美中生物医药协会会刊

CABA Connect

Chinese-American BioMedical Association Official Newsletter

Summer 2013
Volume 4, issue 1
CABA
P. O. Box 600241
Newtownville, MA 02460

in this issue

Dear CABA members and friends,

We feel delighted and proud to present you with another issue of CABA Connect – the official newsletter of Chinese-American BioMedical Association. First of all, we would like to take this opportunity to express our heartfelt gratitude and appreciation to Dr. Qinglin Che and the entire editorial team for shepherding and gracing CABA Connect throughout the development and publishing process. Their commitment and dedication to reporting CABA's significant events and developments in a timely manner have created tremendous benefits to all members of the biomedical community. More than anything, we also want to thank all those who have read our past issues and the people who are reading the current issue. You are our greatest inspiration.

亲爱的各位CABA成员和朋友们:

我们非常高兴和荣幸地向您呈现新的一期的CABA Connect—我们美中生物制药协会的会员通讯。首先，我们想借此机会对Qinglin Che博士以及整个编辑团队在CABA Connect的编写和发表的过程中的繁重的协调工作和精益求精的态度表示我们最衷心的感谢和感激！他们对CABA的重要活动和发展的及时报道为我们所有生物制药行业的从业人员带来了巨大的贡献。除此之外，我们还想感谢所有的CABA Connect的新、旧读者，正是您们的阅读才使她实现了存在的价值。

Our CABA members come from diverse areas of biopharmaceutical industries and academic environments and enjoy access to the most up-to-date biomedical trends in science and business through our high-quality conferences including CABA Bioforum in February, CABA Annual Conference in April, CABA Biomedical Investment & Entrepreneurship in October and Medical Device and Diagnostics Symposium in December. All CABA events have been well attended by biopharma executives, scientists, professors, prominent entrepreneurs and investors as well as professionals from finance, legal and healthcare fields. We are continuing to fulfill our missions to serve as a networking platform for local professionals and a connecting bridge between US and China in Bio/Pharmaceutical fields.

CABA的成员来自生物制药行业、学术界等各个行业，背景非常多元。通过CABA举办的各种高质量的会议他们接触到了科学和商务的最前沿的动向，包括今年二月份的CABA Bio-forum，四月的CABA Annual Conference，十月CABA Biomedical Investment & Entrepreneurship Symposium和十二月份的Medical Device and Diagnostics Symposium等。 所有的CABA会议云集了生物制药行业的企业高层，科学家，教授，杰出的企业家和投资人，以及来自金融界、法律界和医疗保健行业的领航者。我们将一如既往地努力去实现我们的最初的使命：为本地的各专业人士搭建一个交流的平台，和为美中生物制药行业构筑一座美丽的桥梁。

CABA is a non-profit professional organization and a volunteer-based society. However, the influence and impact of our organization have been far-reaching both professionally and geographically. We are extremely grateful for our members to contribute their time and efforts to helping organize top-notch and informative conferences and symposia. Our appreciation is also extended to our generous corporate members and sponsors for their strong support of CABA events.

虽然CABA是一个由志愿者组成的非盈利的专业组织，但是她的影响力大大地超越了行业和地域范围。我们由衷地感谢所有CABA成员在组织各种顶尖的、内容丰富的年会和研讨会中奉献出的他们的宝贵的时间和精力。同样我们也要感谢我们的各个公司会员和赞助商对我们CABA的强有力的支持!

To facilitate collaboration between the pharmaceutical and biomedical industries across the continents, CABA has organized training programs and workshops as well as social events to promote networking and communication among members. Dr. Shiwen Lin, Chair of Board Director, has successfully led the fifth training program for Wuhan sFDA staffs. CABA has also celebrated the establishment of CABA Wuxi Club in China. CABA has collaborated with 11 professional organizations and co-organized the New England Chinese New Year Gala. Summer outing in August and the New Year gala in February have been our two annual exciting social events for members, along with their families, and other professionals in the greater Boston area.

为了促进跨越两大洲的生物医药和制药行业的合作和交流，CABA举办了各种培训项目，研讨座谈会，社交活动来促进个成员之间的联系和交流。在Lin Shiwen博士，我们的Chair of Board Director，的领导下，我们成功地完成了对武汉SFDA成员们的第5届的培训。CABA还顺利在中国无锡成立了CABA无锡小组。与其他14个专业组织一起成功举办了2013年新英格兰地区华人专业人士中国新年晚宴。2月的中国新年晚宴和8月的夏季郊游是最受CABA以及CABA在大波士顿地区的其他兄弟协会的会员及其的家属欢迎的两大社交活动。

We are still looking forward to our new friends, colleagues and all biomedical professionals to join our organization. Each CABA member has been our great asset. We rely on the contribution and devotion from each one of you to our organization by leveraging your unique background and skill set. We are confident that you will share our values and find this great community service truly rewarding.

我们竭诚欢迎新的朋友、合作者和其他所有的生物医药界的专业人士加入CABA！每一位CABA会员都是我们的无价之宝。您的独特背景和专长、无私奉献和忠诚构架起了CABA的脊梁。今天我们可以无比自豪地说，您将会与我们共享信念：您对这个社会的奉献是这个社会对您的最大的认可!

Sincerely yours,

您最真挚的!

Xiang Yang Yu

喻向阳

President 2013-2014

Chinese-American BioMedical Association (CABA)

美中生物医药协会（CABA）2013-2014年度会长

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Published by:
CABA
P. O. Box 600241
Newtonville, MA 02460
USA
www.cabaweb.org

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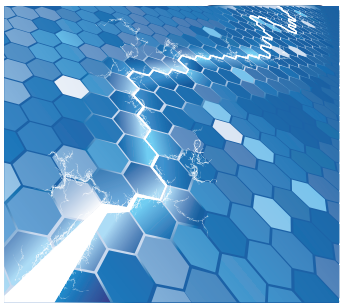

2013 Boston Bioforum: the Fifth CABA Annual Conference

By Hao Li, Executive Committee, CABA

On the beautiful spring Saturday of April 27, by the riverbank of Charles River with bright morning sunshine, blue sky and white sails, over 300 company executives, senior scientists, entrepreneurs and investors from the biopharmaceutical industry gathered at MIT faculty club for the 2013 Boston BioForum "Accelerating Drug Development, from Bench to Bedside", the annual conference of CABA, the Chinese-American Biomedical Association. People flocked to share new scientific discoveries, leading industry trends and emerging business opportunities. The common conviction to help patients and reduce human suffering deeply shared by the speakers and attendees formed bonds that connected everybody. This was best exemplified by the opening remarks of Dr. Angelika Fretzen, VP of Pharmaceutical Chemistry & Development from Ironwood Pharmaceutical, that we need to push scientific boundaries to create new drugs just as the Boston Marathon athletes who push their physical boundaries. Two companies received "Excellence in Innovation" award from CABA, Ariad Pharmaceuticals for its successful effort in developing Ponatinib, an FDA approved drug for CML, and Ironwood Pharmaceuticals for its success in developing Linaclotide, another FDA approved drug for IBS.

The morning session was opened by the presentation of Dr. Angelika Fretzen on "The Development of Linaclotide for the Treatment of Chronic Functional Gastrointestinal Disorders". Following that Dr. Scott Biller, CSO at Agios Pharmaceuticals on the "Science and Strategy at Agios" told a fascinating story on the discovery of a novel metabolite 2HG through collaborations with several Chinese CROs such as Wuxi Pharma, ChemPartner and Viva. 2HG is produced by the IDH mutant enzymes that aberrantly affects epigenome in cancer patients. The session was concluded by the seminar from Prof. Jianzhu Chen, the Ivan R. Cottrell Professor of Immunology at MIT, on the "Humanized Mice for Preclinical Drug Development". In the afternoon the meeting resumed with the talk by Dr. Timothy P. Clackson, President of Research and Development at Ariad Pharmaceuticals, on the "Design and Develoment of Ponatinib, a Pan-BCR-ABL Inhibitor for CML". Dr. Pam Carroll, VP Oncology Scientific Innovation at Janssen, presented Janssen Innovation Centers which present a new collaboration model with biotech companies and academia. The afternoon session also included two panel discussions, one on the alternative careers for biomedical scientists in the legal, investment and business fields, and the other on the achievements and challenges in global integrated R&D collaboration between large pharmas, biotechs and CROs in China and US.

The conference ended on a high note in the evening by the keynote speech from Dr. Roger Tung, President and CEO of Concert Pharmaceuticals on "Building a Biotech Company from the Ground Up". Indeed there is no better place to do that than Boston/Cambridge, by the riverbanks of Charles River.

Focusing on "Accelerating Drug Development", Boston BioForum 2013 Hands out Excellence in Innovation Awards

By David Li and Dongyu Chen, bostonese.com

Cambridge, Mass., April 28, — Boston Bioforum 2013, the annual conference of Chinese American Biomedical Association (CABA), was held on April 27 at MIT Faculty Club. Many attendees traveled from the West Coast or even from China to show their support for Boston and CABA, in less than two weeks after the Boston Marathon bombings.

Group picture at end of afternoon sessions. (photo by David Li)

The theme of this year's Boston Bioforum was "Accelerating Drug Development – From Bench to Bedside." Over 300 attendees from US, Canada and China attended this year's conference. Jun Han, the founding president of CABA, traveled from Shanghai and told me that he marked Boston BioForum 2013 on his calendar months ago.

A number of awards were handed out at Boston Bioforum 2013. Ariad Pharmaceuticals and Ironwood Pharmaceuticals won the Excellence in Innovation awards during the day sessions. These two companies' innovative and cost-effective drug research and development processes were applauded by conference attendees.

During the evening reception, Dr. Shiwen Lin, chairman of the board of CABA, handed out the prestigious award of Excellence in Community Service to "three beautiful young ladies": Zhe Tian, Ellen Fan and Jo Lee, who are all CABA members.

Dr. Phil Zhang, the current president of CABA, gave a brief overview of CABA's major events over the past year. Shiwen thanked Phil service over CABA's six-year history, and especially over the past 12 months being the president of CABA. Dr. Shiwen Lin announced at the dinner reception that Dr. Xiang Yu became the new president of CABA, and Dr. Phil Zhang became a member of the 10-person board of directors of CABA. Dr. Phil Zhang was also awarded the Excellence in Community Service Leadership Award.

Dr. Xiang Yu was the chairwoman of Boston BioForum 2013 Organizing Committee. She thanked Phil for his mentorship over the past year and countless volunteers who helped make the conference a huge success.

During the day-long conference, the following major topics were discussed at the main conference hall:

- Industry Trends and Key Technology Innovations
- Globalized R&D: Resourcing & Collaborations
- Career Development and Entrepreneurship
- Networking Receptions and Vendor Exhibitions

Experts from leading companies and research labs delivered in-depth speeches and panel discussions around the major topics at the Boston BioForum 2013. In the first session, speakers talked about deuterated drug, associated business development and its challenges. As we know, some drugs are metabolized quickly by our body so that the drugs' effects are not so "long-lasting". By replacing the hydrogen atom by deuterium, the drug's in vivo half life can be extended by decreased metabolism, thus the patients can receive more drug exposure and longer treatment time. However, the challenge is that only 3% of patented drugs can be made into deuterated forms which indicates one of the challenges and limitations that drug companies face.

During the second session, the talk about humanized mice was very interesting. Pharmaceutical companies face the challenge that some drugs that work great on mice models could fail in clinical trials due to lack of efficiency. Furthermore, some infectious diseases don't develop in mouse at all. By introducing the humanized mice model, one can hopefully solve these problems. The procedure of producing a humanized mouse involves injecting the human stem cell into the immuno-deficient mice, and you can even target specific organs to make them "human".

The discussions at the first afternoon section brought in the ideas of personalized cancer therapy. It's well-known that patients' responses to certain anti-cancer drugs vary a great extent because of their genetic polymorphism. One of the speakers told a story about a young boy who was diagnosed with cancer. His tumor sample was taken from his body, planted in different mice which were subsequently treated with different anti-cancer drugs. The efficacies were compared, and the best therapy was selected and applied to the little boy. Attendees were asked to think about the possible opportunities of cancer treatment, provided that no "all-purpose" anti-cancer drug ever exists.

