2025 Session Topics

ASSOCIAL

Potency Assay for Novel Products

Podium Talks Now Being Recruited:

CTICES

- Strategy for Potency Determination of Gene Therapy Products
- Analytical and Regulatory Challenges in Developing Potency Assays for Cell Therapies Targeting Rare Diseases
- Potency Assays for Novel Vaccine Products
- Designing a Cell-Based Assay for Potency Testing of Plasmid API: Challenges and Solutions

New Validation Approaches

Podium Talks Now Being Recruited:

- Use of Total Analytical Error to Support Validation Studies
- Practical Aspects of Validating Precision and Accuracy According to the ICH Q2 (R2)

AI & Automation for Bioassays

Podium Talks Now Being Recruited:

- Automation Case Study for a Protein Therapy
- Paving the Way to Assay Automation: Improving and Simplifying a Complex Potency Assay

Statstical Tools

Podium Talks Now Being Recruited:

- Limiting Potency Bias from Allowed Non-Similarity While Protecting the Similarity Pass Rate
- Digital Twin for Bioassay Method Development

Assay Development Strategies for Potency and Biomarker Assays

Podium Talks Now Being Recruited:

- Advancing Cell-Based Potency Assays: Strategies and Challenges in Developing a Robust Functional Assay for Monoclonal Antibody
- Bioassays Provide an Effective Approach to Replace Comparative Efficacy Trials in Confirming Biosimilarity
- Case Study: How To Transfer a Potency Assay Without Pain

3 days of **podium**presentations and multiple networking opportunities!

In-Person: Rotterdam, Netherlands

NEW! Poster Session included in Main Podium

Still Accepting Podium Abstracts and Posters

Abstract Submission

Accepted Talks From:

Sanofi

Novartis

Novo Nordisk A/S

Baxalta Innovations

Dark Horse Consulting

Charles River Labs

Parexel

Precision Bioassay Inc