

# BEBPA 2020 US Bioassay Conference

25-27 March 2020

*Our First Ever VIRTUAL Conference!*

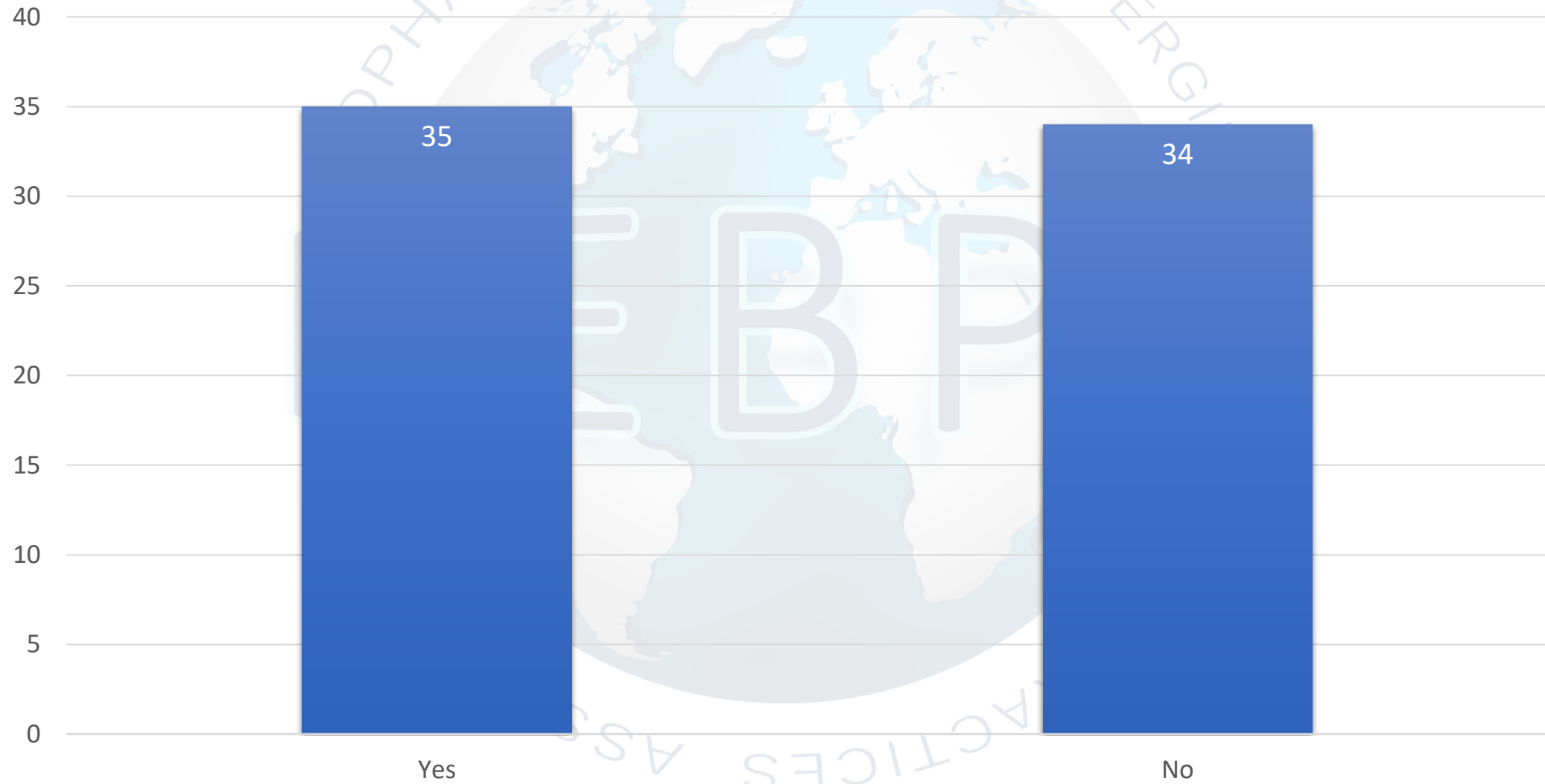
**Audience Survey**



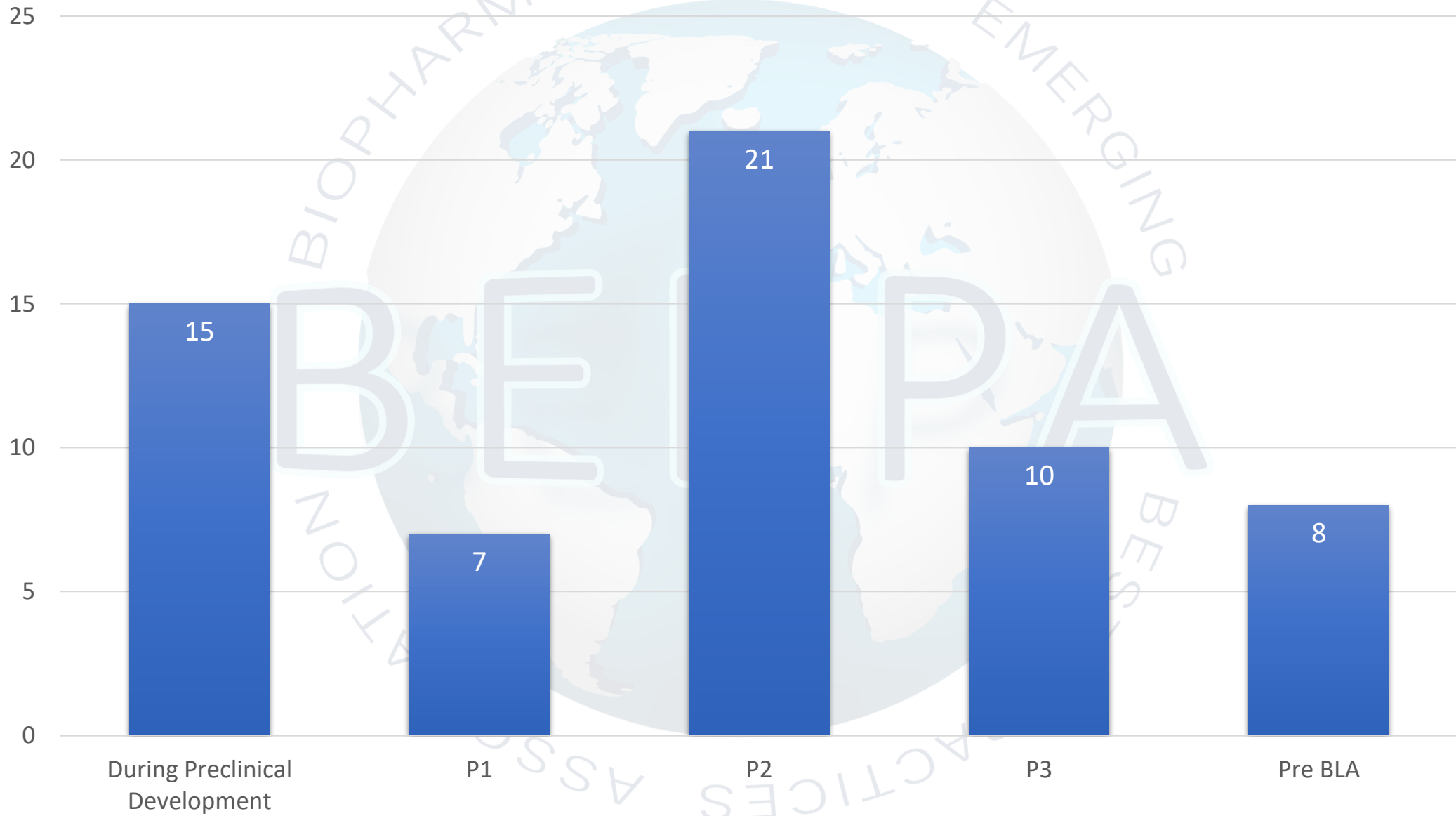
# Session 1: Bioassays for Complex Products

Session Chair: Bassam Hallis

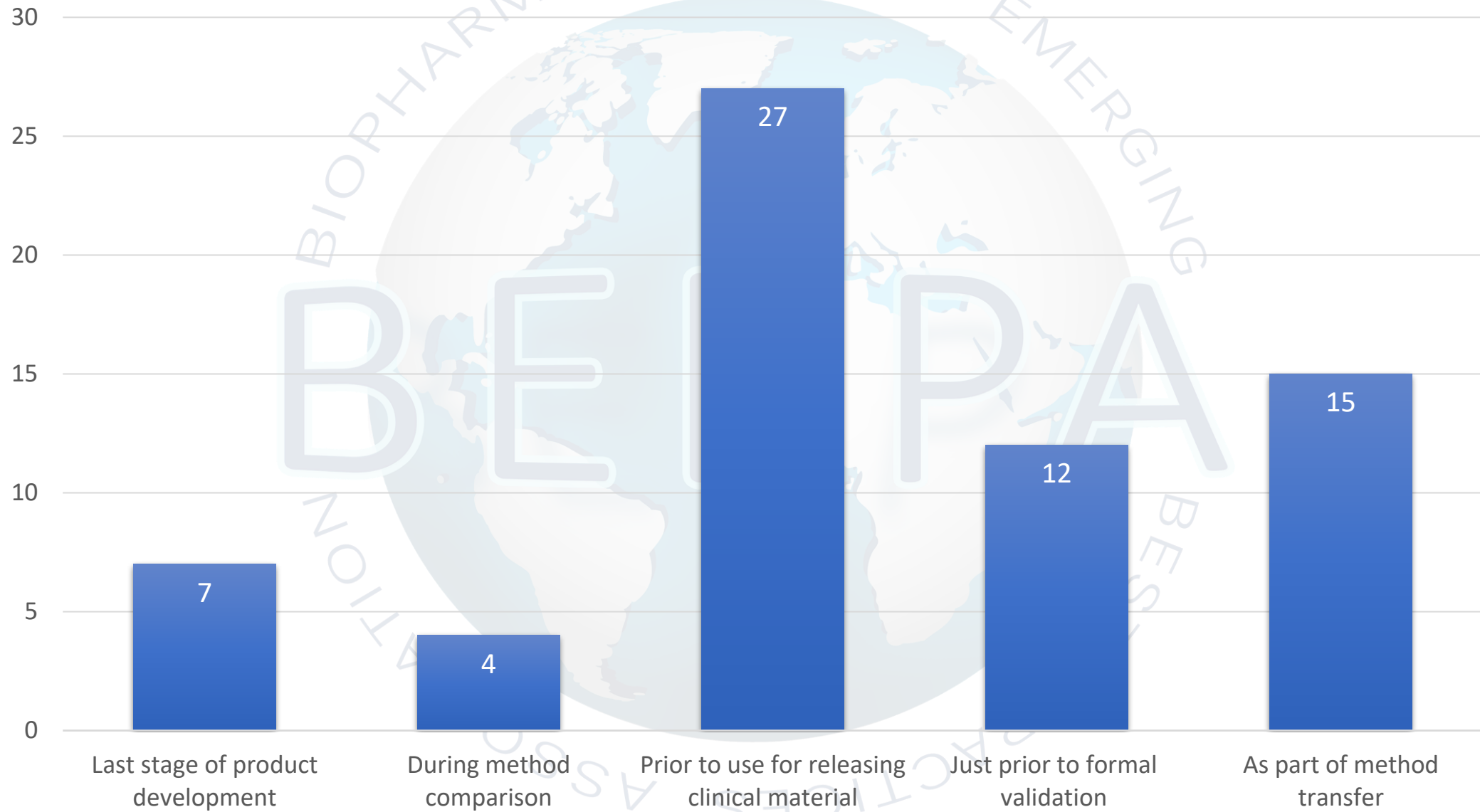
## 1.1 Does Your Company Have Any Products for Which the Mechanism of Action (MoA) is Unknown?



