

美国药典在线点播课程 USP On-Demand Webinar

针对细胞和基因治疗产品活性与免疫基因特性筛选的 体外功能生物活性检测方法的开发：挑战与机遇

Development of In Vitro Functional Bioassays for Potency and Immunogenicity Screening of Cell and Gene Therapy Products: Challenges and Opportunities

课程时长 Course Duration: 25分钟 25 minutes



免费视频课!

课程介绍 Course Description:

细胞和基因疗法有可能治愈以前无法治愈的疾病，并从根本上改变许多其他疾病的发展轨迹。然而，新疗法的发展伴随着一系列的挑战和风险。与传统疗法的大批量生产和质量检测相比，这些单个批次的细胞产品需要特定的活性检测来显示生物活性。

因这些细胞治疗产品的复杂性，选择和开发合适的体外生物活性检测方法面临一定的挑战。第一步是要确定一个复杂产品的具体功能和作用方式。另外，在体外试验中使用不同类型的细胞组合来表现作用方式，需要在不同的水平上进行优化和微调。开发和优化生物活性检测方法来筛选间充质干细胞的免疫抑制功能将作为案例与您分享。

除了活性评估外，体外生物测定可用于筛选干细胞产品不需要的免疫原性。特别是随着越来越多地使用同种异体的现成疗法，体外生物测定法在给药前评估干细胞制品的免疫原性具有重要的价值。

(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。)

In Cell and gene therapies have the potential to cure previously untreatable diseases, and fundamentally alter the trajectory of many other diseases. Cell and Gene Therapies have the potential to cure a broad spectrum of diseases and modify the progress of many other diseases. However, the development of new therapeutics comes with a series of challenges and risks. In contrast to traditional therapeutics large batch manufacturing and quality testing, these individual batches of cell products require specific potency assays showing the biological activity. Due to the complexity of most of these cell therapy products, the selection and development of a suitable in vitro potency bioassay comes with certain challenges. Identifying the specific function and mode of action of such a complex product is the first step. Additionally, representing the mode of action in an in vitro assay using a combination of different cell types, requires optimisation and fine tuning on different levels. As an example, the development and optimization of a bioassay to screen for the immunosuppressive function of Mesenchymal Stem Cells will be shown.

Next to the evaluation of the potency, in vitro bioassays can be used for the screening of the unwanted immunogenicity of Stem Cell Products. Especially with the increased use of allogenic 'off the shelf' therapies, in vitro bioassays to assess the Immunogenicity of Stem Cell products prior to administration in human can have significant value.

(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专业人士、细胞和基因治疗产品开发人员、生物活性检测监管评审人员、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

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讲师介绍 Instructor:

Sofie Pattijn, 比利时ImmunXperts SA公司首席技术官

Sofie Pattijn, CTO, ImmunXperts SA

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。

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