Sino-American Pharmaceutical Professionals Association

Newsletter

SAPA-GP:
Building bridges between United States and China
Advancing global collaboration in pharmaceutical sciences

Career Development:
Take Full Charge of Your Professional Future
Are you on the right track?

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Dear Fellow Members and Friends,

Sino-American Pharmaceutical Professionals Association – Greater Philadelphia Chapter (SAPA-GP) was founded in 2002. SAPA-GP is one of the most active and cohesive associations with the greatest impact on pharmaceutical R&D in Greater Philadelphia, a region home to the complete bioscience continuum from first-class research to global pharmaceutical companies and biotechnology firms with strong supports from government and professional service firms. In addition to holding an annual conference in each June, SAPA-GP also organizes scientific symposiums, career development workshops, Chinese New Year party, summer picnic throughout the whole year. Functioning as a bridge and a link between United States and China, we periodically holds business and investment seminars and forums for numerous high-tech industry parks from China. Also, we organize various delegation groups to attend conferences and visit industrial parks, universities and hospitals in China annually.

With the theme of Global Pharmaceutical Collaboration – Building bridges between United States and China, this issue is focusing on our significant bridging efforts for China Medicinal Capital at Benxi New City. Our great endeavor in building global pharmaceutical connections are exhibited in two interviews of the Chinese pharmaceutical force: one company leading the Chinese market (Yangtze River Pharmaceutical Group) and the other pioneering R&D innovation in China (Simcere Pharmaceutical Group). We interviewed Dr. Steve Yang, one of our scientific board members, to provide farsighted overviews in emerging markets. Furthermore, we report our most recent event- Career Development Workshop in last December as well as present Dr. Jiangfan Li, who has been excellently serving SAPA-GP for over nine years, in our SAPA-GP member spotlight. Finally, we provide two scientific mini-reviews covering the hot topics of medical device and pediatric clinical trial. We sincerely hope that you will become better acquainted with the SAPA-GP organization and its people as well as benefit inspirationally from the reports and scientific reviews within this SAPA-GP issue.

The past decade has been a wonderful season in the history of the SAPA-GP. There have been many meaningful accomplishments. In pursuit of the celebration of 10th anniversary of SAPA-GP and its glorious path, we need fresh ideas and innovative approaches. The 10th SAPA-GP Annual Conference will be held on the campus of University of Pennsylvania, Philadelphia, on June 22-23, 2012. It would be a grand gathering for U.S.-China Biopharmaceutical Congress. I sincerely invite all of you to join us in the celebration of SAPA-GP’s great success of the past 10 years.

With the widespread globalization, innovation, and collaboration of the pharmaceutical industry, looking forward to 2012 and beyond, we are facing more challenges, however, our opportunity is unlimited. To fulfill our common goal requires all our best efforts.

I look forward to continuing our healthy and open exchanges of ideas and working together to fulfill our roles this year.

Very truly yours,

Laura

Laura Hong, MD, PhD
SAPA-GP President
Interview with Dr. Steve Yang, Head of R&D, Asia & Emerging Markets, AstraZeneca

Emerging Landscape for Global Pharmaceutical R&D

Di Wu, Sean Zhang, and Xinhe Guo

What are the strategic visions of multinational corporation(s) for the emerging markets?

From AstraZeneca’s perspective, will we continue to grow our presence in the larger emerging market countries, such as China and Russia for example, and extend our geographic footprint by increasing our involvement in high-growth small and mid-size markets.

From an R&D perspective, the emerging markets, particularly Asia, are already an important part of AstraZeneca’s drug development programmes so, unlike some players, we haven’t had to make a huge leap to start thinking of the countries and regions of the emerging markets as being a core part of our global R&D strategy. As you may be aware, we are one of the few major global pharmaceutical companies with substantial internal research operations and experience in both China and India. Those investments, which we view as long-term in nature, will continue to strengthen our current position and help us deliver innovative medicines to improve the lives of patients.

Broadly speaking, our R&D efforts in the emerging markets and Asia are focused around three key pillars: firstly, we will drive business there by bringing products to market as quickly as possible - through faster launches and stronger life cycle management. Secondly, we aim to deliver innovative medicines focused on meeting the needs of patients in Asia and the emerging markets. Whether it is liver cancer, stomach cancer, tuberculosis or diabetes, we aim to focus our efforts on diseases which have heavy burdens in those parts of the world. Patients and physicians have every right to demand that we focus on these devastating diseases. Thirdly, we’ll access R&D capabilities in those regions as a source of science and innovation.

This is important as innovation is at the core of everything we do at AstraZeneca.
What are the challenges within the emerging markets?

Globally, there are number of well documented challenges that the pharmaceutical industry as a whole face in the development of new medicines and also in patients having access to our innovative products. Fewer products have been developed into Phase III in recent years, which has been compounded by fewer products being approved by regulatory authorities worldwide as they face the pressures of competing priorities for resources at a governmental level and also within health departments.

When we approach R&D, which is the area I am directly involved in and responsible for across the emerging markets, we don’t view operating in those countries and regions as being any more or less challenging than other parts of the world. We don’t think of approaches to R&D based on geography but on delivering quality. When you have talent available – and we believe there is genuine talent within Asia and the emerging markets – you can deliver quality and innovation.

At AstraZeneca we believe an important approach to R&D, not only in the emerging markets but globally, is to recognize the importance of collaborating with ‘best in class’ partners. We’ve come to realize that we can’t do everything alone and that we need a nimble, flexible approach that will enable us to act quickly on emerging opportunities and deliver innovative medicines faster. Ultimately, that involves taking a collaborative approach to R&D by working in partnership with others to improve outcomes for patients and society.

To address this we have in place, and will look to expand, our network of highly talented academic and medical institutions that have complementary, in-depth expertise across Asia and the emerging markets.

What are the advantages in building R&D centers in the emerging markets?

Having a significant R&D presence in emerging markets such as Asia as we do at AstraZeneca, allows us to be closer to the patients we serve and the partners we collaborate with. It also enables us to tap into the talent available there – both internally and externally – all of which will drive innovation for us and give us a competitive advantage.

Certainly, one of the biggest advantages that the emerging markets and Asia offer us is access to that talent, which we firmly believe to be comparable to anywhere in the world. Also, the strong history of innovation in places like China and India offers us the opportunities to collaborate with ‘best in class’ medical and scientific institutions. This means we are better able to develop more meaningful, innovative products and therapies to address the unmet medical needs of patients.

What are the talent needs for multinational corporations in the emerging markets?

Recruiting and retaining the best talent is hugely important to us. This applies equally to the emerging markets as it does to other parts of the world where we have R&D operations. The worldwide challenges in doing so are not too dissimilar. We’re fortunate as we’ve managed to continue to attract high calibre local talent and returnees in places like China. These talents have solid academic and industry experience and will play an important role in shaping our future success.

We always aim to have the right people in the right roles, focusing on the right outcomes for patients. Our retention record over the last few years demonstrates that we can build an excellent team and continue to provide exciting learning and growth opportunities for them. By achieving this I’d certainly view AstraZeneca as an employer of choice in emerging markets such as China.

…and what opportunities are there for people currently working in the US

There are a number of potential areas of opportunity that qualified R&D employees currently working in the US may wish to consider. These range from roles within the life sciences and associated industries to
careers outside of those obvious and immediate to their academic backgrounds.

It could be argued that currently within the US and other markets in the West, peoples’ ability to move beyond narrowly defined roles is somewhat limited and the competition is fierce. For some scientific professionals there, moving beyond purely technical and professional roles into management roles at a science-related company like AstraZeneca could prove extremely difficult.

Conversely, those same people could find themselves much sought after, as mobile and extremely desirable candidates for employment across a wide spectrum of roles in the emerging markets, should they choose to move there. For some people, a move to Asia for example could significantly advance their careers and even propel them into roles outside of science, R&D and healthcare.

However, as there are a raft of skills needed which may vary from person to person, not everyone will have all the skills required and some will be need to receive training in completely new areas to achieve their career goals.

I would still recommend to anyone thinking of making such a move to at least explore what the possibilities could be for them and their particular skill sets.

What has been the impact of multinational corporation’s strategic visions for emerging markets on US R&D?

As a global biopharmaceutical company, AstraZeneca is agnostic as to where we make our R&D investments whether it is in the East or the West, in emerging or ‘developed’ countries. Also, we believe it does not matter where a discovery lead comes - whether internally from our own scientists or externally from one of our partners - as long as it has the potential to address an unmet medical need and benefit patients.

Would you mind sharing some advice toward career development for young scientists and entrepreneurs?

The emerging markets and Asia offer outstanding opportunities for scientists. From our point of view, Asia in particular is an exciting pharmaceutical R&D environment, offering strong opportunities to find creative ways to meet growing health challenges. For me personally, I get excited that Asia, and particularly my home country of China, are both in ‘front and centre’ positions within the industry and also within AstraZeneca.

Seeing our R&D efforts being led by Chinese and Asian scientists looking at Asia-specific diseases for the benefit of Asian people is for me the single most exciting development of the past few years and possibly in the years ahead, too. I’d strongly recommend to any young scientist that they consider working in a dynamic, fast-paced environment such as Asia. I can guarantee that they would experience working within a very important context, too due to the heavy local disease burdens and significant unmet medical needs. That is undoubtedly crucial work.