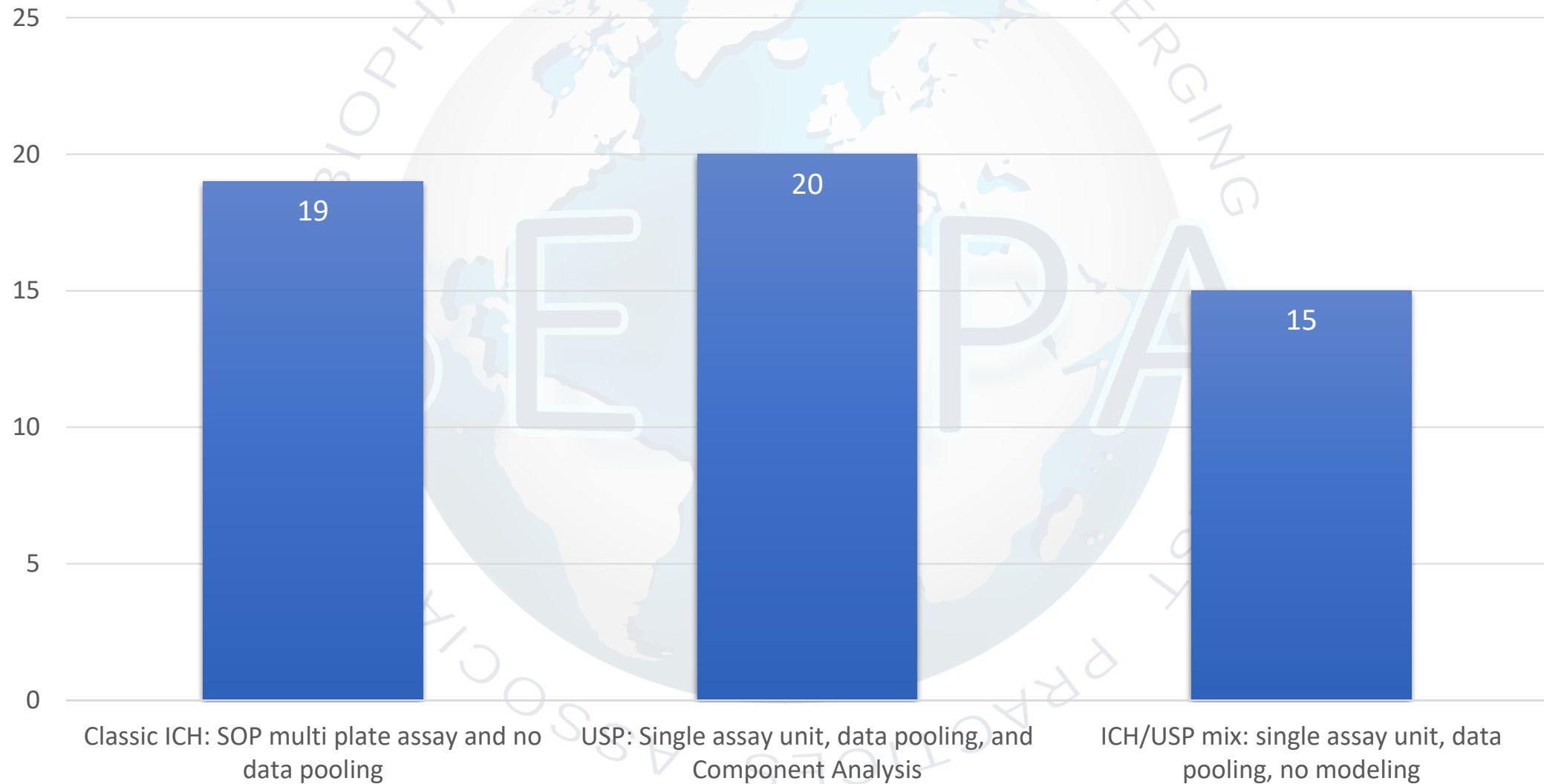
## 1.2 At Which Phases Have You Replaced Your Potency Assay?



