

## 美国药典在线点播课程 *USP On-Demand Webinar*

### 美国药典“通则<1060>基于质谱的治疗性蛋白多属性方法 (MAM)” 的最佳实践 Best Practices for Mass Spectrometry-Based Multi-Attribute Method (MAM) for Therapeutic Proteins USP General Chapter <1060>

课程时长 **Course Duration:** 63分钟 63 mins



免费视频课!

#### 课程介绍 **Course Description:**

与传统方法相比，生物治疗分析测试的多属性方法 (MAM) 因具有提高效率 and 提供更详细的产品质量属性 (PQAs) 信息的潜力而越来越受到关注。本课程将重点介绍美国药典标准和用于支持 MAM 产品表征和质量控制的工具。课程也将介绍影响 MAM 质量和一致性的考虑因素、加强方法稳健性的方式和案例研究。

*(该课程的现场版本录制于 2023 年 6 月 14 日)*

Multi-Attribute Method (MAM) for analytical testing of biotherapeutics is gaining traction due to its potential to improve efficiency and provide more detailed information on product quality attributes (PQAs) as compared to conventional methods. This webinar will focus on the development of USP standards and tools to support MAM for product characterization and quality control. Considerations that impact the quality and consistency of MAM, approaches to enhance the method robustness, and case studies will be discussed.

*(The live version of this recording took place on June 14, 2023.)*

#### 参课对象 **Who Should Attend:**

负责治疗性蛋白产品的生产与测试的科研人员、管理人员和法规监管人员

Scientists, managers, and regulatory experts responsible for the manufacture and testing of therapeutic proteins

#### 授课语言 **Language:**

英语 (含英文字幕) English (with English subtitles)

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### 美国药典“通则<1060>基于质谱的治疗性蛋白多属性方法 (MAM)”的最佳实践 Best Practices for Mass Spectrometry-Based Multi-Attribute Method (MAM) for Therapeutic Proteins USP General Chapter <1060>

#### 讲师介绍 Instructor:

- 景丽博士, 美国药典全球生物制品资深科学家  
**Dr. Li Jing, Principal Scientist, Global Biologics, USP**

景丽博士是USP全球生物制品部门的资深科学家。景博士领导一个联络员团队, 与USP专家委员会和多个蛋白质、多肽和碳水化合物专家顾问组共同协作, 制定支持生物药质量评估和开发的标准。近期, 景博士与USP MAM专家顾问组合作, 制定“通则<1060>基于质谱的治疗性蛋白多属性方法”。景博士拥有美国佐治亚大学分析化学博士学位, 以及复旦大学化学学士学位。她曾就职于多家生物技术和制药公司, 专注于蛋白疗法和候选疫苗的开发。

Dr. Li Jing is a Principal Scientist in USP's Global Biologics Department. Dr. Jing leads a team of liaisons working with the USP Expert Committees and multiple expert panels for proteins, peptides, and carbohydrates to develop standards that support biopharmaceutical quality assessment and development. Recently, Dr. Jing worked with the USP MAM Expert Panel and developed General Chapter <1060> Mass Spectrometry Based Multi-Attribute Method for Therapeutic Proteins. Dr. Jing holds a Ph.D. in Analytical Chemistry from the University of Georgia and a B.S. in Chemistry from Fudan University. Dr. Jing has worked for several biotechnology and pharmaceutical companies, focusing on the development of protein therapeutics and vaccine candidates.

- **Da Ren 博士, BioTherapeutics Solutions 公司创始人**  
**Dr. Da Ren, Founder, BioTherapeutics Solutions**

#### 报名方式 Register Procedures:

本课程免费! 请登录 USP 会议与培训中文平台, 点击这里 ([课程报名](#)) 进行在线报名。

#### 课程有效期 Access Duration:

课程在线观看有效期: 自在线报名成功日起, 14 天内有效, 逾期课程访问通道将自动关闭。

(报名成功后您会收到课程登录信息通知邮件)

Access to this course expires 14 days from the date of registration or until you mark it 'Complete' in your transcript—whichever occurs first.