It is worth remembering that over half of the world’s population lives in Asia Pacific and the region is expected be home to more than 60% of the 380 million diabetes cases globally by 2025. Also, stomach and liver cancers are more prevalent here, with higher mortality rates in Asian patients. Sadly, China and India also have large patient populations for major respiratory diseases such as Chronic Obstructive Pulmonary Disease (COPD) and asthma – some 28 million asthma patients in China and 32 million in India according to the World Health Organisation.

Being part of the solution to those healthcare challenges is work that maybe challenging but ultimately, the rewards for the successes when they arrive, are deeply satisfying.
领军中国药业  锐意开拓进取

--扬子江药业集团徐镜人总裁访谈录

Di Wu, Tingyi Zhou

请简单介绍一下公司重视研发的战略和策略？

徐镜人：近年来，在中国政府的引导和支持下，药企自发地积聚创新的能量正向新药研发领域传导。据称，“十二五”期间，新药创制重大专项将力争自主创制30个创新药物，完成200个左右药物大品种的改造和技术再创新，同时基本建成国际一流的药物创新体系。紧紧抓住这一重要的战略机遇期，扬子江药业集团转变研发思路，加快推进由过去仿制为主，向创新为主、仿创结合转变，提出了由“扬子江制造”向“扬子江创造”转变的战略口号，扎实推动中药、化学药、生物药“三药并举”研发创新策略，努力把企业打造成为具有国际竞争力的企业。

一是，加快扬子江新药研究院建设，进一步完善研发创新体系，促进科技成果转化。通过强化研发创新团队建设，大力实施全球人才引进策略，引进多名高资深的海归研发人才。强化自研立项、专项申报工作，立项研发品种以创新药为主；积极申请国家重大新药创制专项、国家发改委高技术产业化专项，争取国家创新资金扶持。“十一五”期间，集团每年按销售额3%以上的比例投资于科研活动，用于科研场所建设、科研平台搭建、科研团队组建及科研项目研发等。集团研发领域已涵盖化学药、现代中药、生物药以及药物制剂技术等，形成上下游技术科学分工、合理联动的科研机制。

二是，着力推进产学研联盟和国际合作，在国内，依托驻北京、上海等地子公司优势，与高校、科研院所建立产学研联盟，以风险共担的方式与合作伙伴进行更高层次的合作。在国外，加强研发国际交流与合作，新近成立的美国分公司正在全球范围内积极地寻求与生物技术公司及科研院所的产品及项目合作。扬子江与荷兰 TNO 工程院和欧洲药典委员会签订合作协议，启动植物药项目的欧盟注册工作以及中药标准的制定，开创了走向欧盟的新路径。
三是，建立创新立项论证机制、创新风险评估机制及创新激励机制。创新立项论证机制及创新风险评估机制要求每一创新项目立项及开发时必须开展市场、开发技术、生产工艺技术及质量控制技术论证及评估，通过上述两大机制的实施，使企业的研发、生产、质量控制及销售部门全程介入到企业创新活动之中。为充分调动科技人员创新激情，深度挖掘科技人员创新潜力，集团每年都重奖创新研发有功之臣，最大限度地激发了广大科研人员开拓创新的热情。

公司开始国际化的历程和举措。

徐镜人：扬子江药业集团在国内市场稳健发展的同时，注重国际市场的开拓，近年来在推进国际化进程方面做了很多有益的探索，积累了一些经验，取得了一些突破：

2006 年 4 月 26 日至 27 日，博鳌亚洲论坛国际医药产业大会移师扬子江药业集团召开。牵手博鳌，为扬子江药业洞开了一扇了解世界、参与世界的大门，使我们一下站到了全球医药产业发展的高端，来重新审视和决断、布局企业发展战略。

2010 年 11 月 25 日，扬子江药业集团收到德国官方机构颁发的欧盟 GMP 证书，为固体制剂产品进军欧盟市场打开通道。

2010 年底，扬子江药业将旧金山作为登陆点开设了驻美办事处及全资的美国分公司-泛太平洋生物制药公司，正式启动了进军美国市场的第一步。

2011 年 8 月，Mark L Powell（Previous Senior Vice President of Non-clinical Development, BMS）加盟扬子江，领军扬子江的新药研发。

这四个标志性事件，见证了我们走向国际的信心与成效。近年来，集团积极借鉴跨国医药企业先进的企业制度、管理方式和运营方式，使公司的运作更加符合国际惯例。一是，更加高度关注目标市场信息，参与国际专业展会，加强海外市场调研，力求准确掌握相关的认证及注册信息，为海外市场的开拓提供有效的信息资源。二是，紧扣产品立项、产品注册、产品推广等环节，选择开发具有合适价格、规格以及良好的质量，能满足目标市场要求的产品。三是，努力突破发达国家设置的技术壁垒，适应市场准入的条件，扬子江药业正在积极实施国际认证工作，例如：FDA 的 ANDA（非专利仿制药）申请、WHO 的预认证以及美国的 FDA cGMP 认证等，通过这些认证来增加商机，扩大海外市场份额。

经过不断探索，截止目前，扬子江药业已经在 11 个国家和地区共成功注册了 50 个品种 54 个规格，另有 29 个品种、31 个规格的品种形成销售，海外贸易额呈现不断增长喜人态势。

扬子江药业应用哪些独特的营销策略和技术创新成为了国内一流的企业？它的企业特色是什么？

徐镜人：多年来，扬子江药业集团始终坚持奉行“以市场为导向”的经营理念，大力实施研发创新和市场营销“双轮驱动”战略，培育企业的核心竞争力，保持了企业的持续、健康、快速发展。

目前扬子江的销售团队 4000 余人，营销网络覆盖全国 6000 多家医院、2.5 万家药店。主要的特点一是产品策略多元化，扬子江药业现已形成中西药并重，处方药和非处方药并举，覆盖抗微生物用药、心脑血管系统用药、消化系统用药、抗肿瘤用药、解热镇痛药等领域 20 多种剂型、200 多个品种的多元化产品体系，满足了市场用药的需求。二是确立大品牌、大品种、大市场、大终端、广覆盖的市场战略。细分市场、做深做透，采取具有市场
竞争力的合理的价格策略，开辟空白市场，做大薄弱市场，做强成熟市场，拓展新兴营销渠道，把终端销售重点定位于医院的同时，兼顾零售市场、农村用药市场开拓，将产品质量优势转化成客户的利益和价值。三是建立一套卓有成效的“激励+风险+利益”环环相扣的营销体系，形成“千钧重担人人挑，人人肩上有指标”的压力机制，为销售连年增长奠定了坚实的基础。

技术创新方面，扬子江历年来持续加大科技创新投入，坚持高标准要求构建与国际接轨的科技创新平台，建成了国家级企业技术中心、中药制药工艺技术国家工程研究中心、药物制剂新新技术国家重点实验室等研发创新平台，同时在北京、上海、广州、南京、成都等高端城市建有分设机构；积极推进产学研合作，与国内数十家高校、科研院所联合，进行创新药物的开发；引进了一批具有海外研发工作经验的高层次人才加盟企业，形成了一支近300人的研发创新团队；全面实施化学药、中成药和生物药“三药并举”研发创新战略，形成“生产一批、研发一批、储备一批”的梯队式研发格局。“十一五”以来，集团相继对60多个新品种立项开发研究，其中一类新药10多项，半数以上为具有自主知识产权品种，为企业快速发展提供了产品支撑。

公司最大的特色在于质量文化和创新文化。企业始终视质量为生命，每年轰轰烈烈开展两次“质量月”活动，现有20多个产品质量已达到美国、欧盟、英国、日本药典标准检验出厂；在中国医药行业QC成果评比中，扬子江药业蝉联QC成果一等奖总数“六连冠”。企业还被中国食品药品检定研究院指定为挂牌实训基地。优越的产品质量，也是企业赢得市场的重要筹码。

扬子江药业的创办人徐镜人总裁经过艰苦创业和打拼，使扬子江药业从1997年开始就跻身于中国医药业前五强。他对我们年轻一代的医药研发工作者有什么教导和告诫？

徐镜人：医药研发具有“高投入、高风险、高回报、周期长”的特点，需要广大医药研发工作者前赴后继付出艰辛的努力。我希望广大年轻的研发工作者：要摈弃浮躁和急功近利，踏踏实实搞科学研究，力求在针对重大疾病创新药物和生物药研发方面有所作为，为人类的健康事业作出贡献。一要养成团结协作精神，共同攻关；二要有奉献精神，甘当无名英雄，不要人人都想出头；三要勇于实践，努力提高自主创新能力；四要加强对外界信息和了解和吸收，走高信息道路。此外，社会也要为科学家创造更加宽松和谐的科研环境，建立有利于人才尖、成果勃发的科研制度。

美国著名战略研究学者马丁·雅克在《当中国统治世界——中国的崛起和西方世界的衰落》一书中曾这样描述中医，“中国已有两个领域在全球享有巨大影响力：饮食和传统中医，虽然后者影响力要小得多……中医的全球影响力似乎也有可能持续扩大。”请问徐镜人总裁如何看待中医药的国际化？