### 1.3 When Do You Qualify/Characterize/Verify Your Assays?



## 1.4 What Type of Validation Do You Usually Perform for Your Potency Assays?

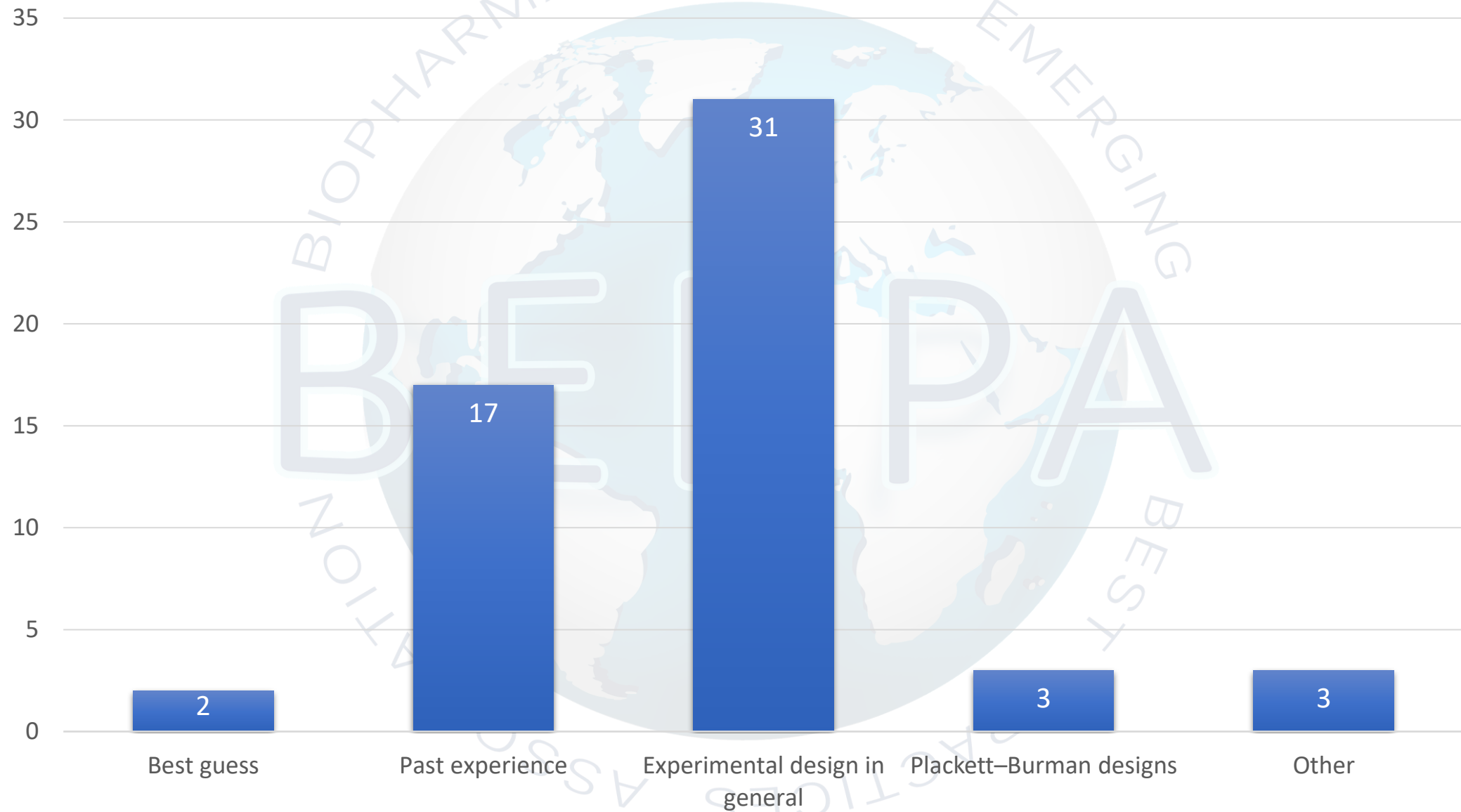




## **Session 2: Statistical Tools**

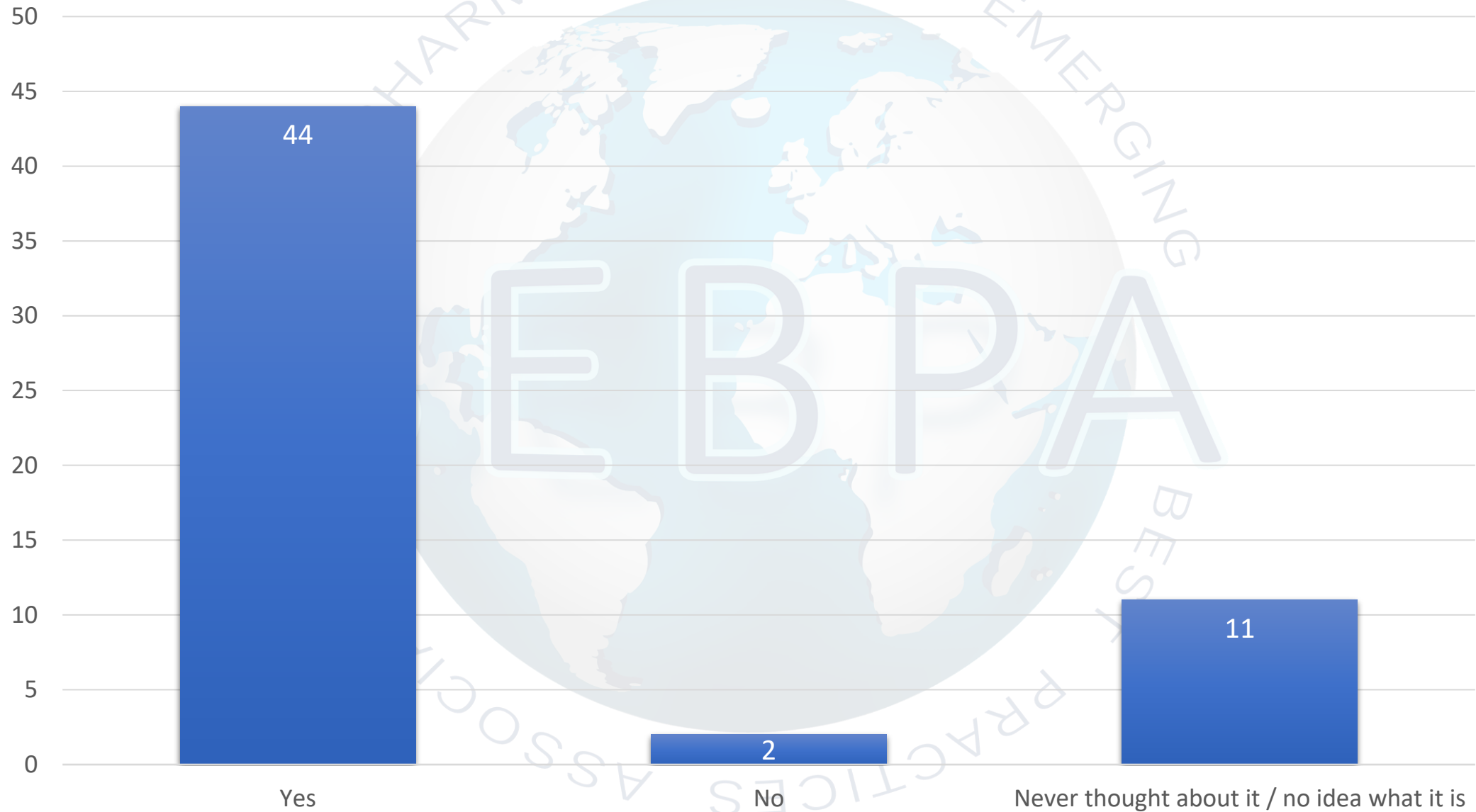
Session Chair: David Lansky

## 2.1 When You Specify Factor Tolerances, How Do You Set Them?

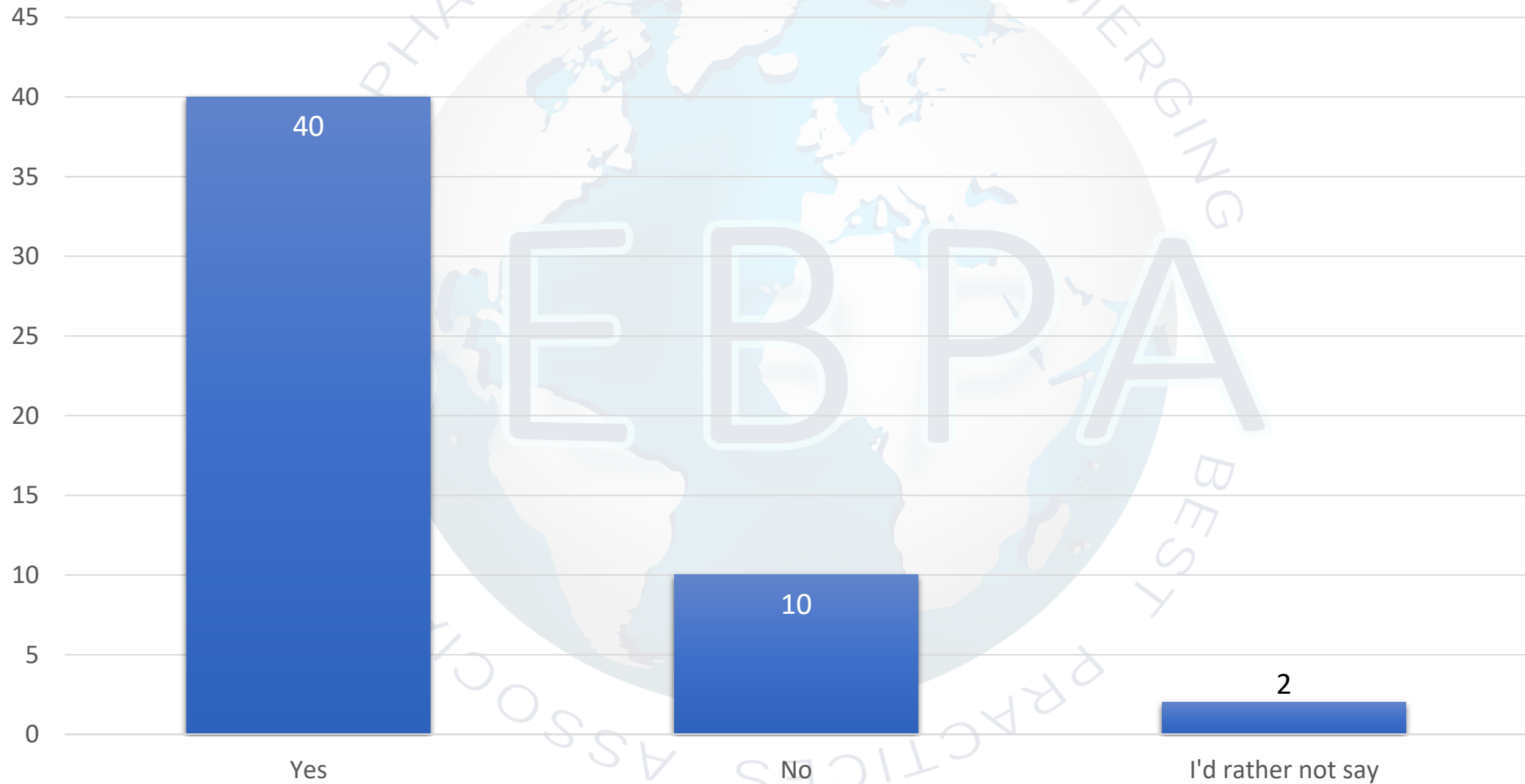




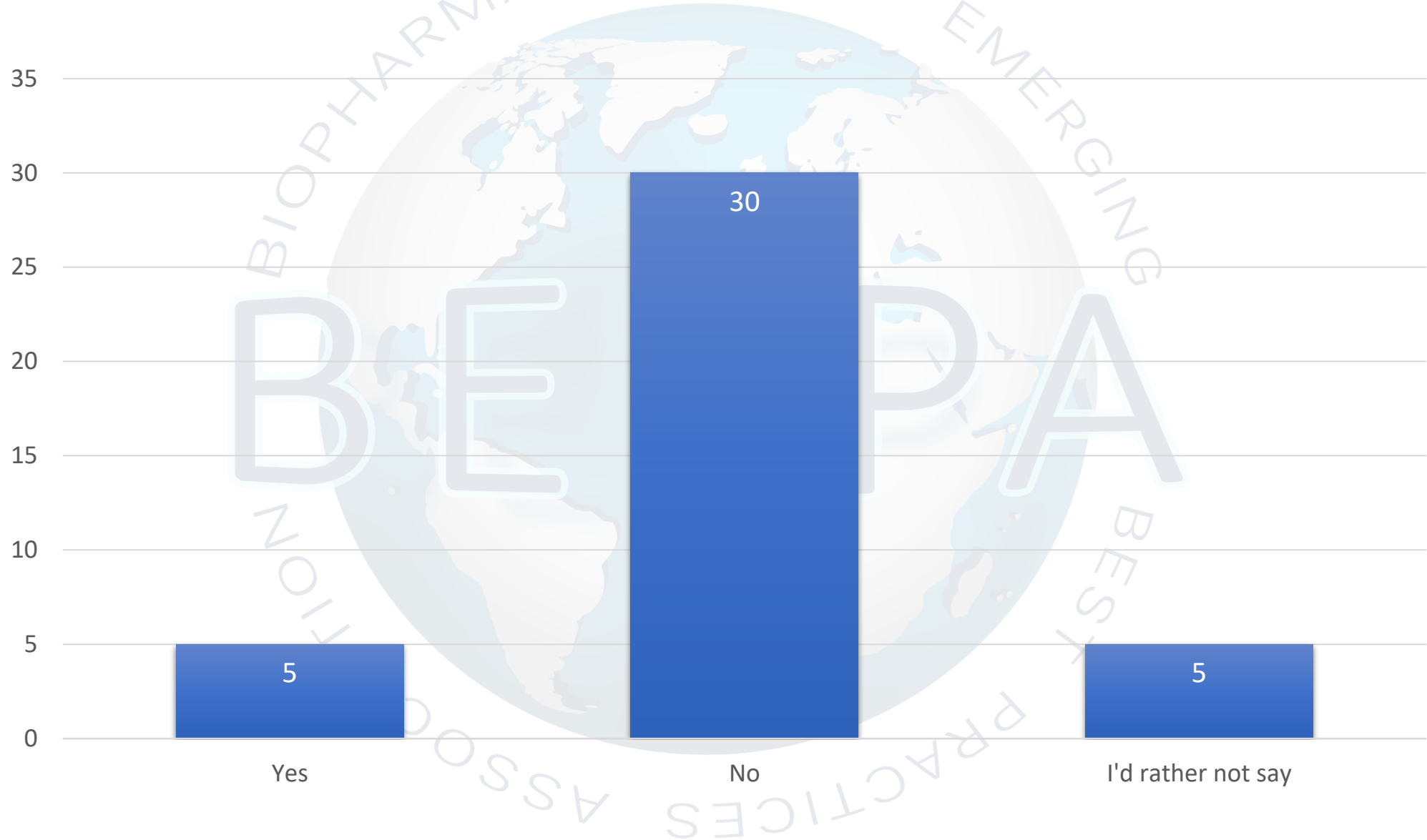
## 2.2 Is Not Knowing the False Negative Rate a Problem?



