The 2nd China International Biopharma 4.0 Summit

March 21-22, 2019 Shanghai, China

8:00 Registration & Networking

8:50 Opening Address

I. Policy

9:00 Interpretations on the “13th Five-year” Development Planning of China’s Pharmaceutical Industry

-Necessity to establish the unified Industry 4.0 Standard for the pharmaceutical industry
-Establishment of the centralized production base for small-variety medicine (inadequate medicine) centered on the supply side
-Integration of the pharmaceutical industry into the three national strategies

Wu Haidong
DeputyDirector of Department of Consumer Goods of the Ministry of Industry and Information Technology

II. Pharma Digitalization

9:30 Digitalization enables Smart HQ, group management and manufacturing base

-How to seamlessly connect base data to a group’s HQ
-VR and visualized digital facilities enable transparent group management
-How ABC（AI，Bigdata &Cloud）and informatization impact smart facilities
-Centralized R&D, digitalized design and operation for facilities management

Rohini R. Deshpande
VP Process Development
Amgen

9:50 Developing strategies for biosimilar drugs in China

Scott Liu
CEO
Henlius

10:20 Tea Break & Networking

10:45 Integrated software enables Industry 4.0 for biopharma companies

-Achieve Industry 4.0 step by step by evaluating a company’s current manufacturing and management ability and providing suitable solutions
-Integrated engineering to operation solutions help improve efficiency and productivity while ensuring patient safety and product quality
-Seamless integration solutions enable all-around combination of hardware and software at equipment, shop floor and corporate level

Emerson(Sponsor)

11:25 Implications of "4+7 Centralized Urban Pharmaceutical Procurement" program on generics

-How to maintain the profitability against dramatic cut on ASP for the bidding winners？ Is there any potential quality hazard of the drugs ?
-How to maintain the market penetration against a highly competitive market after the bid failed?
-Will the generic makers without a diversified portfolio and key technologies be doomed to be merged or integrated as more and more quality consistency evaluation to be carried out?

CTTQ， CFDA，BMS, etc....

12:05 Luncheon

III. Biopharmaceutical intelligent manufacturing

13:30 Investment in Building up a World Class Biomanufacturing in China

-How Biopharmaceutical manufacturing will fuel technology innovation
-Flexibility is key for future biomanufacturing, with speed and cost-effectiveness supporting
-Investment in advance technology to reach future state in smaller and more flexible facilities

Frank Ye, Ph.D.
Senior Vice President of Technical Operations
Hangzhou Just Biotherapeutics

14:00 Single-use system new design concept and localization of Saint-Gobain

14:40 Under the B Pharma Supply Chain Improvement, Share of USA FDA this new Good Supply Practice

As a member of the industry team with the Xavier University I have developed together with the University itself and USA FDA this new Good Supply Practice which will become an industrial standard during the next year on the field of the supplier qualification.

ViliamKovac
Global Supply Chain Compliance
ROCHE

15:10 Tea Break & Networking

15:35 Industry 4.0 & Track B

GE HealthCare

16:15 Integrating Next-generation Process, Technology and Operation to Modernize Biomanufacturing

-This talk will describe Biogen’s approach to modernize biomanufacturing by integrating highly productive manufacturing processes, enhanced process controls and efficient operations.
-This next-generation manufacturing (NGM) mode will be implemented in Biogen’s new facility in Solothurn, Switzerland, which will start production in 2019.
-The Solothurn facility is designed to deliver up to 20 metric tons of biologics drug substance annually from the two biomanufacturing cells (BMCs).
-The Solothurn facility will use industry leading manufacturing processes capable of delivering 10 g/L cell culture titer, advanced process controls for robust and consistent manufacturing performance and fully automated recipe driven operations.
-The Solothurn facility exemplifies a solution of high throughput, high efficiency, and modernized biomanufacturing to supply high volume demand biologics.

Canping Jiang Ph.D.
Head of Manufacturing Sciences in Biogen’s Solothurn facility in Switzerland

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16:45 Keynote round-table discussion: Path of Transformation

Successful Strategic Transformation of Bristol-Myers Squibb to Biological Pharmacy!

The global pharmaceutical giants are transforming into oligarchs after the financial crisis in 2008, but they remain comprehensive corporations in terms of the corporate business structure. Different from other companies, BMS has successively eliminated the non-pharmacy business,and gradually transformed into a biological pharmaceutical company according to the corporate strategy. In the past decade, BMS has overcome numerous difficulties in the transformation with a firm belief. The current rising profit rate and simplified corporate structure have proved that BMS made a correct decision ten years ago. What enlightenment does the successful transformation of BMS bring forth to the pharmaceutical enterprises under a similar economic environment ten years later?

16:45 BiologicalPharmaceutical4.0 leader round-table

Round table 1:

Large size is no longer the strength for pharmaceutical companies, but compactness has gradually become a tendency

Excellent leaders are always tough and decisive. They can formulate aggressive plans with great insight to change the development path of the company instead of waiting for external turnarounds. Large size is no longer the strength for pharmaceutical enterprises, but compactness has gradually become a tendency. However, maybe we shall have a clear and objective understanding of the current status of the company to judge whether it is suitable to us.

