
Shanghai, China
March 16-17, 2016

What’s New for Biosimilars 2016:
- Unravel Biosimilarity Factors in Up-Down Stream Development
- Develop Clinical Trials based on Latest Regulatory Guidelines

Spotlights in Novel Vaccines 2016:
- Unveil Most Cutting-edge Novel Vaccine R&D Progress Worldwide
- Explore Best Practices in Quality Control from Discovery, Development to Industrialization

From Biosimilars Forum You Will Achieve:
- Up-to-date guidelines and requirements in clinical waiver/supplement from EU and China
- Entire design sharing in biosimilarity from project initiation to IND
- Learn the most effective strategy from origin: cell strain construction, quality analysis
- Discuss high quality development in biosimilars’ up-to-down stream process

From Novel Vaccines Forum You Can:
- Follow-up ChP, GMP Latest Requirements and Advanced Practices in Novel Vaccine Quality Control
- Learn Antigen Design and QbD Industrialization to Ensure Quality from Start
- Understand Novel Vaccines’ Latest Progress: HIV, Universal Influenza, Therapeutic Cancer Vaccine and Next –Generation Adjuvant Technology, etc.
- Discuss Model Structure and Endpoint Evaluation in Pre-clinical and Clinical Trials to Quicken Market Access

Hot Line: +86 21 60527081  Email: wcbf@bmapglobal.com  Website: www.bmapglobal.com/wcbf2016/
World-China Biosimilars Forum 2014 was held successfully on Mar. 6-7, 2015 in Wuhan, China. The forum was hosted by Wuhan Biolake, organized by BMAP Global Co., Ltd and supported by Humanwell Group. There were altogether 225 attendees.

During the time that Chinese biosimilars regulatory had not been released, WCBF invited both EU and FDA regulatory affairs representatives, along with the USP experts, to discuss the successful experiences in EU and FDA that can be examples to China. Meanwhile, WCBF also invited Chinese Biopharmaceutical KOLs sharing hot topics like biosimilarity, scale-up manufacturing, etc.

2nd World-China Biosimilars Forum 2015 was held successfully on Mar. 18-19, 2015 in Wuhan, China. The forum was hosted by Wuhan Biolake, organized by BMAP Global Co., Ltd and supported by Humanwell Group. There were altogether 232 attendees.

With the releasing of “Biosimilars R&D and Assessment Technical Guidelines” and other relating policies by CFDA, WCBF gained great attention. According to the in-depth investigation towards industrial KOLs by BMAP, WCBF carried most focused topics and invited world top speakers accordingly. The participants were very surprised to see that Chinese local biopharmas had been willing to really share their experiences and mistakes during bioprocessing and biomanufacturing to remind others not to repeat same mistake, according to the organizer’s requests. This is very rare in similar events.

Who Should Attend?
- Senior Management from Business Development, R&D, and Quality Department of Leading Biotech Companies
- Scientists from Leading Research Institutions and Universities
- Government Officers on Biopharm & Vaccine Registrations
- Biotech Entrepreneurs
- Senior Executives from CROs and CMOs
- Legal and Regulatory Professions
- Senior Executives from Bio Test and Process Service Providers

Testimonials

John Patava, Senior Director, Quintiles
I think that the program put together by BMAP was really first rate, and there was sufficient variety and breadth of subject matter to make for a highly informative and interesting meeting. So well done from that point of view.

Chris Ma, Senior Manager, Merck Group
The biosimilar forum organized by BMAP is very informative and quite helpful to our work, which is the most impressive forum I have ever attended surrounding biosimilar topics.

Xuepeng Deng, Director, Shandong Ruiying Pioneer Pharma
Through regulatory and case analysis, I learned the essence of Biosimilars R&D Guideline which is totally different from past. The forum pointed out the direction of approval and process, which could avoid detours for us.

Ying Huang, VP, Lvzhu Biotech
Speakers that the forum invited were all experts in this industry. Topics includes all aspects of Biosimilars, from which I deeply understand biosimilars regulatory requirements, market prospect, industry progress and precautions in all stages. All in all, I benefit a lot from the forum. Thank Committee!
FORUM 1: World-China Biosimilars Forum

China is now in the prosperous development of Biosimilars, and meanwhile CFDA released Technical Guidance for R&D and Evaluation of Biosimilars in March 2015. Biopharmaceutical industry pays close attention to the various evaluation practices - pharmaceutical, pre-clinical and clinical trials. On the basis of past two successful forums, 3rd World-China Biosimilars Forum will bring together the latest hot progress and challenges at home and abroad, starting from biosimilarity evaluation to specially focusing on the real challenges of Cell Strain Development and Clinical Trials, to help domestic biopharmaceutical enterprises know how to ensure product quality from start, R&D cost saving and accelerating the pace of market access.