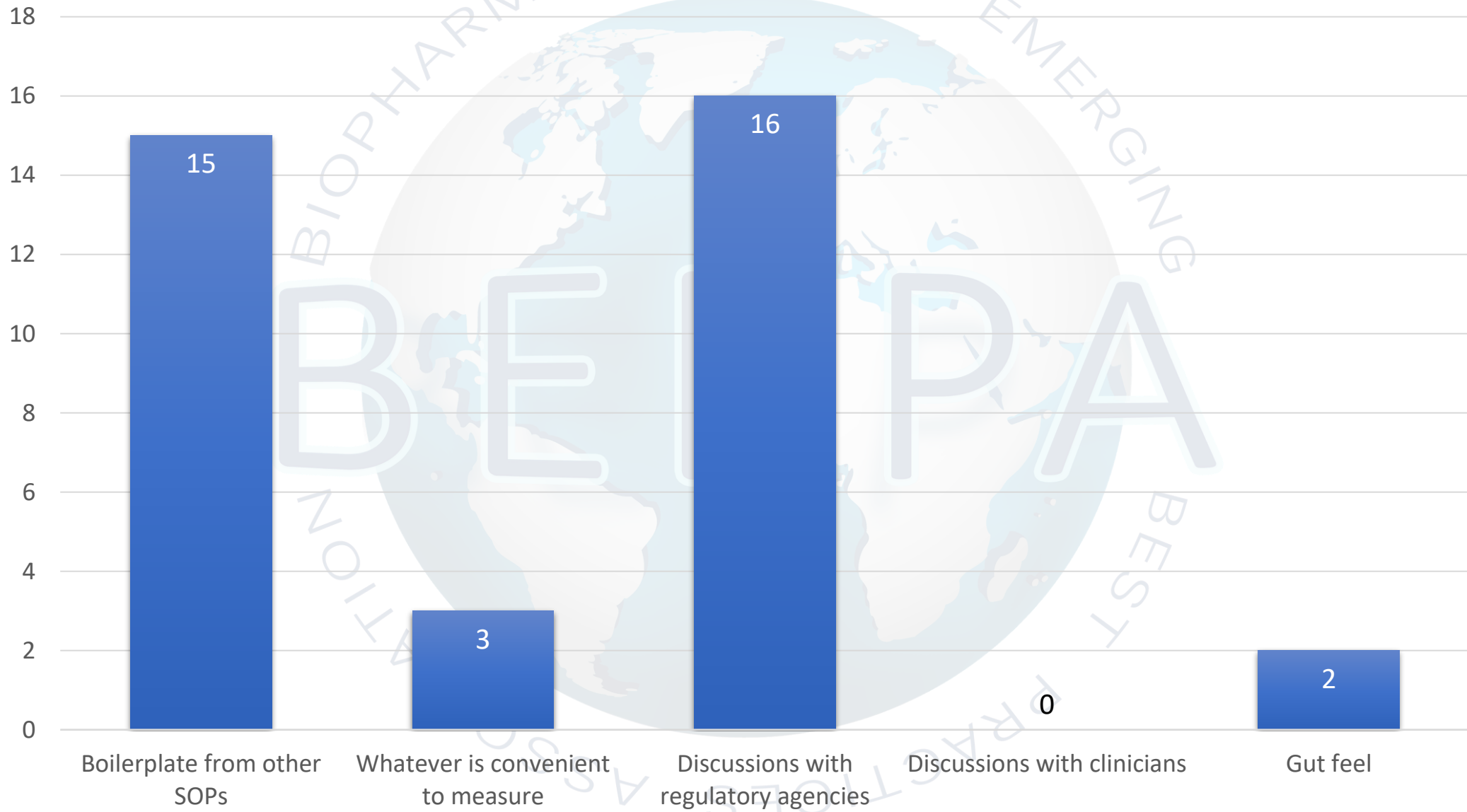
## 2.3 Do You Discuss These Issues with Risk Assessors in Your Company?



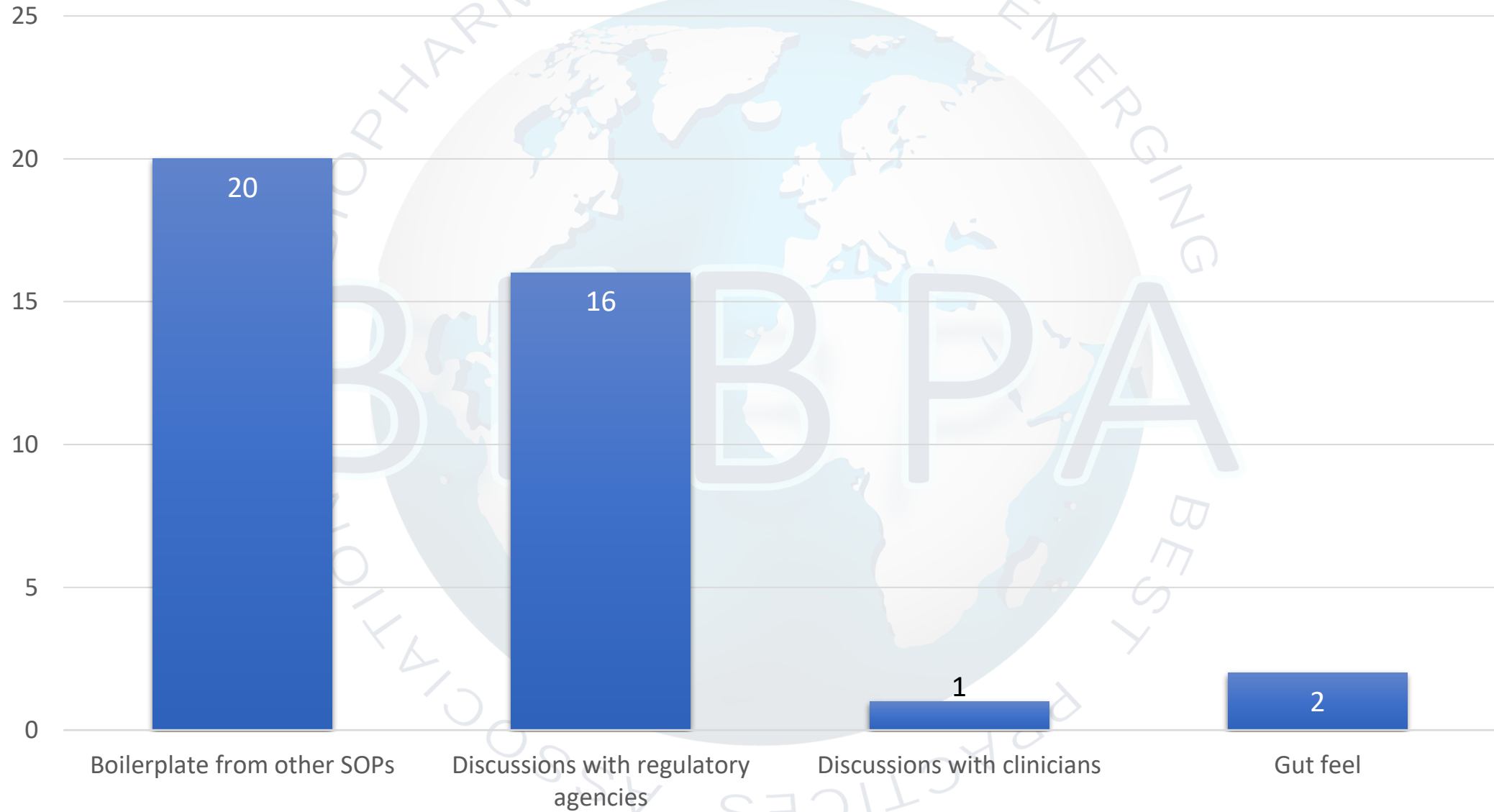
## 2.4 Do You Discuss These Issues with Clinicians?



