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2024 美国药典治疗性抗体药物质量与分析技术交流会

USP Therapeutic Antibody Drugs Workshop on Quality and Analysis Technologies 2024

2024 年 4 月 17-18 日　中国 | 上海
April 17-18, 2024, Shanghai, China

主办 **Host：** 美国药典委员会 (U.S. Pharmacopeial Convention)
协办 **Co-host：** 上海市食品药品检验研究院 (Shanghai Institute for Food and Drug Control)

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会议介绍 Conference Introduction：

生物医药领域近年来在全球范围内备受瞩目，而治疗性抗体药物作为其中的翘楚，一直备受关注。回顾历年全球畅销药物排行榜，抗体药物在 Top10 榜单中占据了半壁江山，展现出强大的市场潜力和价值。随着技术进步和法规监管与政策的支持，中国抗体药物产业呈现出蓬勃发展态势。在单克隆抗体的基础上，抗体-药物偶联物 (ADC) 和双特异性抗体也取得了显著进展，进一步推动了抗体药物产业的多元化发展。在全球化合作的大背景下，中国抗体药产业在 2023 年取得了重大的国际突破。美国食品药品监督管理局 (US FDA) 先后批准了两款国产抗体药物在美上市，这一里程碑事件标志着国产抗体药物的质量已经逐步与国际标准接轨，不仅彰显了中国抗体药物产业的实力和水平，也为中国生物医药产业的国际化发展打开了新篇章。

抗体药物的质量控制与分析是至关重要的环节，涵盖了理化标准、活性分析、杂质控制等多个方面，需要运用分子生物学、细胞生物学、质谱与色谱等多种分析技术，并涉及从设计开发到上市后变更的产品全生命周期管理。对于抗体药物生产企业而言，提升分析能力、建立合适的药物质量标准、确保产品的安全有效和质量可控是一项具有挑战性的任务。

美国药典委员会 (USP) 作为具有 200 多年历史的药品质量标准制定机构，致力于制定有助于确保药品和食品的质量、安全性和效用的公共标准及相关方案，为改善全球健康状况做出了卓越的贡献。USP 始终关注生物制品领域的发展，在过去几年中，USP 一直积极与国内利益相关方交流与合作，助力生物医药产品质量提升。

本届会议汇聚了来自国内外药品标准制定机构、法规监管机构、抗体药物研发生产企业、CRO/CMO 组织、科研院校的技术专家和意见领袖，将围绕标准建立、理化分析、活性方法开发、工艺相关杂质等多类专题展开深入交流和讨论。通过分享经验和观点，与会者将能够深入了解抗体药物领域的最新动态和技术进展，为未来的研究和产业发展奠定基础。我们期待与您共同探讨抗体药物领域的未来发展，为人类健康事业做出更大的贡献。

The field of biologics has attracted worldwide attention in recent years, and therapeutic antibody drugs have been the focus of attention as the leading ones. Looking back at the ranking list of the world's best-selling drugs over the years, antibody drugs account for half of the Top 10 list, showing strong market potential and value. With the support of technological progress, regulation and policies, China's antibody drug industry is showing a vigorous development trend. On basis of monoclonal antibodies, antibody-drug conjugates (ADC) and bispecific antibodies have also made significant progress, further promoting the diversified development of the antibody drug industry. In the context of global cooperation, China's antibody drug industry has made significant international breakthroughs in 2023. The US FDA has approved two domestic antibody drugs for marketing in the United States, marking a milestone event that indicates the quality of domestic antibody drugs has gradually been in line with international standards. This achievement not only demonstrates the strength and level of China's antibody drug industry, but also opens a new chapter for the international development of China's biologics industry.

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The quality control and analysis of antibody drugs is a crucial step, covering many aspects such as physicochemical characterization, bio-activity analysis, and impurity control. These processes require the use of various advanced analytical techniques such as molecular biology, cell biology, mass spectrometry, and chromatography, and involves the management of the entire product life cycle from design and development to post-market changes. For antibody drugs manufacturers, improving analytical capabilities, establishing quality standards, and ensuring the safety, efficacy, and quality control of products are challenging tasks.

USP is a drug quality standard-setting body with a history of more than 200 years. It is committed to developing public standards and related programs that help ensure the quality, safety, and effectiveness of drugs and foods, and has made outstanding contributions to improving global health. USP has been paying attention to the development of the field of biological products. In the past few years, USP has been actively communicating and collaborating with domestic stakeholders to jointly improve the quality of biomedical products.

