

美国药典在线点播课程 *USP On-Demand Webinar*

质粒 DNA 作为细胞与基因治疗起始物料的质量考量 Quality Considerations for Plasmid DNA as a Starting Material for Cell and Gene Therapies

课程时长 Course Duration: 44分钟 44 minutes

课程介绍 Course Description:

对于细胞和基因治疗过程中使用的质粒 DNA，包括 mRNA 的生产，大家希望有更多的指南。基于此，美国药典委员会 (USP) 开发了一个通则来明确质粒 DNA 的最佳实践。课程将重点介绍质粒 DNA 作为下游生产的起始物料，包括采购和生产、质粒质量与检测、风险管理、以及残留杂质等内容。

There is a need for more guidance regarding plasmid DNA used in the manufacturing of cell and gene therapy processes, including the production of mRNA. Recognizing this gap, United States Pharmacopeia (USP; MD, USA) has developed a general chapter to define plasmid DNA best practices. This webinar will focus on plasmid DNA as a starting material for use in downstream manufacturing operations, comprising topics such as sourcing and manufacture, plasmid quality and testing, risk management, and residual impurities.

参课对象 Who Should Attend:

研发、制造与生产部门的实验室人员；生产企业和 CRO 公司的科学和管理人员；QA/QC 专员和审计人员；法规监管人员等。

Lab personnel in research and development, manufacturing and production, Scientists and managers of manufacturing and contract research organizations, Quality assurance and quality control specialists and auditors
Regulatory professionals.

授课语言 Language:

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

讲师介绍 Instructor:

Rebecca C. Potts, 美国药典委员会全球生物制品部门高级科学家 II
Rebecca C. Potts, Senior Scientist II, Global Biologics, USP

Lawrence Thompson, 辉瑞副研究员
Lawrence Thompson, Associate Research Fellow, Pfizer

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.

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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.