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

细胞治疗产品原料的质量鉴定

Qualification of Raw Materials Used in the Manufacturing of Cellular Therapies

课程时长 Course Duration: **30分钟** 30 minutes

免费视频课！

课程介绍 Course Description:

对细胞治疗产品的原材料进行质量鉴定，需要使用风险评估策略来对生产过程的关键组成部分进行分类。除了细胞培养添加剂，辅料和其他配方成分必须达到质量要求，以确保生产过程的一致性以及细胞治疗最终产品的质量和安全性。课程将讨论细胞治疗产品开发所面临的关键挑战，以及用于帮助确保细胞和基因治疗的一致性的鉴定项目的类型。通过学习，您将能解释生产细胞疗法的工艺开发人员所面临的挑战，确定细胞治疗产品生产用原材料的现有美国药典标准，开发细胞治疗产品原材料鉴定的内部流程。

Qualification of raw materials used in the manufacturing of cellular therapies requires the use of risk assessment strategies to categorize the critical components of a manufacturing process. In addition to cell culture supplements, excipients and other formulation's components must meet the required quality to ensure consistency in manufacturing and subsequently the quality and safety of finished cell therapy products. This presentation will discuss the critical challenges facing the development of cell therapies, and the type of qualification programs to help ensure consistency in the manufacturing of cell and gene therapies. Upon completion of this webinar, you will be able to:

- Demonstrate the challenges facing developers of processes for manufacturing cell therapies
- Identify existing USP standards for raw materials
- Develop internal processes for the qualification of raw materials.

参课对象 Who Should Attend:

从事细胞和基因治疗开发工作的 QA、QC、工艺开发、生产、监管专业人员。

Individuals involved in the development of cell and gene therapies from Quality Assurance, Quality Control, Process Development, Manufacturing and Regulatory professionals.

讲师介绍 Instructor:

Jim Richardson 博士，前美国药典委员会科学部门全球生物制品高级科学与标准事务联络人

Jim Richardson, Ph.D., Former Senior Science & Standards Liaison, Science-Global Biologics, USP

Jim Richardson 博士曾是美国药典委员会(USP)科学部门全球生物制品标准开发组高级科学事务联络人，领导细胞和基因治疗等新兴技术的标准制定工作。他曾在 Advanced BioScience Laboratories 和 Fighting Blindness 基金会负责疫苗和生物制剂开发的转化科学活动工作，以预防和治疗事务性科学活动以及传染病和视网膜疾病。作为一名病毒学家，Jim 曾从事 ViroMed Biosafety 公司病毒清除测试和 Genovo/Targeted Genetics 公司 AAV 载体开发和鉴定的工作。Richardson 博士在纽约西奈山医学院获得了生物医学博士学位。

Dr. Jim Richardson previously worked in the standards pipeline development group within the Global Biologics at USP, leading efforts to develop standards for emerging technologies such as cell and gene therapy. In previous roles, at Advanced BioScience Laboratories and Foundation Fighting Blindness, he led translational science activities for the development of vaccines and biologics to prevent and treat transactional science activities and infectious and retinal diseases. Trained as a virologist, Jim has also held positions responsible for performing viral clearance testing at ViroMed Biosafety and AAV vector development and characterization at Genovo/Targeted Genetics. Dr. Richardson earned his PhD in Biomedcial Sciences at the Mount Sinai School of Medicine.

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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:

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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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