徐镜人：“中医药国际化”口号喊了多年，基本还一直在家门口徘徊。中医药虽然传播到世界160多个国家和地区，但普遍难以打入国际医药的主流市场，大部分只能在华人圈子里使用。一个不争的事实是，中医药理论体系的科学内涵尚未被人们广泛接受和理解，中医药在防治人类现代疾病和促进健康方面的作用还远未得到充分发挥。我认为，中医药国际化需要过五关：一是法律关，中医药在大多数国家和地区只是补充与替代，没有以处方药的身份进入主流医疗体系；二是资金关，国外药品和生物药注册门槛越来越高，需要的资金支持让很多企业望而却步；三是标准关，国外以安全为借口设置“绿色贸易壁垒”；四是文化关，中医药“说不清、道不清、道不清”。
不明、听不懂”，很难让外国人有文化认同；五是市场关，高投入、高风险并不意味着高利润。中药产业国际化，可分为产品国际化、企业国际化和产业国际化三个层次，产品在国外上市只是国际化的第一步。如何让很多国家将中医药纳入国家医保体系并给予法律保护是解决中医药国际化发展的关键。

中国中医药标准化最近得到国际标准化组织(ISO)的极大重视，于2009年专门成立了新的技术委员会，ISO/TC249。中医药技术委员会(ISO/TC249)的建立，为中医药进入WTO认可的国际标准化体系铺平了道路，具有划时代的深远意义。中国中医药标准化对扬子江药业有何具体影响？

徐镜人：ISO为中医药设立单一的技术委员会，旨在协调全球中医药行业各技术标准的研究和制定。ISO中医药技术委员会（ISO/TC249）的建立，标志着深深扎根于中华民族传统文化的中医药学，进一步得到国际社会的认可。在国际贸易游戏规则中，通过WTO认可的ISO发布中医药国际标准，为中医药给世界人民提供安全、有效的健康服务产品保驾护航，必将大大推动中医药国际化的进程。因此，我们要充分重视和利用WTO和ISO的游戏规则。

在探明中药作用机理等中药现代化难题之外，中医药技术ISO标准若要真正国际化依然需要各方条件的成熟。最大的制约还是中医药如何在国际上被更多国家认可的问题。另一方面，由于新的标准制定或决定未来行业的准入门槛，并提高整个产业的创新能力，对中药企业而言意义重大。在国际标准的制定过程中，特别需要中药现代化的标杆企业尤其是原创型企业加入其中，充分互动。我们要利用这一契机，参与标准研究和制定工作，努力适应新形势发展的要求。

扬子江药业因其中医药产品驰名中外。在中医药产品及其化学药品国际化方面，特别是打入北美市场上，有什么具体设想、计划和步骤？

徐镜人：扬子江药业在推进国际化方面坚持走渐进式路线，在进军北美市场方面还需突破若干技术壁垒，如严格的药品审批程序、很高的淘汰率，再加上临床试验的高额费用和漫长时间等。在北美市场开拓方面，早期我们将以中药保健品、仿制药和医疗器械等边缘产品市场的开发为主，中后期将尝试新药市场的开拓。具体想法如下：其一，作为我们拥有优势的中成药，早期以保健品或食品添加剂的形式在美国推广，因为在审批程序上的可行性也相对可控，这在战略上成为理想的模式。其二，凭借扬子江药业多年的仿制药经验，利用一些剂型的生产技术水平已达到国际标准的优势，主动承接北美药商生产外包任务，抓住美国医药行业很多专利药即将到期的契机，仿制产品抢滩北美市场将成为可能。其三，与美国药企、科研机构建立合作关系，采取雇员、顾问、合作创业、合作项目等灵活的用人及合作机制，尝试各种方法，开发适合北美市场的扬子江药业产品，从而开拓新药市场。其四，选择1-2个适合美国市场的中药品种，作为新药注册批准，从而打开扬子江中药最为新药进入美国主流市场的缺口。总之，北美市场的开拓需要根据目标市场的限制程度和市场的动态，采取了灵活多样的形式，稳步推进。

扬子江药业集团近年来与许多国内外学术团体共同举办过多次学术研讨会。大费城美中医药协会很高兴于今年六月在美国费城与贵公司共同举办“扬子江之夜”美中医药业研讨会。请问徐镜人总裁对我们这次合作有何感想？

徐镜人：通过举办“扬子江之夜”美中医药业研讨会，我们和海外的药界华人起到很好的沟通交流
作用。能结识许多美国医药界华人科学家，我本人感到非常荣幸。这次研讨会，使大家对扬子江药业有了更深的了解，加深了相互的信任，为我们今后更广泛的交流与合作作了许多铺垫。从我，我们也及时了解到美国生物医药界发展的最新动态，就一些合作项目进行了初步的谈判，基本达到预期的目的。我们希望依托大费城美中医药协会的牵线搭桥，希望大家给予扬子江药业集团的发展更多的关注和支持，建立更广泛、深入的交流与合作，携手研发创新和国际化事业！

李江帆，数学博士，1992年毕业于美国宾夕法尼亚大学，师从著名几何学家Eugenio Calabi攻读微分几何。李江帆博士毕业后，一直在美国从事计算机软件的开发工作。目前在Johnson & Johnson做临床药物试验（Clinical Trials），从事编程和数据分析。

1983年在复旦大学数学系读完本科后在复旦数学所学习微分几何。由于众所周知的原因，当时出国留学极其困难。后来在导师的帮助下，冲破重重阻力，于1986年来到美国“访问学习”（只允许一年）。现在的年轻人可能理解不了当时中国的环境，当时的艰难磨练人的意志。以后不管面临多大的挑战，都能直面而对。

自2002年SAPA-GP成立以来，一直从事于SAPA-GP的IT/Programming服务。SAPA-GP的网页一直稳定可靠即时地运作，就是建立在他的踏实工作之上。李江帆博士工作踏实，技术上精益求精，善于编程和计算方法的研发。“兢兢业业，慎之始终”是他一贯的作风。多年的工作经验使他能处理所有的算法语言和软件系统，是世界上一流的软件工程师。他所管理的SAPA-GP网站多年来从未出过差错。

他能处理所有的算法语言和软件系统，是世界上一流的软件工程师。他所管理的SAPA-GP网站多年来从未出过差错。

李江帆说，“在我看来，SAPA是一个纯粹的科技性组织。SAPA的成员绝大多数是华裔科技工作者，包括世界上一流的科学家。在这里和同伴们一起学习，互相交流，收益很多。”
先声药业: 中国创新药物研发的领军者

--先声药业首席科学官王鹏博士访谈录

Sean Zhang, Di Wu, and Roger Luo; Photograph: Kun Wang

王鹏博士

先声药业是中国市场上是集生产、研发、销售为一体的独特的新型药物集团，也是中国第一家在纽约证券交易所上市的化学生物药公司。请问先声药业走在中国医药企业前列的先导因素和企业特色有哪些?

先声药业始终以“在重大挑战领域创造革命性药物”为目标，企业战略上将研发作为企业核心竞争力，并将每年将销售收入的6-8%投入新药研发工作，这在国内的企业中是很少见的。先声在南京有2万平米的研发中心，1.4万平米的上海研发中心也已投入使用。近年来，先声一直在大力引进高端人才，两年内已引进海外人才20多位，其中有11人是在美国工业界有10多年研发经验的资深专家。

持续创新的理念在先声里一直得到宣扬和鼓励。先声的创新药物开发很注重合作研发，包括国际化合作和国内合作，并且充分利用中国的本土优势，包括人员低成本优势、营造创新文化的优势，以及在国内做临床研究成本领先等优势。我们希望能够在中国能创造一种独特的、被证明是成功的创新药物研发模式。

先声药业先后与施贵宝和默沙东两家跨国药企合作，协力共创合作经营关系。请问先声药业与跨国药企合作的理念是什么？可否介绍一下先声药业与默沙东公司合作的战略意义、方针、具体规划等？

自2007年起，先声药业开始通过专利许可、共享权益等方式引入国际合作项目，积极探索多种国际合作模式，提升国际化研发能力。我们在外方早期研发基础上合作开展后续研究，利用中国研发成本和临床试验的明显优势，大大缩短新药开发周期，提升企业规范化新药研发能力和国际竞争力。总的来说，大概有四种模式：

持续创新。
模式一：引进美国小型科技公司的早期创新药项目，开展合作研发，共享研发成果的全球权益；

模式二：直接引进具有成功开发上市创新药品的美国中型制药公司已进入临床试验阶段的原创新药，获得在中国进行独家开发的权益，加速创新药在中国研发的进度；

模式三：与著名的跨国制药公司合作，引进早期创新项目，利用中国低研发成本和临床试验病例丰富的优势，加速推进创新药的研发效率。

模式四：与著名的跨国制药公司开展全方位合作，首先在国内组建合资公司，优势互补，承担双方品牌产品的市场开发和商业推广；同时在此基础上进一步开展双方的产品研发、制造、注册和营销等多方面合作。

