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

疫苗生产的细胞库
Cell Banking for Manufacturing of Vaccine

课程时长 Course Duration: **4.5小时** 4.5 hours

课程介绍 Course Description:

本课程将介绍与细胞库和表征相关的国际协调委员会 (ICH)、世界卫生组织 (WHO)和美国药典 (USP)指南。内容涵盖关键的细胞库概念和使用，包括良好的生产实践、准备和工艺流程。课程内容适用于重组工程生物产品的细胞基质，以及一些疫苗的具体内容。课程包含实践练习和问答，帮助学员更好地了解用于生产疫苗和其他生物制剂的细胞库的适当开发、克隆和表征，这是这些产品获得许可和一致性的关键组成部分。

通过学习，您将能够：

- 解释细胞库
- 根据 ICH 指南和 USP 通则描述细胞库
- 解释原代细胞的识别、确认和选择
- 总结细胞结构分析的基本原理
- 描述细胞历史中必须记录的最关键要素
- 总结细胞和细胞库的表征
- 描述与细胞库相关的存储、控制和物流

This course will provide International Council for Harmonization, World Health Organization, and USP guidelines related to cell banking and characterization. Key cell banking concepts and usage will be covered including good manufacturing practices, preparation, and process flow. The course content applies to cell substrate for a recombinantly engineered biological product along with some vaccine-specific content. Participants will be engaged in practical exercises and Q&As to reinforce learning. Participants will better understand suitable development, cloning, and characterization of cell banks for the production of vaccines and other biologics as critical components for the licensure and consistency of these products.

Upon completion of this course, you will be able to:

- Explain cell banking
- Describe cell banking in terms of ICH guidelines and USP general chapters
- Explain the identification, qualification, and selection of primary cells
- Summarize the rationale for the analysis of cell construct
- Describe the most critical elements of the cell history that must be documented
- Summarize the characterization of cells and cell banks
- Describe storage, controls, and logistics as it pertains to cell banking

参课对象 Who Should Attend:

研发细胞生物学家、研发制造商、研究分析员、生物技术生产商、药物微生物学家等

R&D Cell Biologists, R&D Manufacturers, Research Scientists, Biotechnology Manufacturers, Pharmaceutical Microbiologists

授课语言 Language:

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

美国药典委员会中华区总部 USP-China
中国（上海）自由贸易试验区富特北路 520 号（200131）
Tel: (86) 21-68619800, Fax: (86) 21-68619810
E-mail: uspcn@usp.org, Website: www.usp.org

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

疫苗生产的细胞库
Cell Banking for Manufacturing of Vaccine

讲师介绍 Instructor:

Maura C. Kibbey 博士，美国药典委员会全球生物部门高级科学研究员

Maura C. Kibbey, Ph.D., Principal Scientific Fellow, Science - Global Biologics, USP

作为 USP 全球生物部门教育和培训高级科学研究员，Kibbey 博士与其他科学专家和讲师一起，致力于为 USP 生物制品的利益相关者带来更多的专业培训课程。在担任教育和培训高级科学研究员之前，Kibbey 博士负责管理科学事务联络人小组，与 USP 五个专家委员会和多个生物制剂、多肽和抗生素专家小组共同合作，制定支持生物制品质量评估和开发的标准。在加入 USP 之前，她任职于华盛顿特区的生物技术和诊断公司、以及美国国立卫生研究院。她的科学专长包括开发和验证许多不同的测试类型，用于测量单个分子、它们的活性或相互作用。她发表了 40 多篇同行评议文章，并被邀请为许多科学会议的演讲者或研讨会组织者。

Dr. Maura Kibbey is Principal Scientific Fellow for Education and Training in USP's Global Biologics Department. Dr. Kibbey collaborates with scientific experts and trainers to bring more educational offerings to USP's biologics stakeholders. Previously, Maura directed a team of liaisons working with the five USP Expert Committees and multiple Expert Panels for biologics, peptides, and antibiotics to develop standards that support biopharmaceutical quality assessment and development. Before joining USP, Dr. Kibbey worked for several biotechnology and diagnostic companies in the Washington DC area as well as at the National Institutes of Health. Her scientific expertise includes development and validation of many different assay types for measurement of individual molecules, their activities, or binding interactions. She has published over 40 peer-reviewed articles and has been an invited speaker or workshop organizer for numerous scientific conferences.

Victor Maqueda，美国药典委员会顾问，USP Consultant

Victor Maqueda 先生在制药领域拥有 30 年的资深工作经验，担任与 WHO、美国、欧盟标准相关的国际审计师和顾问。

他是世卫组织外聘审计员和顾问。自 2002 年起担任日内瓦世界卫生组织的外部审计员、顾问和培训师，对联合国疫苗供应商（印度尼西亚、中国、印度、韩国、欧洲、美国、加拿大、俄罗斯和巴西）和疟疾、艾滋病毒、肝炎（印度、日本）的体外诊断快速检测进行审计。完成 30 多次世卫组织资格预审的审计工作，是 WHO TRS 的官方审查员（例如，新版生物 GMP 要求，TRS 999）。

Victor Maqueda 先生也是 GMP 和质量体系培训师、审计员和顾问。自 2001 年以来，在制药、疫苗和医疗器械领域从事 cGMP 培训、审计和辅导工作，包括厂房设计、验证和确认、注射剂和眼科产品的无菌工艺操作、灭菌工艺（蒸汽、环氧乙烷、干热和伽马辐射灭菌）。对中国和意大利的经销商与原料药供应商进行第三方审计。为印度、美国和墨西哥药厂提供 GMP 咨询，并担任 ISO 9001/13485 主审员。

Thirty years of international, senior level experience in the pharmaceutical field in the private industry and as international auditor and consultant, as per WHO, US and EU standards.

- WHO external Auditor & Consultant. Since 2002 as external auditor, consultant and trainer for the World Health Organization, Geneva, to qualify UN suppliers of vaccines (Indonesia, China, India, South Korea, Europe, US, Canada, Russia and Brazil), and in-vitro diagnostics rapid tests for Malaria, HIV, Hepatitis (India, Japan). More than 30 audits for WHO Prequalification performed. Official WHO reviewer of WHO TRS (e.g., new GMP's for Biological, TRS 999).
- GMP & Quality System Trainer, Auditor & Consultant. Since 2001. Pharmaceutical, Vaccine & Medical Device industries. cGMP training, auditing, and coaching. Plant design. Validation & Qualification. Aseptic process operations for injectable and ophthalmic products. Sterilization processes (steam, ethylene oxide, dry heat and gamma radiation sterilization). Third party audits of Distributors and API suppliers in China, Italy. GMP Consultancy in pharmaceutical plants in India, US and Mexico. ISO 9001/13485 Lead Auditor.

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

疫苗生产的细胞库
Cell Banking for Manufacturing of Vaccine

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.

培训费用 Fee: 700 元人民币/人　RMB 700/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
   银行 Bank:　美国银行有限公司上海分行

2. 发票领取：快递/邮寄方式提供　Invoice is available after successful registration.

美国药典委员会中华区总部 USP-China
中国（上海）自由贸易试验区富特北路 520 号（200131）
Tel: (86) 21-68619800, Fax: (86) 21-68619810
E-mail: uspcn@usp.org, Website: www.usp.org