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

疫苗生产的质量控制
Quality Control of Vaccines Manufacturing

课程时长 Course Duration: **5.5小时** 5.5 hours

课程介绍 Course Description:

本课程为支持疫苗质量控制的生物分析和分析实验室提供最佳实践。课程介绍了分析方法验证、制药微生物实验室的要求、水系统、动物测试、GMP 实验室的设备校准和维护等方面的基础知识。课程以重组乙型肝炎疫苗为案例，介绍疫苗相关的 WHO 指南，以及不同类型疫苗的安全性、特性、强度、纯度和质量的常用测试。同时，也将回顾与美国药典通则相关的保质期、标签和流通相关的稳定性研究。

通过学习，您将能够：

- 总结并讨论 WHO 技术报告系列，961，2011 附录 2 药品微生物实验室的良好生产规范
- 解释在良好生产规范环境下对实验室设备的确认、维护和校准的期望
- 描述用于疫苗放行的分析方法验证的详细要求
- 总结并讨论 WHO 制药用水的良好生产规范。WHO TRS 970 附录 2，包括水系统的确认和控制
- 确认并讨论在每个生产阶段用于确保疫苗安全性和有效性的常用测试，阐述发布乙肝疫苗所需的典型测试
- 列出支持疫苗生产、质量控制、稳定性试验和效力测定的美国药典通则及其内容
- 总结 ICH Q5C- 生物技术/生物制品的稳定性测试 - WHO/BS/06.2049 - 疫苗稳定性评估的最终指南

This course provides best practices for bioanalytical and analytical laboratories that support the quality control of vaccines. The course offers fundamentals on analytical method validation, requirements for pharmaceutical microbiology laboratories, water systems, animal testing, equipment calibration and maintenance in a GMP laboratory. Using the recombinant hepatitis B vaccine as a case study, participants will be introduced to WHO guidelines that support vaccines as well as common tests that support the safety, identity, strength, purity, and quality of different types of vaccines. Expectations for stability studies that support the shelf life, labeling, and distribution will also be reviewed as they relate to USP general chapters.

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

- Summarize and discuss WHO Technical Report Series, 961, 2011 Annex 2 good manufacturing practices for pharmaceutical microbiology laboratories.
- Explain expectations for qualification, maintenance and calibration of laboratory equipment in a good manufacturing practices environment.
- Describe detailed requirements for analytical method validation commonly used to release vaccines
- Summarize and discuss WHO good manufacturing practices for Water for Pharmaceutical Use. WHO TRS 970, Annex 2 including qualification and control of water systems.
- Identify and discuss common tests used to ensure safety and efficacy of vaccines during each stage of production. State the typical tests required to release Hepatitis B vaccine.
- List the USP chapters and content that support vaccine manufacturing, quality control, stability testing, and potency assays.
- Summarize ICH Q5C – Stability Testing of Biotechnological / Biological Products - WHO/BS/06.2049 - Final Guidelines on Stability Evaluation of vaccines

参课对象 Who Should Attend:

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 Manufacturers, Research Scientists, Biotechnology Manufacturers, Pharmaceutical Microbiologists

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授课语言 Language:

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

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，她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.

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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.

培训费用 Fee: 1200 元人民币/人　RMB 1200/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.

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