BEBPA 2023 U.S. Bioassay Conference

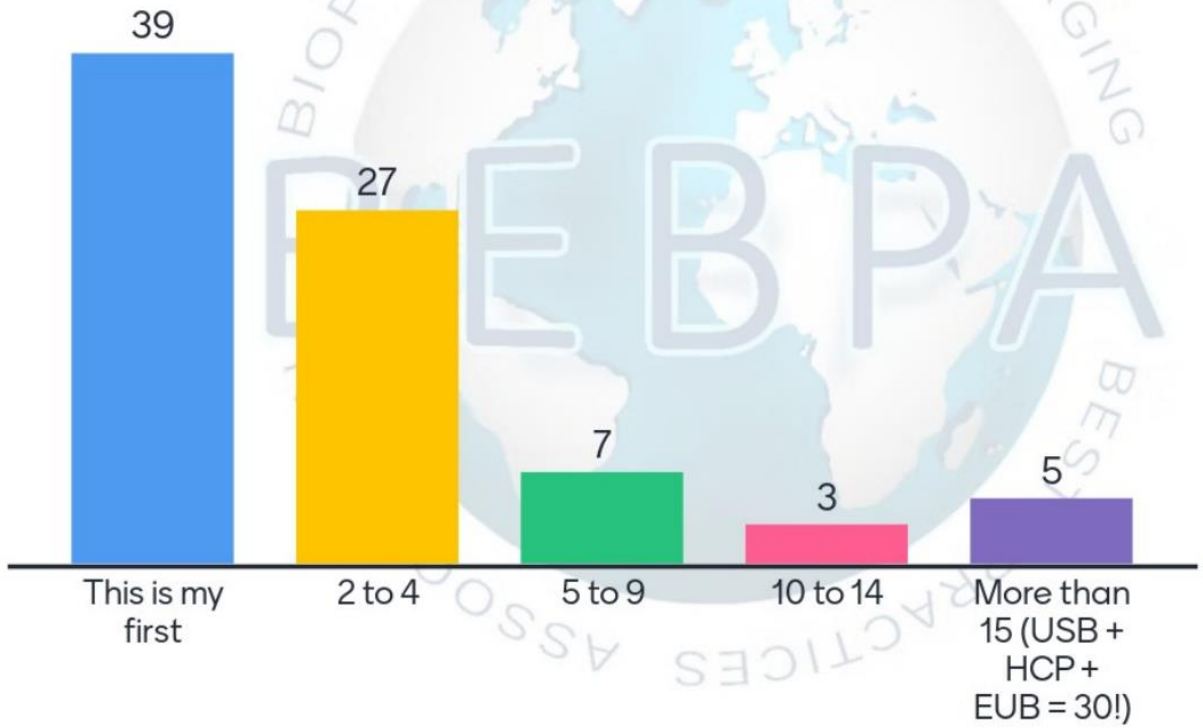
14-16 March 2023
Seattle, WA, USA
Hybrid Event

Welcome Back & Introduction

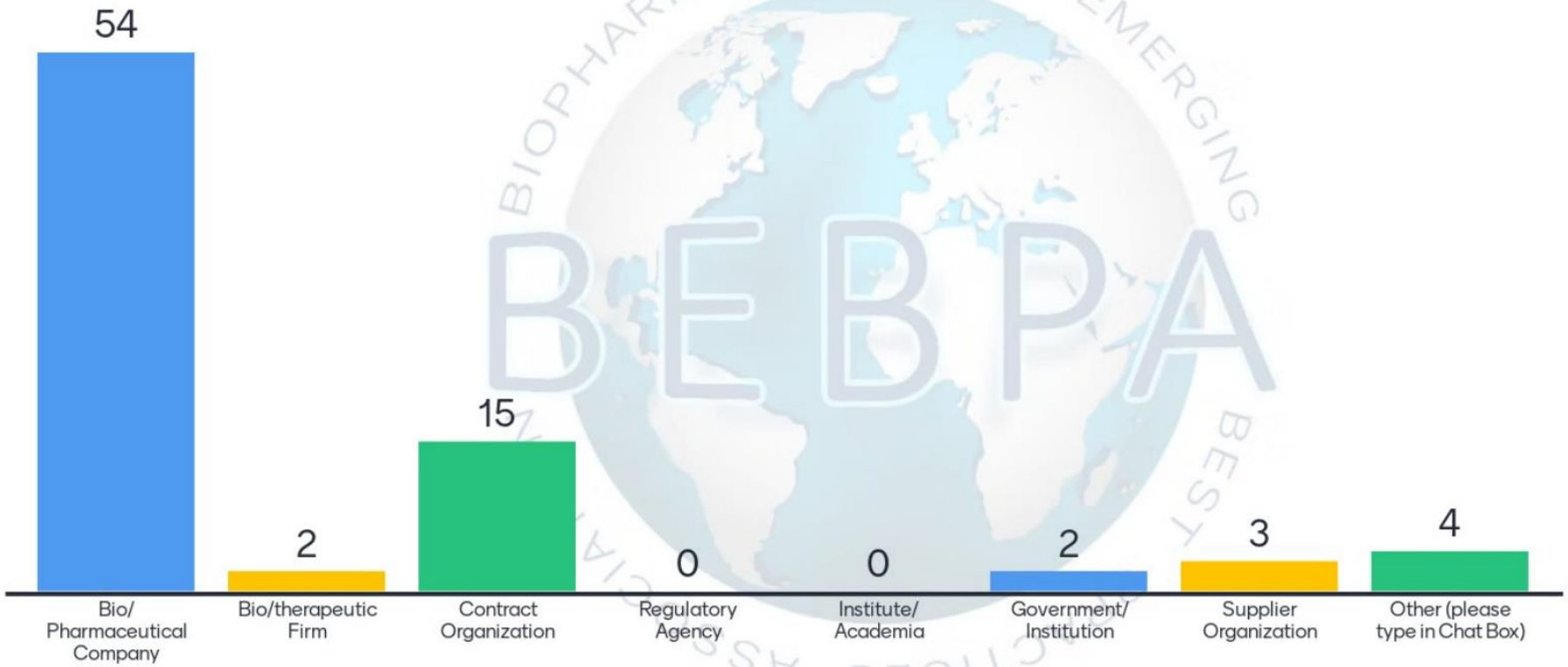
Laureen Little, President of BEBPA

Audience Surveys

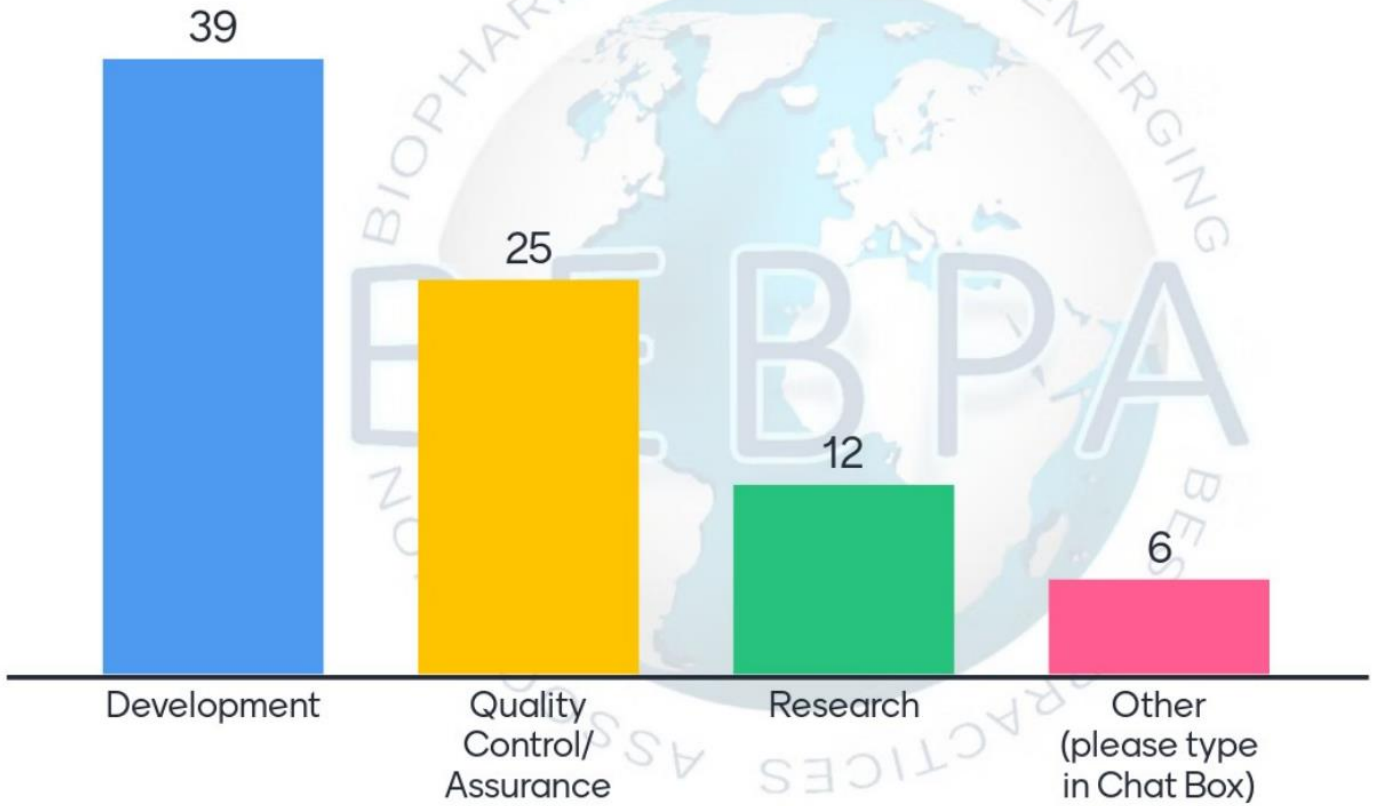
i.1 How many BEBPA Conferences have you attended?



