美国药典在线点播课程 USP On-Demand Webinar

疫苗监管和 WHO 资格预审的考量
Regulatory and WHO Prequalification Considerations for Vaccines

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

课程介绍 Course Description:

本课程将讨论世界卫生组织（WHO）的疫苗资格预审程序。学员将更好地理解实验室信息文件和产品说明文件，以及来自评估员和检查员的额外期望。课程也将涵盖国家监管机构和国家药品控制实验室对疫苗的评价，因为它涉及批放行证书和参与联合国疫苗项目。

通过学习，您将能够：

- 总结和讨论 QC 实验室的关键预审步骤
- 描述如何按照 WHO 的要求准备实验室信息文件
- 根据 WHO 评估联合国购买的疫苗的可接受性的程序来解释产品说明文件 (PSF) 的内容
- 讨论关于监管机构对疫苗批次放行的 WHO 指南宗旨和范围
- 确定并讨论疫苗生产商、国家监管机构和国家药品控制实验室的责任
- 描述批次放行程序的细节和批次放行证书的详细内容
- 讨论用于监测疫苗批次的最佳实践

This course will address the process for World Health Organization prequalification of vaccines. Participants will better understand the laboratory information file and product summary file as well as additional expectations from evaluators and inspectors. The evaluation of vaccines by national regulatory authorities and national control laboratories will also be covered as it relates to the lot release certificate and participation in United Nations vaccine programs. Participants will be engaged in practical exercises and case studies to reinforce learning

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

- Summarize and discuss critical prequalification steps for quality control laboratories
- Describe how to prepare laboratory information files per WHO
- Explain the sections of a product summary file (PSF) per WHO procedures for assessing the acceptability of vaccines purchased by United Nations
- Discuss the purpose and scope of WHO guidelines for the independent lot release of vaccines by regulatory authorities
- Identify and discuss the responsibilities of the vaccine manufacturer, the national regulatory authority and national control laboratories
- Describe details of the lot release procedure and important elements of the lot release certificate
- Discuss the best practices used to monitor vaccine lots

参课对象 Who Should Attend:

研发制造商、研究分析员、生物技术制造商、药物微生物学家等

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

授课语言 Language:

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

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疫苗监管和WHO资格预审的考量
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讲师介绍 Instructor:

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.

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.

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