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

生物活性检测方法验证可接受限度的设定
Setting the Acceptance Limits for Bioassay Validation

课程时长 Course Duration: **25分钟** 25 minutes

免费视频课！

课程介绍 Course Description:

近年来，生物活性检测的生命周期管理概念被提出。它与 ICH Q8 指南中质量源于设计的概念密切相关，但这和 ICH Q2 中只关注验证步骤的建议形成了对比。ICH Q2 众所周知的核对表方法不能保证方法预期用途的未来结果的质量。利用测定结果的总误差有助于缩小这一差距。但要如何建立总误差的接受限度，以确保测定符合其目的？ 课程将介绍一种基于概率的策略来观察产品标准之外的结果，同时考虑到有关过程和分析性能的所有不确定性。

（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。）

Recently, the lifecycle management concept for bioassay was introduced. It is strongly related to the Quality by Design concept given in the ICH - Q8 guidance. This contrasts with ICH - Q2 recommendations that only focus on the validation step. ICH - Q2's well - known check - list approach fails to provide assurance of the quality of future results with respect to the intended use of the procedure. Using the total error of the assay results helps closing this gap. A common question, however, is how to establish acceptance limits on the total error to ensure that the assay fits its purpose? In this talk, we will present a strategy based on the probability to observe results outside of the product specifications, while taking into account all the uncertainty about both the process and assay performances. *(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

讲师介绍 Instructor:

Perceval Sondag 先生，美国默克公司　　Perceval Sondag, Merck & Co., Inc.

授课语言 Language:

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

报名方式 Register Procedures:

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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）

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