17th Annual

# EUR Bioassay Conference

## 25-27 September, 2024

Hybrid Conference
In-Person: Hilton Prague Hotel
Prague, Czech Republic

*All times are in Central European Summer Time*
*Slides not available for distribution are highlighted in RED*

## Day 1 | 25 September

**8:00** Check In for In-Person Attendees

**9:00** In-Person Workshops

**10:30** Morning Break

**11:00** In-Person Workshops

**12:00** Lunch

### Session 1: Regulatory Updates

*(All Attendees Welcome)*
***Session Chair:*** *To Be Announced*

**13:30** Welcome and Logistics

**13:45** Session Chair Introduction and Audience Survey

***Podium Talks Now Being Recruited:***

- Overview of ICH Updates
- Review of FDA Guidances for Gene Therapy

**15:00** Q&A

**15:20** Afternoon Break

***Podium Talks Now Being Recruited:***

- When is Comparability Required in a Regulatory Filing
- How to Perform Comparability

**16:50** Q&A

**17:15** Conference Day 1 Adjourns

**17:15** Networking Reception

### Workshop Options

*(In-Person Attendees Only)*

**Workshop 1**

A Primer On The Statistical Aspects Of Comparability Assays

**Workshop 2**

Practicalities of Product Reference Material (PRM) for Potency Assays to support Clinical Studies

One of the most important steps in the development of a potency assay is the identification, use and maintenance of reference material throughout the life cycle of the potency assay. Once a product reaches late stage clinial studies such as Phase III, the entire organization focuses on how to handle PRM. This workshop will cover steps in this process in early development and in early (PI and PII) clinical studies. Potential topics for discussion include:

- Selection of PRM for releasing clinical material
- Qualification of reference material
- Bridging Interim PRM with early stage potency assays
- Requirements for monitoring the reference material during clinical studies

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## Day 2 | 26 September

**9:00** In-Person Interest Groups

**10:30** Morning Break

**11:00** In-Person Interest Groups

**12:00** Lunch

### Session 2A: Implementing Automation in Your Bioassay
*(All Attendees Welcome)*
***Session Chair:*** *To Be Announced*

**13:30** Session Intro and Survey

***Case Studies Now Being Recruited:***

- Adding Modular Components of Automation in a Cell Based Assay
- Can Artificial Intelligence Help Us Develop Bioassays?
- Developing Potency Assays In 384 Well Plates

**15:30** Q&A

**15:50** Afternoon Break

### Session 2B: Lifecycle of a Bioassay
*(All Attendees Welcome)*
***Session Chair:*** *To Be Announced*

***Case Studies Now Being Recruited:***

- R&D to the Development Lab
- Support Systems Required As We Start Releasing Clinical Material

**17:20** Q&A

**17:40** Conference Day 2 Adjourns

### Interest Group Options
*(In-Person Attendees Only)*

**Interest Group 1: Identifying and Eliminating Sources of Variability in a Bioassay**

Bioassays are technique driven methods. We hear this constantly and we experience it routinely. When? Often when we transfer a cell-based bioassay the receiving laboratory experiences a performance change. The precision might improve or worsen. The overall signal in the dose-response curve may go up or down. These differences are typically due to small technique differences from lab-to-lab, analyst-to-analyst, small changes in rare reagents, use of platform equipment. How can we identify these changes during our development process, rather than waiting until a crunch time during a critical method transfer?

**9:00** Introduction and Survey

**12:00** Interest Group Concludes

**Interest Group 2: The Practicalities of Validating (or Characterizing) a Bioassay**

We hear many great studies in our podium talks about various approaches to validating bioassays: utilization of a classical ICH approach vs. a quality by design approach. It is less often that we discuss more of the "mundane" aspects of the validation, such as:

- What does a good (one that will pass QA scrutiny) validation protocol look like?
- Is there a pre-validation protocol? If so what does it contain? (training records, calibration status?)
- Do we write a validation report? Or is simple list of results sufficient?
- How many "failed" runs are ok? Or does this constitute an assay robustness failure?

These topics and more are up for discussion!

**9:00** Introduction and Survey

**12:00** Interest Group Concludes

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## Day 3 | 27 September

**9:00** In-Person Interest Groups

**10:30** Morning Break

**11:00** In-Person Interest Groups

**12:00** Lunch

### Session 3:
### Technical Hurdles For Certain Products

*(All Attendees Welcome)*
***Session Chair:*** *To Be Announced*

**13:30** Session Intro and Survey

***Podium Talks Now Being Recruited:***

- Forced Degradation Studies for Gene Therapies
- Forced Degradation Studies for Cell Based Products

**15:00** Afternon Break

***Podium Talks Now Being Recruited:***

- More Than 1 Assay Needed For ADC Assays?
- Developing and Validating Flow Cytometry Assays

**16:30** Q&A

**17:00** Closing Comments

**17:15** Conference Concludes

### Interest Group Options

*(In-Person Attendees Only)*

**Interest Group 3: Cell and Gene Therapy Discussion Group**

There are many new technical issues surrounding the development of potency assays for Cell and Gene Therapies, let's get together and discuss our successful and not-so-successful approaches. Potential topics include: What is the MoA and what do I do if I don't really know what it is? Are there sample preparation issues? If so how do we make sure the material being tested is representative of our product? What about forced degradation studies? Can we prove the potency is stability indicating?

**9:00** Introduction and Survey

**12:00** Interest Group Concludes

**Interest Group 4: Data Analysis**

So many questions and even more answers. (We are dealing with statisticians here!) Let's get together and talk about how to handle those strange and wonderful assays whose dose-response curves are less than ideal. Topics open for discussion include: Upper asymptotes: what to do if we don't have them, or they don't match or are poorly defined. What about those crazy outliers in the dose-response curve? Can we use outlier approaches? Which system suitabilities criteria really protect our assays and which are just for show. These are just some topics open to discussion. Submit your own and help shape the conversation.

**9:00** Introduction and Survey

**12:00** Interest Group Concludes