Is it the new way out for traditional pharmaceutical enterprises to invest several billion in the biological pharmacy? Why newly established biological pharmaceutical companies gain great popularity?

The capital industry entered into depression at the beginning of 2018, but the biological-pharmaceutical industry has good prospects. Many young biologicalpharmaceutical enterprises have successfully made IPO before they obtain the approval from FDA for clinical test. It is a brand-new campaign for traditionalpharmaceutical enterprises to make investments in the biological pharmacy no matter whether they are optimistic about the prospects of the biological pharmacy, or they realize transformation due to the pressure of performance. Will the investment made by Sanofi in JHL or the alliance between Eli Lilly and Company and Cinda bring a brighter future for investors and newly established enterprises?

Round Table 2:

It will become inevitable for enterprises to invest in the digital technology in future!

The companies that fail to regard the digitalization as the key part of the transformation strategy maybe should reconsider their plan.Is it worthwhile for leaders to make investments in the digital technology to improve the customer experience, enhance the product quality and service level, improve the internal efficiency and develop new business modes?

17:45 Round Table Q&A

17:50 End of Day 1

Day 2 (Session A) Single-use system and smart manufacturing in Biopharma

8:30 Registration &Networking

8:50 Application of international pharmaceutical single-use system (SUS) and technical guidance

-Necessity and rationality of promoting SUS in pharmaceutical industry
-FDA's opinion and regulatory expectation of SUS
-Overview of currently applicable SUS standards
-United States Pharmacopeia's choice of drug manufacturing system and opinions and standards for verification

Dr. Dennis Jenke
Member of Packaging Material and Circulation Committee, USP, Chairman of Pharmaceutical Plastic System Expert Group, Chief Scientist of Triad Scientific Solutions

9:20 Global Single-Use concept and facilities design – The Journey to Build the World's Largest Single-Use Modular Facility in China

-Feasibility analysis on single-use facilities
-How to implement single-use solution to optimize up-streaming processing
-Advantages and feasibility of single-use solutions in down-streaming separation and purification

Mr. Racho Jordanov
CEO
JHL Biotech Inc.

9:50 Smart and effective solutions for cGMP manufacturing of AAV based Gene Therapy Products

-High degree of complexity for AAV based manufacturing processes require innovative approaches to achieve quality and cost targets
-Smart design of AAV dedicated multi-product plants positively impacts output and reduces compliance risks
-Robust process validation strategies reduce patient and approval risks

Roman Necina
SVP Process Development & Technical Services
Shire

10:20 Tea Break & Networking

10:45 Sartorius StedimBiotech(Sponsor)

11:25 Recent Advances in Cell Culture Platform of WuXi Biologics

-Application of single-use biotechnology in scale-up and tech transfer
-Innovated cell culture processes to improve productivity;
-Application of high throughput screening tools in accelerating CMC progress

Huilin Zhu, Ph.D
Director, Cell Culture Process Development
WuXi Biologics

11:55 Luncheon

13:30 Hybrid modeling and enhanced DoE strategy to ensure manufacturing quality in Biopharma

-Importance of implementing QbD in Biopharma
-Ensure efficiency and quality from hybrid modeling to simulative development and mass manufacturing (transferred from lab technology to workshop)
¬-How to use hybrid modeling to enhance and implement DoE during fermentation?
-How to mine manufacturing data and implement online monitoring of key quality parameters based on PAT to achieve continuous manufacturing

Alex Marchut
Principal Scientist
Advanced Technology Center of Excellence
Technical Operations, Janssen Supply Chain

14:00 The Validation Method Introduction of Extractables and Leachables for Single Use System and Filters based on QbD Approach

QbD is a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, and it can be implemented on the SUT design, manufacture and process validation (such as Extractables and leachables, E&L) steps. Determination of extractables and leachables (E&L) is important as E&L compounds from plastic SUS components and filters potentially can leach into final drug products and compromise efficacy and safety. In this overview, we will share the implementation, challenge and optimization of E&L validation method.

Pall (Sponsor)

14:40 Deliver high quality vaccines globally in compliance with local regulations

-Production of vaccines is one of the most complicated and long manufacturing and control process amongst pharmaceutical products
-Up to 70% of the standard production time of a vaccine is dedicated to quality control, duplicated by tests performed by national control labs
-Like any other pharmaceutical product, vaccines are regulated by multiple local regulations as there is no harmonized regulatory processes in the world
-With never ending increase of regulatory requirements, the situation is reaching a point which may trigger more than ever supply issues of vaccines
-Let's call for action so that local regulations do not represent a barrier for continuous improvements and innovation for vaccines and ultimately Public Health

Thierry Gastineau
Associate Vice President /
Head of Global Regulatory-CMC for Vaccines
sanofipasteurs.a.

