GreyRigge Associates

Immunogenicity of biologics & advanced therapies

Overview

This programme provides a practically grounded introduction to immunogenicity of biologics and other advanced therapeutics, such as gene-based therapies and their vectors. It will guide you from immunological principles, to clinical testing for immunogenicity occurrences, risk assessment and assay life cycle, with a view on regulatory compliance.

Course Structure

Module	Subject Area
Module 1	Fundamentals of immunology and tolerance
Module 2	A beginner's guide to immunogenicity with case studies
Module 3	How can we predict immunogenicity, if at all?
Module 4	Immunogenicity Risk assessment and case studies
Module 5	Immunogenicity assays, binding (I) and neutralizing assays (II)
Module 6	The assays life cycle I – development, qualification/validation
Module 7	The assays life cycle II – development, qualification/validation
Module 8	Cell banking for neutralizing assays and use of DoE
Module 9	Introduction to Integrated Summary Immunogenicity – where it all comes together

Audience

This programme is suited for biopharmaceutical CROs, company R&D/clinical/Regulatory departments. Drug modalities covered in this course including biologics such as mAbs as well as ATMP gene and cell therapies with a special focus on use of viral vectors

Duration and Delivery

This course is delivered over 2 days and can be face-to-face or remotely. Course content and duration can be tailored to the specific needs of the requesting organisation, with individual modules offered as standalone sessions.

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