This workshop brings together scientists and opinion leaders from domestic and foreign drug standard setting organizations, regulatory agencies, antibody drug research and development production enterprises, CRO/CMO organizations, and academic institutions. Participants will engage in in-depth exchanges and discussions on topics such as standard establishment, physicochemical analysis, bio-active method development, process-related impurities, and more. The workshop will provide a valuable platform for participants to exchange ideas and promote the development and innovation of the antibody drug industry. By sharing experiences and perspectives, participants will be able to gain insight into the latest developments and technological progress in the field of antibody drugs, laying a solid foundation for future research and industrial development. We look forward to discussing the future development of the antibody drug industry with you and making greater contributions to human health.

参会对象 Who Should Attend：

治疗性抗体药物领域的原料药/制剂生产、研发人员；国际注册和法规事务人员；国际市场开发人员；质量负责人及其专员；质量标准、法规监管人士；质量和技术研究的学术机构/科研单位人员；以及其他对研讨会主题感兴趣的人员。

Therapeutic antibody drugs API/formulation manufacturing and R&D; international registration and regulatory affairs; international marketing; quality control and quality assurance; standard-setting and regulatory; academic research involving quality and analytical technologies; others interested in the topics of the workshop.

会议地点 Location:

上海锦江汤臣洲际大酒店 InterContinental Shanghai Pudong

地址：上海市浦东新区张杨路 777 号

Address: No.777 Zhangyang Road, Pudong District, Shanghai

会议语言 Language：

中文/英文（提供同传服务） Chinese / English (simultaneous interpretation will be offered)

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会议主题与嘉宾 Topics and Speakers：

第一天 Day 1　17th April 2024

标准建立与提高 Standards Establishment and Improvement

美国药典生物制品与单抗药物标准进展 Overview of USP Biologics and mAbs Standards Update

Annu Uppal，美国药典委员会科学事务与战略总监

Annu Uppal, Director, Scientific Affairs & Strategy, USP

单抗药物：质量与监管考量 mAbs Drugs: Quality and Regulatory Aspects

Susan Kirshner，美国食品药品监督管理局药品评价和研究中心生物学家

Susan Kirshner, Biologist, CDER, US FDA

单抗制品中吐温含量分析方法的研究进展

Research Progress of Analytical Methods of Tween Content in Monoclonal Antibody Products

俞小娟，中国食品药品检定研究院单克隆抗体产品室

Xiaojuan Yu, Division of Monoclonal Antibody Products, National Institutes for Food and Drug Control (NIFDC)

内毒素分析控制和法规要求 Endotoxin Analysis Control and Regulatory Requirements

高华，中国食品药品检定研究院原药理室主任

Hua Gao, Former Director of Pharmacology Department, National Institutes for Food and Drug Control (NIFDC)

理化表征 Physicochemical Characterization

中国抗体产业发展现状与展望

Development Status and Prospect of Antibody Industry in China

陈迎，中国医药工业信息中心行业研究员、市场学术部总监

Jemilia Chen, Researcher & Marketing Director, Chinese National Pharmaceutical Industry Information Center

生物制品质量控制中的分析方法生命周期管理

Analytical Procedure Life Cycle in Biologics Quality Control

Amanda Guiraldelli Mahr，美国药典委员会科学事务经理

Amanda Guiraldelli Mahr, Scientific Affairs Manager, USP

质量考量：产品与过程相关杂质分析

Quality Considerations: Product and Process Related Impurity Analysis

Annu Uppal，美国药典委员会科学事务与战略总监

Annu Uppal, Director, Scientific Affairs & Strategy, USP

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会议主题与嘉宾（续）Topics and Speakers (Cont.)

分析超速离心技术在生物药质量控制中的应用
The Application of Analytical Ultracentrifugation (AUC) in the Quality Control of Biopharmaceuticals
李文奇，清华大学蛋白质制备与鉴定平台主管/高级工程师
Wenqi Li, Facility Manager of Protein Purification and Identification/Senior Engineer, Tsinghua University

ADC 药物质量控制挑战　ADC Drugs Quality Control Challenges
齐桂平，荣昌生物制药(烟台)股份有限公司质量研究总监
Guiping Qi, Director, Quality Research, RemeGen (Yantai)

第二天 Day 2　18th April 2024

生物活性　Biological Activity

USP 通则<86> “使用重组试剂进行细菌内毒素测试” 和内毒素控制
USP General Chapter <86> and Endotoxin Control
Huiping Tu，美国药典委员会科学部门通则资深首席科学家
Huiping Tu, Senior Principal Scientist, Science-General Chapters, USP

