美国药典在线点播课程 USP On-Demand Webinar

生物活性检测标准的原则与实践
Principles and Practices for Bioassay Standards

课程时长 Course Duration: **20分钟** 20 minutes

免费视频课！

课程介绍 Course Description:

标准品对生物制品的开发和控制至关重要。USP 建议报告与标准品相关的测试物的活性，一些实验室也使用标准品作为对照。但是，考虑到它们的重要性，对于标准品的来源、标准品确认和稳定性评价的基础与手段、或者一级标准品的使用都没有达成共识。课程将讨论用于报告生物产品活性的标准品的原则和实践，并提出获取和评估生物产品的策略。这些建议将通过分析方法的质量源于设计相关的实践，强调引用标准品的适用性，以及在开发和质量控制过程中减少与它们的使用相关的不确定性和决策风险。

（本次录播课内容来自 2019 年 9 月 18-19 日举行的第八届 USP 生物活性检测研讨会。）

Reference standards are essential to the development and control of biological products. USP recommends reporting potency of test articles relative to a reference standard, while some laboratories use these also or instead as a control. Considering their importance, however, there is no consensus on the source of a reference standard, the basis and means of reference standard qualification and stability evaluation, or the use of a primary standard. This talk will discuss principles and practices related to reference standards used to report potency of biological products and propose strategies for their acquisition and evaluation. Those proposals will borrow from practices related to quality by design for analytical methods, highlighting fitness-for-use of a reference standards as well as reduction of uncertainty and the decision risks associated with their uses during development and quality control.
(This on-demand recording is from the 8th USP Bioassay Workshop, held September 18-19, 2019.)

参课对象 Who Should Attend:

生物制药和疫苗行业的专业人员、细胞和基因治疗产品开发人员、生物活性检测监管审核人员、生物类似药生产商、生物活性检测软件开发人员、统计学工作者、生物活性检测 QA/QC 专员。

Biopharmaceutical and vaccines industry professionals, Cell and gene therapy product developers, Regulatory reviewers of bioassays, Biosimilar manufacturers, Bioassay software developers, Statisticians, QA/QC specialists for bioassays

授课语言 Language:

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

报名请登录 USP 会议与培训中文平台，点击这里（课程报名）进行在线报名。

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生物活性检测标准的原则与实践

Principles and Practices for Bioassay Standards

讲师介绍 Instructor:

Tim Schofield 先生，美国药典委员会统计学专家委员会成员，CMC Sciences 公司

Tim Schofield, USP Statistics Expert Committee Member, CMC Sciences, LLC

在 CMC Sciences 公司之前，Tim Schofield 先生任职于以下公司：GSK 全球疫苗技术研发高级顾问和美国法规事务总监、MedImmune 公司分析生物技术部门高级研究员、Arlenda 公司非临床统计负责人和美国区总经理、Merck 研究实验室非临床统计部门负责人。

Tim 于 1976 年获得了 Lafayette 学院的数学学士学位和宾夕法尼亚大学沃顿商学院的统计和运筹学硕士学位。Tim 是美国药典委员会统计学专家委员会成员，参与过一系列与质量源于设计、分析方法开发和验证、稳定性和标准相关的行业计划。同时，他也是 IABS 出版委员会主席和 NIST 客座研究员。

Prior to starting his own consulting business Tim Schofield worked at:

- GSK as a Senior Advisor in Global Vaccines Technical R&D, and previously a Director in US Regulatory Affairs,
- MedImmune as a Senior Fellow in Analytical Biotechnology,
- Arlenda as US Managing Director and Head of Nonclinical Statistics, and
- Merck Research Laboratories heading the Nonclinical Statistics department.

Tim received a Bachelor of Science degree in Mathematics from Lafayette College, and a Master of Arts degree in Statistics and Operations Research in 1976 from the Wharton School of the University of Pennsylvania. Tim is a member of the USP Statistics Expert Committee and has participated in industry initiatives related to Quality by Design, analytical method development and validation, stability and specifications. He is the Chairman of the IABS Publications Committee and a Guest Researcher at NIST.

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报名方式 Register Procedures:

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（报名成功后您会收到课程登录信息通知邮件）

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