关于默沙东与先声合作：

这是一次创新的合作关系，在这次双方的合资企业中，我们将融合双方的专业知识和广泛的资源，将建成一个适合双方目标的一个合资企业，也就是结合我们的研发、注册、生产、销售能力的一个合资企业。先声药业是中国领先的一个制药企业，拥有注册、研发、销售、生产品牌仿制药和创新药的能力。默沙东是全球第二大制药企业，这次双方的合作，可以给我们提供更好的机会，来提高我们产品的可及性，能够为中国患者提供更多高效创新的医疗产品和服务。

默沙东与先声药业的此次合作，将结合我们双方最出色的产品。我们将致力于提高在中国对心血管疾病的治疗和护理。此外我们还将侧重糖尿病治疗领域，我们将提高西格列汀的可及性，这是一个治疗二型糖尿病的 DPP-4 的抑制剂。从长远来看，我们将双方向利于建立一个长期的国际化的一个合资企业。

2011年6月的第7届美国医药协会年会上，先声药业着重谈到运用合作伙伴关系，增强研发能力。请问先声药业是如何联合国内外合作关系伙伴来整合资金、人才、信息等方面的因素，在新药研发上走在中国医药企业的前列？先声药业如何挖掘潜力，继续保持这种优势？

先声的国际合作是一个循序渐进，不断探索的过程。作为一家中国本土公司，我们一直在不断寻求海外的合作机会。最初是和两家比较小型的美国科技公司合作，在积累了一定的经验后，和中型的科技企业 OSI 合作。其后分别在2010年和2011年与国际制药巨头百时美施贵宝进行了两项创新药物开发项目的合作。2011年7月，我们还和全球第二大制药公司默克进行了合作，双方共同在国内设立合资公司，谈判历时9个月，相关的文件就多达2000多页。在逐步积累国际合作的经验的同时，我们在海外合作公司的指导下按照国际标准和模式进行新药开发，也大大提高了自身的研发能力。跨国公司对于合作方的实力非常重视，合作前会进行全面而谨慎的调研考察，而随着先声国际合作的步步推进，我们自身的实力也在不断的增强，这是一个良性循环。

先声药业的企业文化独具特色，重点强调员工的梯队建设和在职培训，能否用实例介绍给海外的朋友们？

就研发系统来说，我们引进了国外先进的药研模式，但也结合中国制药行业的特点及先声自己的经验。比如，在项目推进上，我们采用国际通行的项目管理模式，但赋予项目负责人更大的自主权。我们的项目负责人权限比国外药研项目负责人权限很多，而这是符合中国特点的。
在研发人员激励制度方面，我们也按照国外大公司普遍的做法，建立了管理和技术的“双轨晋升制度”，但我们的晋升和激励力度更大、更加灵活。我们优秀的研发人员每年都可以晋级甚至跳级，在项目中作出突破性贡献的人才还会有“里程碑奖励”，等等。

我们设有“求索论坛”，每个月都会邀请知名的科学家来进行讲座，平均每周都会邀请到业内的专家来对研发人员进行各方面的培训。

在2011年2月大费城美中医药协会举办的职业发展论坛中，您(先声药业的首席科学执行官王鹏博士)讲述了先声丰富的国内外医药研发工作经验和独到见解，受到大家一致好评。在这里，可否对我们年轻一代的医药研发工作者分享您在中美医药研发的独到经历和两国经历的对比以及其人生感悟和对中国医药前景的展望？

近十年来，中国医药行业年复合增长率超过了20%，远高于全球的增长率，中国的医药市场潜力已超过美国等发达国家。而且中国对新药好药的需求很大，但是国内的药物研发能力和发达国家相比还非常薄弱，从个人职业发展角度而言中国有更大的发展空间。

中国在研发成本和临床试验上有着明显的优势，而与海外公司合作则可以吸收对方很多新药开发的经验，快速提高自身的研发水平。但是也不能一味的照搬国外的模式，国内的新药研发有其自己的特点，而创造出一条符合中国特点的创新药物研发模式也正是先声想要做的。
Market Share and Technology Development of Coronary Stents

‘Patrick’ Haibo Gong

What is stent and how does it work?
Coronary stent, a tube-like mesh, is mainly used as a scaffold to provide the coronary artery with sufficient mechanical support and keep the artery open. The targeted patients normally have coronary heart disease and thus need a treatment called percutaneous coronary intervention (PCI). Coronary stents have become the default device in PCI and successfully prevented early recoil and later vascular remodeling, which are the major limitations of balloon angioplasty.

Coronary Stent System

Market share and competition in China and worldwide
The global market for drug-eluting stents (DES) is valued at $4.6 billion in 2010 and is projected to exceed $8.0 billion by 2015. Boston Scientific and Abbott Vascular are the major players in the U.S. DES market, together reporting more than half of all DES revenues. Other U.S. manufacturers include Medtronic and once leading, but now left-behind, Johnson & Johnson subsidiary: Cordis Corp. China DES market has been dramatically increasing for years. In 2002, only 40 thousands stents were used in China, but 500 thousands stents were implanted in 2010. This number is projected to be 750 thousand in 2012. Currently MicroPort, Lepu Medical Technology and JW Medical dominate China DES market valued at approximately 0.6~1 billion in 2011.

Current technology
DES dominate current stent market since bare-metal stents have suffered from thrombosis and restenosis, which have brought rather painful experiences and heavy economic burdens to patients. In a controlled manner, the drugs coated on DES are continuously released into patients’ arteries for a certain period of time. As a result, the proliferation of endothelium and fibroblast is prohibited. This prevents development of thrombus and fibrosis, which could block the artery and cause restenosis.

Future developments
The new generation of Bio-absorbable stents (BAS) is designed to stay in patients’ arteries for a certain healing period and then disappeared leaving no toxic products. Over this period of time, BAS provide sustaining mechanical support and release beneficial drugs to help patients’ arteries keep open and regrow. Once the healthy and strong arteries form, there is no utility or advantage from stents and their presence was even shown to be relevant to late thrombosis and chronic inflammation. In other words, the patients merely need a temporary stent until healing, but current DES permanently stay in a patients’ body.
Considerations on Pediatric Pharmacotherapy and Clinical Trial

Di Wu

Pediatric indication – Greatest needs for drug therapy in children

About 11% to 79% of drugs prescribed in pediatric medicines are off-label or unlicensed. In China, only 64 (5.8%) of 1103 drugs in hospitals were labeled for use in pediatrics with 400 million children in China in 2006. Once the medication attains approved for use in adults, it can be legally prescribed to anyone for any reasons, in spite of the lack of pediatric testing or proper labeling. Dr. Dianne Murphy of the FDA’s Office of Pediatric Therapeutics has said: “We found out that you can’t predict how kids are going to handle things.” The fundamental difference between growing children and adults demands the pediatric clinical trials testing safety and efficacy of the drugs. However, the pediatric population is a vulnerable group and should be protected against any unethical conducts. Moreover, the lack of incentives for pharmaceutical companies to conduct pediatric clinical trials in the first place delays more drugs with pediatric labeling into the market. The drugs where a large percentage of the market share is in pediatrics are exceptional and were studied thoroughly before entering the market (e.g. vaccines and some antibiotics). Without timely pediatric labeling information, pediatricians would prescribe off-label medicines if they want to provide up-to-date medicines to their patients.

Among the off label medicine in the United States outpatient setting, there were approximately 96% of cardiovascular-renal, 86% of pain, 80% of gastrointestinal, and 67% of pulmonary and dermatologic medication prescriptions were off label. Unlicensed or off-label drug utilization in the neonatal intensive care units is far greater than in older children. In order of frequency, the most common causes for off-label prescriptions were, lower than recommended dose, higher than recommended dose, below the recommended dose, and unlicensed formulation with lower than recommended dose as the most common reason. In a prospective cohort study conducted in the neonatal intensive care unit of the Royal Women’s Hospital of Melbourne, Australia, the most frequently off-label drugs were morphine, methylxanthines, phosphate, paracetamol, dopamine, and dobutamine. Unlicensed drugs included spironolacton and sodium chloride.

A strong relationship between the number of different medications taken by a child and the percentage of unlicensed and off-label drugs, and a higher risk of adverse drug reactions (ADRs) unexpected from adult experience. The increased risks of ADRs in children association with lack of pediatric labeling, were due to different pharmacokinetics and pharmacodynamics characteristics of drugs, or errors in dosing adjustment or formulation. Likewise, the absence of pediatric labeling expose pediatric patients to ineffective treatments caused by under dosing, and excluded pediatric patients from important therapeutics. Given the facts that children are
considered as “therapeutic orphan” in drug development and utilization, clinical trials to ascertain safety and efficacy of drugs being used off label or unlicensed in the pediatric patients are highly demanded.

**Trials in children by development phase**

Growth and development are the two aspects of the children. Ontogeny and development of drug-metabolizing enzymes, transporter, receptors, and organs make quite different absorption, distribution, metabolism, excretion of drugs and their effects on developing organs during the different development phases of children. Compared with adult clinical trials, pediatric clinical trials are more expensive and should be carried out in different age phases along the pediatric age continuum: preterm neonates/full-term neonates, infants, children, adolescents based on continuous growth and maturation (e.g. size, organ function).

International Conference on Harmonization (ICH) defines five classes of age in pediatrics.