Region's Top Innovators in Bio-medical Research Recognized at Boston BioForum 2012

By David Li, bostonese.com

Panel discussion

Boston-Cambridge area has long been the hub for life science research. On April 7, Boston BioForum 2012 was held at MIT Faculty Club in Cambridge, Massachusetts. The day-long conference was packed with 4 sessions, 2 panel discussions, 25 speakers, and more than 400 attendees. The conference was hosted by Chinese-American BioMedical Association (CABA). In its five-year history, CABA's contribution to the greater Boston's biomedical community and in bridging US and China in this field was well recognized by many speakers and attendees at Boston BioForum 2012.

The 2012 Excellence in Innovation Award was presented to Novartis, Idenix Pharmaceuticals and Bristol-Myers Squibb to recognize their contributions in the field of HBV drug development to help Hepatitis B patients. Hepatitis B is a major health issue in many developing countries and it is endemic in China. The Leadership in Community Service Award went to Pfizer for its continuous support to the life science community, including organizations like CABA.

An international award of Advocate Excellence for Chinese Biomedical Enterprise was presented to Dr. Yan Li, director in chief, Wuhan SFDA, China to recognize her vision, leadership and significant contributions to the educational exchange between China and US in the field of food and drug regulatory affairs and impact in the SFDA policy-making in China to promote public health. Four members of Wuhan SFDA were enrolled in CABA's training program in Lexington, MA last summer.

In accordance with the theme of "Meeting the Challenges through Innovation", Boston BioForum 2012 presented the Innovator of the Year Award to Dr. Chiang J. Li to recognize his outstanding contributions and achievements in the discovery and development of first-in-class anti-cancer therapeutics to help patients with hard-to-treat cancers. Dr. Li delivered a well-anticipated and inspirational keynote address in the evening session, titled "Building an Innovative Biotech: Lesson and Secrets" to put a fitting end to Boston BioForum 2012.

Industry Leaders Exchanged Perspectives at BioPharma Outlook 2012

By Ting Ren, Chinese-American BioMedical Association

June 17, 2012, Cambridge MA – On the eve of BIO (Biotechnology Industry Organization) 2012 Convention, BioPharma Outlook 2012 was successfully held at MIT Faculty Club in Cambridge, Massachusetts. It was jointly presented by Chinese-American BioMedical Association (CABA) of Boston and Chinese Biopharmaceutical Association(CBA) of Washington DC. BIO 2012 is one of the most important conferences in the biopharmaceutical industry. It attracts more than 15,000 attendees around the world.

Mr. Tom Watkins, CEO and President of Human Genome Sciences and Chairman of the Board of Directors of BIO delivered an inspirational keynote speech. He started with an overview of current challenges in the health care industry, then emphasized the dedication of BIO in facilitating communications and collaborations among industry professionals, investors, and policy decision-makers.

Following Mr. Watkins' talk, three speakers shared their perspectives from three angles: health care policy, investment climate and R&D innovation. Firstly, Dr. Yuanli Liu, Director of China Initiative at Harvard School of Public Health, discussed the current situation of healthcare reform in China. He summarized the key challenges of health care in China into triple "A"s–"availability", "affordability", and "appropriateness". New financing strategies, drug regulation policies, and public hospital development are the focuses in China's next five-year plan. Policies around these issues will have a direct impact on the health care industry.

From public to the private side, the next speaker, Dr. Wei Li, shared his experience and perspective as a health care venture capitalist. As a Principal at Fidelity Biosciences, Dr. Li gave an overview of Fidelity Bioscience's investment history and current portfolio in China, which shed light on the investment environment in China. He highlighted Fidelity's new initiative in the biosimilar market.

Lastly, Dr. Luke Li, Executive Director, Head of Global Biotherapeutic Technologies of Bio-Innovation at Pfizer, discussed the hopes to bring real value to patients–innovation in drug R&D and promising development candidates. He shared his knowledge of recently approved drugs and late stage candidates with novel mechanisms and addressing significant unmet needs.

The attendants also represented a wide spectrum of the biopharmaceutical industry, functionally and geographically. In addition to CABA and CBA whose members are mostly scientists, industry professionals and investors from east coast, Bayhelix, Hong Kong Association of Massachusetts and San Diego Sino-American Biotechnology and Pharmaceutical Professionals Association (SABPA) co-sponsored the event. Members of several Chinese organizations such as China Council for the Promotion of International Trade, and several Chinese biotech companies also joined the event. Despite the diversity, we are all striving to fulfill the real value for patients, healthy return for investors, and successful commercialization for pharmaceutical/biotech companies.

(from left) Last three presidents of CABA Chaoyang Dai, Zhihong Chen, Phil Zhang, Tom Watkins (Chairman, Board of BIO), Lin Sun-Hoffman of CBA, Irene Robin of BIO Shanghai and Yihan Wang of CABA at BioPharma Outlook 2012.

The 2013 CABA Biomedical Investment and Entrepreneurship Symposium Report

By Zhigang Wang, Qinglin Che, Youxin Zhang, Phil Zhang, Deqiang Niu, Chinese American BioMedical Association

The 2013 Chinese American Bio-Medical Association (CABA) Biomedical Investment and Entrepreneurship Symposium (CABA Investment Symposium) was held at the Doubletree Suites in Boston on Saturday, October 19, 2013. The theme of the symposium was "Biotech and Pharma Investment in a Challenging Time". The meeting attracted more than 100 prominent entrepreneurs, investors, biotech and pharma executives, academic and industry scientists, as well as professionals from the legal, finance, and healthcare fields. The full-day program featured two plenary sessions and two panel discussions. A workshop on investing for retirement was hosted by Gwen Ren of Morgan Stanley's Boston Office during lunch break. With supports from all speakers, panelists, CABA EC members and friends, and corporate sponsors, the symposium is a sound success.

The morning plenary session, chaired by Dr. Philip Zhang, Immediate Past President of CABA, featured three prominent speakers who spoke on topics critical to the biopharmaceutical industry: early stage innovation, university start-ups, and external research.

The first speaker was Dr. Amir Nashat, Managing Partner at Polaris Venture Partners, a leading venture investor life science across the United States and Europe. Dr. Nashat shared with the audience his insight on global trends in VC investment in life science and the key components in early-stage biotech innovations and their roles in the development of life-saving therapeutics. As an investor behind many successful biotech companies, Dr. Nashat's talk offered a unique perspective many in the audience felt was very beneficial to their understanding of VC's role in supporting early-stage innovations.

Dr. Jason Wen, Director of Technology Transfer and Licensing at Boston College, gave an overview of the many facets of biotech start-ups built on technology licensed from academic institutions. Since many ground-breaking innovation in life science comes out of university research labs, a critical first step of successful commercialization is licensing the technology from the university to a company dedicated to move the innovation forward, a process unfamiliar to most scientists in the field.

Then, Dr. Yugui Gu, who heads external research in drug discovery at Cubist Pharmaceuticals, gave a first-hand account of the important roles external research plays in moving drug candidates through the research and development process, eventually becoming approved products benefiting patients. Dr. Gu pointed out that while cost-saving and increasing capacity remain important considerations in external research, more and more focus is being placed on access of external talent and creativity.

The afternoon plenary session was chaired by Dr. Allen Che, Vice President of CABA. It opened with a talk about medical technology investment strategies given by Jack Liu, Senior VP of Morgan Stanley Global Wealth Management Group. Through a systemic analysis, he summarized the recent investment trends in the healthcare sector. Many of the data were freshly extracted from the company updates presented at 2013 Morgan Stanley Global Healthcare Conference held last month in New York City, and the conclusions are very convincing.

Following Mr. Liu's talk, Dr. Jinbo Lee, cofounder and CSO of Scilligence of Burlington, MA, shared with the audience the secrets behind the growth of Scilligence, a technology start-up. By identifying the challenges the pharma & biotech communities are facing during the era of globalization and R&D remodeling. Scilligence, a two-year old company, has developed and commercialized its cheminformatic products to affiliate the communications among researchers around the globe. Scilligence's products are well recognized by the market in both the US and China. Its leading clients include Wuxi AppTec, Celgene, Genetech and Merck etc.

Back to the technology side, the third speaker of the session, Dr. Weiwen Ying, Synta fellow of Synta Pharmaceuticals of Lexington, MA, introduced to the audience the newly launched HDC platform for oncology drug development. Taking advantage of the large population of HSP90 proteins in tumor cells, HDC platform creatively employs HSP90 inhibitors (HSPi) as a carrier to selectively deliver other clinically proven chemotherapeutic agents or novel payload into the tumor cells through a covalent bonded chemical linker. The huge benefits on lowering the toxicity of the anti-cancer agents towards normal cells and boosting the cancer cell killing efficacy, as demonstrated in the encouraging in vivo results, make HDC a very promising platform for new oncology therapy development. Synta welcomes partnership and investment discussions to make this platform more available to the pharma community. Dr. Ying's presentation was well received by the audience, and the discussion was well extended to the coffee break. Dr. Ying's achievement was recently highlighted in C&EN, the esteemed member publication of the American Chemical Society (ACS).

The first panel discussion, entitled "Cross Border Investment in Life Science Industry" was moderated by Jonathan Fleming, Managing General Partner, Oxford Bioscience Partners. Featured panelists were Dr. Katherine Bowdish, Vice President of R&D and Head of Sunrise, Sanofi; Dr. Xin Huang, Healthcare Partner, Suzhou Cowin Venture Capital; Linda Ji, Partner, Nixon

Peabody; Dr. David Xie, Associate, Oliver Wyman; and Dr. Ting Xu, Founder and CEO, AlphaMab. This panel focused on Chinese healthcare industry's unprecedented growth during the past decade and the resulting large amounts of private equity investments and strategic M&A activities. Despite the growing interest in investments, the environment remains challenging to navigate, due to complex commercial landscape, the perceived lack of truly innovative technologies, and high valuations for the best companies.

The panelists first discussed whether innovative healthcare technologies exist in China, given the contradictory evidence of rapidly increasing number of patent filings with the lack of marketed domestic innovative products. Panelists agreed that many patents filed in China have low quality and limited commercial value. It is commonly seen that companies file patents solely for the purpose of meeting the criteria of innovative status for benefits granted by Chinese government. On the other hand, panelists also acknowledged the difficulty for one company to develop and commercialize an innovative technology from the concept to marketed product. Even in developed countries, this process usually requires multiple companies to complete, with frequent licensing and acquisition activities. Given the lack of experience, Chinese companies may not be able to complete this process independently in recent years. A more realistic strategy might be participating in a few stages within the process. For example, AlphaMab tried to license healthcare technologies from top-tier academic institutions around the world, develop them into a mature stage, and then out license to bigger companies with more commercialization expertise.

Overall, panelists were optimistic on the investment opportunities in China but aware of the complexities and risks related to cross-border investing. Challenges may easily arise from the differences in company culture and government policy.

Panelists finally commented on the possibility of building global presence for a Chinese company. Given the large domestic market, building global presence may not be prioritized by many Chinese companies. Panelists felt it may be challenging for current big Chinese companies due to the lack of experience and internal driver but expressed optimistic opinions regarding the emerging truly innovative companies.

The second panel focused on "Global Outsourcing: How Can We Build a Win-Win Relationship?" Dr. Deqiang Niu, Director of Medicinal Chemistry, Celgene Avilomics Research, Inc. led the discussion. Dr. Taiping Chen, Vice President, In Vivo Pharmacology, Viva Biotech Ltd.; Dr. Mohan Thiruvazhi, Director of Business Development, GVK BIO; Mary Beth Walsh, Director of Business Development, BioDuro; Dr. Tiansheng Wang, Research Fellow, Vertex Pharmaceuticals, Inc.; Dr. Chaoyang Dai, Vice President, Acebright, Inc.; Dr. Sherry Yu, Director of Global Business Development, Sundia MediTech; and Dr. Jin Zhao, Senior Scientist, Genzyme participated in this panel.

Nowadays, if you have been in a pharmaceutical company or a biotech company for a while, there is a very good chance that you have interacted with some CRO companies and have been using their services. Today's CROs provide services spanning across all aspects of drug discovery, from chemistry, biology, to pharmacology, toxicology and early developments. As the trend of global outsourcing continues, it will be beneficial for us (from both sides) to understand what is critical for a successful collaboration and how can we build a long lasting, win-win relationship.