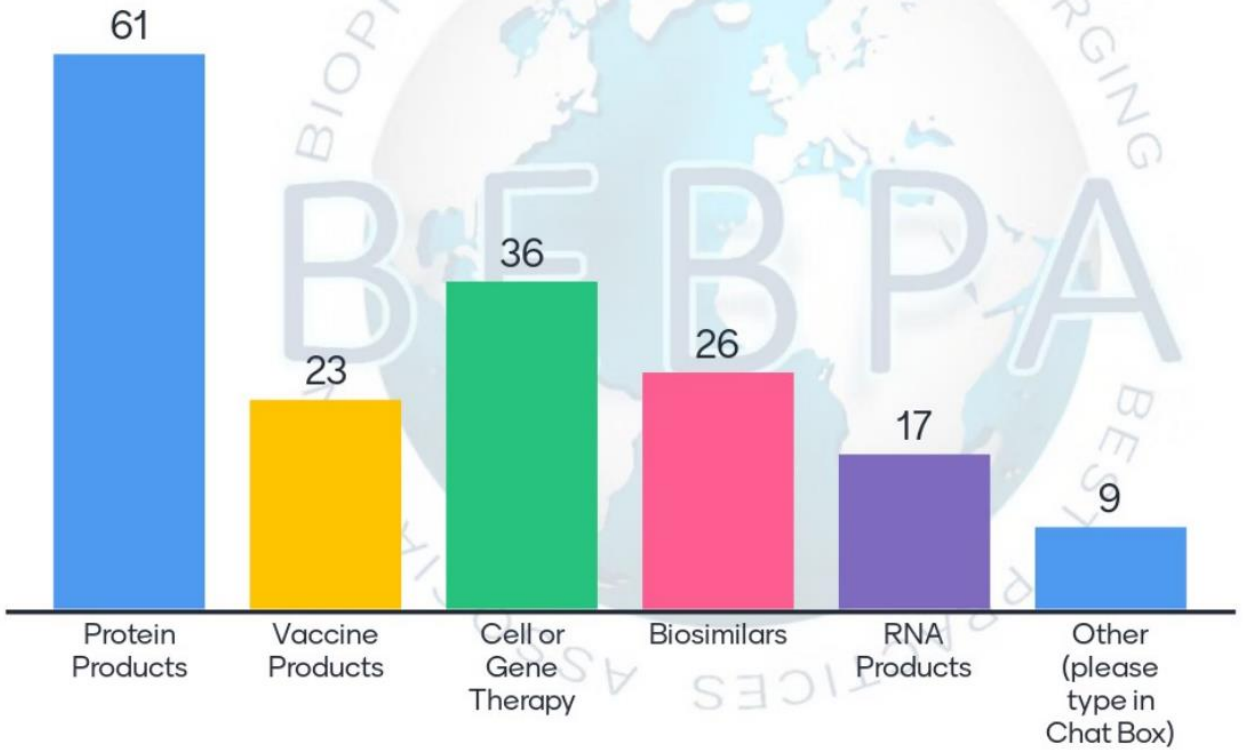
i.2 What type of organization do you work for?



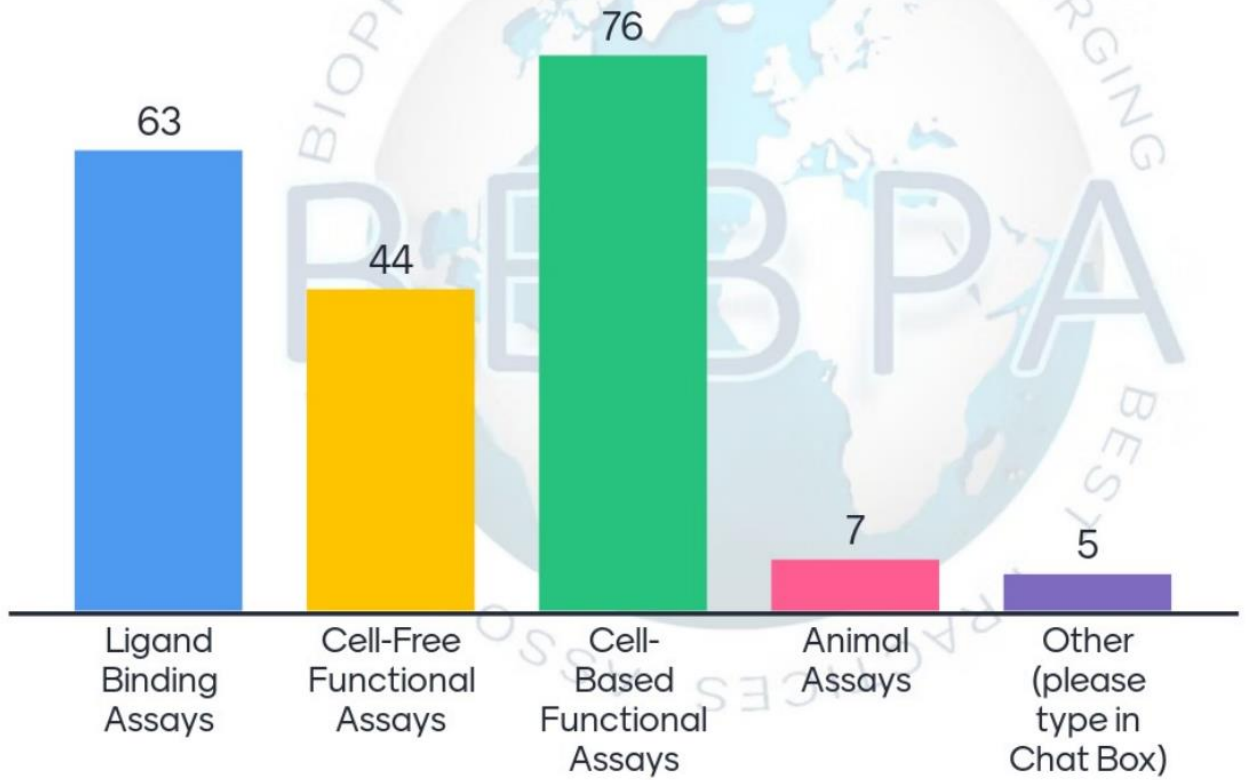
i.3 What part of the organization do your work for?



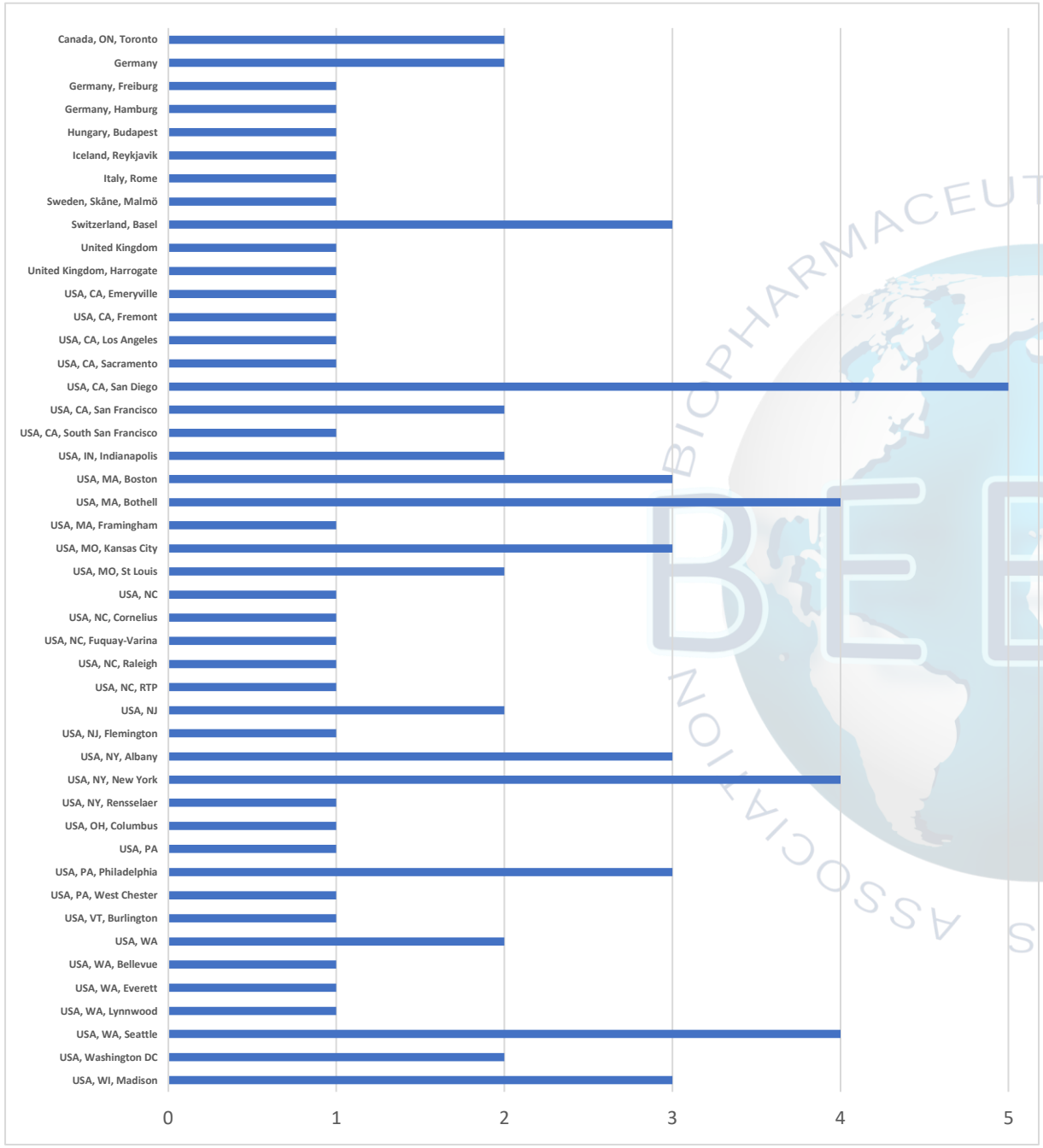
i.4 What type of products do you work with? (Check all that apply)