1. Preterm neonate: less than 36 weeks gestation, between 0 and 27 days;  
2. Full-term neonate: between 0 and 27 days;  
3. Infant: between 28 days and 23 months;  
4. Child: between 2 and 11 years;  
5. Adolescent: between 12 and 16-18 years, according to the legislation in the countries.

Dynamic development changes in body composition and organ function and nonlinear growth process, especially during the first ten years of life, have different impacts on drug disposition and action during different phases in the pediatric age continuum. Simply normalization of dose by a function of either body weight or body surface area could afford overdosing or under-dosing in different phases of pediatrics.

**Absorption**

Age-dependent developmental changes in physiological composition and function can affect rate and extent of drug absorption when drugs are administered by extravascular routes and penetrate physical, chemical, biological barriers into human body. Multifactors, including intraluminal pH in gastrointestinal tract, biliary function, gastric emptying, intestinal motility, drug-metabolizing enzymes and efflux transporters, determine the rate and extent of drug absorption for oral drugs. Usually the rate of most drugs absorbed is slower in neonates and young infants compared to older infants and children.

**Disposition**

Age-dependent body composition and circulating plasma protein affect drug concentrations in circulation and distribution. Larger extracellular and total body water and reduced amount of the total plasma proteins were observer in neonates and young infants.

**Drug Metabolism**

The quantity and activity of drug-metabolizing enzymes change dramatically in neonates and young infants, which warrants age-dependent dose adjustment in these pediatric phases evidenced by numerous examples. For example, CYP3A7 is a primary CYP isoform expressed in fetal liver. CYP3A7 expression peaks after birth and declines to undetectable levels quickly afterward. The activity of CYP enzymes appear in following order: CYP2E1 (within hours of birth), CYP2D6 (after CYP2E1), CYP3A4 and CYP2C (2C9 & 2C19) (within first week of life), CYP1A2 (1-3 months of life).

**Renal Elimination**

Renal function determined by dynamic maturation and treatment related alteration have greater impacts on disposition and elimination of drug excreted extensively via renal routes. Gestational age and postnatal adaptation are two determining factors on
renal function. Renal function starts to mature early during fetal organogenesis and is complete by early childhood.

Pharmacodynamics

Pharmacodynamic effects of drug remain poorly explored in pediatric population. For example, human neonatal increased sensitivity to morphine may due to the pharmacokinetic difference but not to pharmacodynamic difference, because opioid receptors are not fully developed in the rats after birth and mature along till adulthood. It is evidenced by no correlation has been identified between morphine concentration (0-450 µg/l) and the pain response to neonatal endotracheal suctioning in a large cohort of preterm neonates, where common target analgesic concentrations at 10-20 µg/l. The absence of suctioning effect at such high concentrations of morphine pointed to under developed opioid receptors in preterm neonates.

Pharmacogenomics

Pharmacogenomics affects both pharmacokinetics and pharmacodynamics of drugs. Single nuclear polymorphisms could affect in drug metabolism in neonates but its extent remains unclear due to the immature clearance. Further, activity of drug-metabolizing enzymes, transporters, receptors are determined by multi-genes. Pharmacogenomics explain variability of dose-response relationship among patients. Understanding the interplay among pharmacokinetics, pharmacodynamics, and pharmacogenomics provides knowledge for age-dependent dose individualization in pediatrics.

Conclusions

Age-dependent growth and development exhibit different effects on drug disposition and action and thereby provide evidence on dosing optimization and individualization in pediatric patients. Further, potential severe side effects can be revealed in drug safety study in different phases of pediatric population. Therefore, pediatric clinical trials should be carried out in age-appropriate fashion to describe efficacy and safety of drugs used in pediatrics.

Unlicensed and off-label usage of a drug in children limits phase VI clinical trials (post marketing surveillance), which could identify ADRs in children much quickly and systematically. Pediatric labeling and necessary incentives to pediatric labeling are steps toward standard phase VI trials in pediatrics.

The design for pediatric clinical trial is fundamental and critical to the success of phase I-III trials in this special population. Modeling and simulation approach plays an important role in critical design and dose optimization in pediatric clinical trials. Incorporating prior knowledge from adult trials into pediatric trials facilitates, trial design, data analysis and dose finding in pediatrics (e.g. Bayesian method).
Are You on the Right Track?

John Sun

A recent discussion within the SAPA leadership sparked an idea to start a column on the SAPA Newsletter dedicated to the topic of career development.

Quite often, people think that career development is a serious topic to be contemplated only at a particular forum or at a remarkable occasion. In fact, it is a continuous process that requires frequent evaluation, reflection, and adaptation.

Recently on a sunny Saturday morning in early December when I was driving to the Career Development Workshop hosted by the SAPA-GP in Fort Washington, the GPS directed me to a route that I was not familiar with. Thinking that I had enough time, I went along. It was a scenic route rather than the usual highways that I take. Mostly I enjoyed the ride but I have to admit for a few moments I felt not as comfortable or at ease. Did I get lost? Suddenly it occurred to me that career development is very similar to a journey we take. Sure, it has a destination, but there are several optional routes to get there. Certainly the preferred route is shorter, with less traffic, and quicker time to get there. It would be better if the ride is enjoyable as well. Like driving, where is the GPS and the compass at the course of our individual career development?

Albeit with different background and track record, many SAPA members started brilliantly (often with stellar academic achievement), and share similar dreams and common goals: to be more successful in career development and find satisfaction in personal life. Yet over the years, some have achieved far more significantly and some are still yearning for that special moment to shine. From time to time, we may feel getting stuck or reached a plateau (yikes – the feeling of hitting the glass or bamboo ceiling). Naturally we may blame the external environment which is not in favor of our growth; or wonder where the next savior to save us is. Why, why, we ponder and wonder, while riding out the storms and waiting for the next big opportunity to appear.

Career development is indeed a heavy topic and has real implications to our life. Financial gain is one of the main manifestations but it is not all. Career development definitely has its own science and list of best practices that we might not have a chance to learn and acquire at school. In our life journey, how we choose our route may be based on the initial situation (internal and external) and projection, then coasting along the way (talking about job security). But what was right before doesn’t mean it is right forever. It’s fine if you are feeling content and comfortable with the way you are doing, but you might not achieve your full potential and maximize your capacity if you do not choose and adapt the career path appropriately.

Reflecting on my own career development, I was lucky enough to have several wise mentors and friends who have offered honest, prudent advice (although sometimes not pleasant or easy to hear and accept), and pointed to the right direction; also naturally I had some painful lessons learned along
the way as well. Clearly, career development does not follow a simple linear equation, rather along a mysterious path or a treacherous route.

Each one of us is the driver of our own vehicle, in charge of our own destination and deciding the route we pick. Just like different cars on different highways, to pick the right course is not necessarily an easy task. You need the right skillset and positive attitude to face uncertainties, grab all the serendipities and make the rights decision, even when facing adversary situations such as crisis.

“Then why SAPA”, you may ask. Well, as we all know, SAPA has an extensive collection of Chinese pharmaceutical professionals spanning across the US and China that you can find common interests and to network with, not to mention that career development is one of the core missions that SAPA believes genuinely. The career workshops organized by SAPA HQ and regional chapters are primary examples which offer the forums that provide precious opportunities for us to share, explore, learn, and shine together.

In the recent years, the pharmaceutical industry landscape in the US has entered a challenging era because of the patent cliff, payer pressure, and increasingly stringent regulatory requirement. In the mean time the pharmaceutical industry in China is spurring to life and advancing rapidly. Also, some members with entrepreneurial spirit had started their own businesses. To survive and better yet, to strive in such an environment presented new challenges, and also offered historical opportunities to all of us as well. SAPA is in a unique position as a premium organization to offer more help to its members for better career development.

So, when was the last time you have thought your own career development? What drives you? I hope you take a moment to reflect and think deeply, and to act swiftly when needed.

About the author:

John Sun is a passionate believer and practitioner of career development. He is a Global Program Team Director at Novartis, and has held positions with increasing responsibilities at the Chinese Pharmacopeia Commission, Wyeth Consumer Health, Kos Pharmaceuticals, Schering-Plough, and sanofi-aventis. John has a PhD in pharmaceutics and an MBA, and he is also a certified Project Management Professional (PMP). Your comments on this article are welcome and should be sent to johnsun.sapa@gmail.com.
Take Full Charge of Your Professional Future

--SAPA-GP Career Development Workshop

Report: Bin Shi, Di Wu; Photograph: Yongguang Zhao, John Sun

A career development workshop, organized by Sino-American Pharmaceutical Professionals Association-Greater Philadelphia (SAPA-GP), was held in Fort Washington PA on December 10, 2011. The distinguished speakers from the industry and academia shared personal career journeys and presented enriched discussions on important career development topics. More than 100 people coming from PA, NJ and mainland China attended this great event.

Laura Hong, President of SAPA-GP welcomed the attendees by reiterating SAPA-GP's missions, introducing SAPA-GP's current and future events, and acknowledging the workshop sponsors. She also presented to the audience the SAPA-GP's 2012 table calendar, designed by the pharmaceutical professionals volunteering at SAPA-GP.

