



药协通讯

Sino-American Pharmaceutical Professionals Association Newsletter

第七十四期

二零一一年十一月七日出版



本期特别报道:

One SAPA, One Dream

——访 2011-2012 SAPA 主席黄宝国博士

美中药协领导层峰会成功举办

卷首语

成长就是主流

文：李行

《药协通讯》第 72 期的文章《风从中国来》在中国医药领域的主流媒体《医药经济报》再发表，受访嘉宾华海药业美国公司的首席科技官郭晓迪博士“对于一个像我们这样在美国刚起步的公司，SAPA 提供了一个很好的信息交流、资源共享的平台”的一番感言，通过纸质和网络双平台与中国医药行业的 50 万读者分享。

长城非一日建成，小康非一日之功。SAPA 从过去的低调前行到如今的倍受业界关注，我们不会为此受宠若惊，也不必因此骄傲自大。我们一直在努力地发展壮大，我们以一颗平和之心脚踏实地走在通向主流的道路上。我们期待在更多的主流媒体上留下 SAPA 成长的痕迹，在更多的主流场合听到 SAPA 日渐成熟的声音。所幸的是，岁月的实践把历史的真知告诉我们——成长就是主流。

在 SAPA 领导层峰会上，大家的激情不约而同地为“一个 SAPA”大道至简的理念点燃，相互的渗透团结和鼎力支持会让一个团队更强大，让前进的步伐更有力。这时候主流就是一种领导力和凝聚力！

在成长的道路上，难免会有不同的声音，有时会面临棘手的挑战，但我们会重新审度异议的价值，会用包容去海纳和用尊重去融合，只要最终的方向还是在正确的轨道上朝前进。这时候主流就是一种宽容力和执行力！

在非典的时期，中国政府驻纽约总领事馆点名希望 SAPA 能召集专家学者为中国政府在医学上提供治疗建议和和政策上提供信息咨询，SAPA 全力以赴不负使命。这时候主流就是一种信任力和影响力！

在未来的蓝图里，在求真务实中求创新，在与时俱进中求多元，撬动最前沿的信息资源，引领美中两国的医药领域风向，推动医药行业更稳健更理智地发展。这时候主流就是一种思考力和远瞻力！

我们不刻意追求主流，但我们成长的岁月就刻写在主流的征程上！



本期目录

栏目	题目	作者	页码
卷首语	成长就是主流	李行	2
SAPA 特别报道	One SAPA, One Dream ——访 2011-2012 SAPA 主席黄宝国博士	李行	4
	美中药协领导层峰会成功举办	陈大鹏	6
SAPA 访谈录	Preparing Your Net in Emerging Markets: A Look at Two Success Stories	Charlie Zhang, Jack Zhang	9
新栏目 法规专家一席谈	How to Effectively Interact with the FDA: Formal Meetings	Andrew Jiang	11
SAPA 会议论坛	SAPA 19 th Annual Conference ——Transforming Pharma/ Biotech Industries through Innovation and Partnership	Nora Xu, Tycho Heimbach	13
	一个海归在中国的创业之路 ——SAPA 中西部分会成功举办第一次活动	张宏兴	18
SAPA 协会活动	药协和网协暑期郊游成功举行	龙江, 等	19
	2011 美中药协中秋野餐活动圆满举行	沈小乐、包振鸿	20
SAPA 桥梁之声	开创中美高新科技合作新前景 ——中国无锡新区投资创业说明会美国费城纪实	吴荻, 等	22
SAPA 协会活动预告	美中药协 (SAPA) 临床统计和编程研讨会即将召开	Cindy Song	25

责任主编：李行 陈纪文

特邀顾问：童华宜

版式编排：朴素芬 李行

封面摄影：朴素芬

封面设计：朴素芬

编委成员：陈大鹏 黄宝国 朴素芬 吴荻 吴国胜 项信珍

Copyright©2011, by the Sino-American Pharmaceutical Professionals Association

SAPA 特别报道

One SAPA, One Dream

——访 2011-2012 SAPA 主席黄宝国博士

文：李行



黄宝国博士, 2011-2012 SAPA 主席

刚出任 SAPA 第 19 任主席 2 个多月, 黄宝国博士感到身上的担子很重。对于一个有将近 19 年历史 4000 多名会员的协会, 对于一个已在制药领域华人华语圈极具影响力的组织, 在其下一个十年里程, 大家所期待的不仅仅是过去辉煌成就的再创和重现, 更希望这个平台的发展能有创新有突破。引导这样的革新需要一个这样的掌舵人——具备智者的未雨绸缪, 慧者的纵观全局, 谋者的高识远见。

宝国在众望所向中接过这个重任, 表示将用其智竭其慧尽其谋把这项集体的事业往前推进。他虽感压力却很有信心, “这是极具挑战的事情, 但我们这个团队有很多能干的理事和会员, 我们在一起能迸发出很多新的想法, 也能把很多想法付诸实现。我们最大的梦想和最终的目的就只有一个——更好地为会员服务”。

三大工作重心

没有规矩不成方圆, 没有规划不及长远。不只是在 他上任后 10 月初的 SAPA 领导层峰会, 早在 8 月的 SAPA 总部第 19 届年会上, 宝国早已分享他对这个组织的发展规划。虽然可能侧重于在他任期内的计划, 但每一个行动纲领的成功执行都将促使 SAPA 在理念上组织结构上发生耳目一新的变化, 而这个变化的渗透力将深度蔓延和长期持续。

他用三个首要重心总结这个富有革新使命的规划, “一是通过全球化交流提升 SAPA 的正面形象和影响力, 交流的核心原则是” 一个 SAPA (One SAPA)”, 交流将定期通过 SAPA《药协通讯》等传媒、网络、宣传手册等工具传递至任何医药相关渠道所能达到的各个角落; 二是优化 SAPA 人才资源合理分工, 多个分会的相互融合与参与, 为 SAPA 可持续性发展培养领导团队; 三是进一步为会员举办高质量的学术性讲座, 为会员接触多元学术领域和开拓工作视野提供平台。”

一个 SAPA 行天下

“One SAPA 这个理念非常重要, 是发展规划中的重中之重”, 宝国在对他的规划目标作了一番说明之后, 再次强调了这个核心原则问题。团结就是力量, 不是支过时的经典名曲, 而是今天 SAPA 这个大家庭稳定和谐的主旋律, 是长远发展立足所

在。SAPA 发展至今, 分会逐渐增加, 会员日益增多遍及美中两国东西南北。维护 SAPA 这个岁月沉淀信誉积累的品牌, 不只是一任主席一名会员的责任, 也不是一朝一夕的事情。

在谈及“SAPA 如何发展成一个更具有主流影响力的协会”这个颇引深思的问题时, 宝国继续坚持, “这个发展的前提是我们要达成共识, 就是只有一个 SAPA。SAPA 总部将进一步和各个分会之间的交流与合作, 团结与合作让 SAPA 变成一个更强大更具影响力的组织。如果没有向心的凝聚力, SAPA 将不能整合实力优化资源, 无法发挥互补优势, 影响力反而会被削弱”。

宝国也很感兴趣地延伸他对这个话题的构想, “在这个基础上, SAPA 将更多地与主流专业协会合作举办学术讲座和研讨会, 更多地与美中两国的主流媒体有互动往来通过他们让更多的人了解和关注 SAPA, 进一步建立和巩固与各制药公司之间的良好合作关系从而取得公司领导层的鼎力支持, 他们积极参与 SAPA 的活动也无疑帮助提升 SAPA 的形象, 吸引更多的眼光”。

SAPA 的优势与价值

SAPA 走过 19 年的岁月, 会员的结构也从当初局限在化学相关专业的一小部分人到今天几乎覆盖医疗卫生产业所有专业和多样化背景的 4000 多人, 这正是 SAPA 的优势所在。SAPA 纵横广深的发展历程也折射出美中两国生物制药行业高低起伏的变化风云。

Q: 时下美国的制药行业不景气, 这对 SAPA 有什么影响?