16th Day One

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<td>09:00</td>
<td>Discussed CMC Part of China’s Biosimilars Evaluation</td>
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<td>09:45</td>
<td>Update on Biosimilars Regulation in Europe</td>
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<td>EMA Perspective: Case Sharing on Waiver and Supplement in Late-stage Development of Biosimilars</td>
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<td>11:45</td>
<td>Design and Development of Biosimilar mAbs in China: From Project initiation to IND Filing</td>
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<td>Internationalization Strategy and Tactics Sharing for Global Biosimilars Development</td>
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<td>Establishing Clinical Plan to Accelerate Market Access</td>
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<td>Orientation and Comparability Design in Biosimilars Clinical Trials</td>
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<td>Statistical Perspective: Scientific and Rational Consideration in Enrolled Patient Number</td>
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Internationalization Strategy and Tactics Sharing for Global Biosimilars Development
- What’s first step to start up biosimilar internationalization?
- Regulatory considerations to EU/US
- Emerging markets’ regulations
- Market evaluation and acceptance
- IP strategy

China Biosimilar Developers Soon Going Global?! -aspects to be addressed when entering the EU market with biosimilar products ‘made in China’
- General aspects and market entry situation
- Potential barriers and critical questions for EMA filing
- Influence on trial design and comparator supply

Panel Discussion: The Correlation of Pharmaceutical Quality Analysis and Pre-clinical/Clinical Evaluation
- Which specifications are related to drug activity?
- Which quality characters will influence drug vivo behavior?
- How to resolve the correlation of construction and function in complex protein?

Moderator: Xiangyang Zhu, CEO, Huabo Biopharm
Panelists: Zheru Zhang, CEO, Shanghai JMT Bio Inc

Establishing Clinical Plan to Accelerate Market Access
- Principles behind Biosimilar development
- The key factors to shorten time of clinical trials
- Designing methodology to guide 1 and 3 phase clinical practices
- Clinical practice case study in 3 phase

Statistical Perspective: Scientific and Rational Consideration in Enrolled Patient Number
- Compared to innovative drug, what’s the difference between the two?
- Scientific consideration on enrolled patient in all phases for biosimilars
- What’s the suitable selection for new indications?
### Day Two

#### 17:50 - 18:00
**Panel Discussion: Confronting the Challenges of Mass Reference Products and Funds in Late-stage Clinical Trials**
- The necessity of reference research in clinical trials
- Resources for purchasing reference products
- How to minimize the cost and elevate feasibility of clinical trials
  
  **Moderator:** Qing Zhou, CSO, Genor Biopharma Co., Ltd

#### 11:45 - 12:00
**Monitoring Strategy on Biosimilarity of Protein Post-Translational Modifications in Up-and-Down Streams**
- What's the category of PTM and how to correctly modify in the first step?
- How to minimize the risk (variant, isoelectric point offset) of PTM?
- Quality tracker and control strategy to ensure PTM quality
  
  **Claudia Lin, Vice President of Quality, Innovent Biologics**

### Lunch Break

#### 12:30 - 13:30
**Culture Medium/Additive's Optimization to Upgrade Protein Quality**
- Novel additive to improve cell culture process
- Novel additive to recover quality in later phase of development
- Impurity considerations

#### 14:00 - 15:00
**Downstream Process Development**
- Purification and Identification Comparison Strategy on Impurities in Biosimilars' Scale-up
  - Analyzing the possible impurities, and choosing suitable purification strategy
  - How to ensure similarity after purification?
  - Case study on impurity analysis and identification after purification

#### 14:45 - 15:00
**Corresponding Solutions on Biosimilars Uniformity Between Batches**
- Key factors considered in process stability and uniformity
- Quality control's strategy
  - How to handle glycoprotein in different batches and bioreactors
  - How to make all variants in different phase under control