## 2.5 How Do You Choose the Metrics to Look for Non-Parallelism?



## 2.6 How Do You Set the Limits For These Metrics?

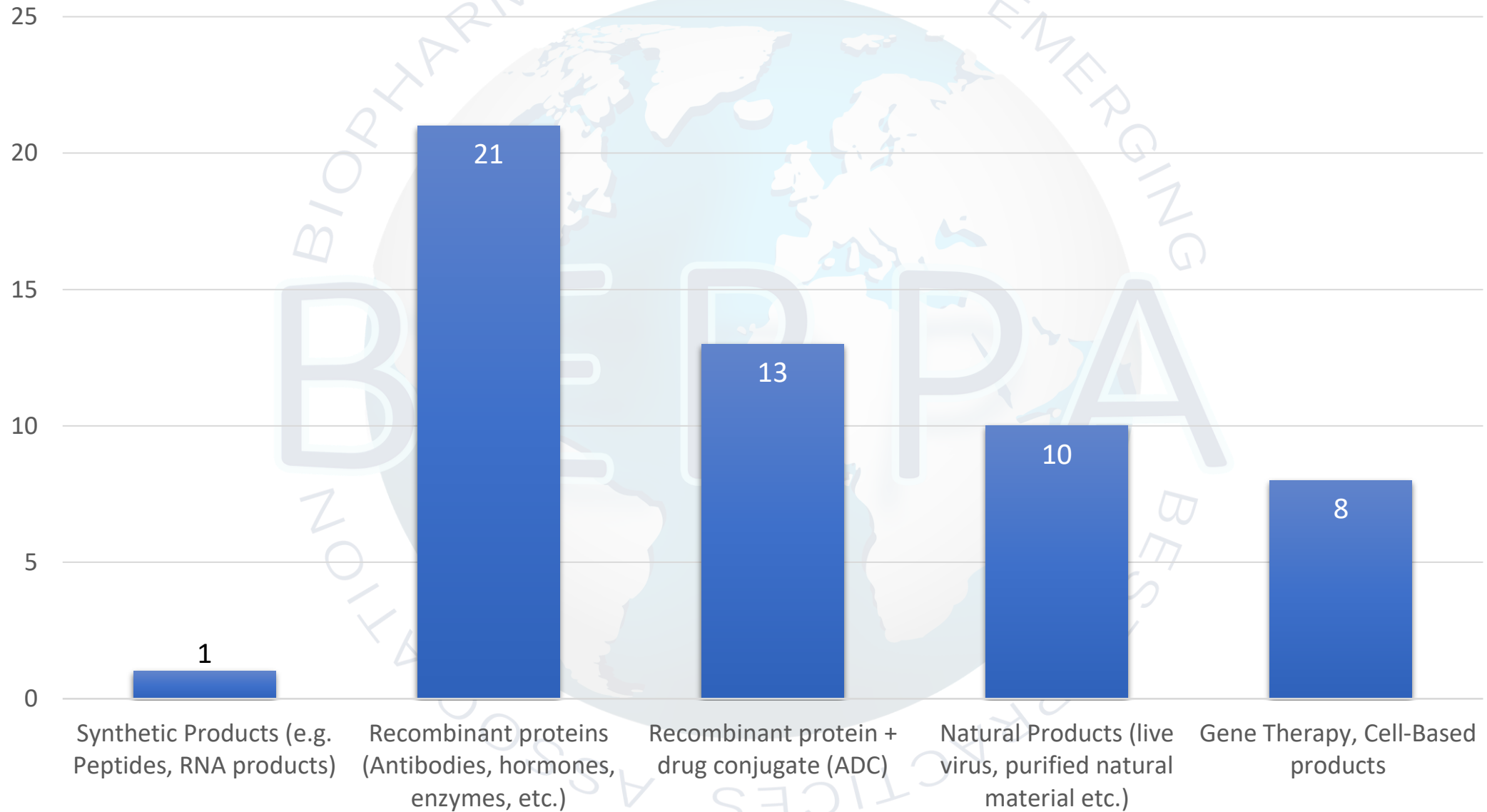




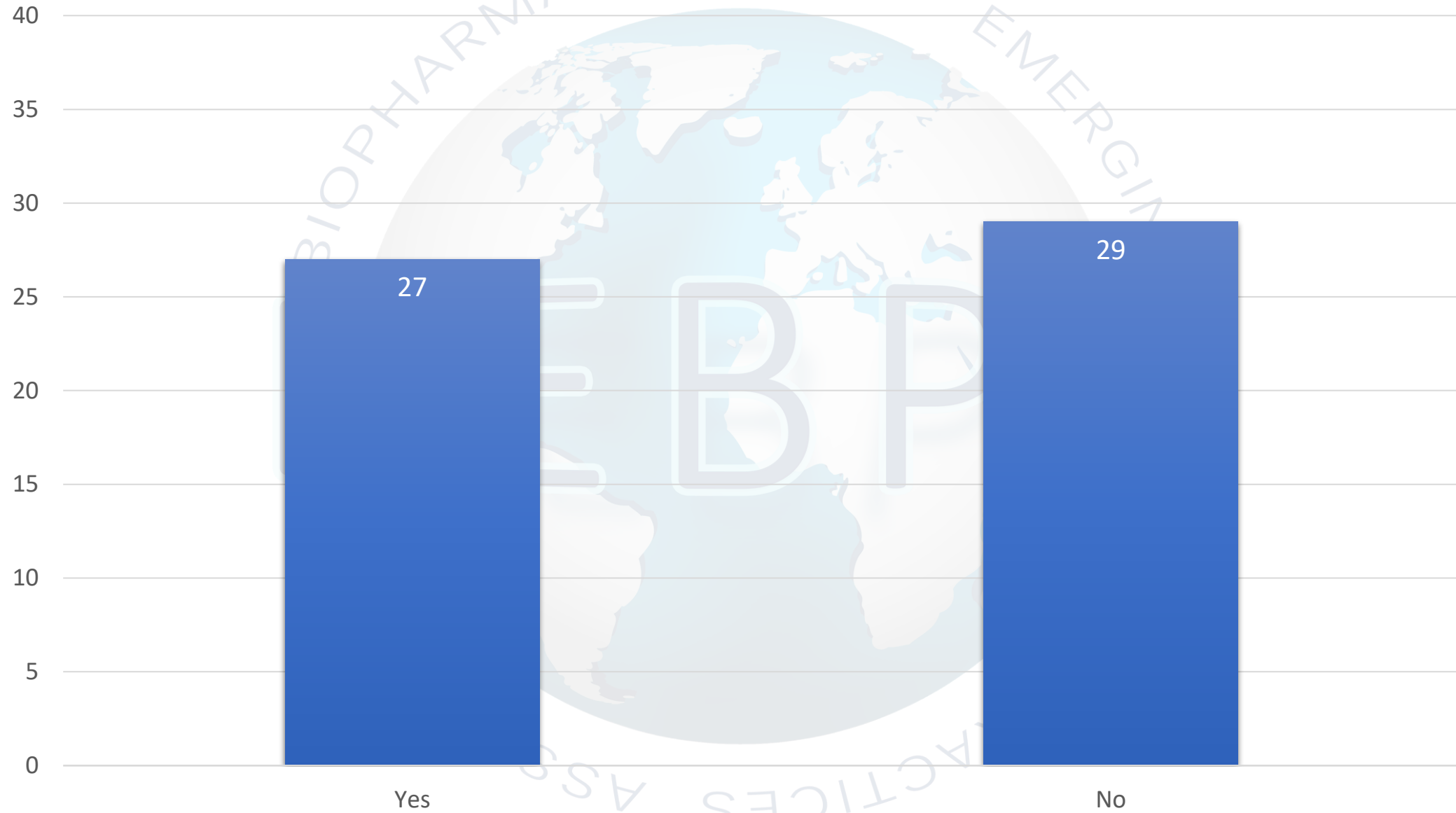
# Session 3: Lifecycle of Potency Assays