A: 对 SAPA 而言可能就是在获得制药公司的赞助资金方面与以前相比难度增加, 但实际上这给 SAPA 带来的正面影响比负面影响更大。首先 SAPA 举办的活动吸引到更多的人来参加, 更多的人意识到

SAPA 这个平台的价值和益处, 更多的人通过这个平台和机会扩展自己的知识领域, 建立自己的人脉网络, 寻找新的发展就业机会。而 SAPA 非常愿意帮助大家在学习上充实自我, 在战略上把握时机, 共同走出短暂低谷。

Q: SAPA 在促进中国医药产业的发展发挥什么样的作用?

A: 中国的医药产业结构主要分三大块: 传统的国有大型企业和民营企业, 发展势头正猛的外包 CRO 企业, 还有就是新兴的生物技术或创新性小型公司。传统的企业过去占有垄断优势安于现状, 直到现在的中国的医药市场由于跨国公司的加入重新洗牌而备受压力, 发展的重心也开始向创新倾移。CRO 产业发展空间很大同时竞争也很激烈, 这个产业在中国的出现对医药行业是个从未有的变革。小型公司起步艰难, 但他们的雷厉风行让大家看到新产品的希望。

无论是产业结构里的哪一块产业链里的哪一环, SAPA 都能在信息方面和人才方面提供资源。近年来, 无论是由国内远道而来的参观访问团还是由 SAPA 在中国协办的学术会议, SAPA 都能根据对方的需要和特点, 提供“量体裁衣”式的培训。例如指导国内的企业如何有效地与美国 FDA 交流沟通, 如何有的放矢的达到美国 FDA 的 GMP 标准, 如何引进国外的先进技术等等。同时 SAPA 汇聚了大量的在学术上有深造在工作中有经验的人才, 无论是专业型还是复合型精英, SAPA 都能为中国医药产业的发展推荐合适的专业人士。

一个小时的轻松对话即将结束时, 黄宝国主席强调, “我们时常听到有很多好的建议, 这些建议能够促进 SAPA 更健康的发展。只要在团队里面平和沟通好, 能思量取舍好, 能协调平衡好, 我们 SAPA 就会继续朝前进, 更好地为会员服务的宗旨就能实现, 让每一个会员都为成为 SAPA 的一分子感到骄傲和自豪”。

SAPA 特别报道

美中药协领导层峰会成功举办

文：陈大鹏

图：李才、潘志卫

2011年10月1到2日,美中医药开发协会(SAPA,以下简称药协)在纽约 Suffern 市 Crowne Plaza Hotel 成功举办了第四届领导层峰会(Leadership Team Summit)。来自波士顿地区,新泽西,纽约,费城,芝加哥和药协中国俱乐部等七十余名药协的董事和理事们共聚一堂,针对如何发展壮大美中药协,顺应美中两国制药业的最新变化趋势,以及如何更好的为会员和社区服务等议题进行了热烈而且富有成效的讨论。

峰会伊始,药协总部会长黄宝国博士首先致欢迎词。他表示,峰会自2006年开办至今,规模逐渐壮大,在药协发展的过程中扮演着极其重要的角色。他还积极评价了各个分会的踊跃参与。比如说纽英伦分会有23名董事和理事从波士顿地区驾车4个小时参加会议,大费城分会有14名董事和成员赶来,药协中国俱乐部有6名董事理事专程从中国赶来,还有3名新理事从芝加哥和印第安纳州地区赴会,给大家留下了非常深刻的印象。

峰会的议程是以黄宝国会会长所倡导的“一个SAPA”的理念及三大工作重心为主线展开。第一项议程是由资深董事童华宜博士和徐志新博士主持。他们用创会以来的亲身经历与大家重温了药协的章程(By-laws)和行为准则(Code of Conduct)。药协自93年创办至今将近二十年,逐步发展成为有五千名会员的专业组织,这在全美国的成千上万个华人协会中,可以说是最成功,最具有影响力,受主流社会认可的华人专业组织之一。这其中最根本的原因,就是因为药协始终贯彻依法办事的民主作风。在人事高度流动的美国社会和制药行业,一部优良的章

程和行为准则确保了药协始终遵循其宗旨和目标,即不谋求任何经济和政治利益,踏踏实实为药业发展,科技交流和教育,以及会员和社区服务提供平台和做出贡献。

除了章程和行为准则,非盈利组织的会计制度,报税细则和法律法规对于药协的健康和正常运作也十分重要。职业会计师(CPA) George Shen 和纽英伦分会的法律顾问 Ian & Helen Liu 律师为大家就这些问题作了耐心的讲解。与会者普遍觉得受益匪浅,很多细节的问题得到了专家的授业解惑。



图一：峰会现场座无虚席。

在为期一天半的会程中,药协的各个功能小组也利用难得的见面机会,和同仁们分享经验和心得,总结教训,探讨更高效的运作方式。可持续性发展(Sustainable growth),全球通讯(Global communication),中国事务(China Affairs),会员(Membership),会计(Accounting),组织章程(Policy),募款(Fundraising),网站建设(Website),法规

(Regulatory), 新闻通讯 (Newsletter) 和科技论坛 (Scientific Symposium) 等小组既达成了未来发展重点的共识, 又明确了可行的实施计划。大家都畅所欲言, 就像自己在家和兄弟姐妹共同讨论家事一样, 对药协的发展提出了很多宝贵的建议和点子, 气氛热烈融洽。

由南京先声药业集团赞助的“先声之夜”晚餐会是本次峰会的一个亮点。先声集团的副总裁兼首席科学官王鹏博士曾在美国制药业奋斗近二十年, 也担当过美中药协的副会长。他特别赞许了美中药协在美两国制药业所扮演的桥梁角色。他籍此机会第一次对外宣布了先声集团的“创新药物创业百家汇”计划。王鹏博士做的统计结果显示从06年至10年国内制药业向中国食品药品监督管理局新药申请的数量总和为126个, 而作为世界新药创新源头的美国在同期向美国食品药品监督管理局申报的数量则高达4363个。中国新药申请呈现不仅数量少且质量低的落后状态。尽管国内医药创业园区不少, 但目前还未有企业上市。本着振兴民族医药工业, 创造国际级创新药的梦想, 先声集团首次提出了以大型企业牵头建立创新工业园区的设想。他们希望能够通过百家汇计划和与美中药协等专业协会合作的方式, 不仅为中国制药业吸引人才, 而且为人才们提供完整研发产业链的增值平台, 实现在十年内产生出中国创造的国际级创新药的梦想。

峰会的重头戏之一是由前任会长陈力组织的讨论海归以及在中国发展职业生涯的专题会。据了解, SAPA 已有不少会员成为海归, 为中国的制药业增砖添瓦。但是, 海归是否真的适用于每个人呢? 前会长夏明德博士结合自身体会表示, 这完全取决于个人的背景和自身条件, 海归只适合有充分准备的人。前会长崔霁松博士则向大家分享了促使她毅然回国的两条根本原因: 1.蓬勃发展的中国制药业提供了她更大的舞台来实现新药创新的梦想; 2.可以更好的教育中国年轻的科学家如何做药物研发, 获得更高人生价值的满足感。陈力还向大家介绍了合同研发外包(CRO) 在中国的现状。当有会员问到SAPA 对于他们最大的帮助时, 几位前任会长都异口同声的答道, SAPA 提供了锻炼领导力和扩大关系网络的机会, 他们实在是受益匪浅。