#### 10:30 - 11:00
**Tea Break**

#### 11:00 - 12:00
**Optimization Strategies of Cell Culture Process on Biosimilars' Quality Stability**
- What are the key process criteria for cell culture process development?
- How to set optimum parameter through DOE to ensure stability?
- Culture medium's ingredients selection consideration
  
  **Changlin Dou, VP, Luye Pharma**

### Upstream Process Development

#### 16:15 - 16:30
**Tea Break**

#### 16:45 - 17:00
**Panel Discussion: Implementing High Quality Manufacturing under QbD**
- How to determine Biosimilars’ quality standards?
- How to determine critical quality attributes?
- How to ensure CQA through PAT monitoring?

### End of Conference Day Two

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**Website:** www.bmapglobal.com/wcbf2016/
In the next few years, China's vaccine industry will grow faster than other traditional medical industry, and the growth rate of innovative vaccine will be expected to exceed 50%. In the positive market environment, traditional vaccine oriented R&D status is also changing and vaccine and therapeutic vaccine represented has become the focus of enterprise strategy and R&D highlights. Domestic vaccine industry environment and regulatory mechanism is making steady improvement, and meanwhile industry are very concerned about practice details such as latest Novel Vaccines' R&D progress, regulatory requirements and industrialization challenges of high quality. World-China Novel Vaccine Forum will gather Novel Vaccines' hot progress and challenges, particularly focusing on entire quality control challenges in industrialization, to help enterprises to achieve high quality management, shorten development time, save R&D cost and speed up market access of Novel Vaccines.

**Theme for 2016:**
Focusing on Innovative and Me-Better Vaccine R&D Progress, and Breaking though High Quality Industrialization Challenges

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<td>China's Epidemic Disease Analysis and Opportunities for Vaccine R&amp;D</td>
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<td>Sharing on International Therapeutic Vaccine R&amp;D and Registration</td>
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<td><strong>QbD Early-stage Structure for Novel Vaccine</strong></td>
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<td>The Application of Next Generation Adjuvant Technology in Novel Vaccine Development</td>
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**QbD Early-stage Structure for Novel Vaccine**

- Discovering and Structuring Stable and Effective Candidate Antigen for Viral Vaccines —— Taking Enterovirus-Sabin Polio and EV71 for Example
  - How to find and capture the perfect sequence?
  - What are key factors and steps in structuring process?
  - How to ensure candidate antigen’s high efficacy and stability?
  - Case sharing from discovery to development
  - Tarek Hussain, Health Consultant, Unicef

**International Emerging Market Demands and R&D Opportunities in Novel Vaccines**

- What’s the regulatory environment of emerging markets (Southeast Asia etc)?
- Epidemiology in emerging markets
- Market size and competitiveness analysis
- Market access and acceptance
  - Tarek Hussain, Health Consultant, Unicef

**Update on Novel Vaccines Guideline in Europe**

- Update the guidance of influenza, malaria, pneumonia etc vaccine
- Definition of therapeutic vaccines to categorize
- The latest quality requirements of novel vaccines with new technology
  - Angela Thomas, Vice Chair CHM, Chair of Clinical Trials, Biologicals and Vaccines Expert Advisory Group MHRA, UK

**ChP 2015: Change and Influence Analysis to Vaccines’ Quality Research and Management**

- What are the changes of New China Pharmacopeia regarding vaccine quality management?
- New test methods introduction to novel vaccines
- The requirements of methodology validation for vaccine
- How to test new technology combined vaccine?
  - Expert from Biologics Division, China Pharmacopeia (Inviting)

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**Novel Vaccine Preclinical and Clinical Design**

**Preclinical and Clinical Trials Sharing on First Dengue Vaccine in the World**

- Recombinant technology utilization in dengue vaccine
- Preclinical studies and its animal model structure sharing
- Clinical trials design and strategy case study
  - Jean-Denis Shu, Senior Medical Affairs Director, Sanofi Pasteur

**Sharing the Clinical Development of the 2nd Successful Cancer Vaccine Launch in US**

- T - Vex mechanism
- Cancer vaccine’s clinical development sharing
- IND/INDA experience sharing in US
  - Jacqueline Huang, Medical Development Director, Amgen

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**Domestic Regulations & International Market Overview**