Session Chair: Kristin Clement

### 3.1 What Type of Products Do You Work On?

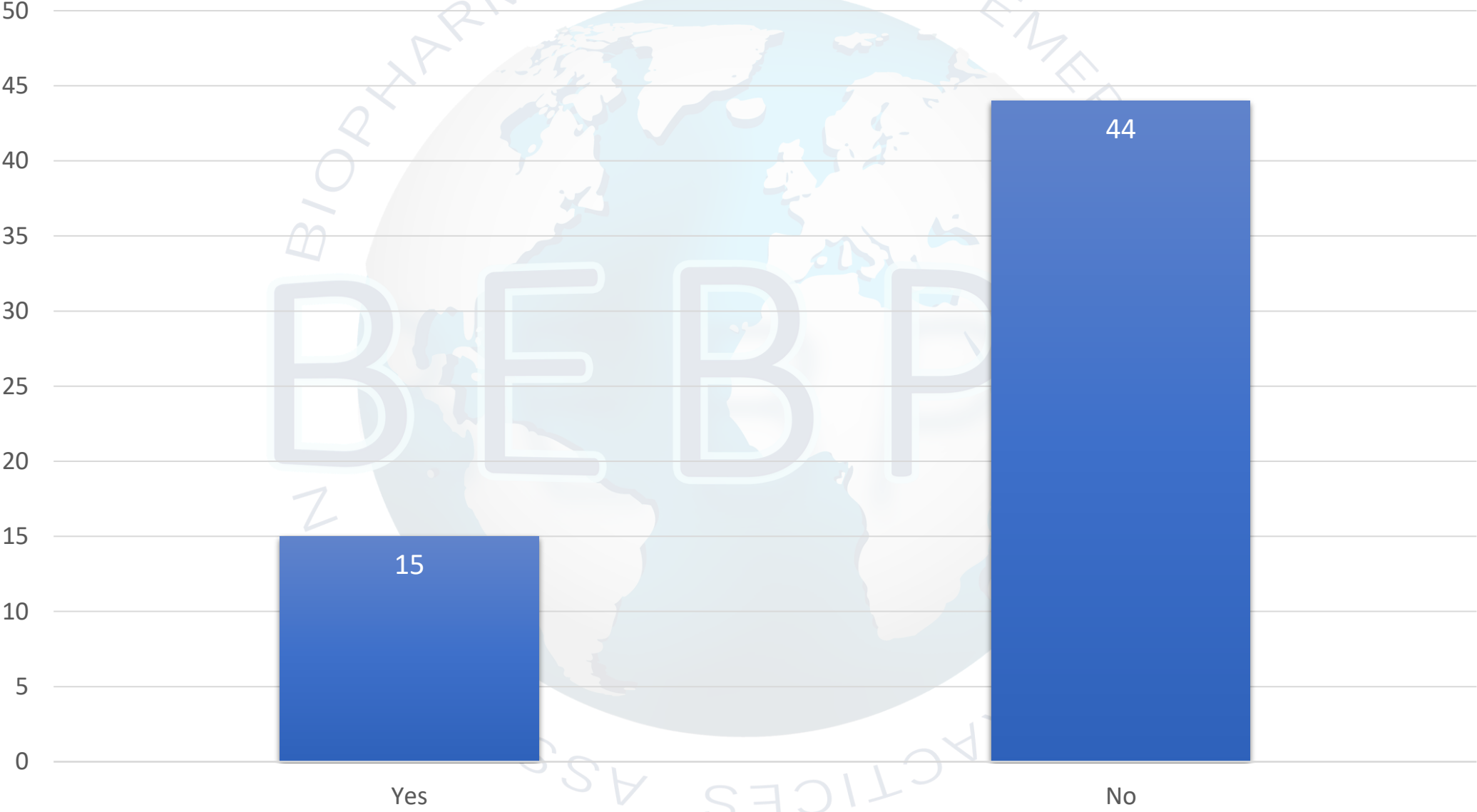


### 3.2 Is Your Product Considered a Break-Through/First-In-Class Product?





### 3.3 Do You Work on Any BioSimilar Products?

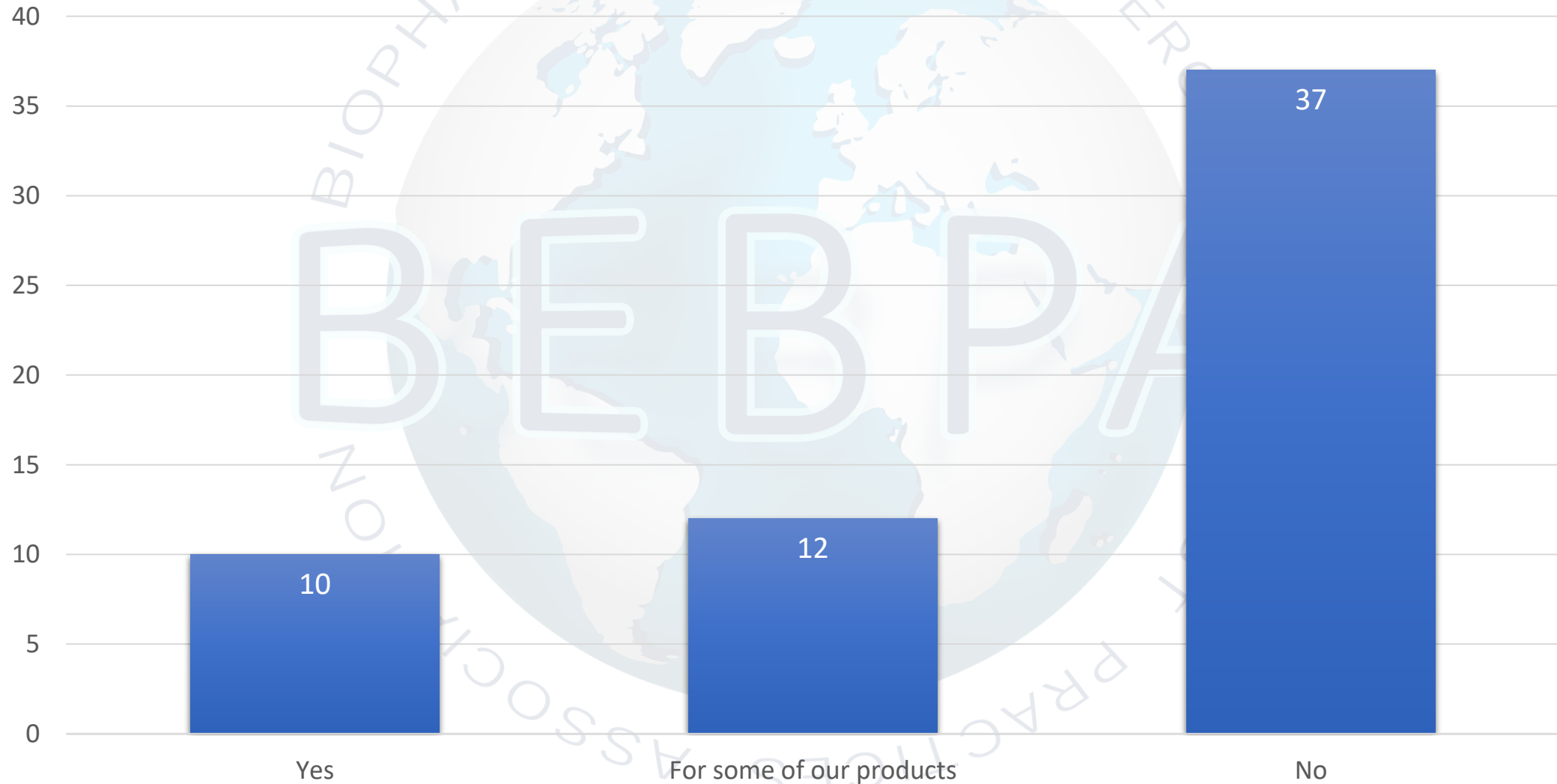




# Session 4: Problematic Reference Material Issues

Session Chair: Sian Estdale

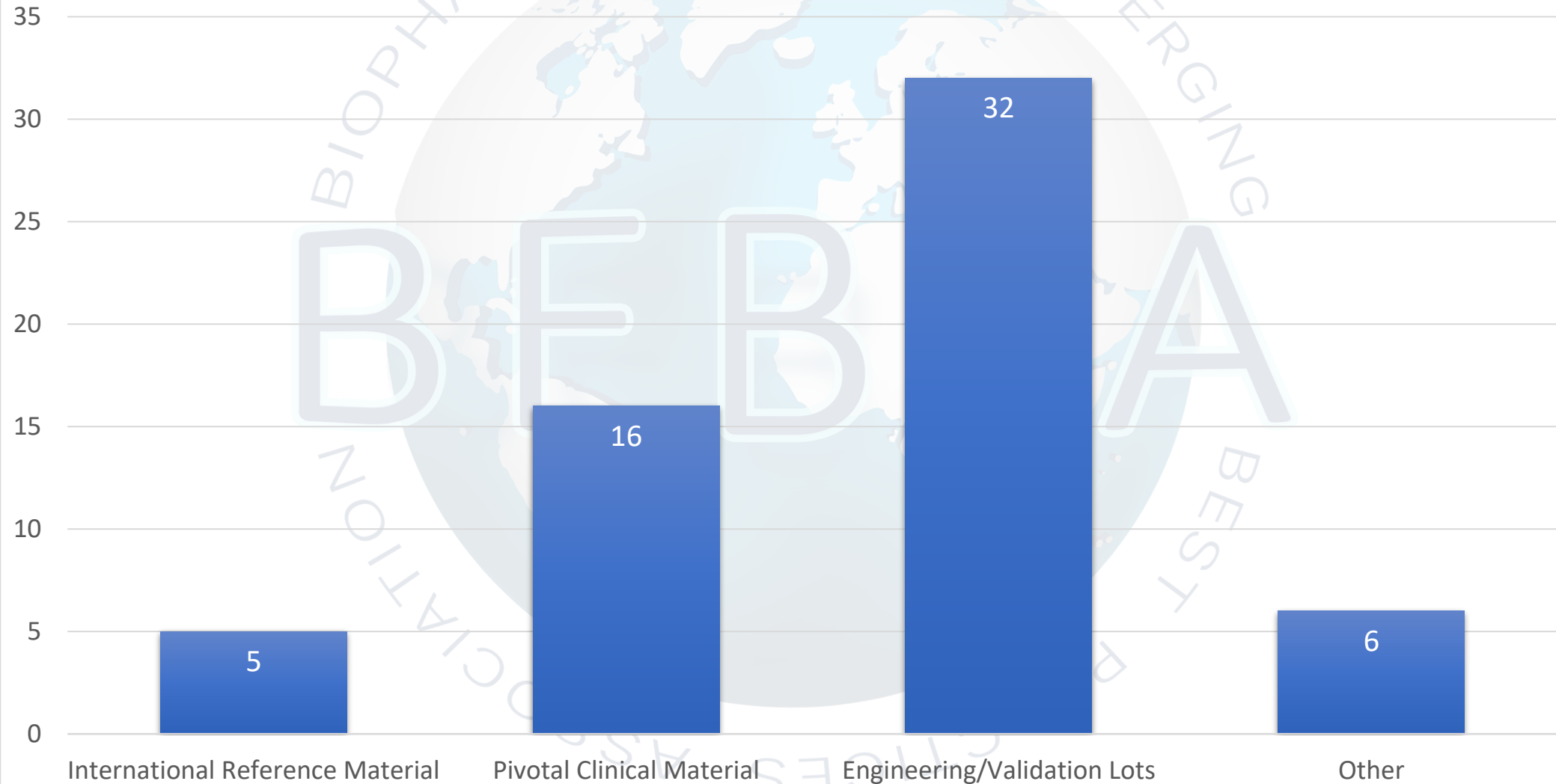
## 4.1 Is an International or Recognized Reference (e.g., USP, NIBSC, WHO) Available for Your Product(s)?



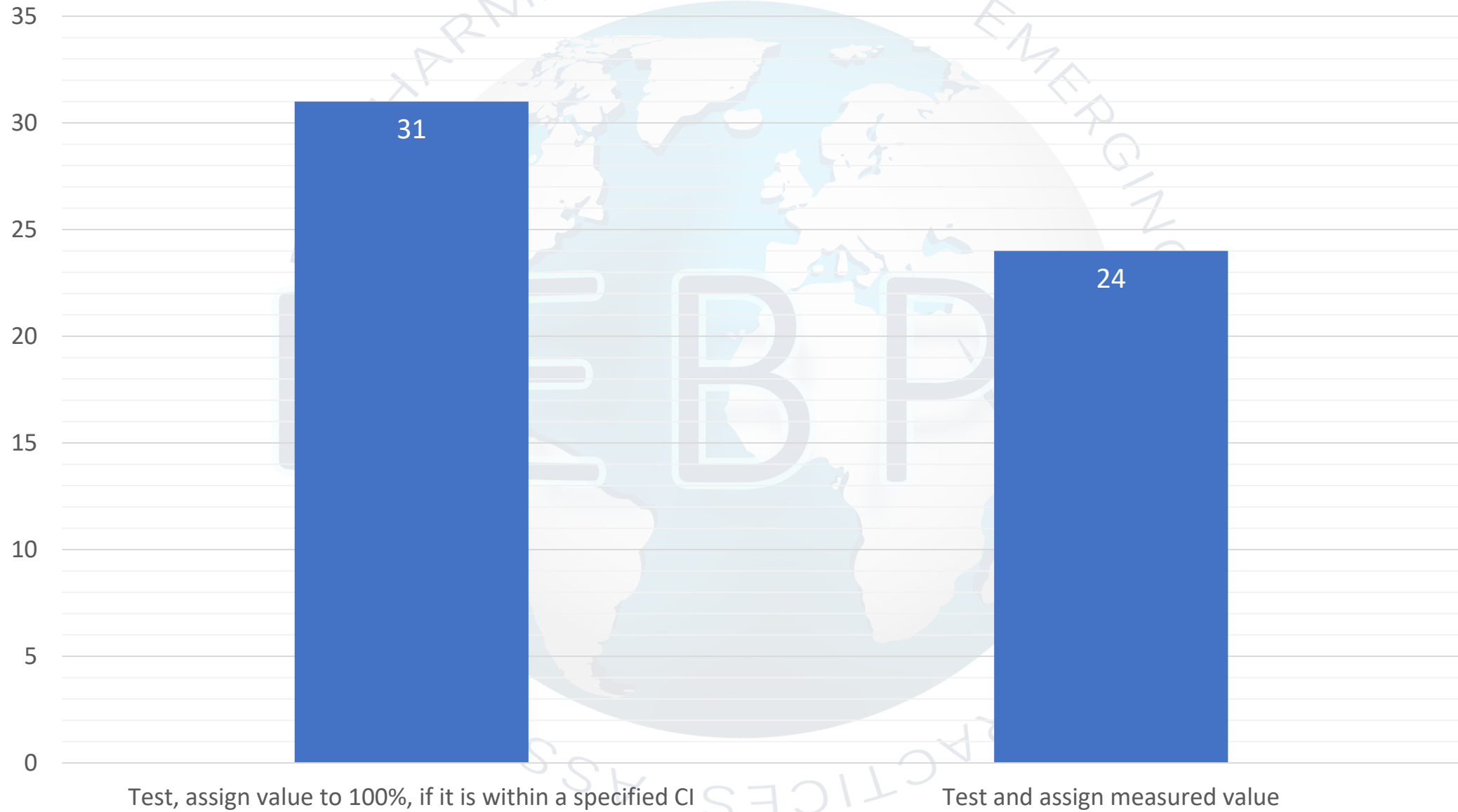
## 4.2 Do You Have a Two-tiered Reference System (one with Primary and Secondary Reference Material)?