图二: 热烈的分组讨论



图三: 各小组讨论到深夜十二点



图四: 药协中国俱乐部在分享经验和心得

在精彩又紧张的峰会当中, 总部秘书长钟晓天, SAPA 大费城分会后任会长张向阳, 资深理事陈新海和冯海霞等组织者们还为大家准备了知识竞赛, 猜字谜和卡拉 OK 等有趣的团队建设活动, 让大家更好的认识和交流。新老朋友们得到了充分的放松, 现场欢笑声不断, 友谊也得到了不断的升华。

在峰会总结发言中,不少资深理事感慨地说,虽然自己在药协奉献多年,这次还是温故知新,学到了相当多的新知识新内涵。许多第一次参加峰会的新理事们表示,一开始没有想到药协运作这么有序,既是一个非常成熟自信的组织,又是一个温暖和谐的大家庭。通过这次峰会系统而又深刻的学习到了药协的整体组织结构和运作方式,非常有收获。据了解,本次峰会有将近三成的新面孔,美中药协还是一个充满年轻朝气的团体。

峰会议程结束前,黄宝国会长宣布成立以下四个专门工作委员会来具体落实峰会的共识:中国事务(China affairs),全面通讯(global communications),法规(regulatory)和科技项目(scientific programs)。他还宣布了每个委员会的负责人和成员名单。最后,总部黄宝国会长,大费城分会洪桂英会长,和纽英伦分会陈敏会长高度评价了为峰会无私奉献的志愿者,并代表所有与会者对他们表示衷心的感谢。



图五:出席美中药协峰会的董事和理事合影。



图六:与先声集团的副总裁兼首席科学官王鹏博士(右起第七位)合影留恋。

SAPA 访谈录

Preparing Your Net in Emerging Markets: A Look at Two Success Stories

Charlie Zhang, Jack Zhang

To the outside observer, the Sino-American Pharmaceutical Association - Greater Philadelphia (SAPA-GP) 9th Annual Conference seems like a social gathering of predominately American Chinese pharmacologists, all of whom sport clean shirts or dresses, as well as a healthy interest in their work with medicine. Thus was our initial impression upon entering Villanova University's Conference Hall, the venue for SAPA-GP's 9th Annual Conference. However, our perspective on these fellow members of the SAPA-GP community quickly changed as we proceeded to interview two speakers at the conference: Doctors Ruiping Dong and Jun Wu. These two speakers are both examples of success in today's competitive world, both examples of how hard work can prevail against possible hardships. Although both men are highly successful today, their paths to their current positions are radically different, a testament to their versatility.

Our first report was with Dr. Ruiping Dong. Upon meeting him, we were immediately told of his exalted position in Merck, Co. as the Senior Vice President, Head of Emerging Market (EM) R&D. An amiable, friendly man, Dr. Dong explained to us his role in Merck and what it means, essentially, to belong to the emerging markets. "In today's pharmaceutical market," Dr. Dong explained, "almost 90% of a company's growth comes from emerging markets, so this is a very important part for

Pharm to keep focusing EM" Dr. Dong continued to explain that emerging markets were nations or areas that are currently developing with huge unmet medical needs and are areas into which large pharmaceutical companies are currently expanding into. Dr. Dong told us of BRIC nations, namely Brazil, Russia, India, and China, as current important areas of "expansion."



Dr. Ruiping Dong (middle), Senior Vice President, Head of Emerging Market R&D of Merck, Co.

Beyond this basic knowledge, Dr. Dong also gave us insight into the challenges that companies face in these emerging markets. Nations that constitute these new areas often have low incomes, which make the access of innovative drugs much more difficult. "In developed countries insurance would usually cover the costs," Dr. Dong said, "but

oftentimes insurance isn't widely available in EM." After posing for a photo with him, we learned that he has served as the Head of R&D Japan & China at BMS, and he had in the pharmaceutical R&D for a long time. Dr. Dong represented the paragon of hard work and dedication, of how maintaining the same area leads to promotion and great success. However, this persistence is not the only way one can make a mark in today's pharmaceutical world.

Our next interviewee was Dr. Jun Wu, the Chairman and founding partner of Cenova Ventures, which as the company name implies, deals with venture capital. We met with Dr. Wu, and the first impression we had gotten was that this man certainly had an intelligent air about him. When we sat down for the interview, Dr. Wu immediately dove into his life story, using it to weave a message about career opportunities and preparing for life. He told us of the hardships he had endured when first came to USA in 1987. Dr. Wu told us that in a month, all of his fees and expenses added up to only \$36, something that he had described as "unimaginable for today's generation." From there, he was able to receive his Ph. D. from the University of California at San Francisco, thus beginning his career as a Research Scientist. However, unlike most, he decided to combine his knowledge of medicine with a novel area: business. Thus, with government and private funding, he co-founded Shanghai Genomics, and it grew to become one of the flagships among the Chinese biopharmaceutical companies established by returnees. After that, he founded Cenova Ventures, a life science specific RMB venture fund in China.

Throughout the interview, Dr. Wu told us about his more sentimental values that he held, how his experiences with lung fibrosis patients inspired him to develop new medicine. Dr. Wu then explained to us his work on Pirfenidone, the world's 1st anti-fibrotic drug created with his prior venture company, a potential "billion-dollar drug." Dr. Wu's story

represents the power of changing decisions, and being prepared to make changes in one's career path.



Interviewing Dr. Jun Wu (left), the Chairman and founding partner of Cenova Ventures

Perhaps the most memorable aspect of both interviews was the mention of how life is like a net. "In life, you study and prepare yourself for the world. That is like making the holes in your nets," Dr. Wu explained. "The opportunities available and the jobs that come up are like the fish swimming in the ocean. However, only a dense net can properly catch all the fish that pass through your net. Thus, by preparing yourselves for the future in many possible ways, you are weaving your net to catch those fish later on in your lives."

By attending SAPA-GP's conference, we most certainly have.

About the Authors:

Both Charlie Zhang and Jack Zhang attended 9th SAPA-GP annual conference (2011) as student volunteers. Charlie is a junior at Wissahickon High School in Ambler, PA; in addition to having an interest in the life sciences, Charlie also is the Student Council President for 2011-2012. Jack, a freshman at Wissahickon High School, enjoys and values academics and has high aspirations for the future.

法规专家一席谈

How to Effectively Interact with the FDA: Formal Meetings

Andrew Jiang

Throughout the pharmaceutical product development and post-marketing compliance, there are many opportunities for direct interaction between FDA and the Sponsor, including formal meetings, inspections, telephone/email contact and dispute resolution, etc. Successful meetings with FDA are one of the most critical factors in moving your new drug through the development and approval process, and getting you on the right track to commercial success. Too often, meetings with the FDA are unproductive and unsuccessful, leaving both parties frustrated and causing delays to your development program that can cost your company significant time and money. In this article, a brief introduction about the formal meetings with the FDA is provided.

In February 2000, FDA published the Guidance for Industry: Formal Meetings with Sponsors and Applicants for PDUFA Products. This guidance was later revised and is entitled Guidance for Industry: Formal Meetings between the FDA and Sponsors or Applicants (May 2009, Revision 1). This guidance provides recommendations to industry on formal meetings between the Food and Drug Administration (FDA) and sponsors or applicants relating to the development and review of drug or biological drug products (hereafter products) regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). This guidance does not apply to abbreviated new drug applications. The following three types of meetings are listed in this guidance:

Type A meeting: a meeting needed to help an otherwise stalled product development program proceed. Examples of a Type A meeting include: dispute resolution meetings, meetings to discuss clinical holds, and special protocol assessment meetings. Type A meetings should be scheduled to occur within 30 days of FDA receipt of a written meeting request.