The first topic for our panelists was 'why do Pharma/Biotechs outsource?' All panelists voiced their opinions. It was great to find that the answers from both the pharma side and the CRO side are aligned: increased capacity, specialty needs, cost-efficiency, and flexibility are the major reasons for outsourcing. Cost is just one of many factors to consider.

When asked 'how do we build a win-win relationship between CROs and their clients?' Our panelists pointed out that understanding each other's needs, building long term relationship, not always price-centric, and ensuring value delivering are among the top of the list. There was one discussion on understanding the culture difference in different regions of the world, which is also critical for building a successful relationship. The panelists also encourage the face to face interactions of the scientists involved from both sides once when possible (i.e. once a year at least).

The last question was 'what is critical for a successful collaboration?' Almost all panelists viewed communication and delivering high quality data/materials as their top picks. Delivering on time or as promised and 'don't over promise' are also critical for a successful collaboration.

Overall, the panel had a very healthy, insightful discussion from all the panelists and some of our audience. The findings here will be useful for both the CRO side and the client's side to understand each other's needs and to build a sustainable, win-win relationship.

This "Biomedical Investment and Entrepreneurship Symposium" has covered a wide range of topics interested to the CABA members and the local community. The participants had enjoyed a wonderful day of learning, discussion and networking. To prepare for this event, many CABA EC members and volunteers had been working tirelessly to invite speakers, raise funds, draft programs, CABA president Dr. Xiangyang Yu, the symposium chair Dr. Zhigang Wang, co-chairs Drs. Youxin Zhang, Liping Zhou and Ji Shi, and more than 25 organizing committee members had worked closely for more than two months to bring out this successful event. Their effort had been greatly appreciated by all.

BIOSIMILARS: READY FOR PRIME TIME?

By Jianfeng Hang, PhD, MRA, RAC

Introduction

In the past thirty years, FDA approved more than 150 therapeutic biologics including recombinant monoclonal antibodies (mAbs) and genetically engineered proteins.[1] These products fulfilled the unmet medical needs and provided patients with valuable treatment opportunities. Often these biologics are the only options for various medical conditions such as hepatitis B, rheumatoid arthritis, hereditary emphysema and some types of cancer. Many originator biologics are very expensive. For example, annual cost for Herceptin, a HER2-positive breast cancer biologic, is $37,000, and that for Gaucher disease drug Cerezyme is $200,000.[2] High costs of biologics limit their availability to broader patient populations, particularly to those in need in less-developed countries. One pragmatic solution to improving the accessibility of the costly originator biologics is to develop their subsequent versions, or biosimilars. Once the patents of the originator biologics expire, the market competition naturally drives the price down. This exercise has proven to be very successful in lowering the prices of small molecule brand-name drugs by the introduction of their generic copies.

More than 12 originator biologics with combined global sales of more than $ 67 billion came off patent at the end of 2012.[3] Patents of blockbuster biologics Humira (2012 sales: $9.3 billion, US patent expires in 2016), Remicade (2012 sales: $8.2 billion, EU patent expires in 2015), Enbrel (2012 sales: $8.0 billion, EU patent expires in 2015) and Rituxan (2012 sales: $7.4 billion, EU patent expires in 2015) will all expire in US and EU in the period between 2013 and 2019.[4]

Sales of biosimilars only contribute a small fraction of the entire biologics market. In 2012, their sales in highly regulated markets for the first time reached 1 billion. Nonetheless, according to a study by IMS Health, a market research firm, this number will increase significantly in the coming years. It IMS health predicts sales of biosimilars will exceed $4 billion by 2016 and $11 billion by 2020. Many investors, including biotech innovator giants such as Biogen Idec and Amgen, are eager to grasp the opportunity presented by biosimilars.[5]

We will discuss the current regulatory scenario of biosimilars in EU and US, the two most regulated markets. The insights from the discussion will help us understand some investment considerations specific to biosimilars.

Current Regulatory Scenario of Biosimilars in EU and US

A. European Experience

The Europe Union (EU) is the pioneer in building legal framework for biosimilars. EU outlined the regulatory pathway to gain a biosimilar medicinal product approval in European Directives 2003/63/EC, Annex I, Part II, section4,[6] differentiated "generic medicinal products" from "similar biological medicinal products" in European Directives 2004/27/EC.[7] The European Commission and the European Medicines Agency (EMA) are the agencies for the implementation of these Directives. The EMA's Committee for Medicinal Products for Human Use (CHMP) is responsible for issuing general and product-specific guidelines to help the industry for biosimilar application.

In April 2006, the first two biosimilar products were approved by the European Commission. They are human growth hormone (somatropin) products: Omnitrope[8] from Sandoz in Austria and Valtropin[9] from Biopartners in Germany. The two approvals were based on comprehensive comparisons against their reference products which resulted in different label claims from those on the originator biologics.[10] On September 10, 2013, the same agency approved the first biosimilar antibody Inflectra, a copycat version of Johnson & Johnson and Merck & Co's Remicade.[11]

14 of the 16 biosimilars approved by the EU to date share only three reference products: Filgrastim, Epoetin, and Somatropin. At least four products have failed the EU approval process (three withdrawals of insulin and one negative opinion on interferon alpha). Even for some biosimilars that did gain approval, their journeys have been bumpy. For example, the clinical trials of two approved epoetins involved more than 600 human subjects with half of them tested on the biosimilar epoetin for at least 24 weeks. This indicates the complexity of demonstrating biosimilarity in practice. Regulators and sponsors are gaining more experience and learning with each application.

The short history of the pioneering biosimilar development and application in Europe taught us some valuable lessons that need to be addressed in the future guidelines:[13] 1) Some differences between a biosimilar and its reference product are acceptable, such as glycoprofile, being expressed from different cell species; but often time they need to be justified, especially for the impurity profile. 2) Comparative trials need to be conducted in a sensitive population with the consideration of batch-to-batch variability in the reference product. 3) Extrapolation from one usage to another is not a given. 4) It is not always necessary to demonstrate efficacy in patients. For example, a biosimilar Filgrastim was approved based on its repeat dose studies in healthy volunteers and non-comparative safety studies sponsored by Apotex.

B. US Experience

To control the surging health care spending, the US government is trying to slow down the rising drug expenditures associated with brand-name drugs. According to the congressional budget office's estimate, biosimilars could save the government 13[14] to 25 billion dollars over the next 10 years.[15] In 2009, Congress passed the Biologics Price Competition and Innovation Act (BPCI Act of 2009), an amendment to the Public Health Service Act (PHS Act), as a start to improve the affordability and accessibility of biologics. The act created an abbreviated approval pathway for biosimilars demonstrated to be highly similar (biosimilar) to a FDA approved originator biologic [section 351(k) of the PHS Act]. It was signed into law by President Barack Obama on March 23, 2010 under the Patient Protection and Affordable Care Act (PPAC Act).

FDA's Draft Biosimilars Guidance Documents

The groundbreaking work on the modern system of generic drugs is the "Hatch-Waxman Act"[16] - the Drug Price Competition and Patent Term Restoration Act. This 1984 United States federal law established the Abbreviated New Drug Application (ANDA) process in section 505(j), founded legal ground for faster approval pathway for small molecule generic drugs. Thousands of less expensive generic drugs were approved ever since and affordability of many drugs was improved dramatically.[17]

The United Sates' contribution to bringing biosimilars into the market cannot yet match their landmark work on the introduction of generic drugs. The US regulatory framework and practice on biosimilars lag significantly behind Europe and even some Asian countries. The BPCI Act of 2009 is six years behind European Directives 2003/63/EC.

As of February 2012, FDA only held 21 Pre-IND meetings, received 9 INDs[18] and no BLAs under 351(k) biosimilars pathway (no 351(k) application is submitted yet to this date). These low numbers reflected some serious concerns from the sponsors and the potential biosimilars investors - the lack of clarity in regulations was discouraging the development and commercialization of biosimilars in the US. Providing the interested parties with certain predictability and more detailed guidance was imminent for FDA.

On February 09, 2012, FDA issued three long-awaited biosimilar draft guidance documents that are designed to help the industry to develop biosimilars and to compete with originator biologics. The agency released the fourth guidance outlining how sponsors should plan to use formal meetings to interact with the agency before and during the application process on April 01, 2013.[19] The first three guidance addressed scientific, quality considerations of biosimilars and clarified some issues regarding the implementation of the BPCI Act of 2009. The pivotal document of the three is the "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product."[20]

Draft Guidance on Scientific Considerations of Biosimilars

The guidance focuses on addressing the issue: how similar is enough to be biosimilar? At the beginning, FDA uses most common protein products as examples to discuss the complexities of biological products in detail and to show the difficulty of proving biosimilarity. It is pointed out that primary amino acid sequence, higher order (secondary, tertiary and quaternary) structures and enzymatic modifications including glycosylations can all make proteins different and lead to heterogeneity. In addition, many factors such as temperature, moisture, light, and even packaging or delivery materials can affect protein modifications and change their higher order structure.

Limited by resolution, detection limit, and processing speed of current analytical technologies, in most cases it is very challenging, if not impossible, to determine structural and functional differences between two proteins from slightly different manufacturing sources. Considering the presence of impurities generated during the processes, added formulation agents and excipients in the biological products, the degree of certainty of using structural analysis and functional assays to determine the biosimilarity of two proteins is not high at all.

Despite the advances in the state-of-the-art analytical technologies for biological products, the agency is fully aware of their limitations. A "stepwise approach to developing the data and information needed to support a demonstration of biosimilarity" is hence recommended. The sponsors can start with extensive analytical, physiochemical and biological characterization of the proposed product to show the degree of similarity to the reference product. FDA then evaluates the information and suggests necessary animal and human tests accordingly to the sponsor to further demonstrate biosimilarity of the two products. The agency will consider the product's complexity, stability, formulation, manufacturing process and clinical data in comparison with the reference product, and then determine the extent and scope of these tests on a case-by-case basis.[21]

FDA will use a Totality-of-the-Evidence approach to evaluate all data and information submitted in support of demonstrating biosimilarity, including "structural and functional characterization, nonclinical evaluation, human PK and PD data, clinical immunogenicity data, and clinical safety and effectiveness data."[22] FDA will allow the sponsors to skip repeating studies that are not necessary to address residual uncertainty, therefore speeding up the application process and saving costs for the sponsors.

By definition under the PPAC Act, a biosimilar is "a biologic product that is highly similar to a reference biologic product notwithstanding minor differences in clinically inactive components, and it has no clinically meaningful differences from the corresponding reference product in terms of the safety, purity, and potency."[23] It is clear that minor differences are allowed in clinically inactive components. Currently, biologic products are process-dependent. Different manufacturing processes can possibly change a protein product in four ways: (1) protein sequence; (2) protein composition by different enzymatic glycosylations or phosphorylations; (3) higher order structure; (4) impurities, formulation reagents, excipients, etc. Any subtle changes may alter the efficacy and the safety profiles of the product. Immunogenicity is also a critical issue; even small amount of impurities may stimulate immune responses. Unfortunately, current analytical and functional assays cannot detect subtle protein structural changes and impurities. Based on these facts, the guidance suggests that the sponsors at least run one human clinical studies, either immunogenicity or PK/PD if applicable. If residual uncertainty exists, comparative safety and effectiveness may be needed for the determination of biosimilarity.

It is apparent that many suggestions in this draft guidance document are designed to address the issues raised from European experiences.

Draft Guidance on Quality Considerations of Biosimilars

The draft guidance document titled "Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product"[24] has some overlap with the scientific considerations draft guideline, and it focuses on analytical studies necessary to assess biosimilarity. The discussion on the importance of extensive analytical, physiochemical and biological characterization is repeated in this guidance.

Draft Guidance on Interchangeability and Exclusivity

The third draft guidance, "Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009",[25] answers some important questions about certain statutory terms and requirements.

Interchangeability between biosimilar and its branded reference is a key issue for payers and providers to request a switch. Without proving it, stakeholders cannot lower health care spending by substituting a pricier brand name product with a new biosimilar. The draft guidance discusses several approaches to evaluate interchangeability. Unfortunately, FDA does not support that the available state-of-the-art technology is sufficient for establishing such claim. This will unavoidably discourage the investment on biosimilars.

