

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。

(本课程的现场版本录制于 2023 年 6 月 21 日)

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.

(The live version of this recording took place on June 21, 2023)

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.

美国药典在线点播课程 *USP On-Demand Webinar*

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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.