i.5 What type of assays do you develop? (Check all that apply)



i.6 Where are you from? What city/state/country?)



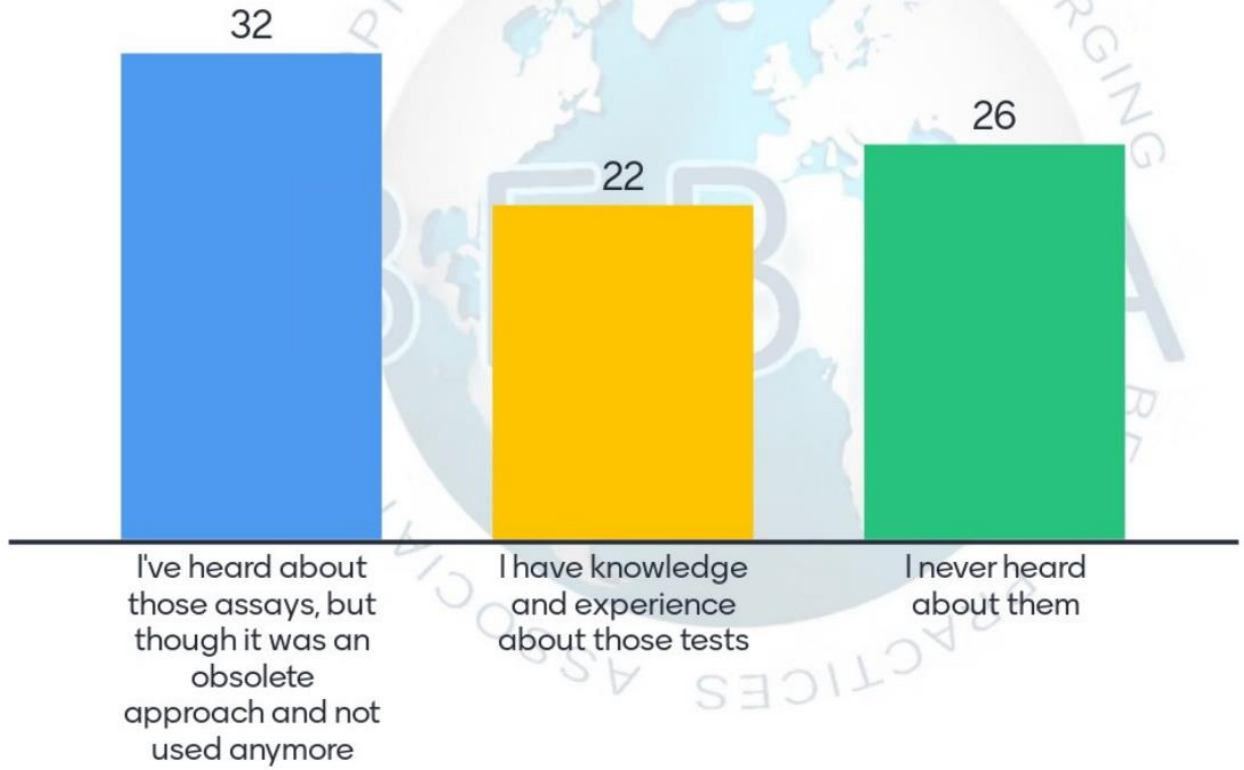
i.6 Where are you from? What city/state/country?)

Session 1: Assay Lifecycle

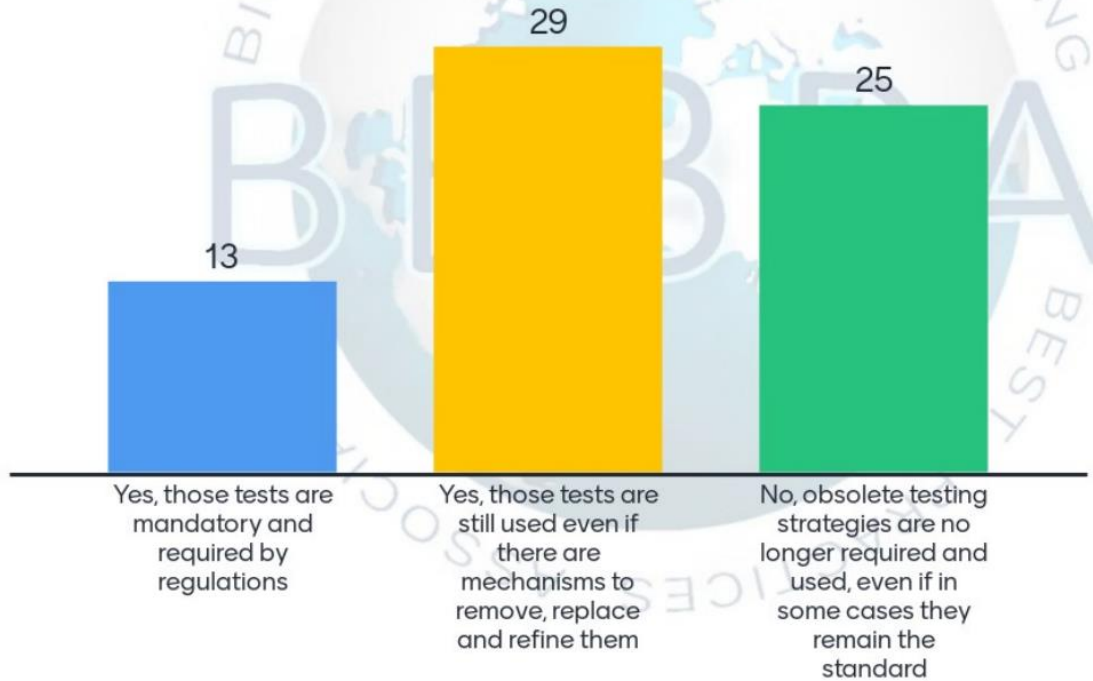
Session Chair: Laureen Little, President of BEBPA

Audience Surveys

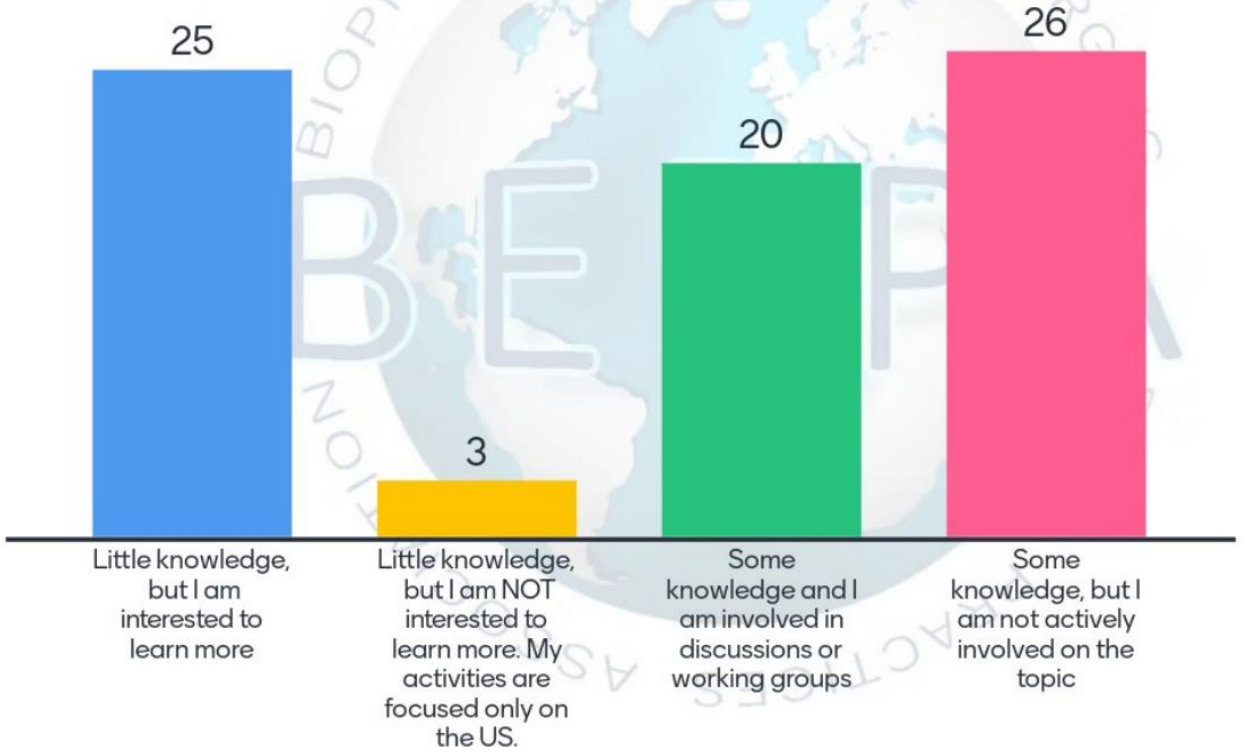
1.1 What is your experience with in vivo tests for human and veterinary batch release tests?