Jacks Lee, Vice President (VP) and Plant Manager of manufacturing, West Point, Merck, gave the keynote speech in career development. During his 50-minute vivid and inspiring talk, with only one slide, he emphasized five words for the professional development of the "complex molecule" of people: Success, Significance, Core, Principles, and Actions. There is "no short cut to success." The combination of capability, the systems, luck, connection of head to heart, could be the secrets to anyone’s success. Respecting people, agreeing with people, greeting people, and interacting proactively with people are the keys based on the well-known principle that, teamwork is an efficient way to move mountains. Jacks emphasized that everyone has the most impact on his/her career, therefore, he encouraged everyone to start small, start now, and set up a foundation to accelerate career development.

The second speaker was Joe Powers, PhD, MBA, managing director in the Office of the Vice Provost for Research, University of Pennsylvania (Penn). Joe is principally responsible for overseeing Penn's industry research and educational partnerships in China across multiple therapeutic areas and university-wide process improvement. He shared his career journey from industry to academia, living and working with PASSION. Passion is an ardent love or affection, an enthusiasm, and an intense desire. It is a spirit, a "soft" skill that cannot be taught, and you have to hire someone who has it. He stated five keys for staying passionate: 1. Take regular inventory; 2.

Mr. Jacks Lee presents the keynote speech
Create a "passion support group" because passion is contagious; 3. Seek a "passion mentor"; 4. Commit to passion as the guide; and 5. Take time to be inspired and rejuvenated. “A career path may not lead to happiness, but a happiness path can make for a wonderful career.”

Dr. Peng Wang presents the keynote speech from the point of view of a returnee

Peng Wang, Chief scientific officer (CSO) and VP of Simcere, presented the second keynote speech. Peng is one of the national experts of Chinese government's "Thousand Talents Program", the Jiangsu Provincial "Innovation and Entrepreneurship" leader and Shandong Provincial "Taishan Talents-Pharmaceutical Expert." Simcere is a leading Chinese pharmaceutical company listed in NYSE in 2009 (symbol SCR) and one of the leading pharmaceutical companies in research and development (R&D) innovation in China. Dr. Peng Wang introduced various types of jobs in China for oversea returnees as well as current status of innovative R&D in China in a manner of smaller scale and lower quality compared with that in United States. Even though "me-too drugs" (generic drugs) are the major programs in Chinese Pharma and Biotech industries nowadays, innovative R&D in China has just started to boom. Dr. Wang foreseed that China would become a R&D center of the world in the future. He introduced Simcere's innovative models, including international collaboration, internal entrepreneur's program, and 100 innovative small biotech programs, and focused on western innovative new drug R&D projects and recruiting talented individuals. Simcere's "operating while constructing" model establishes "Innovative Research Venture Capital Fund" to help new projects growing from start-ups into intermediate scaled till mature: three typical stages of all the new projects, while Simcere plays the roles of "babysitter" roles as an assistant or a partner during the three respective stages. By sharing resources, risks & benefits and gaining support from various resources in China, Simcere is setting their goals of seeking more international collaborations, exploring new mechanisms for innovative drug R&D in China, and developing world-class innovative new drugs within 10 years.

Dr. Roger Shi, a professor at Penn State University (PSU), presented "Industry vs. Academia: Is the grass greener on the other side?" Dr. Shi has been working as an associate professor and full professor at PSU for 6 years after conducting research as a senior scientist in Eli Lilly for 11 years. He compared the green (good), brown (bad), and black (ugly) "grasses" in both industry and academia from his own working experience. His metaphor involving two monkeys describing the frequent changes of upper management in big phamas in recent years tantalized the audience with bursts of laughter. Once again he cited "there is no free lunch", as echoed from other speakers. Dr. Shi emphasized the following points: Everyone is their own boss; let the dreams fly, follow their passions, and never give up.

Dr. Jie Du, President & CEO of JDP Therapeutics Inc., shared her own experience on how to become an entrepreneur and what is involved with entrepreneurship. She elaborated the work that an entrepreneur should perform before starting up a company, including conducting market research, being proactive, having a good lawyer, several advisors, key opinion leaders, and an accountant/tax advisor on his team. She shared her visions and experience on how to transition a comfortable
corporate employee to an entrepreneur by starting with a project, being fully prepared both financially and mentally, being a salesman, living outside of the comfort zone, looking outside the box, and taking a calculated risk. She added, a great chief and a few good soldiers are required for a successful entrepreneur, Dr. Du pointed out that the road to entrepreneur is a tough but exciting road.

John Remmey and Michael Mazza, the recruiters of Aerotek, presented the No. 1 US recruiter company-Aerotek. They shared the website thingamajob.com for the audience to search and connect with their business.

Mr. Stuart Diamond gives an excellent talk titled “Negotiation skills”.

More than 100 people attended the career development workshop

The afternoon keynote presentation given by Stuart Diamond, MBA, Practice Professor of Wharton Business School, CEO and President at FourStar Aviation, internationally recognized negotiation expert, and author of the book "Getting More – How to negotiate to achieve your goals in the real world". He stated 12 reasons why most people are bad negotiators, and 12 invisible strategies that change everything you thought you knew about negotiating. One strategy is to value what a person says no matter what it is. Another one is to start smaller by beginning with a place where they cannot say no. Negotiation is everywhere. Like math is to science, negotiation is to society. After his excellent talk, Mr. Diamond signed more than 50 copies of his book--“Getting More”.

A ceremony of signing collaboration agreement between SAPA-GP and China Medicine Capital at Benxi New City was held between morning and afternoon session. Mr. Lü Wei, the Deputy Director of China Medicine Capital at Benxi New City and SAPA-GP President, Laura Hong, participated in the signing of the agreement. Ms. Xiaou Dong, the special advisor to Benxi Municipal Government, presented "New opportunities in China Medicine Capital at Benxi New City." China medicine capital at Benxi New City is the second national Bio-Pharmaceutical industry base in northeast of China. It is a booming city focused on medicine, health care, innovation and opening. They eagerly seek international talent to bring them to Benxi New City with their novel biomedical products. "Marshaling the full resources and wisdom of the province to make Benxi a leading city in pharmaceutical industry" is their goal. Benxi sent an eight member delegation led by Party Committee Secretary Gang Rui, traveling all the way from China to east coast of US - the trip itself demonstrates the dedication and commitment of Benxi government. Mr. Gang announced one billion RMB funding will go to the entrepreneurs once their manufacturing product proposal is approved by an expert committee. The funding is to speed up the entry of clinics and make the products industrialized in a timely fashion. Also, a standard manufacturing facility with one million square meters could be utilized by the new industry to support R&D, production, and
national/international collaboration. Still, each entrepreneur could be awarded 10 million RMB for their business development projects and relocation to Benxi.

After the workshop, the authors of this report interviewed several attendees. Dr. David Dai, a clinical pharmacology scientist from Novartis has driven 2 hours from NJ for this workshop. He expressed his interests in Dr. Peng Wang's talk, especially the biomedical business model in Simcere. David considered that patent might play an important role in R&D in China pharmaceutical industry, as revealed by successful examples in Simcere. He also pointed out the Chinese industry can target US market in the future, similar to the success of the Indian pharmaceutical companies supplying generic drugs in US market. Dr. Cassie Zuo, who was a visiting professor from China and has been studying at the Children's Hospital of Philadelphia for less than three months, had great impression on Jacks Lee's talk. She completely agreed that money is not everything; instead, motivation and passion are the major drivers of a successful career. Two Ph.D. students, Hao Wu and Kun Wang, both from University of Medicine and Dentistry of New Jersey, wanted to thank SAPA-GP for organizing this interesting workshop, which provided the biomedical updates of China pharmaceutical industry. They learned practical knowledge of how to connect their current PhD programs with future job market. In addition, they considered that the workshop provided invaluable information for those who might go back to China for future career development especially.

No doubt, any successful event organized by SAPA-GP is attributable to the excellent volunteers supporting SAPA-GP. The outstanding volunteers for the career development workshop were: Bin Shi, Zhibiao Fu, Ouyang Si, Hong Ye, Tingyi Zhou, Lili Guo, Kun Wang, David Dai, and Cassie Zuo.

The organizing committee of the career development workshop is dedicated to provide the prominent program and operation schemes in the Delaware Valley area. Sean Fu, Mabel Ju, and Yonggang Zhao are the organizing co-chairs. Weiguo Dai, Laura Hong, Zak Huang, Jiangfan Li, Yin Liang, Jingsong Wang, Di Wu, Mike Yu, and Sean Zhang also helped organize and operate this memorable career event.

