美 国 药 典 在 线 点 播 课 程 USP On-Demand Webinar

合成多肽药物开发过程中的标准和分析方法的演化
Evolution of Specifications and Analytical Methods During Synthetic Peptide Drug Development

课程时长 Course Duration: **60分钟** 60 minutes

免费视频课！

课程介绍 Course Description:

本课程通过案例学习的方式，着重介绍与合成多肽药物工艺和产品相关杂质测定的挑战。标准的开发应在产品生命周期框架中的每个环节予以考量。课程也将对相关法规和药典指南进行介绍。课程讲师 Michael Verlander 博士是合成多肽药物领域的知名专家，他成功开发并获准了多个合成多肽药物。

This on-demand webinar will focus on challenges related to measurement of process and product related impurities with a case study to illustrate the principles. Development of specifications within a product life cycle framework will be included with considerations that are helpful at each step. Regulatory and compendial guidance will be identified so that participants are aware of relevant references. A significant portion of the webinar will focus on challenges related to measurement of process and product related impurities with a helpful case study to illustrate the principles. This on-demand webinar was led by Dr. Michael Verlander, a well-known expert in this field, who has successfully brought many synthetic peptides through the development and approval process.

参课对象 Who Should Attend:

合成多肽药物/CRO/CMO 企业的分析实验员、QA/QC 人员、研发实验员/研发经理、生产技术人员/经理、法规事务专员等。

Analytical scientist, QA/QC analysts, R&D scientists & managers, Manufacturing scientists & managers, Regulatory affairs specialists of Synthetic peptide drug manufacturers, Contract research organizations, Contract manufacturing organizations

讲师介绍 Instructor:

Michael Verlander, D. Phil. 博士，美国药典委员会生物1（多肽和胰岛素）专家委员会委员

Michael Verlander, D. Phil, Ph.D., USP Biologics Monographs 1 – Peptides & Insulins Expert Committee Member

Verlander 博士是 Proactive Quality Compliance 公司总裁，同时也是美国药典委员会生物 1（多肽及胰岛素）专家委员会的委员和专家顾问组成员。他有非常丰富的质量保障和法规事务的工作经验。Verlander 博士毕业于牛津大学有机化学专业，索尔克生物研究所博士后经历，在多肽相关研究领域著有超过 50 篇的论文及专利。

Dr. Verlander, President of Proactive Quality Compliance, Inc., is currently acting as an independent consultant supporting the pharmaceutical industry in the areas of quality and regulatory compliance; he also serves as a member of USP's Biologics Monographs 1, Peptides and Insulins Expert Committee, as well as the Expert Panel. Prior to this, he gained extensive experience in the areas of quality assurance and regulatory affairs in contract manufacturing organizations.

Dr. Verlander received his undergraduate and graduate training in organic chemistry at the University of Oxford and his postdoctoral training at the Salk Institute for Biological Studies, La Jolla, California. He has authored more than 50 scientific papers and numerous patents on peptides and related topics.

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授课语言 Language:

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

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.

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