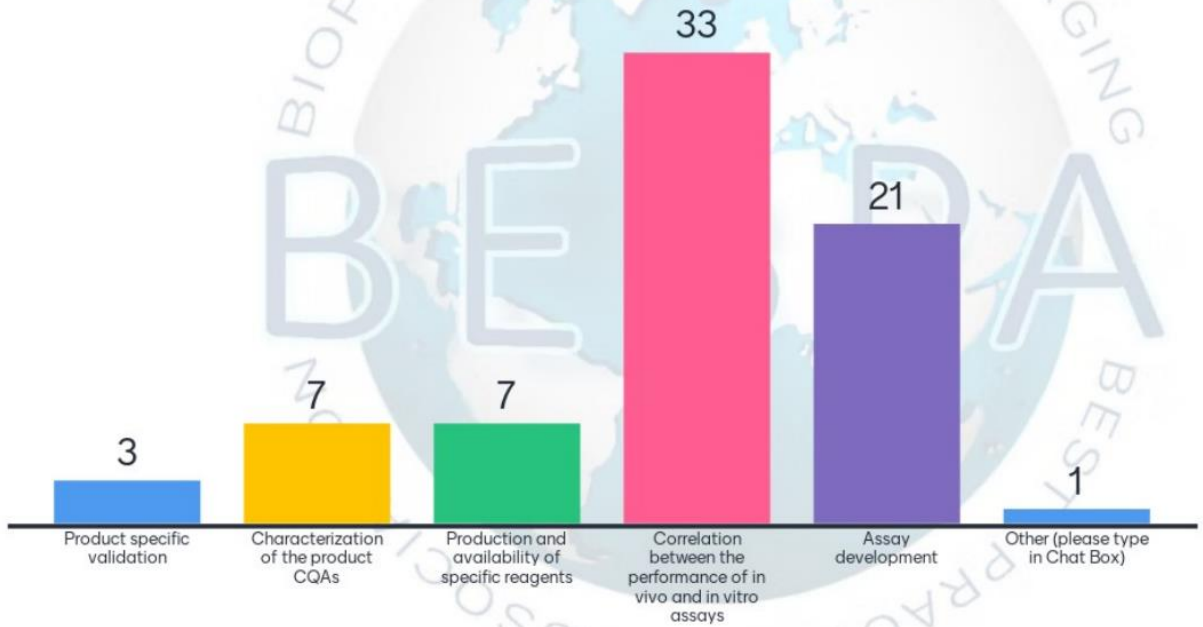
1.2 Do you think that in the US in vivo batch release testing is still the gold standard for human and veterinary vaccines?



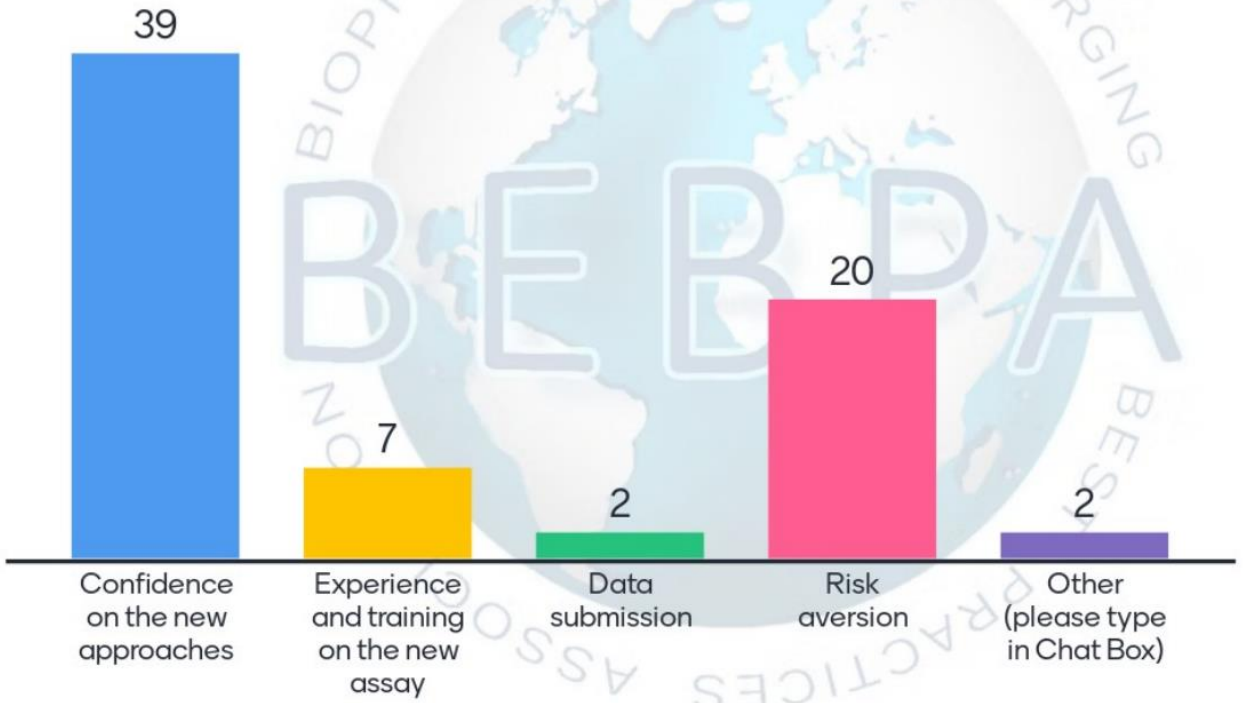
1.3 What do you know about the implementation and regulatory acceptance of in vitro assay outside the US?



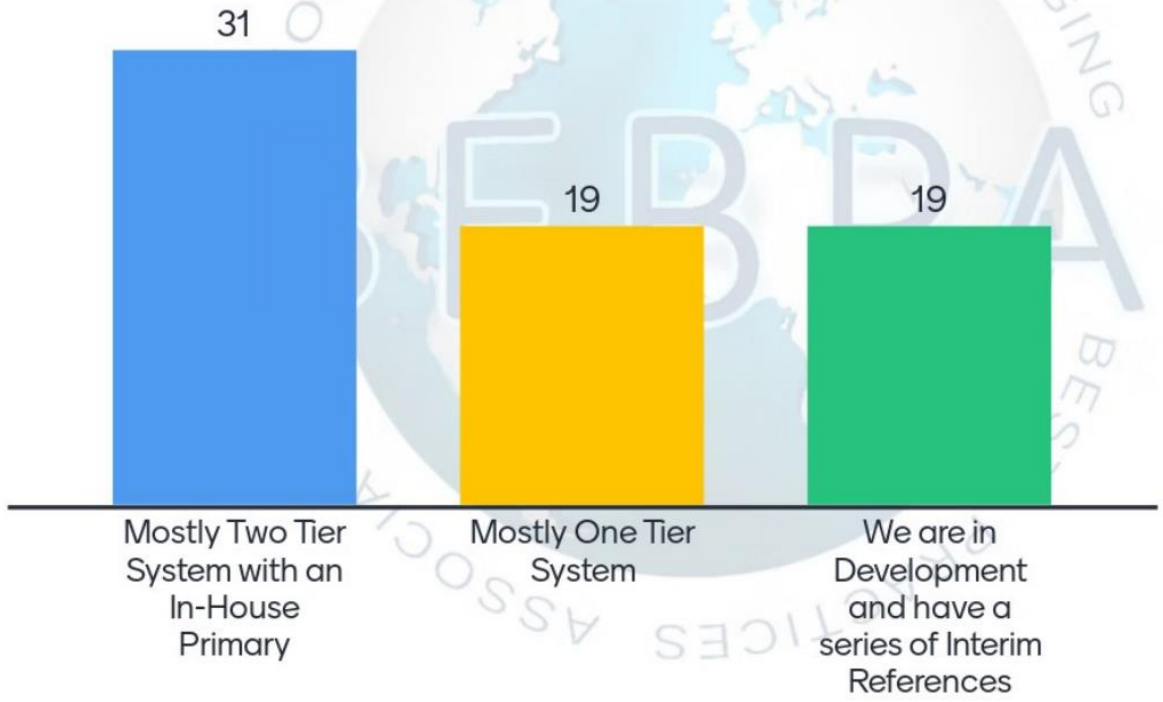
1.4 What are the main technical challenges in implementing in vitro assay?



