IND ENABLING STAGE.

JOB OPPORTUNITIES

AS WE FURTHER DEVELOP IN THE U.S., WE WARMLY WELCOME TALENTS TO JOIN US. IF YOU ARE THE EXPERT IN THE FIELD OF BUSINESS DEVELOPMENT, MEDICAL RESEARCH, AND CLINICAL OPERATION, PLEASE SEND YOUR RESUME TO TALENT@INNOCAREPHARMA.COM. IF YOU WOULD LIKE TO LEARN MORE ABOUT US, YOU CAN CONTACT

EMAIL: INFOR@INNOCAREPHARMA.COM
TELE: U.S. 505-524-1106, CHINA 09-10-06609959
WEBSITE: WWW.INNOCAREPHARMA.COM
Insilico Medicine

Insilico Medicine is a leading artificial intelligence drug discovery company in the world, with R&D and management resources in 6 countries and regions.

The company and its scientists are dedicated to transforming the pharmaceutical industry by developing and applying the next-generation deep learning approaches to drug discovery and drug development. Insilico Medicine develops an AI platform for identification of new therapeutical targets using multi-Omics data and generation of novel molecule structures using AI. The company is collaborating with innovative biopharmaceutical companies to validate its solutions and generate high-quality machine-learnable data. Since 2014, Insilico Medicine published over 100 peer-reviewed papers, applied for over 25 patents, and received multiple industry awards.

For more information, please visit our website insilico.com.
For collaborations, please contact us by email zhu@insilico.com.
Company Profile

Kanghong Pharmaceutical Group was founded in 1996 in Chengdu. It is a publicly traded company committed to the pharmaceutical R&D, manufacturing, and sales for biological products, Chinese traditional medicines, small molecule drugs and medical devices. We now have 13 subsidiaries in Chengdu, Beijing, Hong Kong, Israel and the United States.

Since its founding, Kanghong has based its drug development efforts on "innovation" and "international cooperation" with more than 300 invention patents granted in China and abroad. Till now, there have been 20 clinically proven products successfully launched, enabling “Kanghong” to become a well recognized brand name based on the company's unique products for common diseases in ophthalmology, CNS(central nervous system), endocrinology and pediatrics. Kanghong is also dedicated to the development of innovative products in oncology, immunology and other fields.
Global Leader in Recombinant Technology

- From Human Cells
- 6,000+ mAbs
- Customized recombinant production services
The UnitedHealthcare  
Asian Initiatives Team

It is a UnitedHealthcare goal to help individuals live healthier lives, and for many years our Asian initiatives team has been offering dedicated service assistance to the Asian-American community. As health care continues to be increasingly complex, we would like the opportunity to put our years of experience to work for you.

Working with the Asian Initiatives team
You’ll be glad to know that we take great efforts to simplify processes and customer interaction with us, and we personalize our responses and information based on your preferences. We understand the unique needs of our Asian-American customers; we care about your health.

Customer Care Hotline: 1-800-250-5779
Monday - Friday, 9 a.m. - 5 p.m.

With you every step of the way
We want to help ensure that you have easy access to health care providers, a range of affordable plan options from which to choose and understandable benefits information.

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WWC Professional Corporation Limited Certified Public Accountants (Practising)

WWC Professional Corporation Limited ("WWC") is a boutique professional services firm, established in 1981, with headquarters in California, United States, and offices in Hong Kong, Beijing, and New York. With partners of seasoned experience across various disciplines, in professional practice and corporate roles, the company provides full suite financial and corporate services to clients, including, assurance and attestation, global tax advisory and compliance, support for capital market and transactions, management consulting and global corporate services for SMEs.

Through the years, we have established ourselves as a trusted advisors to our clients around the world, not only from our technical expertise, agility and the ability to create innovative solutions, but also our quality, ethics and integrity.

WWC has more than 500 clients across various sectors globally. The firm has supported 18 clients in their IPO process as financial advisors and reporting accountants, which are now listed on stock exchanges and OTC markets in the United States. WWC is currently a trusted financial advisors to more than 30 companies listed on the SEC, advising them on capital market transactions and M&A activities.