Type B meeting: Type B meetings are (1) pre-IND meetings, (2) certain end of Phase 1 meetings, (3) end of Phase 2/pre-Phase 3 meetings, and (4) pre-NDA/BLA meetings. Generally, FDA will not grant more than one of each of the Type B meetings for each potential application. Type B meetings should be scheduled to occur 60 days of FDA receipt of a written meeting request.

Type C meeting: any meeting other than a Type A or Type B meeting between CBER or CDER and a sponsor or applicant regarding the development and review of a product.

Type C meetings should be scheduled to occur within 75 days of FDA receipt of the written meeting request.

The sponsor or applicant needs to request meetings in accordance with the requirements listed in the guidance. Certain information on the requested meeting and development program will need to be submitted in the meeting request. The CBER or CDER division director or designee who receives a meeting request will determine whether to

hold the meeting and will respond to the sponsor or applicant by granting or denying the meeting within 14 days of receipt of the request for Type A meetings and within 21 days for Type B and Type C meetings. Generally speaking, based on my professional experience, Type A and Type B meetings are often granted, if the meeting is requested in accordance with the FDA's guideline; Type C meeting, however, can sometimes be rejected, often due to the large workload of the review division.

If a meeting request is granted by CDER or CBER, the sponsor or applicant will need to prepare and submit meeting packages within specified time frame. The meeting package should generally contain the following information:

1. Product name and application number (if applicable).
2. Chemical name and structure.
3. Proposed indication.
4. Dosage form, route of administration, and dosing regimen (frequency and duration).
5. An updated list of sponsor or applicant attendees, affiliations, and titles.
6. A background section that includes the following:
 - a. A brief history of the development program and the events leading up to the meeting.
 - b. The status of product development (e.g., the target indication for use).
7. A brief statement summarizing the purpose of the meeting.
8. A proposed agenda.
9. A list of the final questions for discussion grouped by discipline and with a brief summary for each question to explain the need or context for the question.

10. Data to support discussion organized by discipline and question.

Meetings will be chaired by an FDA staff member. The length of meetings is generally one (1) hour. Documentation of meeting outcomes, agreements, disagreements, and action items is critical to ensuring that this information is preserved for meeting attendees and future reference. FDA minutes are the official record of the meeting. The official, finalized minutes will be issued to all FDA attendees (with copies to appropriate files) and to the sponsor or applicant within 30 days of the meeting.

In order to have a productive meeting with the FDA, pre-meeting preparation is critical. The sponsor or applicant should think carefully about how to best communicate product information truthfully and effectively. Experts who will speak at the meeting should be clearly designated. The key to a successful meeting is rehearsal, rehearsal and rehearsal!

About the Author:



Andrew Jiang is the president of Aleon Pharma International, LLC, an international consulting firm that provides strategic regulatory and product development solutions to clients in the pharmaceutical and biotechnology industries. He has extensive experience interacting with the FDA and other major health authorities. Previously he worked for Bayer, Novartis, Wyeth and other pharmaceutical companies in the field of regulatory affairs.

SAPA 会议论坛

SAPA 19th Annual Conference

—Transforming Pharma/ Biotech Industries through Innovation and Partnership

Nora Xu, Tycho Heimbach

The SAPA 19th Annual Conference was held on Saturday, August 6th at Rutgers University in Piscataway, NJ. Pharmaceutical industry professionals and executives gathered at this day-long event to exchange ideas. Designed to inform attendees about Transforming Pharma/ Biotech Industries through Innovation and Partnerships, the invited industry leaders discussed approaches to increase innovation and productivity in the industry and spoke about current trends in the emerging markets.

The event was hugely popular, attracting over 500 guests from the pharma/ biotech industries. The first plenary session convened at 8:45 a.m., followed by two concurrent parallel symposiums occurring from 3:10 p.m. to 5:30 p.m. Guests were treated to a dinner banquet in the evening at the Doubletree Somerset Hotel, which was sponsored by the Nantong Economic & Technological Development Area (NETDA).

The attendees were greeted by an opening remark from the 2010-2011 SAPA President Dr. Jianji Wang, followed by a welcoming address from Mr. Xinghua Zhu, Consul of the Consulate General of the P.R. China in New York. Mr. Zhu applauded SAPA's contributions to the community and discussed the growth of the pharma/ biotech industries in China.



Photo 1: Dr. Jianji Wang, 2010-2011 SAPA President



Photo 2: Dr. Baoguo Huang, 2011-2012 SAPA President

The first plenary session took place during the morning and early afternoon and featured presentations from the following experts:



Photo 3: Dr. Mark Gelbert, SVP, Global R&D, Pfizer Consumer Healthcare



Photo 4: Dr. Jerome M. Zeldis, CEO, Celgene Global Health, & CMO, Celgene Corporation



Photo 5: Mr. John Oyler, CEO, Beigene & Former CEO, BioDuro, Inc.

1. Dr. Mark Gelbert (SVP, Global R&D, Pfizer Consumer Healthcare), Innovation in Consumer Healthcare: A Recipe for Success

2. Dr. Jingwu Zang (SVP, GlaxoSmithKline (China) R&D Company Ltd.), Moving from ‘Made in China’ to ‘Discovered in China’

3. Dr. Danny Howard (VP and Global Head, PK/PD-DMPK, Novartis), Who Cares About Personalized Medicine?

4. Dr. Ruiping Dong (SVP, Emerging Markets R&D, Merck), Can an MNC in China Address the Challenges of Global R&D?

5. Dr. Jerome M. Zeldis (CEO, Celgene Global Health; CMO, Celgene Corporation), The Evolution of Celgene: China, The New Frontier

6. Dr. Jacky Vonderscher (SVP and Global Head, Translational Research Sciences, Hoffmann-La-Roche Inc.), How Roche has Transformed its R&D Model Through Innovation and Partnerships

7. Dr. Frank Jiang (VP and Head, Asia-Pacific R&D, Sanofi), Improving R&D Productivity Through External Partnerships

8. Mr. John Oyler (CEO, Beigene; Former CEO, BioDuro, Inc.), Future of New Drug Discovery in China

Dr. Gelbert and Dr. Zhang discussed innovation in the consumer healthcare and pharmaceutical industries. Dr. Gelbert emphasized innovation as the most important factor in driving the success of consumer healthcare products. He provided different avenues through which existing brands e.g. Listerine, can still be seen as fresh and innovative, through new forms of delivery, new flavors, personalization based on age group, and improved active ingredients. Dr. Zhang briefed the audience on China’s capability to originate innovation, espousing a culture of entrepreneurship. This innovation, he said, needs to focus on China’s changing demographics, the changes in lifestyle, and

diseases which are prevalent in the population, specifically tuberculosis, hepatitis, and lung cancer. Dr. Zhang also provided an overview of GSK's R&D development capabilities in China focusing in the field of neurosciences, which has led to success and now several drug candidates are in Phase I-II trials.

Dr. Howard described the evolution of personalized medicines in the pharmaceutical industry since the human genome was sequenced ca. 10 years ago. Recent legislative challenges include the direct-to-consumer online marketing of some genetic and genomic tests, which led to a "personalized medicine bill" by Congressman Patrick Kennedy to address the barriers to the rapidly evolving field: regulation, reimbursement, and translational research. The Genomics and Personalized Medicine Act would address several issues that have arisen with the increased prevalence of genetic testing, including coverage and reimbursement of personalized medicine products, and provide oversight of genetic tests including the direct marketing by the consumer genomics industry. Dr. Howard also touched on the use of genomic testing in design of clinical trials leading to optimized therapies with increased efficacy through effective individualized treatments.