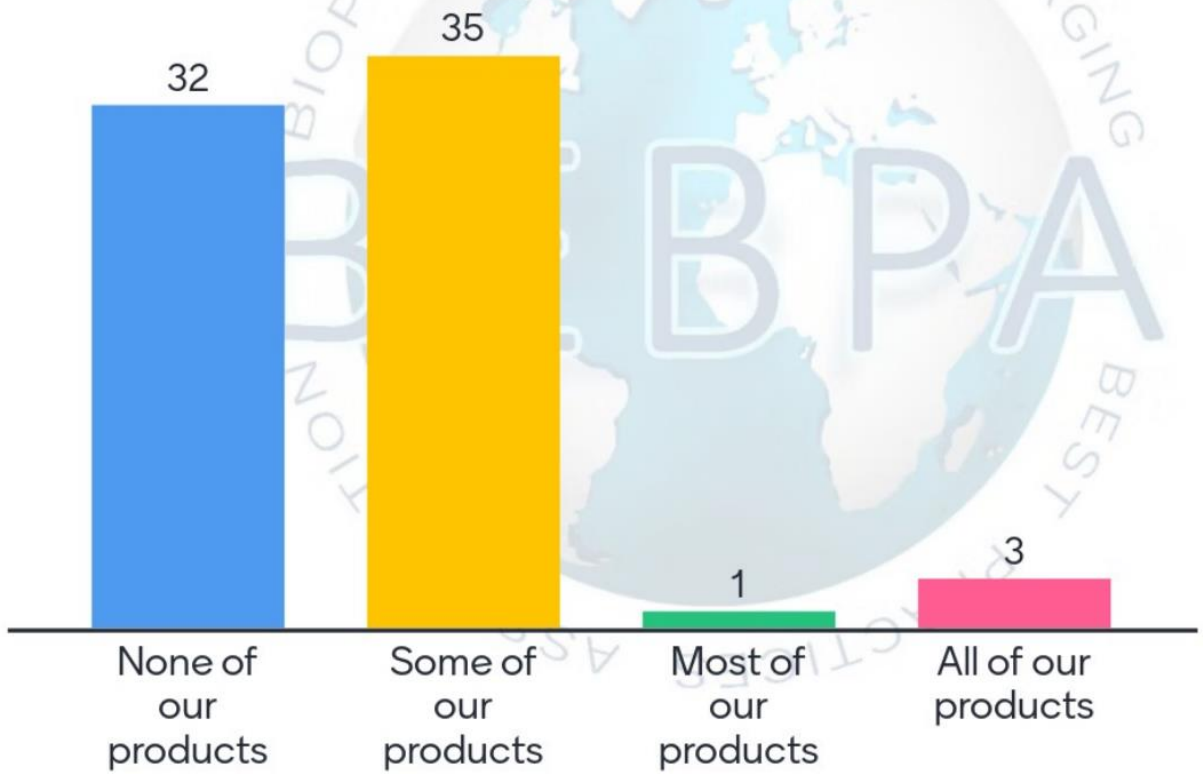
1.5 What are the main regulatory challenges in the acceptance of in vitro assay?



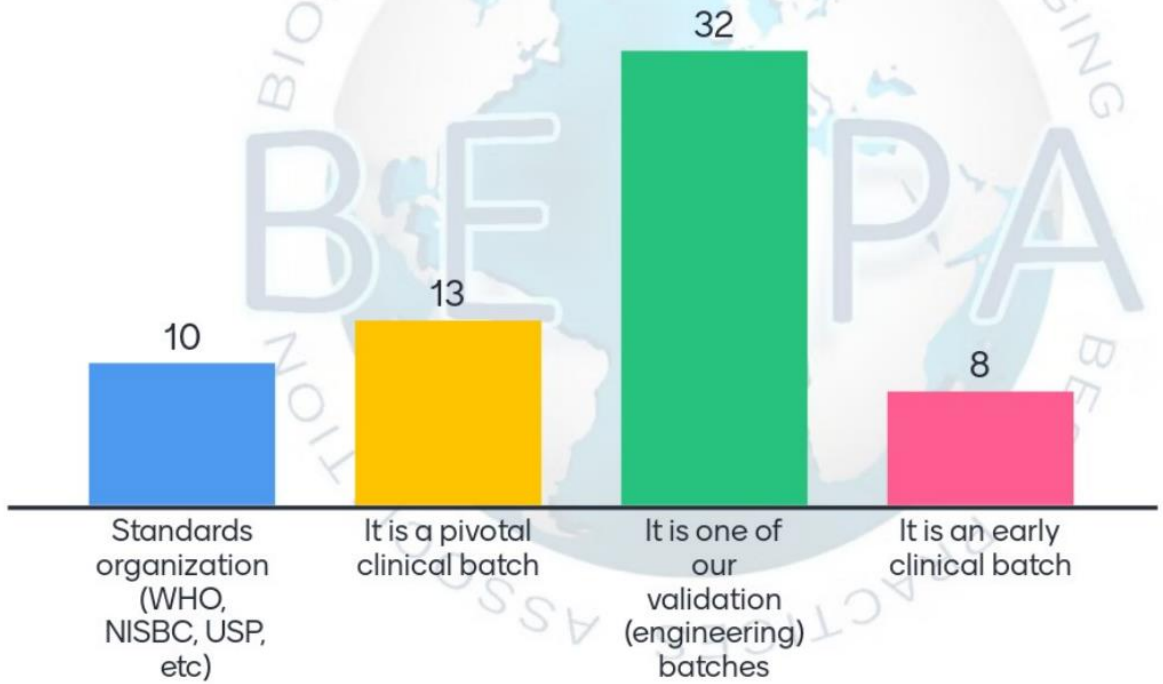
1.6 What type of Reference System do you have?