Overall, the career development workshop, held by SAPA-GP, provided a great platform for biomedical professionals to share successful and sometimes difficult career journeys. The audience learned creative strategies, and leadership and negotiation skills from the different career experience shared in this workshop.
生物治疗医药研究与开发：

记美中医药开发协会纽英伦分会第十四届学术研讨会

供稿：陈大鹏；摄影：潘志卫，孙天霄

美中医药开发协会纽英伦分会（SAPA-NE，以下简称药协）11月5日下午在麻省剑桥市万豪酒店举行了以“生物治疗医药研究与开发”为主题的第14届学术研讨会。据研讨会主要筹办者林庆聪和吴家权两位博士介绍，在宾馆会议厅举行大型学术会议是药协近年来的一次新的尝试。鉴于生物大分子药物研究的热潮方兴未艾，本次研讨会邀请到了数位在生物制药工业界和学术界的知名专家学者，和大家共同探讨生物治疗医药研究与开发的热点和挑战。大约150余名会员和朋友们参加了此次研讨会。

下午1点整，研讨会在药协主席陈敏博士和秘书长会议主席林庆聪博士的热情致词中开幕。首先，来自辉瑞公司的资深主管Juan Almagro博士向大家介绍了用生物抗体工程来做抗体发现和筛选优化的最新进展，以及如何实现新一代抗体治疗药物的开发。

第二位主讲的是来自专程从中国南京赶来的先声药业首席科学官王鹏博士。他首先汇报了中国目前的医药研发的状况以及种种挑战。就大分子生物药物而言，现在全中国有4到5个获批的单抗药物。国内制药业在中国药监局申报临床（IND）的抗体有27个。和国外同行相比，在同一时期（05-10）年，跨国制药公司在美国FDA申报IND的抗体有300个之多。从这可见，中国医药业大分子药的研发还远远落后于发达国家。王鹏博士还提到许多其他方面的问题，比如说中国药监局审批IND的周期非常长，中美之间大分子药研发的差距要远大于小分子药。中国现在并不是那么缺钱，真正急缺的是有经验的高端人才。最后，王鹏博士还向大家介绍了先声药业在大分子药研发的进展。

随后，来自Aura Biosciences的资深副总裁Zahra Shahrokh博士向大家分析了在生产制造大分子药物过程中如何通过工艺改进来解决可比性的问题。在诺华公司担任执行主管的Mark Milton博士则从药物代谢和动力学（PK/PD）的角度为大家解读临床前大分子药研发的独特之处。来自Cerulean Pharma的资深副总裁Alexandra Glucksmann博士用实例向大家说明制剂学和纳米药物学在其公司的大分子药研发中扮演着极其重要的角色。最后，专程从亚特兰大赶来的佐治亚州立大学的王秉和教授向大家汇报了用碳水化合物这种不同于传统蛋白质的大分子来做生物标记物并应用于疾病诊断等等方面的前景。

当晚还举办了“先声之夜”晚宴。先声药业首席科学官王鹏博士进一步向大家说明了由先声药业带头设立的“创业百家汇”计划，并分享了项目计划。
王鹏博士在演讲中还回顾了他在美国制药业奋斗近20年的经历。他曾经就职于位于新泽西州的Schering-Plough公司长达18年，对9种新药的研发作出过重要贡献。2008年，王鹏入选中国千人计划，回到中国，2009年出任先声药业首席科学家。王鹏在美中药协创立初期就加盟，曾经出任过美中药协副会长。目前，美中药协与先声药业签订了合作协议。

在讨论会结束之前，还举行了抽奖仪式。药协会长陈敏博士给两位幸运者颁发了亚马逊Kindle作为奖品。这次生物治疗医药研究与开发学术研讨会由先声药业和Genscript竭诚赞助。陈敏还向研讨会其他组织者：苟大明，李和，李研红，马炯莉，钟晓天，斜理强，赵洁，陈大鹏，黄河，王玉瑶，梁桂青，杨军，朱高忠，潘志卫，龙江，马伟军，杨澜，杜冰帆，王又丹，孙天霄，赵菲莎，殷鹏程，王敏等表示由衷的感谢。

出席研讨会并演讲的嘉宾们

晚宴中，不少会员朋友们和王鹏博士及其他演讲嘉宾热烈互动，就大分子生物药以及整个制药业的发展和挑战做了深入探讨。会后，不少与会者都表示，这次精彩的研讨会不仅带来了很多最新的科研资讯，同时也留给大家很多的思考和启迪。
第一届麻省理工学院中国创新与创业论坛 (MIT-CHIEF):

保健与医药专题论坛

龙 江

第一届麻省理工学院中国创新与创业论坛 (MIT-CHIEF) 于 2011 年 11 月 19-20 日在麻省理工学院 (MIT) 的 Stata Center 举办。纽英伦美中医药开发协会 (SAPA-NE，以下简称药协) 与麻省理工学院中国学生学者联合会 (MIT-CSSA) 联合筹备和主办了 19 日下午举行的保健与医药专题论坛，约有 200 人出席。药协主席李和博士主持了论坛。

李和首先简单地介绍了药协的历史和使命，接着提到中国经济的持续增长和政府的优惠政策带来了医药工业发展前所未有的机遇，多个大型跨国医药公司在中国设立研发中心，大批高素质的医药研发人才归国创业及加盟，大量的来自海外及内陆的风险投资机构的涌入使中国正在成为全球医药发展的最热国家。然后李和介绍了 4 位受邀请的重量级演讲人。他们分别是麻州生命科学研究中心 (MLSC) 的首任总裁及首席执行官 Susan Windham-Bannister，中国华医药的创始人及首席执行官、罗氏上海研发中心前首席科学家陈力，上海伯豪生物技术有限公司 (ShanghaiBio Corporation) 创始人及首席执行官金刚 (Jason Jin)，健赞公司（Genzyme, a Sanofi company）的副总裁傅道田。

Windham-Bannister 女士首先开讲，2008 年 6 月麻州政府启动成立了麻州生命科学研究中心 (MLSC)，负责管理 10 年 10 亿美元的生命科学启动金。旨在促进麻州的经济发展，孵化生物科技、医药、医疗器械、医疗诊断及生物信息企业，在生命科学领域的创新，巩固麻州的生命科学在全球的领先地位，加速充满潜力的诊断治疗康复技术的商品化。成立至今 3 年多的时间，MLSC 已投入 2.17 亿美元，吸引 7.54 亿美元的投资，在麻州的生命科学领域创造了 7 千多个新就业机会。不仅在尖端科技项目上给予支持，MLSC 也重视基础设施的建设、提供新从业人员及中等医药产业员工的实习和培训，从而提高整体从业人员的素质技能。Susan 也举例说明 2008 年 MLSC 通过配套资金 3 年 75 万美元吸引跨国公司 Ipsen 在麻州 Milford 市与 Brigham & Women 联合成立了 Ipsen Biomeasure，研究针对骨关节炎的新型治疗技术。MLSC 也积极参与国际合作，新建立的麻州—以色列创新合作伙伴 (The Massachusetts-Israeli Innovation Partnership, MIIP) 迈出了坚实的一步。

陈力从上海 Roche 首席科学家到自己下海创业成立华医药谈及自己对中国医药创新的切身体会。30 年前中国的医药企业是清一色的国企，随着改革开放的深入，一些西方大型医药企业以合资的形式开始与国企合作如早期的中美史克、西安洋森等。
也是在那时中国医药企业开始思考和学习国际的先进经营管理方式。10年前，一批拥有丰富药物研发经验国际受训的海归如药明康德的李革、开拓者的惠欣等人在上海张江创业掀起了研发外包公司（Contract Research Organization, CRO）成立的浪潮。CRO的出现加速了西方科技在中国的快速转化，使中国药物研发的基础建设平台与国际接轨，也彻底改变了国人从事医药研发的思路和心态。谈及自己在Roche 18年的科研管理经历，陈力戏称自己完成了他的“博士后”训练，华医药是实现自主开发新药梦想的乐园。

金刚从中国“药谷”上海张江的成功经验介绍了中国政府对医药研发创新的优惠政策和大力的经费支持，也客观评价了当前中国医药产业的发展现状及发展趋势。2010年中国实现医药工业总产值11933.82亿元，同比增长27.07%，并将很快成为世界第二大医药销售经济体。政府出台多种专项基金大力支持创新药物研究，如“重大新药创制专项”、“传染病防治专项”等。“十一五”期间政府投入创新药重大专项和863计划共97.7亿元支持医药研发创新，是“十五”期间的2.5倍。目前世界前十名的跨国医药企业有7家落户张江，小型企业240家，CRO超过35家，2009年张江医药产业销售额达到106亿元。“十二五”期间张江计划形成千亿级健康产业集群，拥有百亿级企业5家。机遇与挑战并存，如何克服创新性差、低水平重复严重、产业总体经济效益低下、规范化标准化程度低等制约新药进入国际主流市场的困难也亟待解决。另外解决创新人才队伍建设力度不够，学科带头人、企业家、管理人才储备不足，药物创新投入不足，融资渠道和机制尚不健全等问题也需要下很大功夫。

傅道田演讲的题目是中国的生物大分子仿制药的未来及挑战，是当前医药发展的一个热点，吸引了与会者的浓厚兴趣。生物大分子药物全球的销售额增长极快，从2002年90亿美元增长为现在的大约1250亿美元，预期到2015年将达到1660亿美元。到2020年畅销药中的25个生物大分子药物将失去专利保护，这为生物大分子仿制药的研发及生产带来了空前的机遇。然而生物大分子研发比小分子药物研发过程复杂得多，存在着极高的风险，诸如缺乏足够的品牌药信息而产生很大的技术障碍，生产工艺不够稳定难以确保产品的质量及安全性，需要比小分子药物大得多的投资并且更长的投资回报周期，监管部门对大分子仿制药的政策不健全并且存在变数，上述的多种未知因素使得仿制药研发困难重重。傅博士进一步讲到中国大分子药物研发生产的性价比优势，将在未来的十年间使中国拥有超过美国及欧盟的生物大分子生产能力，并将最终成为全球生物仿制药的最大输出地。