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Our partners and staff are professional and experts with very rich and diverse experience from Big-Four accounting firms and senior finance roles in sizeable organisations around the world. Our collective experience is we are particularly well positioned to bring partnership and synergy between entities in China and the United States.

PATRICK WONG | patrick@wwccpa.com | +1 (650) 533 5090 | +852 6506 1338

Patrick is the Managing Partner of the firm. He joined the firm in 2004 as a partner and is specialised in auditing, IPOs and cross-border capital market transactions for companies in the United States and China. Patrick was the Chief Financial Officer of a technology company listed in the United States, and he held various senior roles in finance and sales with technology companies and a bank. He is a Chartered Accountant of Canada, and Certified Public Accountant of the United States, Hong Kong and Australia.

NORA WONG | nora@wwccpa.com | +1 (650) 638 0808

Nora Wong is a Partner of the firm since 2016. Nora serves clients across many industries and sectors including financial services, construction, manufacturing, and non-profit organisations focusing on assurance and transaction advisory services, especially for companies with operations in China. Nora graduated from the University of California at Davis with a Bachelor of Arts in Economics and Chinese. Nora is a member of AICPA and HKICPA.

BRIAN IP | brian.ip@wwccpa.com | +852 9657 0839

Brian is a Partner who joined the firm in 2012 and has 8 years of experience providing audit, financial due diligence, M&A, and restructuring services to clients, especially IPO projects and clients listed on the SEC in the United States. He is very experienced with PCAOB requirements and in liaising with SEC and regulatory bodies in the United States and Hong Kong. Brian is a member of AIICPA and HKICPA.

PASCO TSANG | pasco.tsang@wwccpa.com | +852 6916 4537

Pasco was admitted Partner of the firm in 2018. He is specialised in capital market and M&A transactions in China and the United States, and from that, he holds very strong relationships with private equity firms, investment banks and regulatory bodies. Pasco has a diversity of experience from his Chief Financial Officer roles with two companies in Shenzhen and Huizhou, with one of them being a SEC registrant. He is also very experienced in US financial reporting requirements and internal control processes. He is a member of the California Society of CPAs.

SAM LEE | sam.lee@wwccpa.com.hk | +852 9812 5665

Sam is the leader of our SME practice and tax expert, serving clients in Hong Kong, China, Europe and the United States. He has vast experience in auditing, bookkeeping, company secretarial, accounting advisory and other corporate services for SME clients around the world. Sam is a member of HKIPCA and ACCA.

DESMOND LAI | desmond.lai@wwccpa.com.hk | +852 9669 5111

Desmond is the Management Consulting Leader in WWC. He has had 20 years of Big Four experience serving clients on auditing and management consulting projects across various sectors in Hong Kong, China, London and Asia Pacific region. He specialises in operational effectiveness, large-scale finance transformation, deals advisory and post-deal integration. Before he joined WWC, he was the Chief Financial Officer of a digital media platform, managing operations and financial affairs of the group in the Asia Pacific region. He is a fellow member of CPA Australia and a member of HKICPA.

MATTHEW WU | matthew.wu@wwccpa.com | +1 (650) 638 0808

Matthew is a CPA and software engineer based in WWC’s headquarter in San Mateo, California. He specialises in financial, information system and internal audit for clients in the United States and other regions. Matthew first joined the firm in 1992. He subsequently took on various roles across different industries, including internal audit and software development for e-Commerce startups and other B2B platforms.

JOAN CHEN | joan.chen@wwccpa.com | +1 (650) 638 0808

Joan joined the firm in 2019. She specialises in tax planning and compliance, including company and personal income tax, property tax and payroll tax. Before joining WWC, she was a Partner of a CPA firm in California, leading tax consulting, accounting advisory and other corporate projects. She is a member of AICPA and California Society of CPAs. She is also an United States Internal Revenue Services (“IRS”) Enrolled Agent who represents clients before IRS.
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