Dr. Dong, Dr. Zeldis, and Mr. Oyler spoke about the strategic advantages of China's market. Dr. Dong cited China's talent pool, government regulations, and cost competitiveness. Mr. Oyler spoke about the potential for untapped research in China. Dr. Zeldis followed suit by speaking about China as the new Silicon Valley of the pharmaceutical industry, and described Celgene's highly challenging development and approval of Thalomid, which involved the innovative creation of the S.T.E.P.S. (System for Thalidomide Education and Prescribing Safety).

Dr. Vonderscher and Dr. Jiang discussed approaches to counter the challenges faced by pharma in the past decade. To confront decreasing

productivity, high attrition rate, and increasing development costs, Roche has relied on innovative concepts such as Personalized Healthcare and partnerships with Academic groups and small Biotechs, said Dr. Vonderscher. The importance of internal collaborations and effective teamwork between various departments such as DMPK, Modeling and Simulation, Translational Sciences (M&S and TS) in MNC's was also stressed. Dr. Jiang said the decline in R&D productivity must be countered by breakthrough R&D innovations and discussed the importance of external partnerships in Asia.



Photo 6: Keynote speakers with SAPA leadership team members (from left to right: Mark Gelbert, Ruiping Dong, Jingwu Zang, Jianji Wang, Xinghua Zhu, Jerome Zeldis, Danny Howard, Baoguo Huang, Kevin Chen)

Before lunch the election results for the 2011-2012 Executive Council members were announced by Dr. Baoguo Huang, the 2011-2012 SAPA President. Dr. Handan He is the new president-elect. Dr. He is currently the Director and Head of Nonclinical Pharmacokinetics and Pharmacodynamics (PK/PD) at Novartis Pharmaceuticals Corporation and has been a SAPA Executive Council member for more than 5 years. Dr. Min Chen of Novartis is the President-Elect of SAPA NE (New England) Chapter, and Dr. Sean Zhang of Bristol-Myers Squibb is the President-Elect of SAPA GP (Great Philadelphia) Chapter.

The first plenary session was followed by two concurrent parallel symposiums, occurring from 3:10PM to 5:30 PM.

The first parallel symposium discussed seizing opportunities in the emerging markets and was co-chaired by Drs. Kevin Chen, Cai Li, Kun Liu, and Ning Yan. Presentations were given by the following experts:

1. Dr. Dan Guo (Executive Director, Emerging Markets, Bristol-Myers Squibb), Strategy for Next-Generation BioPharma Company in China

2. Dr. Richard Soll (SVP, Integrated Services, WuXi AppTec), A Global Perspective of Recent Initiatives across the Value Chain of Drug Discovery and Development

3. Dr. Ben Ni (Senior Director & Head, Partnering & External Innovation (China), Sanofi China), Creating Value through Partnerships

The subsequent panel discussion examined the state of business development in China and included experts Dr. Robert Wenslow from Crystal Pharmatech, Inc., Dr. Zhaoyin Wang from Beta Pharma, Dr. Wenzhi Tian from HuaBo Biopharma Co., Ltd., Dr. Maximillian Yeh from Waterstone Pharmaceuticals ,.

The second parallel symposium focused on revitalizing productivity in the pharma/ biotech industries. It was co-chaired by Drs. Handan He, Jiwen Chen, Yan Xia, and Mingde Xia. Presentations were given by:

1. Dr. Hequn Yin (Director, Oncology Clinical Pharmacology, Novartis), 3-Years of Data Points: Witnessing the Infancy of Innovative Drug R&D in China

2. Dr. F. George Njoroge (Director, Medicinal Chemistry, Merck), Nurturing the Spirit of Invention and Innovation in Biopharma for Enhanced Productivity

3. Ms. Sammy Jiang (Vice General Manager, BIOasis, Shandong International Biotechnology Park Development Co., Ltd.), BIOasis Brief Introduction

4. Ms. Tina Cheng (International BD Manager, Luye Pharma Group Ltd.), Introduction to Luye Pharma

The second panel discussion included Dr. Tianmin Zhu from Zhejiang Hisun Pharmaceutical Co., Dr. Jay Dr. Yuguang Wang from ChemPartner, W. Mason from Spaulding Clinical, Ms. Kristy Hua from Shenzhen (NAROS) China, Mr. and , Dr Nenad Sarapa from Roche. The parallel symposiums were followed by an award ceremony in which outstanding individuals and corporations were recognized by the SAPA Service Excellence Award, SAPA Scholarship and Excellence in Education Program scholarship, Eli Lilly Asia Outstanding Graduate Thesis Award, Johnson & Johnson Asia Outstanding Graduate Thesis in Biotech, and SAPA Corporate Excellence Award.

The SAPA Executive Council presented the SAPA Service Excellence Award to the following individuals for their contributions to the advancement of SAPA through their participation and leadership: Xiaole Shen, John Qiang Tan, Li Chen, Harry Zhang, Kevin Chen, Yan Xia, Handan He, and Xin Du and to the SAPA Newsletter Team, Jiwen Chen, Xing Li, Su-Fen Pu, Huayi Tong, Guosheng Wu, and Dapeng Chen.

The 2011 SAPA Scholarship was presented to three outstanding high school graduates who will continue to pursue an education in the life sciences. They were selected from an applicant pool of over 50 talented students from across the country. Louis Li graduated from Monte Vista High School in Danville, CA and will study Molecular and Cellular Biology and pursue his research interests at Harvard University. David Zhao is from Skillman, New Jersey and will major in chemistry at Princeton University. Benjamin Altman graduated as the

valedictorian of Danbury High School in Danbury, Connecticut and will pursue a dual degree in Engineering and Finance as part of the Jermone Fisher Management and Technology program at the University of Pennsylvania.

The 2011 Eli Lilly Asia Outstanding Graduate Thesis Award and Johnson & Johnson Asia Outstanding Graduate Thesis Award in Bio-tech were administered by SAPA. The Eli Lilly Asia Outstanding Graduate Thesis Award was awarded to twenty-one graduate students from eleven universities in greater China who have made outstanding contributions to the life sciences in the field of chemistry. The Johnson & Johnson Asia Outstanding Graduate Thesis Award in Bio-tech recognized thirty graduate students from greater China, Taiwan and Singapore who have advanced the field of biotechnology.

The SAPA Corporate Excellence Award was presented by the Executive Board to the following companies: Johnson & Johnson, Novartis, Roche, Celgene, Yangtze River Pharma, and Shangdong International Biotechnology (BIOasis) and Luye Pharma. The Award honored these organizations for their contribution to the advancement of SAPA.

The conference was sponsored by the following corporations: Roche, Nantong Economic and

Technological Development Area (NETDA), Novartis, Johnson & Johnson, Yangtze River Pharma, Luye Pharma, Shandong International Biotechnology (BIOasis) Park, SANOFI, Wuxi AppTec, Bristol-Myers Squibb, Celgene, Crystal Pharmatech, Cactus, Fox Rothschild LLP, J&W PharmaLab, Huahai US Inc., Sundia, Beta Pharma, Hisun Pharmaceuticals, Spaulding Clinical, North American Representative Office of Shenzhen (NAROS), Pharma Consulting Services, Bioduro, Waterstone Pharma, Wuhan Biolake, Medicilon, Ken Clark International, Eli Lilly, GenScript, Asymchem, BPBC, Pharmaron, Shang-Pharma ChemPartner, Millipore Corp, and Primera.

