

## 美国药典在线点播课程 *USP On-Demand Webinar*

# 美国药典基因治疗相关标准和最佳实践 USP Standards and Best Practices for Gene Therapy

课程时长 **Course Duration:** 30分钟 30mins



免费视频课!

### 课程介绍 **Course Description:**

基因治疗为解决人类疾病提供了巨大的希望，但其复杂性和多样性给那些寻求标准化材料和方法的人们带来了特殊的挑战。美国药典委员会 (USP) 正在与利益相关方合作，确定并开发支持基因治疗的书面标准和实物标准。课程将概述现有的 USP 标准和实物标准，以及正在开发的标准更新。

(本次录播课内容来自 2020 年 2 月 18-19 日举行的 USP CMC 基因治疗研讨会)

Gene therapies offer tremendous promise to address human disease but their complexity and diversity present unique challenges to those seeking to standardize materials and methods. USP is engaging with stakeholders to identify and develop documentary and physical standards to support gene therapy. This presentation will provide an overview of existing USP documentary and physical standards as well as an update on standards under development.

(This on-demand recording is from the USP Workshop on CMC for Gene Therapy, held February 18-19, 2020)

### 参课对象 **Who Should Attend:**

QA/QC 分析人员；研发科学人员/管理者；CMC 开发项目人员；生产和工艺开发研究员及其管理者；法规事务专员；CRO 和 CMO 企业人员

QA/QC analysts; R&D scientists, managers; Team members in CMC development projects; Manufacturing and process development scientists, managers; Regulatory affairs specialists; Contract research organizations; Contract manufacturing organizations

### 授课语言 **Language:**

英语 (含英文字幕) English (With English subtitle)

### 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。

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### 美国药典基因治疗相关标准和最佳实践

### USP Standards and Best Practices for Gene Therapy

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 Biomedical Sciences at the Mount Sinai School of Medicine.

#### 课程有效期 **Access Duration:**

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