BPCI Act of 2009 clarifies the exclusivity calculus: a 351(k) application may not be submitted until 4 years after the date of the first licensure of the reference product; it may not be approved until 12 years after licensing the originator biologic. In order to encourage the potential biosimilar manufacturers to develop cheaper version of the biological products, the US government tried to shorten the data exclusivity of the originator biologics from 12 to 7 years in the president's budget proposals for fiscal 2012[26] and 2013[27] repeatedly. The new draft guidance has not settled terms for establishing the exclusivity period.

Investment Considerations of Biosimilars

According to a study[28] sponsored by the industry, the average R & D cost of producing an originator biologic is $1.2 billion. It is slightly lower than the average $1.318 billion cost of launching a brand name small molecule drug. The study is widely criticized for its calculation of the costs. However, the idea of similar costs for both forms of drugs is very acceptable.

Originator biologics and biosimilars are created from living organisms. They are complex molecules which are difficult to be characterized by physiochemical methods. As we discussed in the section of the *Draft Guidance on Scientific Considerations of Biosimilars*, minor changes in manufacturing processes may alter protein high order structure and influence protein modifications, further change safety, immunogenicity and biological profile of the biologics. Therefore, purity and quality of the products need to be monitored closely, and expensive comparative clinical trials are often unavoidable. Additionally, the lack of conclusive analytical technologies makes biologics process-dependent. All these factors raise the bar for investors to enter the biosimilar business. As estimated by Andrew Pasternak of Bain & Company,[29] it could cost 100 to 150 million dollars to develop a biosimilar, whereas to copy a small molecule drug may only need 2 to 3 million dollars. It is common that companies establish partnership, mostly between generic ones and big pharma, to manage the risk and share the complementary expertise that is needed for biosimilar development.

Difficulty in providing interchangeability of a biosimilar and its originator biologic is another factor for investors to consider. Since biosimilars are not the same as the originator biologics, many countries do not allow doctors or medical system to use them to substitute their reference products. Additionally, doctors are usually reluctant to choose the unfamiliar new substitutes even when biosimilars are allowed for treating new patients. Furthermore, many approved biosimilars are only 10% cheaper than their brand-name competitors in Europe, far from the expected 30 to 40% savings of the originator biologics. According to an Xcenda research, payers need to see 40% or more in cost savings for an existing patient to require a switch.[30]

Reducing the market exclusivity for originator biologics from 12 years to 7 years in the US was repeatedly proposed in the president's budget proposals. If the proposal is approved, it will help attract more investment on biosimilar development and submission in the US, the potentially largest biosimilar market. However, with the increasingly stringent regulatory environment in recent years, cutting exclusivity to 7 years will discourage the investment on the R & D of originator biologics and other innovations. Brand name companies will have to pursue more aggressive commercial strategies to protect their precious franchise from competition. They may even turn to trade secret to guard their complicated manufacturing process from copycats, which would make the already very difficult follow-on process even more unobtainable.[31]

Patent litigation procedures for biosimilars are complex when a company chooses the biosimilar route for approval under the PPAC Act. The biosimilar applicant and the brand name company must exchange statements and patent lists, follow detailed negotiation procedures. Investors need to take into consideration the lengthy legal process and potential high cost of litigation.

Despite various investment concerns on biosimilars, the US market presents great opportunity for both originator biologic and biosimilar manufacturers in the long run. The setup of the US health care system and the complicated stakeholder relationship make it easier to accomplish higher pricing and larger profit margins for these companies and their investors.

Conclusions

Introducing biosimilars provides us a possibility of saving medical spending on biologics. Some investors and manufacturers are eagerly pursuing these highly profitable products. A market study in 2009[32] forecasted that the global biosimilar market would worth $19.4 billion by 2014, increasing at a compound annual growth rate of 89.1% from 2009 to 2014. In reality, their sales just reached $ 1 billion in 2012. The over-optimistic estimate reveals the industry's anxiety in recent years. We need many quality shows to fill the prime time slots vacated by the innovative products and blockbuster drugs. Some people consider biosimilar as one of the candidates. Does it really deserve such recognition? We are certain that we can answer the question meaningfully in the near future since a clear US pathway for biosimilar approval is available.

With the advances in analytical technology and biological sciences, increasing experience of proving biosimilarity and clearer regulatory requirements, more biosimilars will be accessible to patients. In the period of 14 months after the release of the three biosimilar guidance documents, FDA has received 16 new meeting requests and 6 INDs.[33]

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CABA与东北大学联合培训湖北省药检院访问学者

EDUCATION

凭借2009年以来连续四届培训中国药监系统中高级专家的经验，美中生物医药协会（CABA）2013年7月1日至10月1日又成功完成了第五届为期三个月的培训项目。今年培训项目有很多新异之处，首先前四届受训人员来自中国武汉市食品药品监督管理局（药监局）药品GMP生产及销售稽查专家。今年受训人员是来自中国湖北省食品药品检验院（药检院）实验室专家。聂晶博士，湖北药检院副院长兼中药检验所所长，和郭江红硕士，湖北药检院生物制品检验所所长是来Boston参加2013年培训项目的两位访问学者。CABA与东北大学（Northeastern University）联手，利用该校化学及生物分析研究所Barnett Institute 全球一流的药物分析实验室条件和化学系及全美领先药政硕士项目的师资力量，今年访问学者培训项目更具专业性和权威性。

美国FDA新英格兰地区局长Capt. Shamsi讲课后与两位访问学者合影(左起):范艾琳, 林世文 (培训项目CABA方负责人); Lisa Leveille (美国FDA新英格兰地区分局Supervisory Consumer Safety Officer), Capt. Shamsi (FDA新英格兰局长); 聂晶, 郭江红(访问学者, 中国湖北省食品药品检验院).

CABA-Northeastern- 湖北药检院三方培训项目为两位访问学者量身定作。培训专题包括(1) 生物制品及大分子药物的分析及测定；(2) 生物制品及大分子药物的组成成分分析及其活性成分的研究；(3) 生物制品的生产工艺改进系统；(4) 植物药活性成分的分析及质量评价； (5) 植物药及化学药的体内分析，即药物血药浓度的测定监测，代谢物的检测，代谢途径的研究，对映体的监测和研究等；(6) 新材料、新技术在药物体内分析中的应用等。 在波士顿三个月期间，两位访问学者大部分时间是在Barnett Institute周昭晖教授(Prof. Sunny Zhou)的实验室里度过的。除了利用一流的仪器设备，随时与研究生学者交流外，她们还经常参加校园里讨论会和研究生课程。药政硕士项目的教师大多是有几十年制药研

药工业经验的专家。两位访问学者还让湖北药检院寄送样品，在Barnett Instittue的实验室里进行实战药物分析。她们亲身感受到扎身于前沿的药物分析研究，对制药研药工业界实战药物分析确实有很多推进作用，学术界和工业界是相辅相成的。几年前美国FDA与全球一流的Barnett Institute签订长期合作意向，可见意义深远又符合潮流。

Capt. Shamsi局长签字赠送湖北药检院访问学者有关FDA书籍

CABA 今年承担的培训任务则主要集中在联系协调两位访问学者在Boston地区全球知名制药公司参观调研并聘请制药研药工业界特别是生物制品及大分子药物植物药方面专家授课。两位访问学者的参观调研活动受到了Genzyme和BiogenIdec公司大力支持。两家公司都分别由多个部门多间实验室人员抽出大半天时间接待来自中国药检系统的两位访问学者。CABA方负责培训项目的是现任董事长林世文博士和理事范艾琳(Ellen Fan)，他们深知接待公司的热情是与Genzyme和BiogenIdec公司内华人高管研究员敬业精神和加强中美两国业界同行交流所作的努力分不开的。CABA感谢Genzyme公司蒋一德(Yide Alan Jiang)博士和BiogenIdec祝红丽(Lily Zhu)博士对今年培训项目和两位访问学者参观调研活动的无私支持。三个月期间两位访问学者的参观调研活动还包括全球生命科学顶尖研究所Broad Institute(CABA理事王义楷博士带领)和医学顶尖研究所哈佛医学院系统的Joslin糖尿病研究中心(Anna Xia女士联系)。另外她们还参观了多家当地的药店。专业活动之余CABA还安排两位访问学者参观了解美国历史文化和社区生活，CABA前会长陈志宏博士及许多理事在周末或工作之余来帮助两位访问学者融入交流。在这些参观调研交流活动中，两位访问学者亲身感受到美国制药研药工业界和学术界是如何将药品质量从研发到每批量原材料到生产过程全天候“先天”就植入药物(或器械)，而不只是“后天”靠出厂检验或上市后监管产生出来的。

CABA还聘请制药研药工业界特别是生物制品及大分子药物植物药方面专家给两位访问学者授课。授课专题(和专家)包括美国植物药概况(Roy Upton 博士Executive Director, American Herbal Pharmacopoeia美国植物药典)，美国药品零售管理(Donna Horn药学博士，前麻州药品销售执照管委会主席)， 生物制品及大分子药研发及产品分析过程(丁建梅Jianmei Kochling 博士， Genzyme部门主管)，生物医药 知识产权(CABA前会长张引博士)，美国新药研发现状与趋势(CABA前会长创会董事万昭奎博士，前辉瑞资深主任研究员)， 小分子药物研发到报批上市(CABA共同创始人王义汉博士，前Ariad公司部门主管)，药物分析标准物(CABA现任董事长林世文博士，Agenus公司部门主管)，质量系统(CABA理事曲芸Susan Qu, Genzyme)， 蛋白质同位素标记与质谱定量(CABA理事范艾琳， ArsenalMedical)等。

主管东北六州的美国FDA新英格兰地区分局局长Capt. Shamsi亲自前来会见两位访问学者并讲课介绍该局，将CABA三个月来组织的专家授课推至最高潮。Shamsi局长还向中国药检系统访问学者赠送了美国GMP法律及FDA法规书册。两位访问学者也向Shamsi局长介绍了中国食品药品检验系统属中国食品药品监督管理局分支事业单位，担负着很多类似美国公司自检的质量系统和欧洲质量责任人系统的重任。Shamsi 局长讲课结束后还很高兴见证了两位访问学者接授结业证书仪式。聂晶副院长和郭江红所长深感与SHAMSI局长交流的荣幸和CABA培训安排的专业水准，忱恳表示回国后会以各种途径加强与美国同行交流。

周昭晖教授，林世文博士分别代表东北大学（Northeastern University）和CABA签发培训结业证书。

2013 中国看点

美中生物医药协会专家赴莞考察

考察团参观松山湖展览馆　刘家乐　摄
来源：中国新闻网

中新网东莞6月26日电（刘家乐）近日，美中生物医药协会专家考察团一行10人在国务院侨办及省侨办领导的陪同下来到东莞松山湖高新技术产业开发区考察访问。

作为国务院侨办经济科技司、广东省侨办共同主办的2013“智汇广东”海外人才为国服务博士团广东行活动的两个专家团之一，考察团的7名博士、3名硕士携带10余个生物医药类项目前来交流合作。在与松山湖生物医药局的座谈交流会上，东莞市侨务局纪检组长何妙娟说，生物医药是东莞市发展的重点产业之一，目前正十分需要海外高层次人才的参与与支持，近年来东莞市政府制定了许多引才引智的优惠政策，相对国内其他城市有一定的政策优势，希望今后国务院侨办及省侨办继续支持东莞的引才引智工作，帮助东莞引进更多海外优秀人才，市侨务局将努力为海外人才来莞参观考察、创业兴业提供更好的支持和服务。

考察团团长王义汉博士说，今年3月份他们就在美国波士顿与松山湖生物医药局相关人员有过接触，他们认为松山湖有着良好的发展思路，对生物医药及人才引进十分重视，因此一定要来松山湖看一看。此次来到松山湖果然让他们留下深刻印象，今后将加强与松山湖联系，推动双方交流合作。

近年来松山湖高新技术产业开发区一直把发展生物医药产业放在突出位置，重点放在新药研发、先进医疗器械与设备研发、中药现代化、健康产业及基因产业上，全力打造创新型的生物医药产业发展模式。目前，松山湖已累计引进100余家生物技术企业、研发机构和高等院校，涵盖了实验动物、抗感染药物、基因诊断、海洋药物等领域，形成了从教育、科研、中试到生产、销售的完整产业链条。在座谈会上，专家考察团与松山湖管委会相关人员开展了热烈的交流探讨。

