

美国药典在线点播课程 USP On-Demand Webinar

具有多种作用机制的生物类似药的 生物活性检测方法开发和标准评估的挑战

Challenges of Bioassay Development and Specification Assessment for Biosimilar Product with Multiple Mechanisms of Action

课程时长 Course Duration: 20分钟 20 minutes

课程介绍 Course Description:

生物类似药活性检测的发展是基于对分子作用机理的了解，这要求在产品开发生命周期的早期阶段建立一种基于功能细胞的生物活性检测方法，并将该方法应用于生物类似药的放行、稳定性、表征、以及生物类似药批次和参比制剂批次的相似性评估。随着对参比制剂、监管机构要求、以及技术发展了解的不增加，可能需要对具有多种作用机制的分子进行额外的生物活性检测以进行生产控制。对于具有 ADCC 效应的分子，除了控制 N-链 Fc 糖基化外，可能还需要功能性或替代性的 ADCC 检测来控制 ADCC 活性。课程将介绍生物活性检测方法开发和标准评估的注意事项与挑战。

(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。)

The development of potency assay(s) for biosimilars is based on the understanding of the known mechanism(s) of action of the molecule. This requires the sponsor to establish a functional cell-based bioassay at an early stage of the product development life-cycle and apply the bioassay for biosimilar product release, stability, characterization, and similarity assessment of biosimilar lots and reference product lots. With increasing knowledge of the reference product, requirements from regulatory agencies, and advancement of technology, additional bioassays for manufacturing control may be needed for molecules with multiple mechanisms of action. For molecules with ADCC effector function, a functional or surrogate ADCC assay will likely be required to control ADCC activity in addition to the control of N-linked Fc glycosylation. Considerations and challenges of bioassay development and specification assessment will be discussed in this presentation.

(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:

Ling Gu 博士，美国辉瑞分析研发部门生物治疗药物科学组

Ling Gu, Ph.D., Biotherapeutics Pharmaceutical Sciences, Analytical Research & Development, Pfizer

授课语言 Language:

英语（含中文字幕） English (with Chinese subtitles)

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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:** 150 元人民币/人 RMB 150/attendee

报名方式 Register Procedures:

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