美国药典通则<1108>: 评估 Fc 介导效应的分析测试
USP GC <1108>: Assays to Evaluate Fc-mediated Effector Function
Xiaolei Zhuang，美国药典委员会全球生物制品部门首席科学家
Xiaolei Zhuang, Principal Scientist, Global Biologics, USP

AQbD 理念在基于细胞体外生物活性方法开发中的应用进展
The Application of AQbD in the Development of Methods Based on In Vitro Biological Activity Analysis
段徐华, 上海市食品药品检验研究院 生化药品生物制品/微生物所副所长
Xuhua Duan, Deputy Director, Division of Biochemical Drug & Biological Products/Microbiology, SIFDC

ADC 分子生物活性标准建立的考量
Considerations for the Establishment of Biological Activity Standards for ADC Molecules
施立明，药明合联生物技术有限公司副总裁
Liming Shi, Vice President, WuXi XDC Co., Ltd.

抗体药物活性分析最佳实践　Best Practices of Antibody Drugs Potency Analysis
焦吉祥，罗氏制药产品质控负责人和中国分析技术负责人
Jixiang Jiao, Senior Analytical Technical Lead for Global and China, Roche

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工艺相关杂质 Bio-Process Impurities

会议主题与嘉宾（续）Topics and Speakers (Cont.)

抗体药物分析方法变更 Changes of Antibody Drug Analysis Methods
任民，成都康诺行生物医药科技有限公司质量管理执行总监
Min Ren, Executive Quality Director, Keymed Biosciences Inc.

双特异性抗体的杂质研究和质量控制 Impurity Study and Quality Control of Bispecific Antibodies
熊晖，武汉友芝友生物制药股份有限公司 质量负责人
Hui Xiong, Quality Head, Wuhan YZY Biopharma Co., Ltd.

美国药典标准支持生物制药中 HCP 分析
USP Standards to Support Residual Host Cell Protein Analysis in Biopharmaceuticals
Ying Han，美国药典委员会全球生物制品部门资深科学家
Ying Han, Senior Scientist II, Science-Global Biologics, USP

质谱技术在单抗类制品宿主细胞残留蛋白检测中的应用研究
Study on Application of Mass Spectrometry in Detection of HCP of mAb Products
尹红锐，上海市食品药品检验研究院生化药品生物制品/微生物所重组药物室副主任
Hongrui Yin, Deputy Head, Department of Recombinant Drug, Division of Biochemical Drug & Biological products / Microbiology, Shanghai Institute for Food and Drug Control

抗体药物质量控制中的 HCP 分析
HCP Analysis in Antibody Drug Quality Control
李珍，信达生物制药（苏州）有限公司 生物活性分析经理
Zhen Li, Bio-activity Analysis Manager, Innovent Biologics (Suzhou) Co., Ltd.

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参会费 Conference Pricing：

参会单位 Participant Type	参会费用 Standard Registration Rates	早鸟优惠 （2024.3.25 前报名缴费） Early Bird Discount until Mar. 25th	团队优惠 Group Discount
企业 Industries	RMB 2,300 元/人	RMB 1,950 元/人	同一单位第二人起 50%折扣 50% discount for 2 or more people from the same organization
政府机构 、科研院校 Government, Research Institutes	RMB 1,850 元/人	RMB 1,500 元/人	

备注：1. 参会费包含会议费、资料费、茶歇及午餐费，其他费用自理。
Including fees of attending, conference materials, coffee break and lunch only.
2. 会务组不统一安排住宿。若需要，可联系主办方了解会议酒店信息。
Please arrange accommodation by yourself.

报名方式 Register Procedures：

1. **在线报名：**USP 会议与培训中文平台 www.usp-edu.org，**报名/缴费截止日：2024 年 4 月 10 日**
Make online registration and payment by Apr. 10th, 2024.

   USP-China 人民币收款账户： USP-China account (RMB)

   收款人 Beneficiary:　美药典标准研发技术服务（上海）有限公司
   账号 Account No.:　6841 12464 120
   银行 Bank:　美国银行有限公司上海分行

2. **发票内容及领取**：开票内容- “培训费“或”服务费“或”咨询费“（在线报名时请按需选择）；会后统一发送电子发票至参会者邮箱。
Content of Invoice – “Training fee”, or “Service fee”, or “Consulting fee” (Please select during registration).
E-invoice will be sent by email after the workshop.