About the Authors

Nora Xu is currently a scientist in the clinical supplies group at Forest Laboratories. She graduated in May from Rice University with a bachelor's degree in Chemical Engineering

Dr. Tycho Heimbach is currently a Senior Investigator II in Nonclinical Pharmacokinetics and Pharmacodynamics (PK/PD) at Novartis Pharmaceuticals Corporation. He also serves as the elected Vice-Chair for the AAPS Physical Pharmacy and Biopharmaceutics (PPB) Section.

SAPA 会议论坛

一个海归在中国的创业之路

—— SAPA 中西部分会成功举办第一次活动

文：张宏兴

5月14日，美中医药开发协会中西部分会邀请桑迪亚医药技术（上海）有限责任公司的董事长兼总裁王晓川博士到印第安纳州的 Carmel 市来为会员做题为“一个海归在中国的创业之路”的报告。王博士谈到她在美国芝加哥大学的学习研究的经历，后来决定回国创业，以及她是如何创办和成功的来管理桑迪亚医药技术有限责任公司的亲身经历。桑迪亚医药技术有限责任公司如今成为中国发展最快的 CRO 公司。王博士对想回中国创业的同胞们提出 4 个关键的建议：了解市场（包括您所想进入的行业和时间机遇），资金（包括政府及非政府基金及与董事会的关系），找到好的员工（聘用，训练和留住员工），与政府保持好的关系。总共 50 余人参加了这场报告。听众对回国创业这个话题非常感兴趣，问了王博士很多的在中国创业过程中的实际的问题。这个活动持续了近 3 个小时。通过这次活动，桑迪亚有机会接触到美国中西部的大的制药企业，并且取得了一些合作的机会。

美中医药开发协会中西部分会成立于 2011 年，成员主要包括与生命科学和医药开发相关学科的华裔的职业人员。大部分会员是 ELI LILLY, DOW, ROCHE, ABBOTT 和其他在美国中西部的与医药研

究相关的公司大学。美中医药开发协会中西部分的宗旨是促进中美的医药行业的交流，来提高成员对医药发展全球化的知识，成为中国与美国中西部医药行业交流的一个桥梁。如果有兴趣加入美中医药开发协会中西部分，请发电子邮件给 SAPAmidwest@yahoo.com or 参观网址，<http://www.sapaweb.org/new/index.htm>。



SAPA 协会活动

药协和网协暑期郊游成功举行

文：龙江、周文来、梁桂青 摄影：马炳莉、苟大明

美中药协纽英伦分会(SAPA-NE)和纽英伦中华咨询网络协会(NECINA)联合组织的暑期郊游于星期六(7月30日)在新布罕什尔州 Salem 市的 Canobie 湖滨公园举行, 活动取得了圆满成功。

7月30日, 晴空万里, 是暑期举家外出游玩的好日子。药协和网协会员及亲友逾三百人, 赶到了距离波士顿市不超过一小时车程的聚会地点 Canobie 湖滨公园。与去年在 White Cliffs Country Club (WCCC) 举行的郊游不同, 今年的特色是在会友交流之余, 让家庭成员尤其是正在放暑假的大小朋友们享受到极好的娱乐和放松。公园有超过百年的历史, 1902 年就开始对外开放。现拥有 50 多种 rides, 集表演、游戏、主题嬉水乐园、餐饮等为一体。据本次活动主要组织者料理强秘书长和吴家权理事介绍, 虽然由于午餐场地的接待容量所限, 两个协会只在各自的会员群中通知了这次活动, 没有在任何媒体上做广告, 门票还是早早就售罄了。在特别精心准备的中式午餐会上, 药协和网协新老朋友时隔一年重逢, 大家畅所欲言, 交流经验, 分享心得, 同时享受到丰盛的午餐。

今年刚投入使用的惊险过山车 Untamed 被称为纽英伦最陡的 ride 吸引了不少会友, 97 度角的自由落体紧接着 360 度角的高速翻转, 让人紧张刺激, 明白了玩的就是心跳。Xtreme Frisbee, 巨大的飞盘载人在急速旋转下做钟摆运动, 让你惊魂未定之际感受到超重影响下巨大的冲击力。Kiddie Island 有十多种适合小小小朋友的 rides, 如旋转木马、碰碰车、小恐龙、小独木舟等, 小朋友们快乐的笑声此起彼伏, 颇具感染力。由于天气酷热, 嬉水乐园

Castaway Island 早早就吸引了不少会友, 在炎炎夏日下享受到惬意的清凉。喜欢流行音乐的朋友们也观赏到了地道的真人模仿秀, 演员们以假乱真地模仿超级巨星 Michael Jackson, Janet Jackson, Elvis Presley, Tim McGraw 等人的表演, 使人赞叹不已。不少会友意犹未尽, 流连忘返, 甚至享受到了坐缆车高空观赏焰火的奇妙经历。



图一：药协网协会员到达聚会地点 Canobie 湖滨公园。



图二：药协网协会员在餐馆



图三：会友们准备就餐

这次出游活动让大家玩得开心, 玩得尽兴, 给大家留下了深刻的印象。大家相约明年再见。

药协纽英伦分会在钟晓天、李和、陈敏等人的领导下在近年来取得了杰出的成绩, 极大的提高了药协在业界和社区的影响力。即将离任的李和会长和继任会长陈敏的交接将于下周八月六日在 Rutgers 大学举行的美中药协总部年会进行。同时, 新的分会会长选举也将很快开始。选举和候选人详情可见 www.sapa-neweb.org。想加入药协, 网协未来活动可访问他们的网站, www.sapa-neweb.org, www.necina.org。

SAPA 协会活动

2011 美中药协中秋野餐活动圆满举行

文：沈小乐、包振鸿 摄影：李才、孙壮



图一：野餐组委会成员早早来到公园布置活动场地

和沈小乐的组织下从八月份就开始筹备。最后一个星期三还召开特别会议讨论如何把准备工作压缩到场地和天气确定以后, 以及一旦场地被取消的后备方案。组委会的全面周到的安排得到野餐活动到场各界朋友的广泛赞誉。

参加这次野餐会的包括愈两百五十名 SAPA 会员、朋友, 同事、及家属从新泽西各地, 甚至从康州, 宾州, 华盛顿特区等远处赶来。上午 10 点开始, 野餐组委会, 也是新一届的 SAPA 理事会成员及联络员的全班人马陆续抵达 Johnson 公园, 插路标, 悬挂彩旗, 布置场地, 搬运食品饮料, 四个 BBQ 烤炉同时点燃。夏岩, 项信珍、朴素芬、傅绚等 SAPA 理事热情登记和接待每一位来宾。甘晓东和 Nora Xu 负责把月饼分切成小份。刘晚生, 丁崴, 谭强, 陈纪文等开始烧烤汉堡, 香肠和热狗。11 点, 大批 SAPA 会员、朋友, 同事、及家属相继到达公园。沈小乐准备的茶鸡蛋和卤花生大受欢迎。许多 SAPA 理事, 联络员和志愿家属在赵晖的带领下为大家分发虹城定做的美味佳肴及刚刚出炉的 BBQ。接着大家又分享了甘甜的西瓜。借此还要感谢以下

九月的新泽西秋意渐浓, 美中药协 (SAPA) 2011 年度中秋野餐活动于 9 月 17 日星期六在新泽西 Piscataway 的 Johnson 公园举行。尽管刚刚经历过暴风雨和洪水洗礼的 Johnson 公园还没有完全恢复, 困难的自然条件挡不住 SAPA 会员组织和参加野餐活动的热情。SAPA 活动组织委员会在包振鸿