### 4.3 What is the Typical Source of Your Primary Reference Material?



## 4.4 How Do Value Assign your Working Reference?

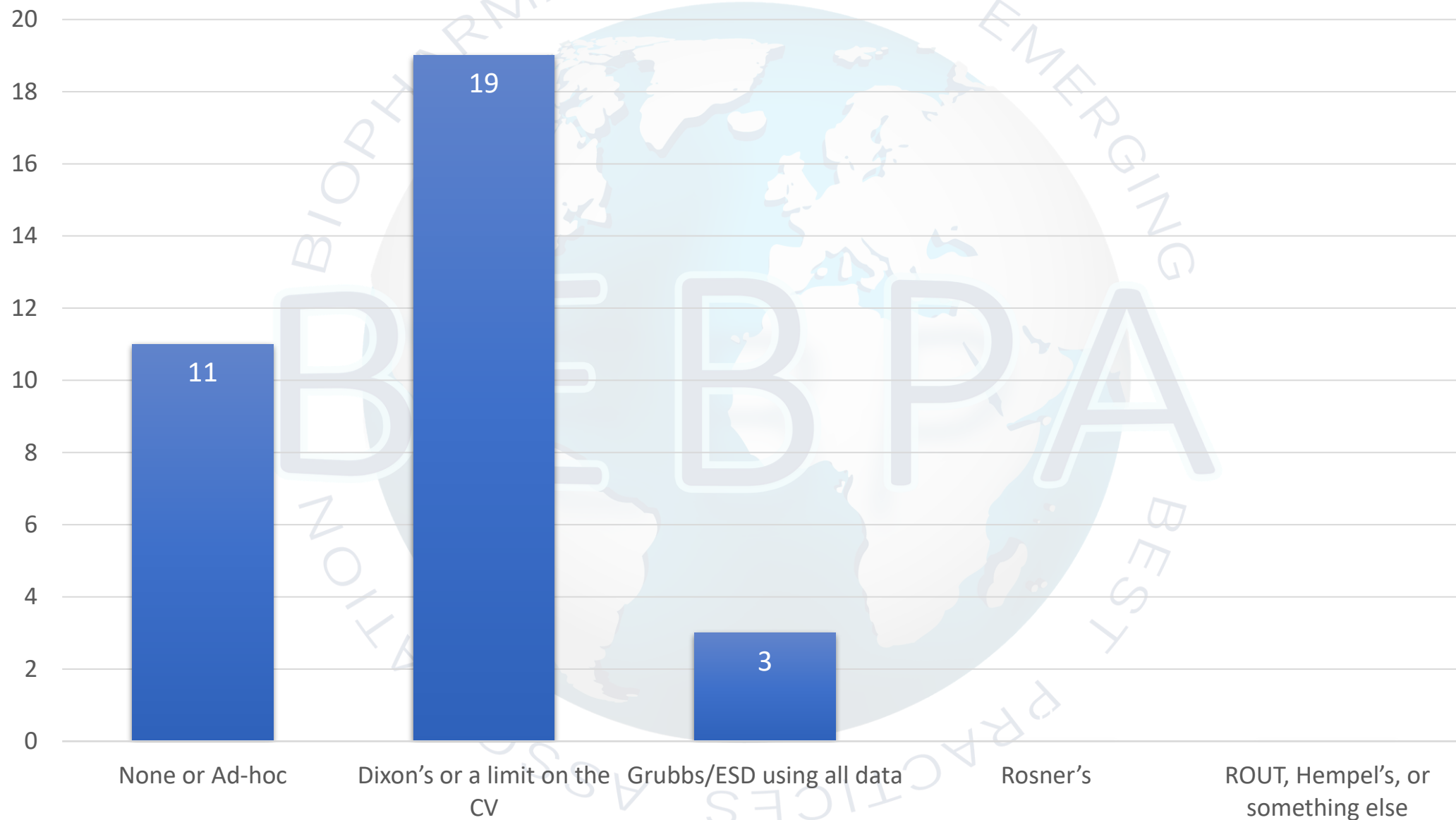




# Session 5: Outliers in Potency Assays

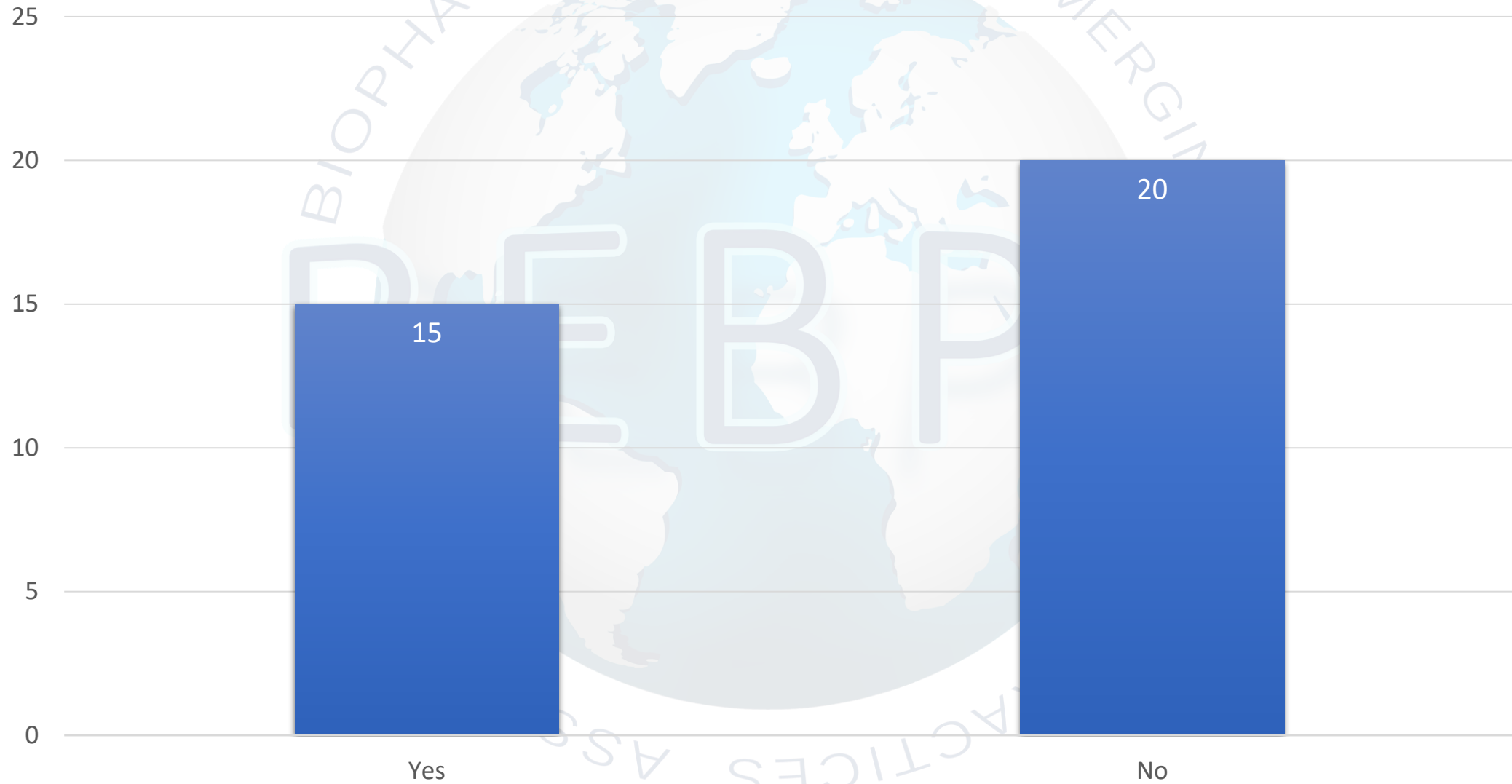
Session Chair: Bassam Hallis

## 5.1 What Outlier Detection Method Do You Use Most Often:

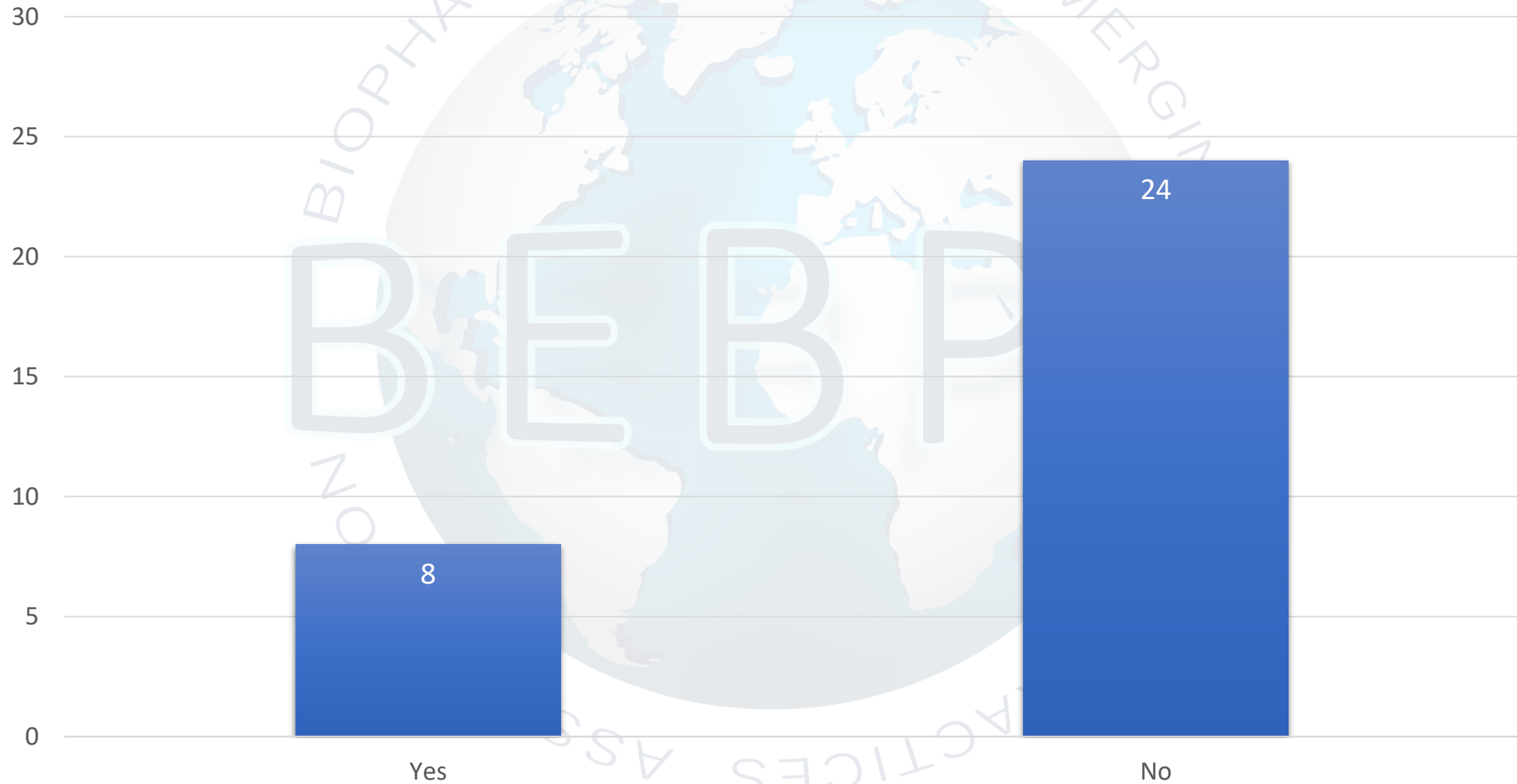




## 5.2 Do You Have Any Sort of Formal Procedure for Looking at Outliers at Multiple Levels, Such as Wells And Samples?