15:10 Tea Break & Networking

15:35 Open for Sponsor

16:05 Study on SUS extract and extractable and localization verification service

-Classification of SUS risks in biologics
-Verification approach for SUS extract and extractable based on QbD concepts
-Representation of extract and extractable associated with drug: advanced analysis method and challenges
-Toxicological assessment method in extract and extractable study

Patrick Evrard, Senior Technical Manager at MSAT
SUS, GSK
NICPBP

16:35 Continuous manufacturing enabled by Single-use technology

-Single-use technology enables fully integrated and continuous manufacturing
-Single-use technology helps facilities reduce time to clean up and verify cleanliness
-The implementation of RABS in internal design can improve the efficiency of sterile manufacturing
-Achieve continuous manufacturing and real-time discharge with advanced and innovative platform technologies and solutions

HenckelThilo
Vice President, Head of Manufacturing
Roche Diagnostics GmbH

17:05 Round Table: Advantages and limits of SUS equipment

-Single-use technology and sustainable development: quantify environmental impacts
-How to control risks in supply chain and what data should suppliers provide?
-How to solve processes regarding dissolved matters and precipitates as well as patient safety risks?
-Prospect of large-scale commercialization of single-use technologies

LivzonMabs

17:50 End of the Summit

Day 2 (Session B) Latest Outsourcing Modes and Biopharma R&D

8:30 Registration &Networking

8:50 Interpretation of MAH policies

-Headwinds in MAH pilot project during its three-year implementation and suggestions for the challenges
-How does MAH deal with complicated situations like corporate relocation, M&As?
-Are MAH researchers capable of being legally accountable as the MAH holders?
-MAH improves drug regulatory responsibilities of regulatory authorities of two places.

Vice Director
Shanghai Food and Drug Administration

9:20 How ADC works as a model for managing outsourcing and implementing innovation

-Manage the challenges in local manufacturing base
-What strategies can be used to improve the manufacturing quality in emerging pharmaceutical oursourcingprojects
-What key methods should be taken to achieve better integration with external supply chain?

Gajendra Ade
Regional Lead-Third Party Manufacturing
AbbVie

9:50 CDMO helps industry resources integrate and promote medical development

MabPlex（Sponsor）

10:20 Tea Break & Networking

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10:35 Addressing the challenges in outsourcing of pharmaceutical manufacturing

-How to manage the supplier base and its complexity
-Which structure could support an effective oversight of the supplier base
-Which risks to be considered when building strategic and large partnerships

Pascal Wotling
Head of External Supply Operations APMA
Novartis Technical Operations

11:15 Panel Discussion：Future innovative profit trends in the CDMO industry

With high technological barrier and strong profitability, CDMO has a government-supported promising future accompanied by ever-increasing competition. What should a company do to improve and innovate its technologies and services to bring back more revenue?

11:55 Luncheon

13:30 The challenges and outlook for biosimilar development with CDMO business format in China

A biosimilar is not regarded as a generic of a biological medicine because the natural variability and more complex manufacturing of biological medicines do not allow an exact replication of the reference medicine. But biosimilars are approved according to the same standards of pharmaceutical quality, safety and efficacy that apply to all biological medicines. Therefore, developers of biosimilars are required to demonstrate through comprehensive comparability studies with the 'reference' biological medicine that demonstrate not only their product is highly similar to the reference medicine, but also there are no clinically meaningful differences between the biosimilar and the reference medicine. Based on both EU and USA established solid framework for biosimilar approval, this presentation will address some key considerations and co-development strategy using CDMO platform. The efficient collaboration model between development companies and CDMO will be explored. The application of risk based approach with Quality by design concept will be discussed. Last but not the least, the advantages of the partnership between CDMO and development companies will be fully demonstrated.

Liming Shi
Sr. Director, QC
CMAB Biopharma

14:00 Innovative CDMO boosts biopharmaceuticals from target to product conversion

GenScript（Sponsor）

14:40 Which criteria are necessary to evaluating the basic performances of a CDMO company as a potential partner from the perspective of risk mitigation?

(expertise, capacity, production output, cost control, supply chain management, etc.)

15:10 Tea Break & Networking

15:35 Drugpatent linkage system and policy recommendations

-Analysis of U.S. drug patent linkage system
-Introduction of Japan and EU drug patent protection systems
-The implications of establishing a drug patent system in China and policy recommendations

Justin Wang
Managing Director in L.E.K.'s Shanghai office,
and a leader in L.E.K. China's Life Science practice

16:05 Open for Sponsor

16:35 Use of Real World Data (RWD) in Drug Development and Regulatory Submission Process

17:00 Round Table: Business modes of contract manufacturing under MAH system

-RWD is collected outside of a controlled clinical trial
-RWD can improve health outcomes and reduce costs
-RWD analysis informs the following:
1.The development of new treatments and cures
2.Medication safety monitoring
3.Optimal clinical practice

John Alter
VP Global Health & Value,
Global Established Pharma Business Unit
Pfizer

17:05 Round Table: Business modes of contract manufacturing under MAH system

-Develop a check-and-balance system on MAH with insurers and third-party assessment organizations
-Learn from mature contract-out modes in Europe and U.S.
-Is MAH obligatory on the effectiveness, feasibility and safety of drugs?
-How to ensure drug quality under MAH system?
-Values from CMOs to end users

17:50 End of the Summit

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