美中生物医药协会专家访问中山 进行项目对接

中新网中山2013年6月26日电 (李润秋)近日，在国侨办经科司、省侨办领导的陪同下，美中生物医药协会专家考察团一行9人到中山市火炬开发区参观考察，并与相关部门和企业进行座谈交流，寻求项目合作和对接。

座谈会由中山市外事侨务局黄识航副局长主持，市食品药品监管局黎汉钊局长、市人才办李全庆专职副主任分别向考察团介绍了中山市健康医药产业发展情况和在招才引智方面的优惠政策措施。健康科技产业基地发展有限公司、华南现代中医药城发展有限公司、康方公司、奕安泰医药科技有限公司等多家企业负责人与考察团成员深入交流，互动频繁。美中生物医药协会董事、前会长，波士顿艾百奥生物医药公司总裁王义汉博士表示，此行效果很好，考察团成员对中山在生物医药健康领域的发展前景充满信心，大家都期待与中山进一步的合作与交流。

据悉，美中生物医药协会(CABA)于2007年在美国波士顿成立，是一家非盈利、非政治性的华侨华人生物医药专业协会。协会现有会员约1500余人，主要来自生物医药公司及医疗器械公司的专业人士，绝大多数具有博士、医师、律师、商业管理硕士等学位。协会每年定期在美举行生物医药、投资、创业与知识产权、医疗器械等领域的学术活动，并多次参与组织在中国举行的生物医药领域的国际学术活动，为促进中美生物医药领域的交流合作发挥了积极作用。(完)
来源：中国新闻网

美中生物医药协会无锡俱乐部成立

2013年6月26日，首届“无锡国际生物医药论坛”暨美中生物医药协会无锡俱乐部成立大会在中国无锡召开。本次论坛由美中生物医药协会与市科技局联合主办、无锡好芳德药业有限公司承办，百余名生物医药产业代表参加活动。美中生物医药协会会长喻向阳以及来自美国辉瑞、雅培、诺华等多家世界500强的生物医药公司的负责人和首席科学家一行15人来无锡市锡山区考察交流。区政府副区长陈建清出席会议并讲话。

喻向阳会长介绍了美中生物医药协会的情况和此次来华访问的目的。该协会是全美生物制药科技领域华裔专业人士的大型非营利组织。协会每年定期在美举行生物医药、医疗器械等领域的学术活动，并多次参与组织在中国举行的生物医药领域的国际学术活动，为促进中美生物医药领域的交流合作发挥了积极作用。 会上“美中生物医药协会无锡俱乐部”在锡山揭牌成立。今后美中生物医药协会将通过这一平台举办更多学术活动并促进美国生物医药领域的交流， 充分利用美中生物医药协会的资源优势和国际影响力促进中国生物医药产业的发展。无锡俱乐部的成立是美中生物医药协会推进创新国际化战略和促进生物药产业发展的又一次新的探索和尝试。

美中生物医药协会 李京京 摄、编

2012 新英格兰专业人士新春盛会 展现华人政经力量

Reported by 李强, 侨报特约记者

1 月 28 日下午和晚上，新英格兰华人专业人士 2012 春节联欢晚会及社区论坛在佛莱明罕镇（Framingham）的喜来登饭店隆重举行。 500 多位医药、IT、金融财会、法律、教育科研等领域华人专业人士、企业家以及各界嘉宾出席了本次盛会，庆祝龙年新年。高级别的来宾、高质量的社区论坛和高水准的文艺晚会，体现了新英格兰地区的华人专业社团近年来团结合作、服务社区，已经成为一股不可忽视的政治和经济力量。

在下午的社区论坛中，分医疗保健生物医药和经贸投资创业职业发展交流两个专题会场同步进行，吸引了众多专业人士踊跃参加。在经贸投资分会场外设有摊位的长城金融集团的杨存辉先生对记者表示很高兴有机会见到这么多的华人专业人士，本次盛会为他提供了一个向专业人士介绍投资理财的平台。

※（左起）晚会主席陈志宏、副总领事董晓军、联邦参议员布朗夫妇、麦永芬在晚宴前合影。(摄影 /李強)

晚宴和联欢晚会在饭店的 7 点开始。晚宴由美中医药协会会长陈志宏博士和毕马威会计事务所合伙人麦永芬女士主持。他们首先感谢联邦参议员布朗推动联邦参议院全票通过了为 1882 年的排华法案对华人道歉的 201 法案。参议员布朗在致词中感谢再次被邀请前来参加新英格兰华人专业人士的春节联欢晚会，并呼吁与会者致电各自的联邦众议员，推动 201 法案在众议院通过后，由奥巴马总统签字生效。

中国驻纽约总领馆副总领事董晓军在致词中对与会者致以龙年春节的问候。他接着说：“2011 年，中国实现了 GDP 增长 9.2%，各方面也得到发展，为金融稳定和世界和平作出贡献。中国的成功离不开海外儿女的支持。作为华人专业协会，对促进中美交流作出重大贡献。”

麻州财政厅厅长葛罗斯曼、康州华裔议员汤伟麟(William Tong)，剑桥市议员张礼能等新英格兰地区政要出席了晚宴，为嘉宾送来的新春的祝福。

汤伟麟在致辞中用流利的中文给华人专业人士拜年。他提到，父亲 70 年代移民来美，在康州一家名叫香港厨房的餐厅上班。正是他父亲辛勤的工作，使他能站在这个舞台上。他希望大家支持他竞选，能够成为美国大陆（不包括夏威夷）的第一个华裔联邦参议员。汤伟麟告诉记者，他参选的联邦参议员席位因为参议员利伯曼（Joe Lieberman）的退休而成为一个通常会吸引多人参选的空位（open seat）。

纽英伦中华资讯网络协会的陆德礼宣读了麻州州长帕特里克、麻州国会参议员凯利和国会议员卡普阿诺的农历新年贺信。

晚宴中，10 多位小朋友手持着一束束鲜艳的玫瑰花，到每一个餐桌前为癌症研究义卖募捐。孩子们的爱心为当天的庆祝活动增添了许多光辉。 晚宴后，上海世博会双语主持人艾诚主持了一场精彩纷呈的文艺晚会。70 多岁的老艺术家张钊的京剧表演凭借深厚的唱功得到台下雷鸣般的掌声。著名古筝演奏家翁慧的独奏、青年舞蹈家官姗、刘沂峰的双人舞《天边》、毕业于复旦大学、在麻省理工学院攻读学位的李美毅的印度歌舞《天竺少女》等精彩节目令人目不暇接。最后，庆祝活动在汪洁领唱的“明天会更好”的歌声中落下了帷幕。

共同组织筹办这场活动的包括北美中华医学会（ACMA），百华协会（BayHelix），美中生物医

药协会（CABA），中美知识产权法律协会（CAIPLA)，128 华人科技企业家协会(128 CUTE），麻州香港协会(HKAMA)，MIT 华人科技学会(MIT CAST），MIT 经济与人才论坛（MIT ETF），纽英伦中华资讯网络协会（NECINA），留美华人企业家协会（OCEAN)，纽英伦金融及会计泛亚领袖会（ASCEND-NE），美洲华人生 物科学学会（SCBA），全美华人金融协会（TCFA），波士顿中国校友会联合总会(BCAAC）。

CABA 举办 2012 投资创业研讨会

Reported by 菊子, 星岛日报记者

美中生物医药协会(CABA)十月廿日在波市双树酒店举办「2012 投资、创新与创业研讨会」，不但专家云集，连中国科技部副部长王伟中都出席助阵，并特别指出，生命科学是中国重点发展的七大战略新兴产业之一，近年努力推动的还有科技和金融结合，加强科技效率等。

中国科技部副部长王伟中来到哈佛大学肯尼迪政府学院进修了二个多月，这还是第一次正式在波士顿的公开场合露面。

廿日晚，他在中国驻纽约总领事馆科技参赞叶冬柏，侨务领事朱星华，以及美中生物医药协会新旧任董事会董事长林世文、王义汉等人陪同下，为美中生物医药协会的 2012 投资、创新与创业研讨会晚宴做主讲者。

王伟中在半个多小时讲谈中，综述了中国科技投资现状、面对的挑战，以及下一步方向。

他指出，中国早从 2006 年就提出建设创新型国家的方向，国务院并颁布国家中长期科学和技术发展规划纲要。政府及民间在科技创新、创业上的投资总额，估计已高达八千六百多亿元，其中来自政府的约五千亿元数额是可以肯定，地方政府占的比率甚至高于 50%，但其中来自民间的部份，数额就不见得准确。

王伟中透露，他获机会来美进修四个多月，学习重点之一，就是政府在辅导、推动创新、创业上该扮演什么角色，起什么作用，怎么样管理，以及美国政府怎么做科技投资等。

留美华人企业家联合会副会长赵进，美中生物医药协会前任会长陈志宏等多人在会中提出各种问题。1984 年从清华毕业，2006 年取得清华管理博士学位的王伟中回答得十分坦率、亲切，没有架子。

美中生物医药协会廿日的这场讲座，由喻向阳担任会议主席，上午探讨人才，下午和中国武汉光谷副主任阎忠宁开联机会议，探讨中国机会，另一场座谈探讨全球机会。

会议的另一名主讲者为诺华公司肿瘤授权策略和过程(Novartis Oncology Licensing Strategy & Process)副总裁 Anne Altmeyer。两场座谈有 CABA 前会长，现为 Acebright 副总裁的戴朝阳等人担任讲者的「生物制药公司的创新与创业」，万昭奎主持的「2012 全球外包策略与趋势」。

※ *中国科技部副部长王伟中(前左六)和美中生物医药协会(CABA)董事长林世文(前右一)、前任董事长王义汉(前右五)、纽约总领馆科技参赞叶冬柏(前右四)、前任会长陈志宏(前左五)、董事曹庆庆(前左四)、前任会长万昭奎(前左一)等人在会中合影。*(摄影 / 菊子)

※ *中国科技部副部长王伟中(中)和美中生物医药协会(CABA)董事长林世文在会议中和出席者交谈。*(攝影 / 菊子)

武汉市(国家)光谷生物城第四次在波士顿举行推介会

Reported by 李强, 侨报特约记者

2012 年 10 月 20 日在波士顿的双树酒店 ”美中生物医药协会 (CABA) 2012 投资创业创新大会” 为武汉市食品药品监督管理局第四届赴美培训小组设了专场, 举办了主题为“聚焦光谷生物城，中国的投资好机会”的推介会，这是光谷生物城推介会连续四年以此模式由 CABA 及武汉药监局在波士顿举行.