在接下来的问题解答时间，四位演讲人与听众进行了精彩的互动，分享了自己对如何加速中国医药领域的科技创新的见解，肯定了上海张江的成功模式得益于政府的优惠政策及巨额的资金投入。最后药协主席李和致闭幕词感谢四位演讲人所作的精彩报告，也感谢论坛协调员，麻省理工学院的戴磊，和论坛主要筹办者：药协副会长陈敏，董事芶大明，麻省总医院主管赵洁，夏尔公司主管朱高忠，默克公司科学家陈大鹏，健赞公司主管蒋一得，药协理事龙江，和前会长马炳莉等的辛勤劳动和杰出贡献，并感谢所有参会者的热情支持。大家都感到学到了很多重要的知识并对明年的MIT-CHIEF充满期待。
SAPA Career Development Symposium an Eye-Opening Experience for Some

John Tan, Hui Zhao, John Sun, and Jiwen Chen

The SAPA Career Development Symposium and Lunar New Year Party was held on January 29, 2012 at Rutgers University in New Brunswick, NJ. The meeting was a huge success, attracting approximately 300 attendees on a cold Sunday afternoon. In contrast to the frigid temperature outside, the atmosphere inside the auditorium was warm and lively. The feedback from the meeting attendees has been overwhelmingly positive. They spoke highly of the topic selections and the quality of the presentations in this well-run event.

Dr. James Boyd, Vice President of Regulatory Affairs at Sanofi, kicked off the symposium with a captivating talk on “Asian Professionals in Corporate America”. Although Asian Americans as a group are perceived to be highly educated and technically competent, they are under-represented in leadership positions in most major companies. Dr. Boyd indicated that keeping one’s head down and engaging only on technical data will not get one up the corporate ladder. Instead, Asian Americans need to have a clear vision and plan, take action steps to overcome cultural and communication barriers, and actively build up networks and seek mentors to succeed in the corporate world.

The next speaker was Dr. Shuhui Chen, Chief Scientific Officer at WuXi AppTec. Dr. Chen had a stellar career in several major companies in the U.S. before taking his current position in Shanghai eight years ago. He has since built a world-class research team of nearly 3,000 members. In his presentation, he compared various career opportunities in the U.S. and China. He advised SAPA members to assess their own strength and passion, consider the growth potential (not just the compensation) of the next job opportunity, before making a decision on career transitions.

Dr. James Boyd gives an captivating talk on moving up the career ladder

The Symposium also had the honor of having Dr. Steve Sun, who had a rather unusual career path, to share his entrepreneurial experiences. After obtaining his Ph. D. and completing a couple of years post-doctoral training, Dr. Sun’s very first job was founding a company called GENEWIZ in 1999. From its humble beginnings, the company has...
become a major biology CRO in recent years, and was voted one of the 50 Fastest Growing Companies in New Jersey, while Dr. Sun himself received the Ernst & Young Entrepreneur of the Year Award the year before.

Ms. Lisa Chenofsky Singer concluded the presentations with a talk on how to leverage social networking for mid-career transitions. She is a career coach and has been featured in several national media outlets. She discussed strategies and practical tips on utilizing social media such as LinkedIn to build up one’s professional network for both career advancements and transitions.

Panel discussions engage the audience

The presentations were followed by a panel discussion with six additional panelists. Drs. Ling Wu (VP, Novartis), Peng Wang (CSO, Simcere Pharmaceuticals), Zili Li (Executive Director, Merck), Litao Zhang (Executive Director, Bristol-Myers Squibb), Rima Matsumoto (VP, Leadership Education for Asian Pacifics, Inc) shared their perspectives on career development. Panelists first shed lights on how they view the definition of "success" based on their personal experience and how they deal with success and failure. They further shared personal examples of skillsets acquired from work experience that is critical for their success. While those Q/A ignited the atmosphere among audience, questioning from audience became more detailed and geared toward specific panelists.

Audience got first-hand information on what it is like to climb career corporate ladder for an Asian professional, what is the corporate career opportunity with a M.D. degree from China, on exploring career opportunities in China, and on many aspects of starting young career as well as own business. Mr. Xiaolin Zhou, Partner at Jun He Law Offices, discussed approaches to avoid legal pitfalls when starting one’s own company, or working and collaborating with Chinese firms.

The mini-job fair, organized by John Tan and Su-fen Pu, has over 100 positions

Symposium organizers with speakers

The event was concluded with a Lunar New Year Party hosted by Helena Feng and Xiaole Shen. The party was composed of lively performances by both professionals and SAPA members, mingled with fun and interactive games. Even though the party was conducted almost entirely in Chinese, several non-Chinese speaking guests commented that they thoroughly enjoyed the event and felt the joy of everyone else without understanding a single Chinese word.
The Symposium continued an annual SAPA tradition that dates back a decade ago. This year more than a dozen companies, both local and global, participated in the mini-job fair with well over 100 positions. It was arguably the largest job fair that SAPA hosted, and several companies with significant expansion plans sent delegates from China to recruit talents among SAPA members. This is especially valuable for the membership in light of the challenging job market in our industry, and the tri-state area has been hit particular hard by several large mergers and acquisitions in the past couple of years.

One of the attendees summed up this first SAPA event of the year, taking a page from a famous TV commercial: Distinguished speakers and panelists with outstanding achievements and precious insights: 10; Hiring companies on site for recruiting talents with great opportunities: 13; Cheers for a great New Year celebration: countless; To make a positive impact on SAPA members’ career development and enriching their lives: PRICELESS.

The Symposium organizers included Charles Bao, Jing Chen, Jiwen Chen, Wei Ding, Helena Feng, Frank Gan, Handan He, Baoguo Huang, Xing Li, Su-fen Pu, Xiaole Shen, John Sun, John Tan, Jianji Wang, Hui Zhao, and Xiaoying Zhang.

### Biostatistics & Clinical Programming Symposium Expands SAPA’s Influences

**Cai Li and Helen Fu**

A full-day Symposium on Biostatistics and Clinical Programming was held at Princeton University on November 19, 2011. It was organized by SAPA and a group of Biostatisticians and clinical programmers from the surrounding pharmaceutical companies. Senior experts of the FDA, Clinical Data Interchange Standards Consortium (CDISC), and major pharmas shared their visions at the plenary session in the morning. This was followed by two parallel sessions “Biostatistics” and “Clinical Programming” in the afternoon. The Symposium concluded with a panel discussion on “Operating in a Global Environment for Biostatistics and Programming: Current Trends and Future Directions”.

Although the topics of the Symposium were in a very specialized area, the event attracted approximately 250 attendees from the tri-state area, and received overwhelmingly positive feedback. The speakers and meeting participants were very impressed with SAPA’s professionalism, detailed planning, and high quality logistical support. A significant number of attendees joined the SAPA membership, with some becoming lifetime members. For other SAPA members who were not familiar with biostatistics or clinical programming,
the presentations provided a valuable opportunity for them to learn some basic concepts and working knowledge of a critical area of drug development. Encouraged by its success, the SAPA leadership team intends to organize similar events with a narrow focus yet broad appeals to the membership in the future.

Dr. Stephen E. Wilson from the FDA described the agency’s plans for developing a standards-based review environment.

The Symposium attracted approximately 250 attendees.

Panel discussion focused on current trends and future directions for Biostatistics and Programming

Symposium organizing committee and speakers

The event was co-sponsored by SAPA, the American Statistical Association (ASA), and the International Chinese Statistical Association (ICSA). Both the ASA and ICSA are leading professional organizations for statisticians. The Symposium is just one example of SAPA’s expanding footprint into the mainstream society.
中国药都沈溪新城代表团访费城中美医药协会

报道：石斌；摄影：赵永刚, 罗锋

中国药都沈溪新城(又称本溪)代表团于十二月十日来到费城，参加了费城中美医药协会举办的职场生涯研讨会，并与费城中美医药协会签署了合作协议书。代表团由冮瑞，本溪市委书记；董晓鸥，本溪市政府特别顾问；卢伟，本溪高新区管委会副主任；吕广义，本溪高新区管委会科技局局长；王瑞杰，辽宁诺维诺制药有限公司董事长；连伟，辽宁科泰生物有限公司董事长组成。本溪市政府特别顾问董晓鸥女士做了热情洋溢的报告。她介绍了本溪的过去和现在，展望了本溪药都的未来。本溪新城是崛起于沈阳和本溪之间的一座生态新城，它将成为国内一流，世界先进的“医药之城，健康之城，创新之城，开放之城”。辽宁省和本溪市政府都高度重视药都新区的配套改革和战略开发。本溪市委书记冮瑞这次亲自带队，足见政府招贤若渴的诚意。冮瑞书记强调，他们这次来美，就是要和SAPA-GP这样的美国医药协会联手，与海外专家接洽交流，希望引进海外人才，希望高水平海外人士带着高水平产品项目到本溪研