联络员在准备工作中的贡献: 代星、朱怡辉、陈明、和 Tong Zhang。



图二: 会员们在轻松融洽的氛围中积极讨论感兴趣的话题



图三: 活动组织者为大家精心准备的烧烤等美食

午餐后黄宝国会长为大家简单介绍了 SAPA 的情况和近期的工作安排。他号召有志于为 SAPA 服务的会员积极参与协会管理工作, 特别强调了近期对于通讯, 网站开发和设计的志愿者的需求。在继任会长何菡菡的组织下, 与会的专业人士按照药物

研发的阶段分四组(discovery, early development, registration, post marketing)进行讨论和交流。另人惊叹的是 SAPA 具备研发、报批和销售各个环节的人才, 这为有心到 SAPA 寻求人力资源和合作伙伴的“老板们”提供了一个卓越的平台。

除了烧烤和同行交流等必备节目, 大家还共同享受了户外运动带来的欢乐。陈新海和王建基组织的排球赛战得难解难分, 拔河更是吸引了大量会员上阵。尽管没有在一起训练过, 场上的队友很快达成了默契。什么时候用劲, 怎样听口号, 如何防守, 从僵持不下到摧枯拉朽就在一转眼。小丑 Milos 的游戏也是一道风景线。孩子们不时传来阵阵的欢笑声, 每个人都得到气球做的小玩具。李才和孙壮忙前忙后找摄影素材, 抢精彩瞬间。



图四: 拔河比赛将野餐活动的气氛推向了高潮

活动结束后, 大家都高兴地离去, 感谢 SAPA 组织的这次野餐活动, 为会员增进联谊提供了难得的机会, 盼望 SAPA 继续举办更多类似的联谊活动。

SAPA 桥梁之声

开创中美高新科技合作新前景 ——中国无锡新区投资创业说明会美国费城纪实

文：吴荻、宫海波、廖志勇、张少庆 摄影：罗锋、穆建西

中国无锡新区投资创业说明会于2011年7月21日在美国费城丽嘉酒店(Ritz Carlton Hotel)隆重召开。近年来，全世界都面临气候变化、能源短缺以及大众的健康需求等共同挑战，因此，中美两国的科技合作已经成为中美战略与经济对话的重要组成部分。本次活动顺应这种历史和时代的迫切需求，开拓中美科技界的通力合作，战胜挑战，实现全球科学、和谐和可持续发展。此次说明会由无锡市政府新区管理委员会主办，大费城美中医药开发协会(SAPA-GP)承办的。来自宾州、费城市政府的官员、美中工商医药科技和教育界的名流精英、费城华人社区领袖、及费城各大高校学生代表，共100多位嘉宾应邀出席了此次盛会。无锡新区与大费城地区六家机构或科研团队当场签定了价值7550万美元的科研经贸协议。此次活动极大地宣传了无锡和无锡高新区卓越的科技人才创新创业环境，扩大了无锡高新区在美国政府部门、著名大学及其医疗机构、制药企业、海外留学人员、华人科技医药团体中的影响力，促进了中美高新科技项目与人才交流与合作，加大了中美科技层面沟通和交流的广度和深度。

无锡市政府新区管理委员会的嵇克俭主任代表无锡市政府新区管理委员会和无锡高新技术产业开发区管理委员会，在接受美国华语新闻媒体采访中，介绍了无锡新区的战略特色和投资创业的优良环境。嵇主任指出，无锡新区是按国际惯例建设的以创新型国际化为内涵的世界一级科技园区。无锡国家高

新技术产业开发区于1992年经国务院批准成立。1995年在高新区基础上成立无锡新区，现辖无锡国家高新技术产业开发区、无锡(太湖)国际科技园、无锡空港产业园等六大功能区，行政管理区域220平方公里，2009年实现地区生产总值806亿元。无锡新区已引进外资项目1600多个，世界500强跨国公司已有50多家投资了近90多个项目。无锡新区在江苏省开发区综合排名中，无锡新区稳居第二位，江苏省唯一进入中央命名的海外高层次人才创新创业基地，在全国54个国家级高新区排名中，无锡新区也处于先进行列。嵇主任进一步强调优良的政策投资环境、绝佳的地理环境、优质的人才储备、和过硬的后勤服务保障是无锡新区的特色和亮点；无锡新区在530企业海外创业给予的优惠政策的兑现上在同行中是最为迅速的。

目前，生物制药在新区投资创业的比例还较小，他希望通过与大费城美中医药开发协会(SAPA-GP)的合作，将无锡作为载体，SAPA-GP作为工作站和平台，吸引承接大中小型的制药企业和创新项目落户无锡新区，吸引更多的生物医药领军人才加入新区的创新发展。嵇主任以阿斯力康为例，具体说明了无锡新区给予医药企业不遗余力的支持有力地保证了阿斯力康在中国无锡顺利创业和成功发展。同时，他对海外大型制药企业发出了欢迎选择无锡落户的诚挚邀请，也对参观过的MERCK等公司表示极大的兴趣和关注。

宾夕法尼亚州经济和社区发展部外商投资中心的 David T. Briel 主任在其后的致辞中介绍了宾夕法尼亚州的商务发展情况。宾夕法尼亚州生产总值为 5332 亿美元，是知名学府和研究机构和国际大都会的所在地。州政府的配套服务和联邦基金为外商投资提供了最佳环境。Briel 主任表示位于世界第五大经济体中心的费城对国际投资有强大的吸引力。外资企业的数量占费城企业总数的 35%，众多国际企业，包括许多中国企业都已经在费城安家落户。Briel 主任热切地欢迎来自中国的、特别是无锡的投资和项目。



图一：无锡市政府新区管理委员会的嵇克俭主任在做开场发言

中国驻纽约总领事馆科技领事朱星华先生在讲话中阐述了中美科技合作基于创新的概念和双赢的策略。他提及今年在美国盐湖城举办的中美省州长经贸论坛所共识的建立机制和平台从而来促进创新的趋势。朱领事分别介绍和比较了费城和无锡两座城市的特点和联手合作的优势。费城周围拥有美国最大的医疗制造工业和教育医疗机构，是生物产业理想的投资地点。同时，无锡市在中国是领导科技复苏和新兴产业发展的重要城市。去年，无锡市的 GDP 位于江苏省的第二名，GDP 增长为 13%，被福布斯排为全国最佳商业城市的第三名（2008）。无锡市的汽车工业，新材料，新能源，生物技术工业都处在全国领先水平。同时，无锡市周围的高校和研究机构为科技交流提供了良好的环境。新一番的经济复苏战略导致了引导性投资，信息技术、先进制造、新材料、节能环保、生物技术、新能源汽

车产业是中国重点发展的方面。他说，企业和高校院所合作高新技术，有利于将科学技术产业化和商业化的。

费城商业部招商办公室 Karen Randal 主任介绍和强调了费城地区拥有得天独厚的地理位置、卓越的人才、一流的公司。根据著名的 Milken Institute 的调查，大费城地区目前在生命科学领域的影响力，在全美各地区中位居榜首。大费城地区是美国第二大医疗研究和教育区域中心，美国最大的儿科医院和研究中心，地区每年获得用于研发的 20 亿美元的联邦资金。目前，六分之一的工作和 15% 的经济活动与生命科学有关。她鼓励无锡新区和费城地区的医药联盟合作。最后，她代表费城政府向无锡新区赠送了象征着费城城市自由精神的自由钟。

随后，无锡新区与大费城地区的刘锦旋博士创业团队、Phytogen 生物科技公司，李亚奇博士创业团队、Baynexus 团队、Agilecom 公司、MEedbiocom LLC，签定了总价值为 7550 亿美元的科研经贸协议，包括新型药芯焊丝、生物代谢苯乙烯产业化、Octam 移动式血糖分析仪、微波 RFID 无源芯片、可调激光/光电分配器、肿瘤疫苗、免疫增强剂。无锡新区还与大费城美中医药开发协会签署了关于“建立海外引才工作站”的协定。双方将在美国共建中国无锡新区海外引才工作站，从而加速人才引进和互动。