这次推介会成为 CABA 2012 投创大会的亮点之一。大会高潮亮点是哈佛大学访问学者中国科技部王伟中副部长演讲, 学者、药物研发行业高管、企业家、科学家、以及金融投资界的专业人士的共 300 余人参加。

推介会专场由 CABA 董事长林世文博士主持，首先由武汉市赴美培训小组的金蕾组长用流利的英语介绍了武汉市基本情况、区位优势、武汉市药监局职能、培训小组的学习目的,然后播放了光谷生物城生物产业园宣传片。会上通过视频连线了光谷生物城的闫忠宁常务副主任，由闫主任详细介绍了光谷生物城产业发展现状以及针对生物医药产业所制定的各类产业政策及人才政策,与其他地区的产业园的优势，并回答了与会者问题。闫主任表示生物城将给中外来园区创业者积极政策和最优质的服务。

光谷生物城位于中国的交通枢纽武汉，是国家级的生物产业基地，建设有包括生物医药园、医疗器械园在内的六大园区，已经吸引包括辉瑞等世界生物巨头进驻。

波士顿铁木药业的喻向阳博士向记者表示，通过这次推介会对生物城有了进一步的了解，觉得生物城很有发展潜力，特别是闫主任因中美时差在办公室通宵度过赶在凌晨视频连线波士顿推介会，让参会者感到了光谷生物城的诚意和敬业精神。

据林世文博士介绍，武汉市食品药品监督管理局已经连续四年派团到波士顿学习，每次为期三个月。他们来美是为了学习 FDA 先进监管理念，并肩负行业监管和推介双重职责，增进波士顿各界对武汉市及光谷生物城了解，促进中美医药行业沟通和交流。

CABA2012 药监法培训班举行毕业典礼

Reported by 李强, 侨报特约记者

中国食品和药物质量的监管是一项关系国计民生的大事，而美国在这方面有上百年的丰富经验。4 年前，美中生物医药协会（CABA）药监法规培训班就是在这样的大环境下应运而生。

CABA 于 12 月 8 日在哈佛医学院的 Dana－Farber 癌症研究所举办专家论坛暨药监法规培训班毕业典礼。哈佛医学院病理学系医学博士和副教授荻野修二出席主题演讲。大会欢送 6 名武汉市食品药品监督管理局学员学成返华。CABA 董事会主席和药监法规培训班承办负责人林世文博士主持会议。中国国际人才交流协会驻纽约总代表郑杰嘉宾出席了讲座及毕业典礼。

※ *部分与会者，CABA 培训部人员，讲员和 6 名武汉市食品药品监督管理局学员合影。*(攝影 /李強)

荻野修二博士当天应邀演讲“分子的病理流行病学（MPE）：新型综合科学”。荻野获东京大学医学博士，在完成了凯斯西储大学的医院实习后，荻野博士在 2001 年加入 Dana－Farber 癌症研究所，2008 年晋升为副教授，并于 2012 年在美国哈佛大学公共卫生学院被聘任为流行病学系副教授。荻野修二博士关于分子的病理流行病学精湛演讲引起与会者的热烈讨论。

今年是美中生物医药协会第四年为武汉市食品药品监督管理局举办为期三个月的培训班。武汉市食品药品监督管理局副主任金蕾、副主任叶小敏博士、稽查分局副主任柯军，以及科员杜江荣、徐贤武、蔡志江当天都做了毕业报告，展示了他们的学习成果。他们表示，在培训期间到波士顿各大全球制药公司、生物技术公司及顶级医院系统参观，的确收获很多。他们对林世文、陈志宏等人在培训期间的所提供的帮助表示感谢。

据介绍，武汉市食品药品监督管理局有 600 多名员工，每年选送精英人员进修，对提升该局的整体作业和国际接轨能力有极大帮助。去年毕业的黄桦、姚盛等人还经常同 CABA 的朋友保持联系，并邀请大家有机会到武汉参观访问。

中美知识产权法律师协会（CAIPLA）创办人和 CABA 会长张引律师、前董事长王义汉博士、前会长陈志宏博士、万昭奎博士、培训班主任 Ellen Fan、哈佛大学医学院的田泽博士、喻向阳博士等人出席了当天讲座及毕业典礼。

四機構合作 探討醫療器械市場趨勢

Reported by 菊子, 星岛日报记者

四機構合作，日前在華森市 IBM 創新中心舉辦 2012 醫療器械和診斷技術研討會，既談市場趨勢，投資機會，更侃論喚醒各人深藏在心中、身裏的意志力，設定目標，就能事業有成。

這場 2012 醫療器械和診斷技術研討會由美中生物醫藥協會張偉負責籌備，今年和紐英崙中華資訊網路協會、北美中華醫學會、哈佛大學醫學院中國專家學者聯合會合作，邀有四名講者，從商業角度談醫療器材，另由史記主持，邀來五人，做一場醫療器械和診斷技術的創業座談。

四場專題講談中，麻州大學醫學院助理教授廉清宇的「喚醒你心裏的力量來成就事業：一名神經科學家揭示不為人知的故事」，最出乎人意料。

廉清宇從他自己小時候在長春，既無電視，也無垃圾食物的環境中長大，高中就創辦過公司，還聘用上海的大專學生來做介面設計這背景說起。如今他行醫忙碌，每天診看廿個病人，常和病人家屬談天，眼看許多人走完他們人生旅程中最後一段日子，絕大多數都忙碌到快要離世，才恍然了悟，自己的一生過得有如奴隸，總在操心個人的財務、工作等狀況，幾乎從未「自由」過。

廉清宇說，觀察世界上那些有錢有權的人，幾乎都並不特別有才幹，受過好教育，或特別有魅力、漂亮。但是，如果人都有差不多同樣的 DNA、體力和智力，人和人之間的差別，到底在那兒？他的結論是意志力，並且要設定目標，讓意志力有個方向，人腦的某個部位，會自然形成新的蛋白質，促使人更深入的思考問題。廉清宇還綜論了獲取意志力的九種原則，包括瞭解現實，有先見之明的知道自己

一生終極目標是什麼，肯主動並懷有感情，面對人生無畏無懼，精神專注，能夠起而行動，總是尋求雙贏局面，懷抱利他主義，擁有自信及肯負責的追求優越性等。廉清宇認為，人生而為人，都很幸運，但生命寶貴而苦短，要學會控制自己的生命及命運就能活得自由，並經由夢想帶來力量。

東方鍊資本(Eastern Link Capital)執行董事(managing director)周雄偉淺談了私募資金在中國醫療器械產品業的機會。周雄偉指出，中國的醫療健保業正在進行改革，有心投資者必須關注法規上的變化。總體來說，中國仍有生產成本低，品質高，可大量生產的優點，中國市場規模巨大到十五億元，也很吸引人。他本人所屬的東方鍊資本公司，有六名合夥人，總部在中國蘇州，分別在北京、波士頓設有區域辦公室，是一家以中國為重心的成長型股權基金(equity fund)，主要投資消費者消耗品、生物科技、能源及資訊科技。80%的投資，都投進了中晚期的市場收購，只有 20%投進還處在早期階段的公司。

2012 醫療器械和診斷技術研討會的其他講者包括橋醫 (Bridge Medic) 首席顧問富雅芳 (Grace Palma)，生物市場遠見(BioMarketing Insight)Regina Au。在座談中和出席者互動的包括 AST 產品研發主任李威聯，麻省總醫院介入腎臟病主任 Steven Wu，哈佛醫學院劉樹柏、宋威等人。

※ 2012 醫療器械和診斷技術研討會主辦人張偉(後左七)的講者及主辦人合影。前排左起，金蕾、廉清宇、周雄偉、Regina Au、富雅芳。第二排右起，史記、陳志宏、劉樹柏、Steven Wu、鄭茹、李威聯、宋威、張偉、張引、王義漢、萬昭奎等人。(攝影 / 菊子)

※ 史記(左起)主持座談。左起為柯軍、金蕾、Steven Wu、李威聯、宋威、劉樹柏等人和出席者分享他們的經驗及看法。(攝影 / 菊子)

※ 2012 醫療器械和診斷技術研討會主辦人張偉(左)介紹北美中華醫學會紐英崙會長(ACMA)廉清宇教授(右)。(攝影 / 菊子)

2013 英格蘭專業人士再辦春晚

Reported by 菊子, 星岛日报记者

第四屆新英格蘭華人專業人士慶祝春節晚會暨社區論壇，十日在牛頓市瑪麗奧酒店再創高潮。五百多名來自各界華裔專業人士，匯聚一堂，以講座論壇服務社區，以文娛表演展現才藝，還邀得麻州財政廳廳長葛羅斯曼做晚會主講人，彰顯份量。

今年共有十五個分屬醫藥、資訊科技、法律、金融、音樂等領域的華人專業人士組織，參與籌備這農曆新春慶祝活動。楊志勇、鄭茹、楊欽釗、廉清宇、林志超等五人擔任共同主席。

楊志勇指出，今年有波士頓中國音樂家協會、紐英侖亞裔專業人士協會(NAAAP)、紐英侖美中醫藥開發協會(SAPA-NE)等至少三個新團體加入合作行列，節目安排也在美中醫藥科技交流、亞裔健康、經貿投資創業職業發展交流等以商機、服務為主的社區論壇之外，增加了「波士頓好聲音」、「新春有緣」等，兼顧文藝、感情層面的活動，內容更為全面。

晚會中還有王藐若、朱曉峰率領一群小朋友，義賣玫瑰花，為滋根基金會籌款的義舉。五百多人同聚一堂的晚宴是活動最高潮。

前述五名主席分別宣讀麻州州長派區克、中領館紐約總領事孫國祥、波士頓市長萬寧路、劍橋市議員張禮能等人的賀信後，介紹了到會的麻州財政廳廳長葛羅斯曼(Steve Grossman)、麻州助理總檢察官曾佳玲、波士頓市不分區市議員候選人吳弭(Michelle Wu)等嘉賓，以及另一名晚會主講人，系列創業家李嘉強。他所創辦的 Biomedical 公司，去年才被大日本住友製藥會社 (Dainippon Sumitomo Pharma Co., Ltd) 以 26.3 億元收購。

葛羅斯曼在會中強調，麻州人口族裔多元化，其中的亞裔在上次人口普查中增加了 46%，是麻州增長最快族群，精英眾多，已儼然社會中不可忽視的力量。他個人自從 2011 年當選為麻州財政廳廳長後，更加力行其早年移民來美祖父的忠告，照顧家庭、發展事業、服務社區，善用兩耳，聆聽意見。

他還借著今年是農曆屬水蛇年，中國有水為財之說為引，笑稱自己的財政廳是送財童子，要把錢財送到需要銀根發展事業的小商家手中。他和華美銀行新英格蘭地區總監葉俊年等人合作，貸款三十五萬元給進升電子公司，就是幫助小企業解決取得周轉資金困難問題的結果之一。他強調自己要做亞裔在追求發展時每一步驟的夥伴，促進麻州的包容性(inclusion)，讓麻州變得更美好。

同時是麻州香港協會會長的葉俊年在介紹葛羅斯曼時，稱許葛羅斯曼的透明度，與重視多元化，不但麻州的所有開銷帳目，已有 85%都可在網上看得到，該辦公室新聘人員，也有 39%來自多元背景。他還指出，葛羅斯曼上任後，已經由合約招標，重新協商銀行投資服務等行動，為納稅人節省了一千一百萬元的服務費用及行政開支。他推出的「小企業銀行夥伴」項目，已和 49 家銀行合作，為 2503 個小商家提供了三億六千二百萬元貸款，間接創造了 2300 個工作機會。

李嘉強也以中國生肖做為講話引子，指蛇會排在生肖中的第六位，比馬還前，全因動用了策略，祝福專業華人們在匯聚出這麼大的一個團體後，能善用腦力，動用策略，把握中國仍是極具潛力新興市場的機會，創造出更好的經濟環境。

表演節目部份，由具專業背景的白雲、曲直和北美中華醫學會會長廉清宇、美中醫藥開發協會董事長林世文搭配做主持。十二個表演節目，個個是亮點，其中在柏克萊音樂學院執教的汪潔，把柏克萊音樂學院的 Michal Sinka 和波士頓中國音樂家協會的林湛濤、張正山、黃少堅及甄若矛等人湊成中西合奏樂團，獨唱「虞美人」、「夜來香」，秦天和 Devonte Roach 二重唱「傳奇」，臧充之和張友炘的數來寶等，都讓許多觀眾留下深刻印象。

新英格蘭華人專業人士慶祝春節晚會最後在龔琛晨伴奏，楊湛萍、裴曉華、楊欽釗、黃玲、張引、邢莉、龔家驪、龍江、趙潔、顧曄、王義漢等人合唱「希望的田野」聲中落幕。

部份熟悉波士頓華人圈歷史者指出，今年這新英格蘭華人專業人士春節慶祝會的另一大成就是，自從大波士頓地區華裔醫藥領域專業人士分成美中生物醫藥協會和紐英侖美中醫藥開發協會兩個組織以來，第一次一起籌辦、出席活動。

參與籌辦這慶祝春節活動的組織分別為，北美中華醫學會，百華協會，波士頓華人音樂家協會，美中生物醫藥協會，中美知識產權法律協會，128CUTE

華人科技企業協會，麻州香港協會，紐英侖中華資訊網路協會，留美華人企業家協會，紐英侖金融及會計泛亞領袖會，紐英侖美中醫藥開發協會，全美華人金融協會、波士頓中國校友會聯合總會，美洲中華醫學會，紐英侖亞裔專業人士協會。

※ *第四屆新英格蘭華人專業人士慶祝春節晚會暨社區論壇主要籌辦者合影。*(攝影 / 菊子)

※ *浮雲相聲社的臧充之和張友炘為晚會表演數來寶。*(攝影 / 菊子)

