

美国药典在线点播课程 *USP On-Demand Webinar*

USP 支持治疗性多肽药物质量标准

USP Standards to Support Quality of Peptide Therapeutics

课程时长 Course Duration: 54分钟 54 minutes

课程介绍 Course Description:

课程概述了美国药典书面标准和实物标准物质，介绍了 USP 现行多肽各论，讨论了新的多肽各论和现行多肽各论的修订情况，以及合成多肽的杂质注意事项。

(本课程的现场版本录制于 2022 年 5 月 25 日)

This webinar provides an overview of USP documentary and physical reference standards, introduces USP existing peptide monographs, discusses new peptide monographs and recent revisions to the existing peptide monographs and talks about the considerations regarding impurities for synthetic peptides.

(The live version of this recording took place on May 25, 2022)

参课对象 Who Should Attend:

监管人士、分析科学人员、QA 分析人员、研发科学人员/经理、QC 分析人员、CRO 人员等

Regulatory scientists, Analytical scientists, Quality assurance analysts, R&D scientists and managers, Quality control analysts, Contract research organizations

授课语言 Language:

英语（含中文字幕） English (with Chinese subtitles)

讲师介绍 Instructor:

Julie Zhang 博士，美国药典委员会全球生物制品部门科学与标准联络官- 部门主管

Julie Zhang, Ph.D., Science & Standards Liaison - Team Leader, Global Biologics, USP

Julie Zhang 博士是 USP 全球生物制品部门科学与标准联络官和部门主管。她的团队负责从抗生素、多肽到复杂生物制剂的各类产品的书面标准和标准物质的开发。Zhang 博士于 2017 年加入 USP，她的工作重点是遵循通则<81>抗生素-微生物检定法。Zhang 博士在药品的开发和监管方面拥有丰富的背景和经验。在加入 USP 之前，她曾任职于多家制药公司，在药品的开发和监管（例如方法开发和验证）方面拥有丰富的分析经验。

Dr. Julie Zhang is a Scientific & Standards Liaison and Team Leader in USP's Global Biologics Department. Her group is responsible for documentary standard and reference standard development for a variety of products from antibiotics, peptides to complex biologics. Dr. Zhang joined USP in 2017 and her focus was on the antibiotics that use microbial assay by following General Chapter <81>. Dr. Zhang has strong background and experience in the development and regulation of drug products. Prior to joining USP, she worked in pharmaceutical companies with strong analytical experience in the development and regulation of drug products such as method development and validation.

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课程有效期 **Access Deadline:**

课程在线观看有效期：自在线报名并缴费成功日起，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)

This course will be only available to you for 14 days from the day of successful registration or until you mark it 'Complete' in your transcript– whichever occurs first.

培训费用 Fee: 200 元人民币/人 RMB 200/attendee

报名方式 **Register Procedures:**

1. 点击[这里](#) ([课程报名](#)) 进行在线报名。

USP-China 收款账户: USP-China account

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

2. 发票领取: 电子发票通过电子邮件发送 e-Invoice is available by email after successful registration.