美国药典在线点播课程 USP On-Demand Webinar

评估 Fc-介导效应的分析方法

Assays to Evaluate Fragment Crystallizable (Fc)-Mediated Effector Function

课程时长 Course Duration: **40分钟** 40 minutes

课程介绍 Course Description:

Fc 介导效应是通过治疗性单克隆抗体的抗原结合片段 Fab 与目标抗原的结合，以及抗体的 Fc 段同补体或多种细胞（如：NK 细胞，巨噬细胞，树突状细胞，单核细胞和中性粒细胞）上表达的 Fcγ 受体(FcγR)结合来共同介导的。Fc 介导效应包括抗体依赖的细胞毒性作用（ADCC），补体依赖的细胞毒性作用（CDC），抗体介导的细胞吞噬（ADCP），以及 Fc 介导的凋亡作用（Apoptosis）。

本次网络课程将介绍一个新的 USP 通则<1108>，旨在为需要选择、建立和验证 Fc 介导效应分析的客户提供指导，包括分析低亲和力的 FcγRs 以及抗体糖基化水平对 Fc 介导效应的影响。通则<1108>本章详细描述了用于评估复杂 Fc 结构域相互作用的的体外分析方法，而对 Fc 介导效应的分析对评价含 Fc 段的治疗性抗体的生物学特征有着重要作用。课程分别介绍了基于细胞平台和不基于细胞平台的最佳 Fc 介导效应的分析和验证方法，也包括了每种分析平台的优缺点以及需要考虑和注意的地方。

通过学习，您将了解不同（Fc)-介导效应活动；回顾用于评估（Fc)-介导效应的各类分析类型、格式和技术；了解应用层面分析方法的选择、开发和验证，用来评估（Fc)-介导效应。

Fc effector function activities are mediated via interaction of the fragment antigen binding (Fab) domain of a therapeutic monoclonal antibody with the target antigen, and the interaction of the Fc domain with complement or various Fc gamma receptors (FcγR) expressed on cells of hematopoietic origin (e.g., natural killer, macrophage, dendritic, monocyte, and neutrophil). The different Fc-mediated effector function activities may include antibody-dependent cell-mediated cytotoxicity, complement-dependent cytotoxicity, antibody-dependent cellular phagocytosis, and Fc-dependent apoptosis.

This webinar will describe a new, informational USP General Chapter <1108> that is intended to provide users with practical guidance regarding the selection, development, and validation of Fc function assays, including the measurement of low-affinity interactions observed FcγRs and the impact of glycosylation on antibody effector function. The chapter details in-vitro assays that assess complex Fc domain interactions critical to the biological characterization of Fc-containing therapeutics. Best practices to develop and validate cell-based and non-cell-based formats for measuring these interactions are provided, as well as advantages, disadvantages, and points to consider for each assay format.

By taking this course, you will:

- Learn about the different Fc-mediated effector function activities.
- Review the various assay types, formats and technologies used to assess Fc-mediated effector function.
- Gain an understanding of the practical aspects of selecting, developing, and validating assays to assess Fc-mediated effector function.

参课对象 Who Should Attend:

实验室经理，资深科学员，研发人员，分析员，合同研发生产机构与合同分析实验室的实验员，生物制品法规专家，生物制药企业 QA/QC 人员，生物检定统计人员。

Lab managers, Principal scientists, R&D, Analytical, Scientists at CDMO's and contract analytical labs, Regulatory experts working in the field of biologics, QA/QC scientists at biopharmaceutical companies, Bioassay statisticians

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讲师介绍 Instructor:

Max Tejada，美国药典委员会Fc介导效应分析专家顾问组副主席；阿斯利康生物制药开发部门杂质生物检定和质量检验组高级总监

Max Tejada, USP Fc Function Assays Expert Panel Vice Chair; Senior Director, Bioassay Impurities and Quality, BioPharmaceuticals Development, BioPharmaceuticals R&D, AstraZeneca

Max Tejada 先生是阿斯利康杂质生物检定和质量检验组高级总监，负责运用最先进的方法对生物制品的产品差异、生物活性、工艺杂质、及新的治疗模式进行检测、表征和量化，使产品在制造工艺、配方和药品开发过程中得以理解和认识。

Max Tejada is Senior Director of Bioassay Impurity and Quality Testing Group at AstraZeneca, which is responsible for implementing state of the art methods to detect, characterize, and quantify product variance, biological activity, and process related impurities for biological products as well as novel therapeutic modalities.

授课语言 Language:

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

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: 250 元人民币/人 RMB 250/attendee

报名方式 Register Procedures:

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2. 发票领取：快递/邮寄方式提供 Invoice is available by express after successful registration.

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