※ *麻州香港協會會長暨華美銀行新英格蘭地區總監葉俊年(左起)、波士頓市不分區市議員候選人吳弭、麻州財政廳廳長葛羅斯曼(Steve Grossman)、BioMedical 創辦人暨董事長李嘉強等大會嘉賓及主辦人之一。*(攝影 / 菊子)

※ *新英格蘭華人專業人士慶祝春節晚會主席鄭茹(左)、楊志勇(右)開場致詞。*(攝影 / 菊子)

2013 新英格兰华人专业人士新春嘉年华 精诚团结 回馈社区

Reported by 李强, 侨报特约记者

2 月 10 日是蛇年春节，暴风雪尼莫过后的波士顿才刚刚开始清理堆积如山的积雪。500 多位新英格兰地区的华人专业人士仍然如期从新英格兰各地会

聚到牛顿市的 Marriott 宾馆，参加新春嘉年华暨社区论坛。用本次活动的联合主席杨志勇的话来说，大家的热情将冰雪都融化了。

※（左三起）黄玲、波士顿市议员候选人吴弭、葛罗斯曼厅长、杨钦钊等与会者合影。（摄影/闫杰）

新英格兰华人专业人士联欢暨社区论坛是本地规模最大的春节庆祝活动之一，由 14 个华人专业协会以及波士顿中国校友联合总会共同主办。整个活动由多个板块组成，从下午两点开始，一直到晚宴和文艺演出结束，长达 9 个小时。麻州财政厅厅长葛罗斯曼（Steve Grossman）在晚宴的主题演讲中，对华人专业人士为麻州经济繁荣所作出的杰出贡献给予了充分的肯定。并鼓励专业人士以他们的才智回馈生活的社区。

在下午的社区论坛中，美中生物医药协会（CABA），中美知识产权法律协会（CAIPLA），128 华人科技企业协会（128CUTE），百华协会（BayHelix）以及全美华人金融协会（TCFA）联合推出了美中生物科技交流论坛。多位医药、法律和财经方面的专家就在中美医药产业投资的多方面问题同与会者进行了深入的探讨。而纽英伦中华资讯网路协会（NECINA）和留美华人企业家协会（OCEAN）有关 IT 创业和 MBA 教育的讨论也吸引了众多听众。

在另外一个分会场，波士顿亚裔健康论坛中，北美中华医学会（ACMA）的医生们就饮食、肥胖和代谢疾病、癌症的预防、亚裔精神和心理健康、心梗和中风的预防　等专题做了讲解。在接下来的免费健康咨询环节，近 20 名各科医生现场提供健康咨询，帮助与会者了解不断变化的美国医疗体系，解答有关健康医疗的问题。

晚宴从晚上 7 点开始，本次盛会的多位联合主席郑茹、杨志勇、廉清宇、王义汉等人宣读了中国驻纽约总领馆孙国祥大使、麻州州长帕特里克、波士顿市长曼宁诺等政　要发来的贺信。

主题演讲嘉宾波士顿生物技术公司董事长李嘉强，在演讲中回顾了在过去 20 年中国的飞速发展给在美国，特别是波士顿地区的华人专业人士所带来的巨大机遇。他说 20 年前，中国的人均 GDP 是印度的一半，而现在是印度的 3 倍。拥有 50 多项专利的李嘉强“以点石成金”作比喻，强调创新是个人乃至一个国家得到发展的关键。

晚宴之后是精彩的文艺演出，四位风采照人的主持人廉清宇、林世文、白云和曲直祝与会者蛇年吉祥。总导演赖振华告诉记者，晚会的准备工作从去年 11 月份就开始，他对波士顿中国音乐家学会的林湛涛、张正山，以及伯克利音乐学院的汪洁等音乐家克服困难前来参加演出表示感谢。“特别值得一提是晚会最后的大合唱，由来自各个协会的代表出演。大家在波士顿音乐学院秦天的指挥下，经过多次排练，演出效果非常好，同时也体现了华人专业人士团结一心的精神，”赖振华说。

美中生醫協會年會 喻向陽接會長

Reported by 黃子怡, 世界日报記者

美中生物醫藥協會（CABA）4 月 27 日在麻省理工學院教員會館舉行年會，主題為「加速藥物開發：從實驗室到臨床」，邀請 30 餘位學者專家，從業界科技、全球資源、生涯規畫等方向進行研討。會中亦辦理新舊會長交接，原任會長張引卸任，喻向陽接棒。喻向陽表示，將延續 CABA 為中美生化界交流媒介的特色，增加會員間的互動。

曾在食品暨藥物管理局(FDA)工作多年的卡曲格(Areta Kupchyk) 表示，FDA 掌管的項目佔美國總消費額 25%。其中對於藥物開發管控尤其嚴謹。從

臨床實驗數據到市場開發廣告方式都有詳細規定。審查的資料不限於公司所呈報的資料，也會追查實驗數據被查刪除的部分。

目前在 Weatherbie 投資公司工作的施國強，解釋投資公司從疾病的重要性、藥物能改善疾病的程度、與專利的年限等因素評估藥品的利潤。他強調，市場大小是以金額數目計算，而不是使用藥物的人數。比如有些抗癌藥物收費可高達一個病人每年 50 萬元，因此是高獲利的藥品。而抗感染的藥物雖然使用者眾多，但藥品種類也不勝枚舉，而且收費有限制，並不屬於獲利高的藥物。

文立民在波士頓學院(Boston College)負責技術移轉與執照部主任的工作。他表示學術界研發技術後託付予業界，並不是為了讓某個公司在市場有競爭力而已。最終目的是希望經由合作的方式，業界能有效運用這些技術與資源，進而造福人群。

Ariad 製藥因其研發治療慢性骨髓性白血病的藥物 Ponatinib，獲 CABA 頒發優良發明獎。研發部總裁克萊森（Timothy P. Clackson）細談 Ponatinib 製造研發經歷與藥物功能。

Ironwood 製藥也獲表揚。該公司研發的 Linaclotide 藥物對改善對大腸急躁症有幫助。化學與研發部副總符銳正(Angelika Fretzen)分享 Linaclotide 藥物治療慢性消化系統疾病的過程。

晚宴中，CoNCERT 製藥總裁 Roger Tung 談如何創立製藥公司。他在 2006 年所創立的 CoNCERT 在製藥備受矚目，他個人亦在 2009 年獲得麻州高科技全能獎 (Mass High Tech All Star Award)。

※ *美中生物医药协会年会上，原任会长张引（左）卸任，由喻向阳（右）接任会长。*（摄影/黄子怡)

CABA 年會歡迎首名女性會長喻向陽

Reported by 周菊子, 星岛日报記者

美中生物醫藥協會(CABA)日前在麻省理工學院教授俱樂部舉行年會，宣佈喻向陽成為該會創立以來的首名女性會長，該會董事人數在卸任會長張引加入後，增為十人。

美中生物醫藥協會董事長林世文笑稱今年是女權高揚年，不但新任會長喻向陽是女性，當晚獲表揚的 3 名義工范艾琳、田澤、李京京，也全為女性。

林世文還報告，該會慣例為會長卸任後，就加入董事會。現任會長張引卸任後，該會董事將增至十人，其中有創會會長韓軍，以及吳俊軍、沈立新等 3 人已回中國發展。韓軍、沈立新當天還特地回波士頓和該會敘舊。

美中生物醫藥協會今年的年會主題為「加速藥物開發：從實驗室到臨床」，30 多名學者、專家及業界高管，講談各自的研發成果、商務行銷策略，包括慢性胃腸功能紊亂的治療，公司的科學與策略，

計劃新產品的定價與市場切入，從病人到病人的癌症治療，人性化的臨床前藥物研發，藥物的設計及研發，腫瘤的故事，整合全球科學村來改善病患的生活等等。

當天下午的兩場座談，一場從法律、投資及商務角度談生物醫藥科學家可有的不同職業，一場談研發合作的全球整合。

在生物醫藥科學家可有的不同職業這場座談中，2012 年獲得 LMG 生命科學之星獎的 Areta L. Kupchyk，目前是 Nixon Peabody 律師樓合夥人。她和出席者分享了她今年一月才發表的，「聯邦食品及藥物管理局(FDA)規範製藥業的權力倍增是誰的責任」這篇文章的精華。

在管理 10 億元資產的機構資產管理公司 Weatherbie &擔任副投資長的戴海(H. George Dai)，從投資公司的角度來談生物醫藥研發。他表示，投資公司會從某一藥物能治療社會中那些重要病症、能改善的程度、專利的年限等因素，來評估該藥品的利潤，進而才做出是否投資的決定。

波士頓學院新聘的技術轉讓及許可辦公室主任文立民，分享了他從研究者轉行成專利轉讓專家的過程，並指出學術界轉讓專利，旨在幫助業界對社會大眾做出更多貢獻。

「全球研發合作的整合」這場圓桌討論會，是當天最壯觀的座談，有來自中國大陸及美國各州的 15 名執行長、副總裁、首席科學家，暢論經驗。包括蘇州安尼康藥物研發公司董事兼技術總監施國強，抗體新藥創製研發首席商務官王忠民，上海桑迪亞醫藥技術公司總經理陳晨，威明頓(Wilmington)製藥科技公司副總裁康富安，上海睿智化學研究公司副總裁吳辰冰，上海創諾華醫藥副總裁李金亮，Acme 生物科學公司董事長張志安，燼療法(Ember Therapeutics)副總裁 Jeff Saunders，鐵木製藥首席調研員(Principal Investigator)喻向陽等人，對於醫藥研發外包的未來前景，各有看法。其中一、二名較為坦率者不避諱的指出，在海外公司也進入中國搶市場，中國工資越漲越高，員工忠誠度相對低落等等情況下，業者都有環境艱困，利潤漸薄的感嘆，也認為這行業將出現兼併、整合趨勢。

美中生物醫藥協會當晚還邀請 Concert 製藥公司董事長 Roger Tung 分享打造一家生物科技公司的經驗，輝瑞(Pfizer)製藥公司醫藥化學主管 John Mathias 講談治療氣喘病的新方法。

※*「全球研發合作的整合」這場圓桌討論會，最壯觀，講者最多。*(攝影 / 菊子)

※ *CABA 新會長喻向陽(左)、CABA 常任理事范艾琳，都是當天受表揚的女性。*(攝影 / 菊子)

※ *Concert 製藥公司董事長 Roger Tung(左起)、Weatherbie &擔任副投資長的戴海、CABA 董事萬昭奎、中國國際人才交流協會駐紐約代表處總代表鄭杰等人在會後討論。*(攝影 / 菊子)

4 專業社團 2013 夏日聯合野餐

Reported by 俞國梁，世界日报记者

第五屆新英格蘭華裔專業人士夏日郊遊野餐會 8 月 17 日在麻州 Hopkinton State Park 舉行。活動由北美中華醫學會（ACMA）、美中生物醫藥協會（CABA）、留美華人企業家聯合會（OCEAN）、紐英倫中華資訊網路協會（NECINA）等四組織聯合主辦，吸引了近 400 名專業人士及家屬一同參加。

在萬里晴空下的草地和湖傍，大家盡情享受暖暖的陽光和豐富可口的美食。野餐採取自助餐結合 BBQ 形式，四會的舊雨新知，三五成群，忙著聯絡感情，互相交流。有些來自同一協會的會員還是第一次見面。

據活動主要組織者之一的周麗萍介紹，雖然連續五年都是在同一個公園舉行野餐會，但是絲毫不影響大家的興趣。不少人每年必到，參與活動，出錢出力，樂在其中。

在留美華人企業家聯合會的桌子前，掛著 MBA 培訓的條幅，吸引了不少人關注。該會教育中心副主任吳凱彬說，該會 MBA 培訓班自 2000 年開辦，現已是第 14 期，學員超過 300 人。通過 14 個周末的密集課程，進行雙語教育，提供學員與國內外企業家的交流和經驗分享。報名網站：www.OCEAN-USA.org/education。