1.7 Is there an International reference available for you product?



1.8 Where do you source your primary reference from?

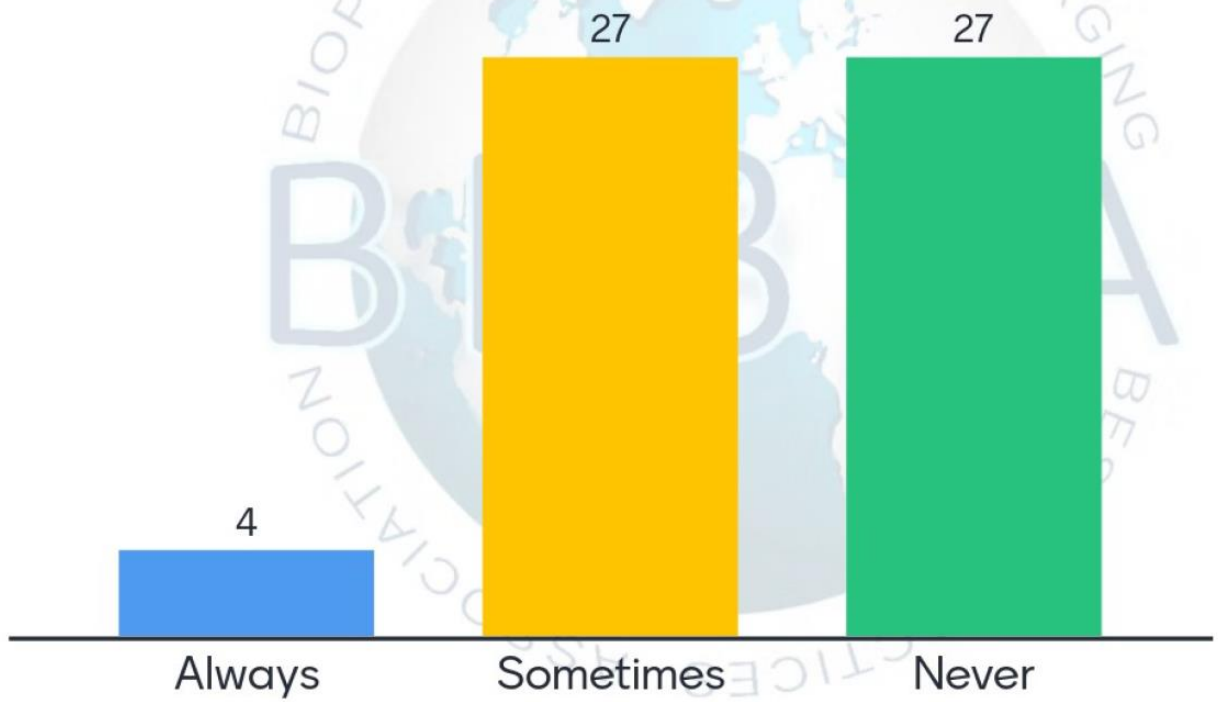


Session 2: Potency Assay Development for Complex Products

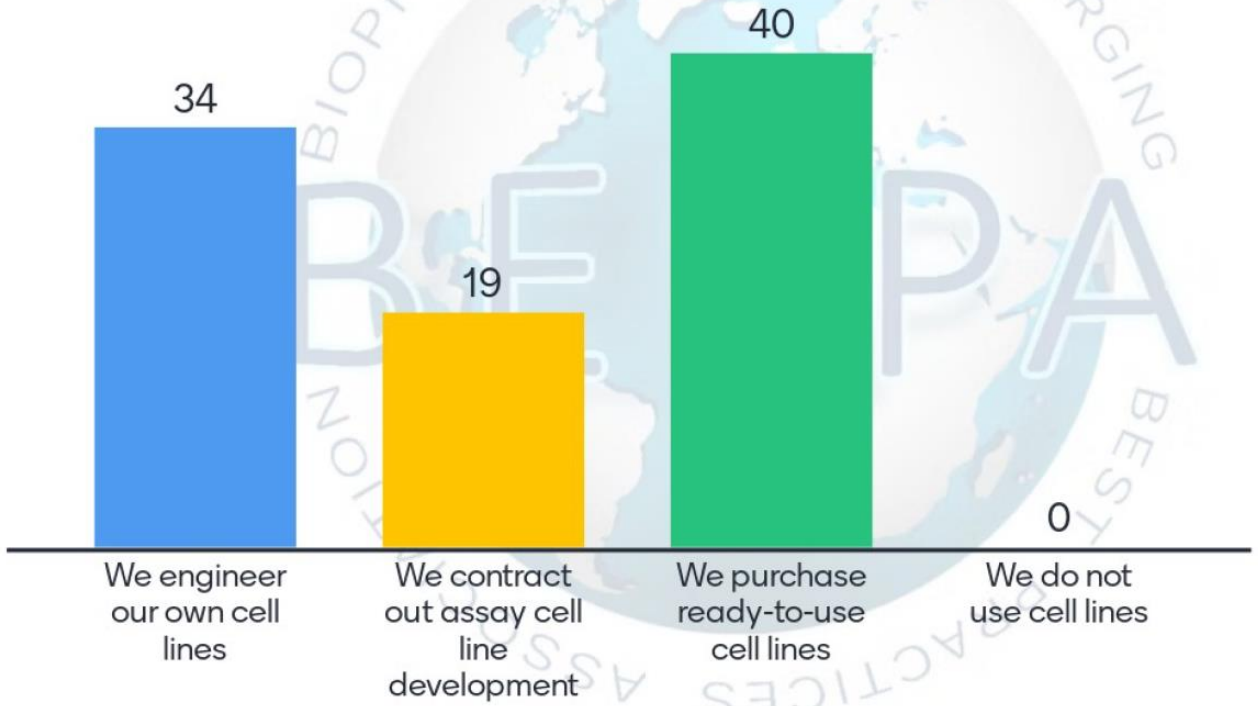
Session Chair: Hans-Joachim Wallny, Executive Director, Novartis Pharma AG Switzerland &
Kristin Clement, Principal Consultant, Bio-Val Consulting

Audience Surveys

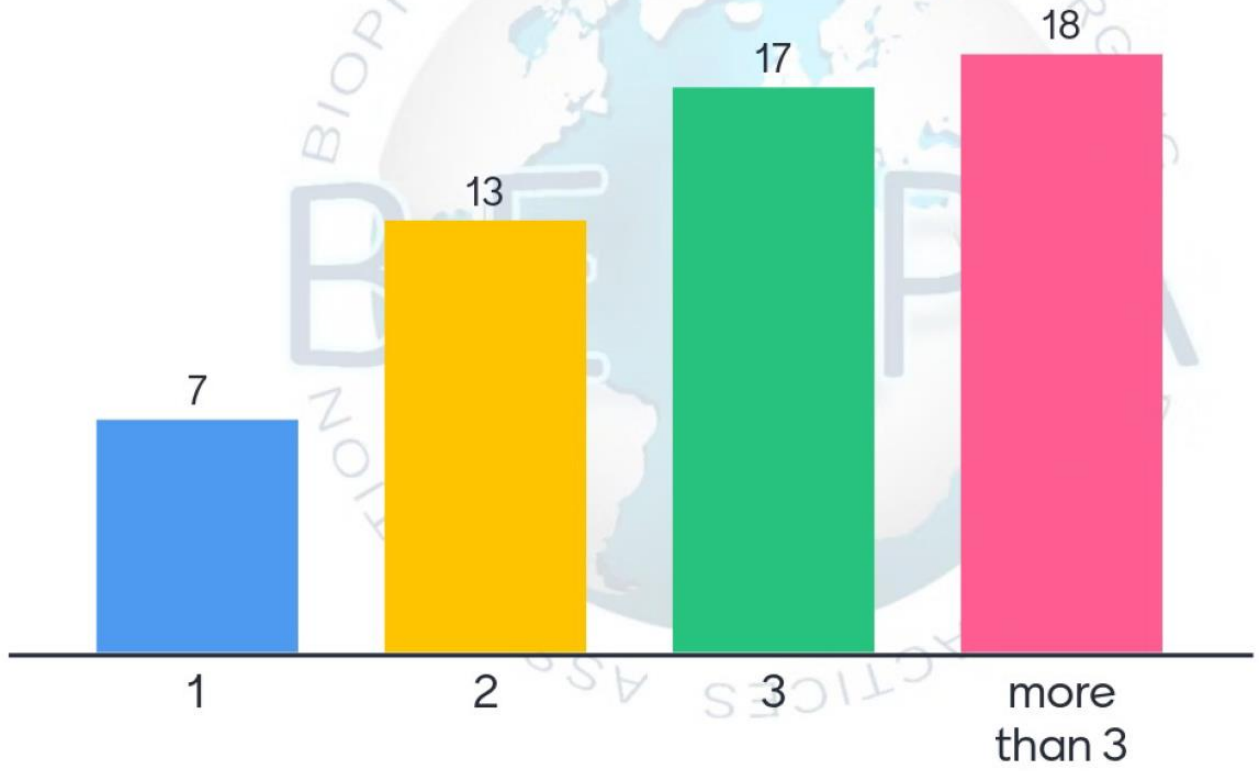
2.1 Do you correlate your functional potency assays to in vivo data?



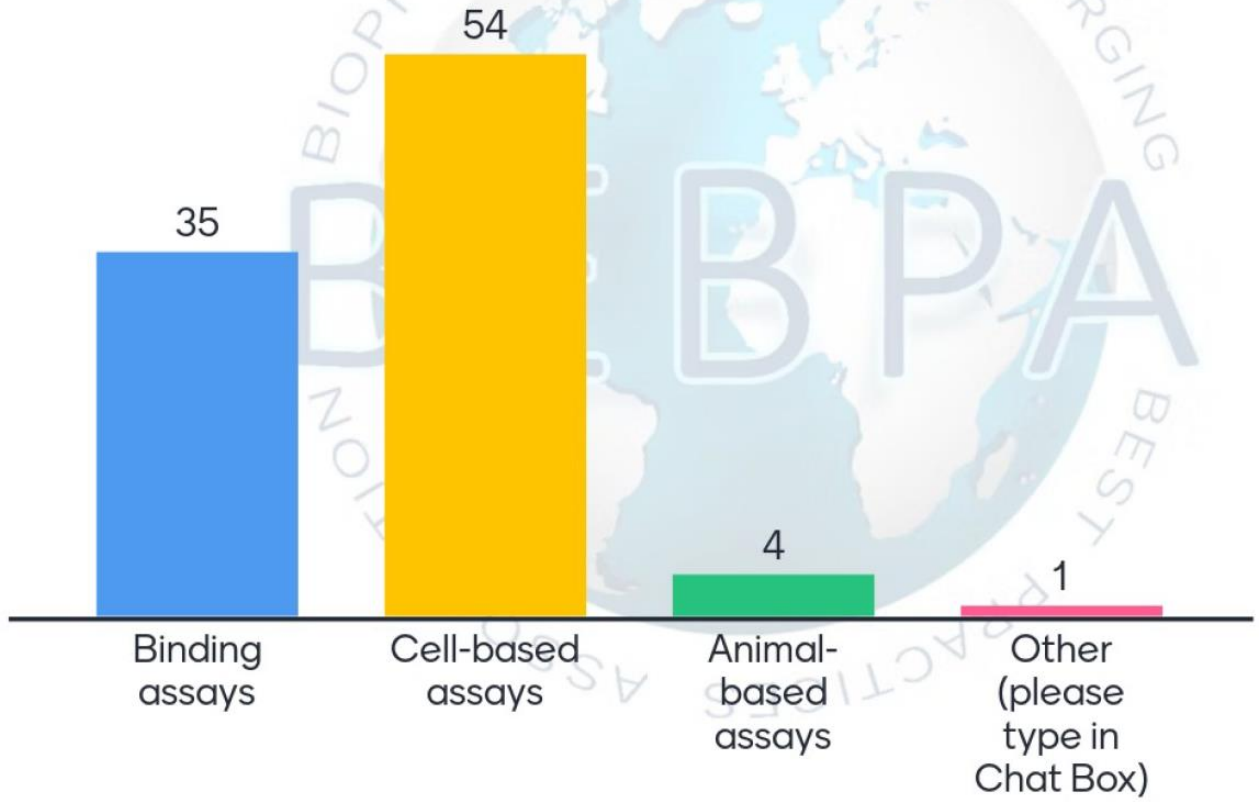
2.2 Do you develop your own cell lines for your potency assays? Or do you purchase/contract from a vendor?