- Epidemiology research update
- What’s the serotype distribution of infectious diseases (eg: pneumonia)
- Opportunities for designing vaccines
  - Prevention

**Tea Break**

**Impact on vaccination from packaging - Prefillable Systems for Vaccines**

- Introduction of prefillable systems for vaccines
- Clinical benefits of prefillable syringe
- Improving patients’ wellness - application of 5 bevel needle
  - BD

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**Luncheon**

- R&D progress in therapeutic vaccine
- How to classify and catalog it in drug registration
- Where are therapeutic vaccines’ opportunities?
  - Ki-Hwan Kim, Director, R&D of JW Creagene, South Korea

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**Welcome Speech**

**Domestic Regulations & International Market Overview**

**Tea Break**

**Impact on vaccination from packaging - Prefillable Systems for Vaccines**

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**Domestic Regulations & International Market Overview**

**Tea Break**

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FORUM 2: World-China Novel Vaccines Forum
March 16-17, Shanghai China

17th Day Two

Panel Discussion: Exploring Scientific and Effective Alternative Endpoints for Clinical Evaluation to Accelerate Market Access

- International regulatory guidelines
- Feasibility of alternate endpoints for vaccines’ clinical trials
- Methods of designing and evaluating with alternative endpoints

Moderator: Bin Wang, Professor, Fudan University School of Medicine

Quality Control for Novel Vaccine Industrialization

09:00 Overall Considerations on Vaccine Quality Control in Novel Vaccine Industrialization
- What are the key quality factors considered in vaccine R&D?
- How to decrease risk to minimum in process and manufacturing?
- Nowadays novel vaccines’ quality requirements

09:45 Coping with the Industrialization Challenges for Integration Process of HPV Multivalent Vaccine
- Revealing the challenge of multivalent vaccine’s integration
- The influence of protein structuring, vector, and adjuvant to industrialization
- How to ensure uniformity and stability in the process of production

John Zeng, EVP, Shanghai Zerun Biotech Co., Ltd

10:30 Tea Break

11:00 Executing Essentials of Manufacturing Novel Vaccines under New GMP System
- What are the new GMP requirements and key factors regarding quality management?
- How to make and control key quality standard in manufacturing and PAT application
- How is traceability and reproducibility satisfied under optimum production line?

11:45 Separation and Purification Strategy of Multivalent & Combined Vaccines Before and After Mixture
- How to define impurities and purification goals?
- How to keep immunogenicity when purification?
- Before and after mixture, how to simplify process of purification?

12:30 Luncheon

14:00 Precision Detection and Analysis Sharing on Conjugate Vaccine’ Polyose and Protein
- Defining polyose’s structure specification
- How to precisely identify protein assay
- How to control polysaccharide and protein ratio

Haifa Zheng, Founder & General Manager, Beijing Minhai Biotechnology Co., Ltd

Hot Novel Vaccine R&D Progress

15:30 Enlightenments from the Discovery of Basic Mechanisms for HIV Vaccines
- HIV mechanism research update and progress
- Novel technologies being used in HIV vaccine early-stage development
- Enlightenments for design and process development considerations

Ling Chen, Distinguished Investigator, Founding Director General (2004-2008), Guangzhou Institute of Biomedicine and Health Chinese Academy of Sciences, EX-Head of China Vaccine R&D Sanofi Pasteur

16:15 Tea Break

16:45 Update of Autoimmune Diseases Vaccine Therapy R&D
- R&D progress in autoimmune diseases vaccine in globe
- Introduce a novel technology platform
- The application in multiple diseases and progress

Bin Wang, Professor, Fudan University School of Medicine

17:30 Designing a Lifetime Immune Influenza Vaccine
- Influenza’s mutation challenges
- The mechanism of lifetime immune influenza vaccine
- How to design it and its development progress

Professor, Margaret A. Liu, Adjunct Full Professor, UCSF; Foreign Adjunct Professor, Karolinska Institutet

18:15 R&D Progress of Anti-cancer Therapeutic Vaccines
- Global anti-cancer therapeutic vaccines’ development
- Compared to immunotherapy, what’s the advantage of therapeutic vaccine?
- T cell-oriented vaccines structuring and its efficacy

Jun Ren, Professor of Medical Oncology, Executive Vice-Dean, Capital Medical University Cancer Center; Faculty, Department of Surgery, Duke University Medical Center

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