美中生物醫藥協會會長喻向陽、前任會長王義漢忙著招呼大家，組織遊戲活動，還親自掛起該會的橫幅。喻向陽正在籌畫將該會網站中英文雙語化，她呼籲義工加入隊伍。

紐英倫中華資訊網路協會（NECINA）會長鄭茹和一眾青年義工忙碌當中，也不忘娛樂。不但這些年輕人打起排球來意氣風發，家裡的小朋友玩起飛碟來也有模有樣。擁有卡內基培訓師證書的鄭茹說 ，NECINA 今年 9 月份將繼續舉辦針對高中生和大學本科生的青年企業家（YES 8.0）免費培訓班，詳情見網站：www.necina.net/web/yes。

北美中華醫學會負責此次活動組織的匡平平，一再感謝其他組織者為野餐會準備所付出的辛勤勞動，並感謝大家的積極參與。

「友誼第一，比賽第二。」組織者還準備豐富多彩的娛樂活動及幸運大抽獎，處處歡聲笑語。

※ *新英格蘭華裔專業人士夏日郊遊野餐會，數百人在組織者和義工們的安排下，井然有序地分享美食。*（攝影 /俞國梁）

浙江赴美高級人才培訓班圓滿結束

Reported by 李强，波士顿華人雙語网

由 27 位成員組成的浙江赴美服務業高級人才培訓班從 9 月 10 日開始，在哈佛大學上課，以及對電子港灣、奧克蘭港、納斯達克、聯邦儲備銀行等機構的實地考察共計三週的培訓，日前返回浙江同正在發國慶節長假的親人團聚。浙江省發改委、人社廳為了辦好好這次培訓班，做了大量準備工作。而培訓班學員在波士頓期間也在培訓之餘，在沃本（Woburn）鎮希爾頓酒店同本地華人專業人士舉行了中秋聯誼餐會。

※ *部分中秋联谊餐会的参加者合影。*（攝影 /李強）

8 月底，由浙江省發改委、省人社廳共同組織，省服務業聯合會、供應鏈協會共同承辦的“赴美服務業高級人才培訓班”正式開班。浙江省發改委副主任黃勇、服務業處處長譚燮良、省人力資源和社會保障廳繼續教育院主任朱旭峰、省外專局局長奚靈平、張紅衛、浙江供應鏈協會秘書長繆姬蓉、以及參加培訓的全體學員出席了此次開班典禮。浙江供應鏈協會常務副秘書長楊向紅主持了會議。

出行前為讓參加培訓的 27 位位學員能夠相互認識，融入到班集體當中，更好地有針對性地學習到歐美髮達國家在服務業領域的先進理念與技術、了解國內外服務行業動態，主辦方邀請了國內頂尖的服務業專家開展了為期兩天的拓展訓練、英語培訓與服務業講座。

同本地華人專業人士聚餐交流

9 月 18 日晚，來自浙江的培訓班學員在哈佛大學上完課後，在下榻的酒店同 30 多位波士頓地區的華人專業協會代表舉行了聚餐聯誼活動。由於當天交通擁堵，聯誼活動比預定時間晚了近一個小時，陸續到達的本地華人專業人士則利用這個時間相互交流。

培訓班班長、浙江省發改委副主任科員張昕先生向大家逐一介紹了培訓班學員。而美中生物醫藥協會會長喻向陽則對學員們在緊張的培訓之餘來參加聯誼活動表示感謝。 128 華人科技企業協會董事張曉明、波士頓浙江大學校友會會長洪保明、紐英倫美中醫藥開發協會會長斜理強等浙江籍專業人士同來自家鄉的學員們交談甚歡。華人專業人士們解答了學員們有關波士頓的各種問題，並互相交流了在企業管理、大數據等高新科技在經營中的運用心得。

浙江樹人大學現代服務業學院常務副院長夏晴女士對浙江省發改委、人社廳組織這次培訓表示感謝，讓她有機會得到在哈佛商學院培訓的機會。協助策劃本次培訓的美中國際商業聯盟會長吳寶健親自從休斯敦來到波士頓安排培訓的具體事宜。北大畢業的吳寶健表示他還準備參加不久將在哈佛大學舉行的第六屆北京大學北美校友代表大會。

CABA 生物業投資創業講座談趨勢

Reported by 周菊子， 星岛日报

美中生物醫藥協會(CABA)日前在波士頓雙樹酒店舉辦 2013 年投資與創業研討會，廿多名講者就生物科技及醫療產業的投資，創業，外包，做了廣泛討論。

CABA 今年的投創會，在會議主席王志剛，CABA 會長俞向陽先後發言後，由前任會長張引主持第一場全體出席的會議。

總部設在麻州華森市，管理 30 億元投資額的 Polaris 創投夥伴公司執行合夥人 Ami Nashat 擔任主講人。他指研發及創新是生物科技產業中很重要的元素。過去幾年，生物科技業出現不少對人類健康影響很大的藥物，但這個產業正面對著資金漸罕，大製藥公司將陸續出爐新藥越來越少的壓力。他也闡述了要籌措資金可有的多種不同方法。‘ 波士頓學院技術轉移及授權辦公室主任文立民，以及 Cubist 製藥公司外部研究主管 Yugui Gu，當天早上分別講談在大學裏面創業，從大學院校獲取選擇權，或專有權，如何和來自大學的投資者合作，外包研究在製藥業已成為非常重要做法的趨勢等。第二場全體出席的會議，由車慶林主持。摩根史坦利全球財富資深副總裁 Jack Liu 以“醫藥科技的關鍵投資主題“，指出未來幾年，公司併購風氣將仍盛行。

Scilligence 公司共同創辦人李勁波指出，跨組織合作，重整研發機構，生物科技公司營運虛擬化，使得如何管理資訊流通，保護智慧財產權成為藥物研發的新挑戰。他以該公司為例，談論如何滿足新研發模式中還未滿足的資訊需求。 Synta 製藥公司學者應偉文（譯音，Weiwen Ying)講談腫瘤藥物發展，令人興奮的新平台。

該一會議另有二場座談，主題分別為“生命科學業的跨界投資”，“全球外包，如何創造雙贏關係”。“生命科學業的跨界投資”這場，由牛津(Oxford)生物科學合夥人 Jonathan Fleming 主持，Sanofi 的研發副總裁 Katherine Bowdish, 蘇州凱風正德創投基金的醫療護理合夥人黃昕，尼克森皮博迪律師事務所律師季學清，Oliver Wyman 專員謝崢，蘇州 AlphaMab 公司創辦人暨執行長徐霆等人交流意見。Jonathan Fleming 指出，中國政府近年來推動生物醫藥產業的努力，很多人都看得見，但迄今未見一家中國的跨國公司，或許是個很值得探討的議題。

“全球外包，如何創造雙贏關係”這場，油 Celgene Avilomics 研究公司醫療化學主任牛德強（譯音，Deqiang Niu)主持。講者包括波士頓本地的健贊公司資深科學家趙進，。Sundia MediTech 全球商務發展主任 Sherry Yu，上海 Alputon 製藥科技公司創辦人暨執行長 Libing Yu 等人。

該會今年的一大特色是有多名原本住在波士頓，現已在美中兩國創業者出席。

※ 美中生物醫藥協會(CABA)會長俞向陽（中右四）及幹部及演講者會後合影。（攝影 /菊子）

※ *美中生物醫藥協會(CABA)董事會主席林世文（右起），會長俞向陽，前任會長張引，前任董事會主席王義漢，曾任會長的戴朝陽等人，利用時間開小會。（攝影 /菊子）*

生物制药投资者和企业家的盛会：2013年美中生物医药协会生物医药投资与创业研讨会

Reported by 董英， 侨报工商记者

近日，2013 年美中生物医药协会（CABA）投资与创业研讨会在波士顿 The Doubletree Guest Suites 隆重召开。每年一度的投资与创业研讨会是 CABA 的几个年度盛事之一。今年的研讨会的主题是“时代的挑战---新形势下投资生物技术和制药行业”。研讨会吸引了近百名中美企业高管、创业者、科学家、学术界人士、政府政策制定者和金融投资专家聚集一堂。

早间全体会议分别请了三位资深人士就生物制药行业的三个重要议题：早期创新、大学初创企业，和企业外部研发进行了深度的探讨。来自纵横全美和欧洲的生命科学投资的领军企业 Polaris Venture Partners 的管理合伙人 Amir Nashat 博士跟与会者分享了生命科学行业的风险投资的全球趋势，早期阶段生物科技的创新的关键部分，以及这些关键部分在整个癌症的治疗产品的研发的巨大作用。作为一个帮助多个生物技术公司成功发展的专业投资人，Amir Nashat 博士的讲话让大家对理解风险投资对早期创新的支持作用有了更加情形的认识。Boston College 的技术转让和许可部的 Jason Wen 博士跟大家强调了公司和大学合作时的知识产权许可授权的重要性。Cubist Pharmaceuticals 的 Yugui Gu 博士以他的亲身经历给大家讲述了外部研发在推动潜在药物产品通过整个研发过程最终成为被批成药造福患者所扮演的重要角色。

在下午的全体会议中，摩根士丹利全球财富管理集团的资深副总裁,Jack Liu 分享了保健行业的大量详实的数据，以及这些数据所预示的投资趋势。位于 Burlington 的成立只有两年时间的年轻企业 Scilligence 的首席技术官李劲波博士指出，生物制药行业全球化和研发重组日益严峻；因此抓住市场脉搏，生产或提供客户所需的产品或服务非常重要。Synta Pharmaceuticals 的首席研究员 Weiwen Ying 博士介绍了该公司刚刚推出的抗癌药物开发平台 HDC，以实例向听众展示了科技创新如何在实践中孕育形成，以及其为生物医药行业带来的变革性技术及新的投资机遇。

本次会议还引发了一个非常有趣的讨论：如何在“全球外包的时代”取得双赢局面？当今世界任何一个在制药公司或者生物科技公司从业的人都会接触到或者使用一些“研发外包公司（CRO）”。由于生产能力限制、特殊的需求、节约成本和自由化等等因素，现今 CRO 公司的服务几乎涵盖了从药物研发的各个方面：化学、生物、药理、毒性和早期研发。随着“全球外包”趋势的进一步发展，探讨制药公司和外包公司之前如何成功合作以及建立一个长期的双赢的关系非常有意义。大家的共识是，价格不应该是合作的唯一因素。价值观的传递，对不同文化的尊重和理解，定期有效的沟通和交流等等才非常的必要和宝贵。

此次会议在大会组委会历时几个月奋战，获得了各与会者“收获颇丰”的赞誉。终于在波士顿的美丽金秋划上了圆满的句号。

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About CABA

CABA is a 501(C)(3) not-for-profit professional organization registered in Massachusetts since May 2007. CABA is committed to promote public awareness of advancement in the pharmaceutical and biomedical industry, professional interactions in the fields of life sciences, global biomedical innovations and business development. As the majority of its members are scientists with Chinese heritage, CABA will operate in two important areas. One is to serve as a platform for its members to develop and advance their careers in the US pharmaceutical and biomedical industry, the other is to serve as a bridge to connect members including corporate members with the scientific and business resources in China thus facilitating collaboration between the pharmaceutical and biomedical industries across continents. To fulfill these goals, we will organize scientific and business symposia, conferences, workshops, in US and China, as well as social events to promote networking and communication among members. We will bring together members, scientists, professionals, government officials and business leaders across the continents under a collaborative environment and achieve their best potentials.

CABA is a volunteer-based society. We rely on members to contribute their time and efforts to build the organization. We rely on corporate members and sponsors to raise fund to support the above activities. We value integrity, honesty, professionalism, community service, scientific excellence, responsibility and accountability. We invite you to explore our organization, and we are confident you will share our values and are interested in becoming a member, devoting your time or efforts, or sponsoring CABA activities. In summary, CABA is built by its members and serves for its members.

CABA Mission

• To promote science, technology, and business collaboration in biotech/pharmaceutical industry;

• To build and maintain a platform through cohesive scientific, professional, and cultural connection that provides high quality services;

• To facilitate networking among scientists, professionals, and entrepreneurs in academia, biotech/pharmaceutical industry and regulatory agencies;

• To embrace advancement of science and commercialization of innovation that will benefit human health;

• To foster collaborations between the United States and China for the development of better biotech/pharmaceutical therapeutics.

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If you have any comments, suggestions or feedback to our organization and our events, please feel free to contact us at cabaconnect@gmail.com. Your comments are important for us to improve in the future. Thank you very much!

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