图二：Karen Randal 主任代表费城政府向嵇克俭主任赠送了象征费城城市自由精神的自由钟。

主题发言由无锡新区管委会副主任朱晓红先生作新区介绍。朱副主任强调, 无锡新区位于世界上第六大城市聚集区的长江三角洲, 三角洲占中国 GDP 的 21.4%。他列举了通用电气医疗系统有限公司、阿斯力康制药有限公司、药明康德、西格玛奥得利奇生化科技有限公司、纽迪希制药有限公司等实例来具体说明无锡新区的赋予生命力的投资和政府支持系统和服务。制药工业在第 12 个 5 年计划中得到新区政府的强力支持: 财政方面重点支持有研发项目的中小企业; 大力建设公共平台, 如中试车间、公共 GMP 厂; 地方政府与中央政府密切合作, 加速新药批准。



图三: 无锡新区管委会副主任朱晓红先生(前排左)与大费城美中医药开发协会会长洪桂英博士(前排右)签署了关于“建立海外引才工作站”的协定。

接下来, 西格玛奥得利奇(Sigma-Aldrich)公司副总裁 Eric Green 先生做了精彩的发言。他用本公司发展创业的具体实例, 图文并茂地指出, 西格玛奥得利奇作为生命科学与高技术的全球领导者在中国有超强、极为成功的业务和业绩。他说, 选择无锡新区来立足是因为其优越的地理位置、吸引人才的能力、专业的工业园管理团队及政府的强力支持等因素。

无锡爱达索纳米技术有限公司董事长、海归企业家梁波博士随后谈到在无锡新区的创业感悟。梁波博士曾是大费城美中医药开发协会第一任会长, 留美多年, 在无锡创业近两年, 中美医药界名副其实的资深学者和精英企业家。他深有感触地说:

“无锡新区的政策非常透明, 官方网站上说到的在现实中都能做到。创业环境好, 政府服务意识强。融资手段灵活、合作伙伴易找”。



图四: 无锡爱达索纳米技术有限公司董事长、海归企业家梁波博士在做投资创业发言

美国 FDA 顾问委员会委员、美国药学会副主席 Jeffrey S. Barrett 博士做了最后的主题发言。Barrett 教授现在担任宾夕法尼亚大学的教授和宾夕法尼亚大学/费城儿童医院多个中心的主任。Barrett 教授指出, 大费城地区众多历史悠久的医院、医生及医疗工作者是与无锡新区合作开发新药、改善和优化临床医疗实践、确定疾病诊疗和疾病发展、发掘医院数据及规范医院管理、使用新型临床药理手段寻求疾病发病机理等的良好契机和基础。美国药学会在 2010 年的年会中邀请到了包括中国药学会在内的相关学会和组织。2012 年美国药学会将在中国建立第一个学生支部。Barrett 教授和他的团队同中国的相关医院、医药企业、高等院校建立了行之有效合作项目, 也正在带领团队培训来美的中国学生学者。他和团队正在积极努力, 促成中美政府间基金合作、法规部门间的沟通、和学术与企业间的跨国际的长久合作, 并希望参与无锡和无锡新区的高新科技发展的宏伟蓝图。

宾夕法尼亚州生物科学技术联盟主席 Christopher Molineaux 主席做了短小精悍的发言。他强调指出, 宾夕法尼亚州生物科学技术联盟将全力支持与无锡及无锡新区间的高新技术产业开发, 特别是在生物科学技术方面。

说明会最后, 大费城美中医药开发协会(SAPA-GP)会长的洪桂英博士做了总结发言。洪会长介绍了协会的使命及其独特的地理位置, 回顾了以往辉煌的协会历史和精彩的协会活动, 以及对大费城地区和美中两国医药研究所作出的杰出贡献和努力。在当下中国医药市场面临发展的黄金时期以及跨国公司大规模将医药研发中心向中国等新兴市场转移的时代背景下, 洪会长热切地期待以海外引才工作站为载体, 让SAPA-GP成为连接中国无锡与美国大费城地区医药研究及开发的桥梁和纽带, 为中美两国科技医药界的合作搭建可靠坚实的平台。洪会长进一步指出, 此次盛会的成功举办来自于无锡主办方, 与会各界中外嘉宾, 负责组织此次活动的筹备委员会、SAPA-GP理事会的领导及其精英骨干。

此次盛会在热烈友好的互动讨论和冷餐会后结束。中国无锡新区投资创业说明会取得了空前巨大的成功, 与会嘉宾不仅亲身从无锡新区的领导和代表了解到无锡诱人的投资创业政策, 也从在无锡实地创业的中外企业家那里得到充分有力的实据。此次说明会极大地带动了无锡和大费城地区的高新科技企业合作、医药研究合作和人才相互流动, 在大费城地区及美国各界人士中产生了巨大反响, 开创

了中美高科技合作新前景, 对于中美关系的稳定发展具有深远意义。

SAPA-GP 新闻通讯组特别鸣谢 SAPA-GP 常务理事
会赵永刚理事、王锋理事、张宗达理事、及
SAPA-GP 项目经理王逊先生。

关于作者:

宫海波目前于德雷赛尔大学(Drexel University)攻读博士学位, 主要研究可降解医疗植入体的设计与制造, 为美国机械工程师协会(ASME)和美国制造工程师学会(SME)的会员。

廖志勇博士从事药学与生物医学研究十余年, 现任托马斯杰佛逊大学(Thomas Jefferson University)研究员, 专攻前列腺癌生物学研究。

张少庆为宾夕法尼亚大学(University of Pennsylvania)物理系在读博士生。现进行蛋白质设计方面的生物物理和生物化学研究。他将于今年秋季起随其研究组到加州大学旧金山分校(University of California at San Francisco)药物化学系完成其博士学位研究。

SAPA 协会活动预告

美中药协 (SAPA) 临床统计和编程研讨会即将召开

Cindy Song

美中医药开发协会(SAPA)2011年临床统计和编程研讨会将于11月19日(星期六)上午8点到下午5点在新泽西州UMDNJ(University of Medicine and Dentistry of New Jersey)召开。届时, 来自FDA(食品药品监督管理局)和CDISC(临床数据交换标准协会)的代表, 以及全球各大制药公司和外包公司(CRO)相关领域的

高层主管和专家 (Johnson & Johnson, Sanofi, Merck, Novo Nordisk, Celgene, BMS, and Everest) 将到会就制药业前景相关的议题发表精采的演讲。

研讨会涵盖的内容包括 CDISC, eSubmission (快速高效的电子化提交报批), 药物研发流程, 统计方法, 及编程技术。另外, 业界专家将主持以“全球环境下的公司运作”为主题的现场讨论会。本届研讨会的目的在于展示现今制药业中统计分析和编程设计方面的挑战与机遇, 同时提供业内朋友一个互相学习和认识的平台。

会议具体地址是: The main auditorium and lecture halls of UMDNJ - 675 Hoes Lane, Piscataway, NJ 08854-5635。本次会议热诚欢迎有兴趣的人士请到 SAPA 网站 <http://www.sapaweb.org/new/index.htm> 获取更多详细信息并报名参加。网上报名注册全天会议费用(包括早午餐): 会员\$25, 非会员\$40, 学生\$10。座位有限, 按登记交费者先后顺序, 额满即止。当天报名, 会有额外费用\$10。我们期待着您的光临。