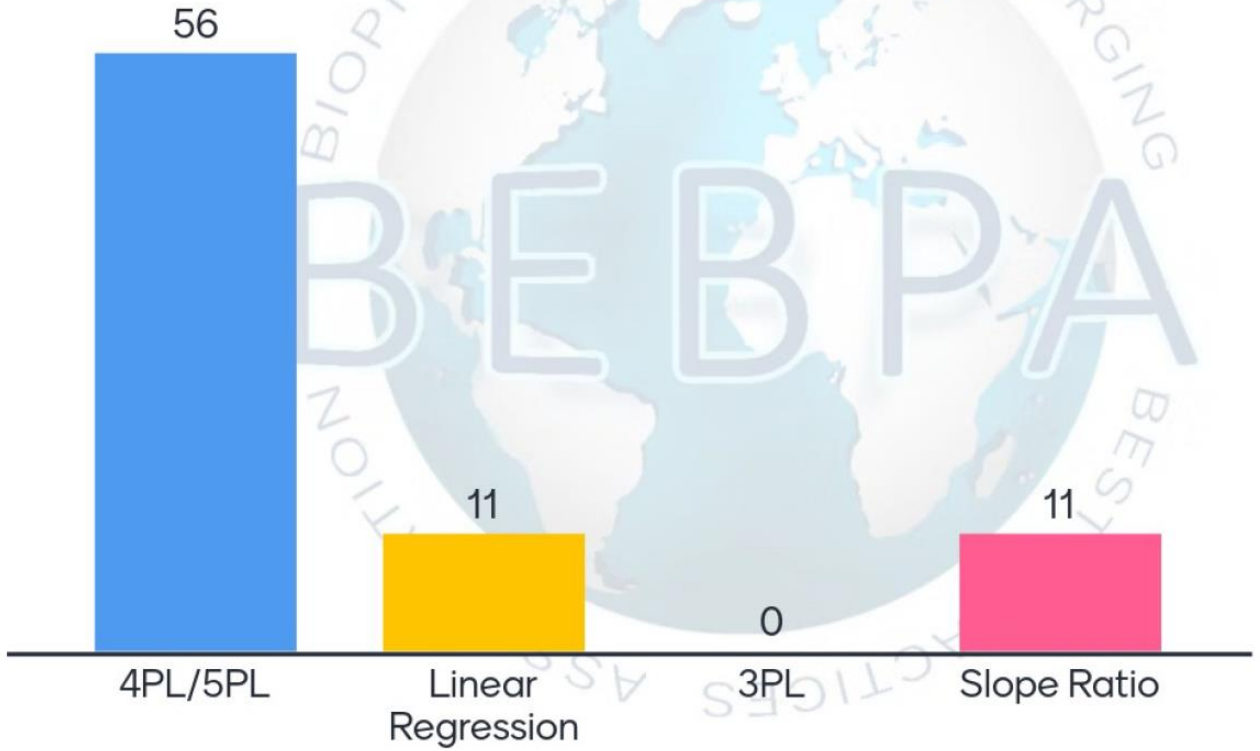
2.3 How many different potency assays do you develop (on average) for complex biologics?



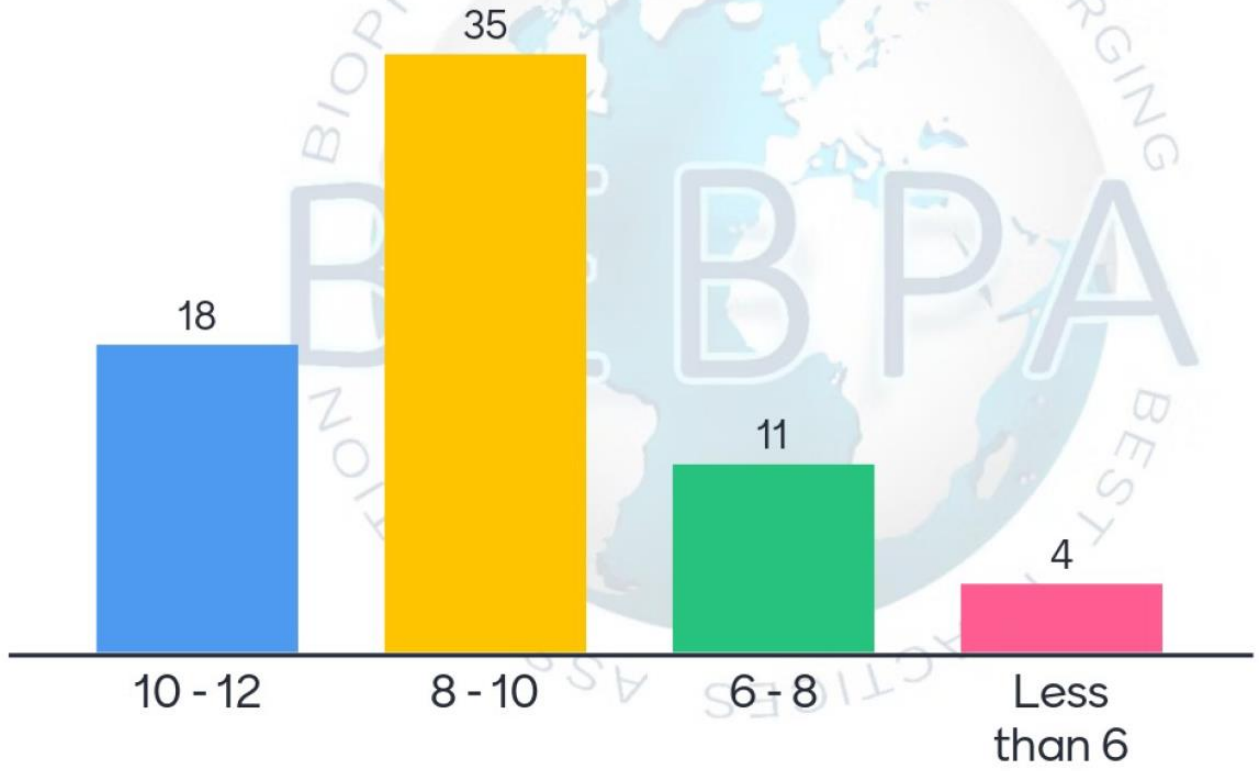
2.5 Which assay formats do you use for determination of potency for complex biologics



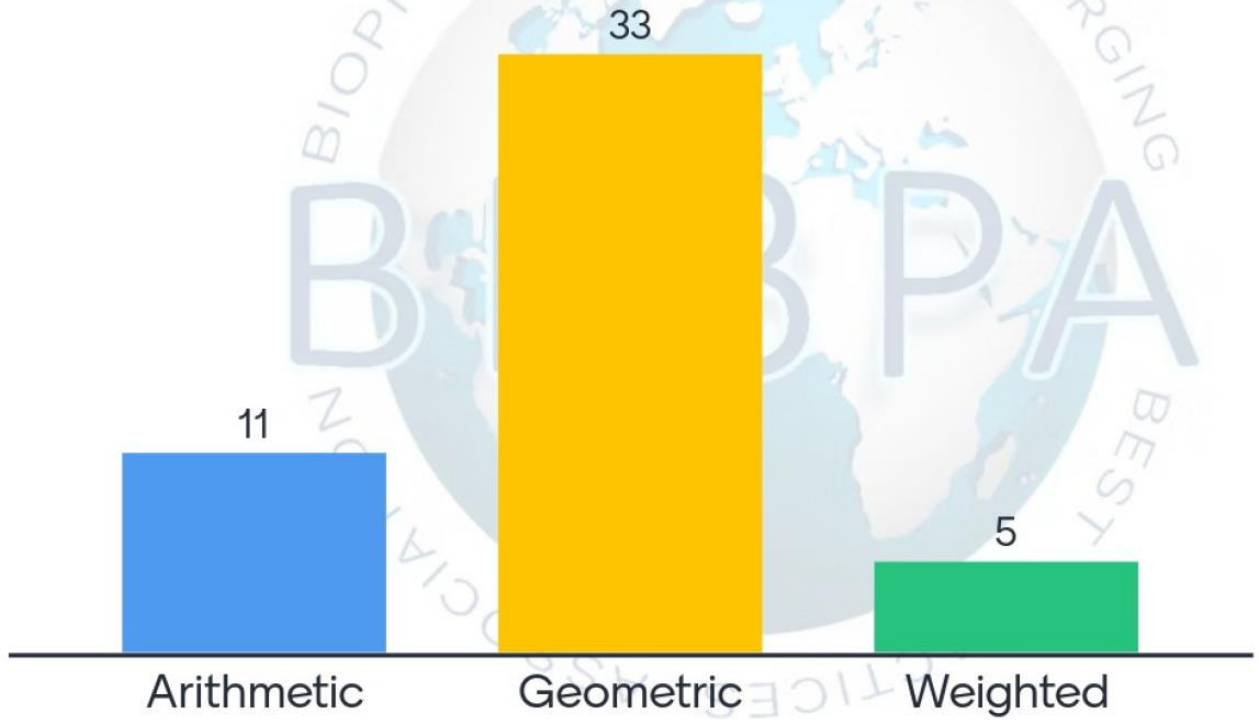
2.6 Which statistical model do you use to analyze data from your potency assays for complex products