### 5.3 Do You Have an Outlier System That Involves Periodic Review of Outliers of Various Types by Analyst, Position, Sequence, etc.?

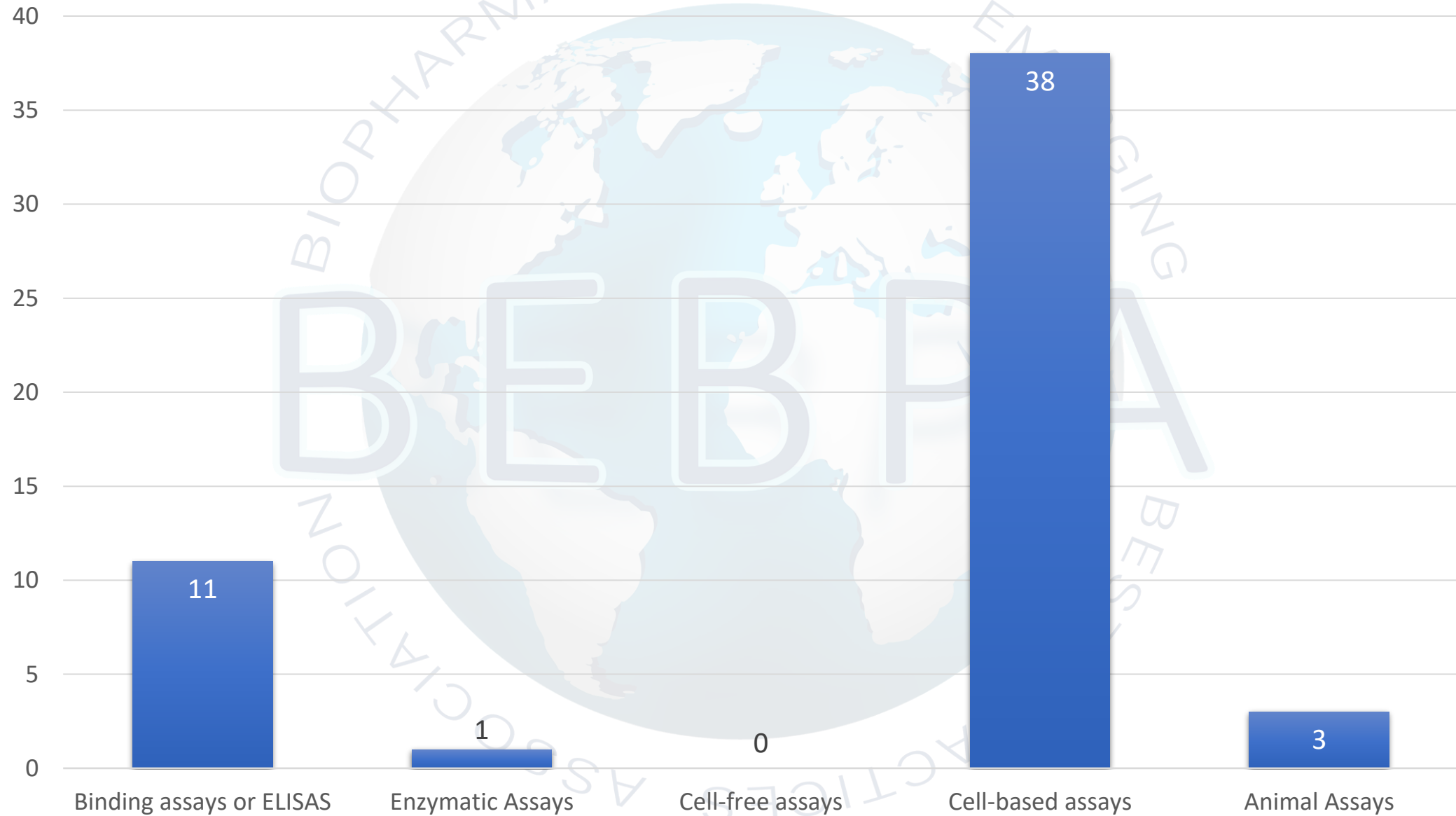




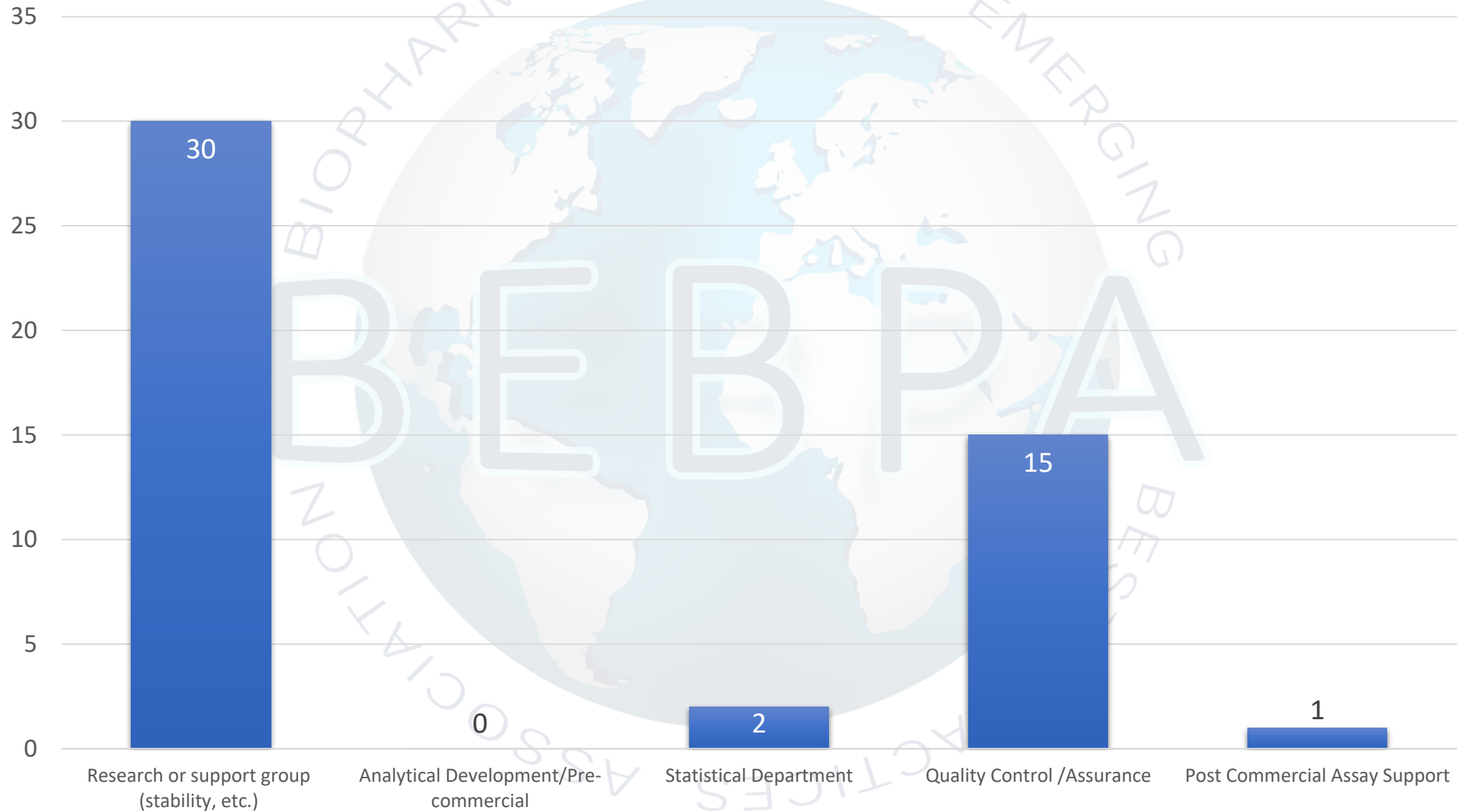
# Session 6: Product Specific Method Development

Session Chair: Steven Walfish

## 6.2 What Type of Potency Assays Do You Primarily Use?



## 6.3 What Part of the Organization Do You Work In?



**THANK YOU**

for attending BEBPA's  
2020 US Bioassay Conference

*Our First Ever **VIRTUAL** Conference!*

*We could not have done this without YOU!*