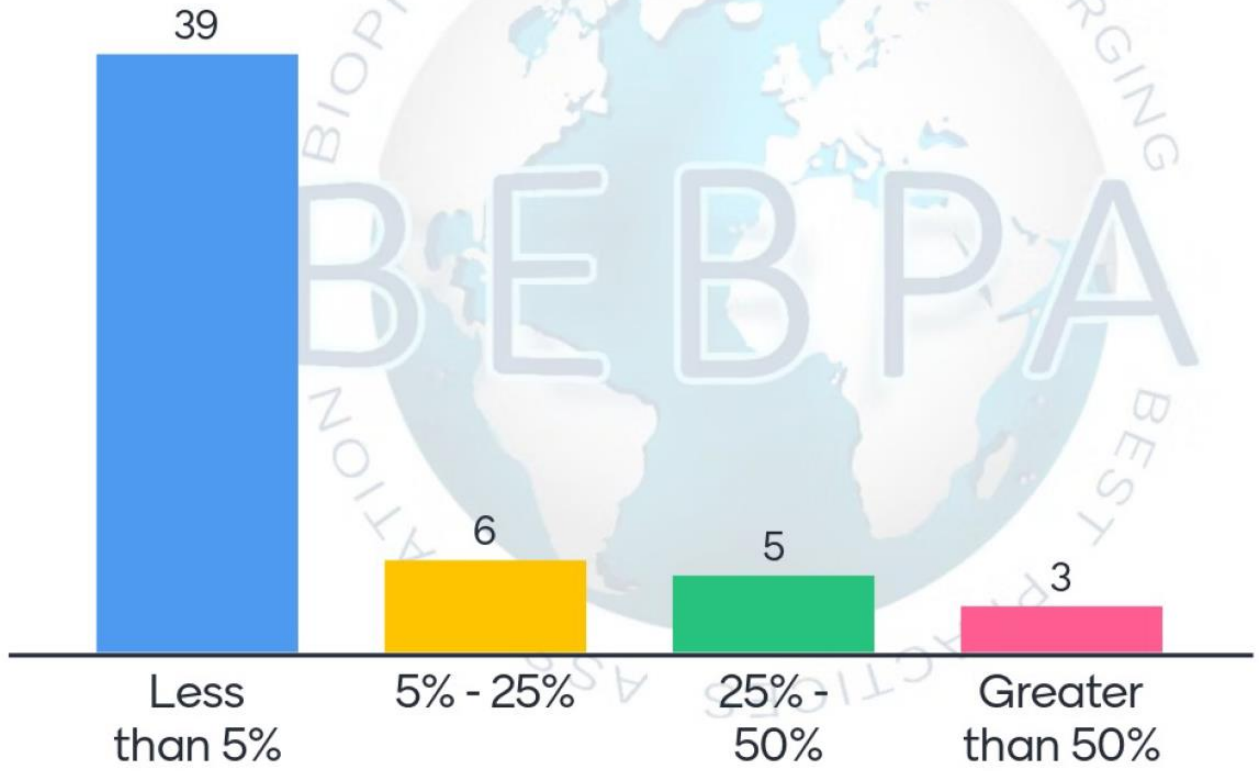
2.7 For your potency assays for complex products, how many data points define your reference standard curve?



2.8 What method does your laboratory use to combine independent relative potency values?



2.9 What percentage of your assays do not have a well defined upper or lower asymptote?

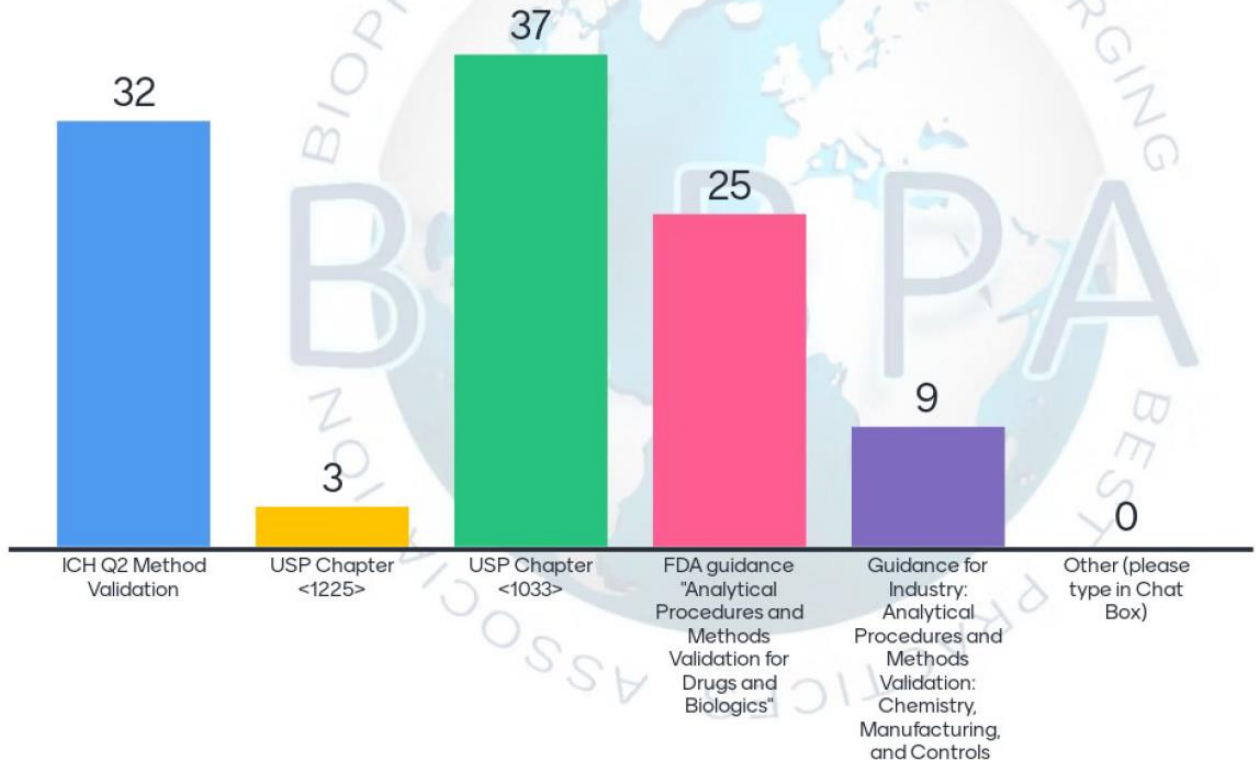


Session 3: Statistical Tools

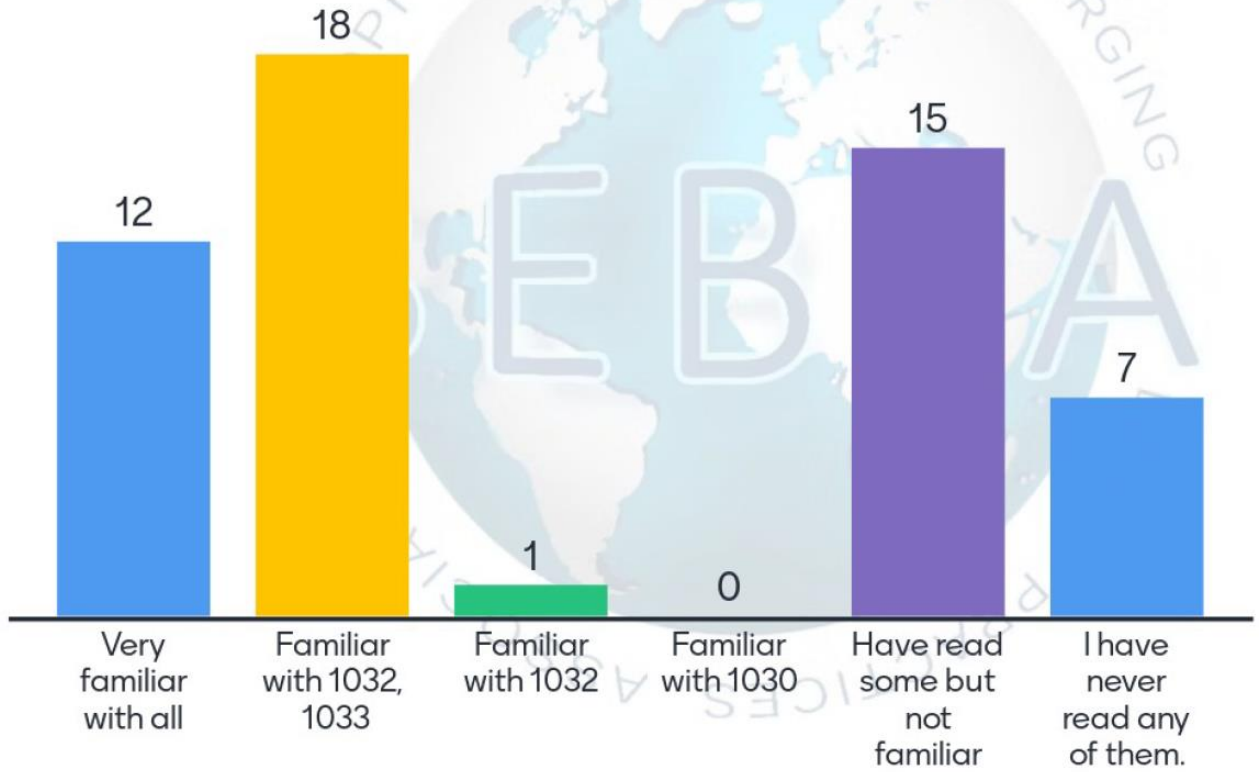
Session Chair: Nancy Niemuth, Consultant, Act Two Consulting

Audience Surveys

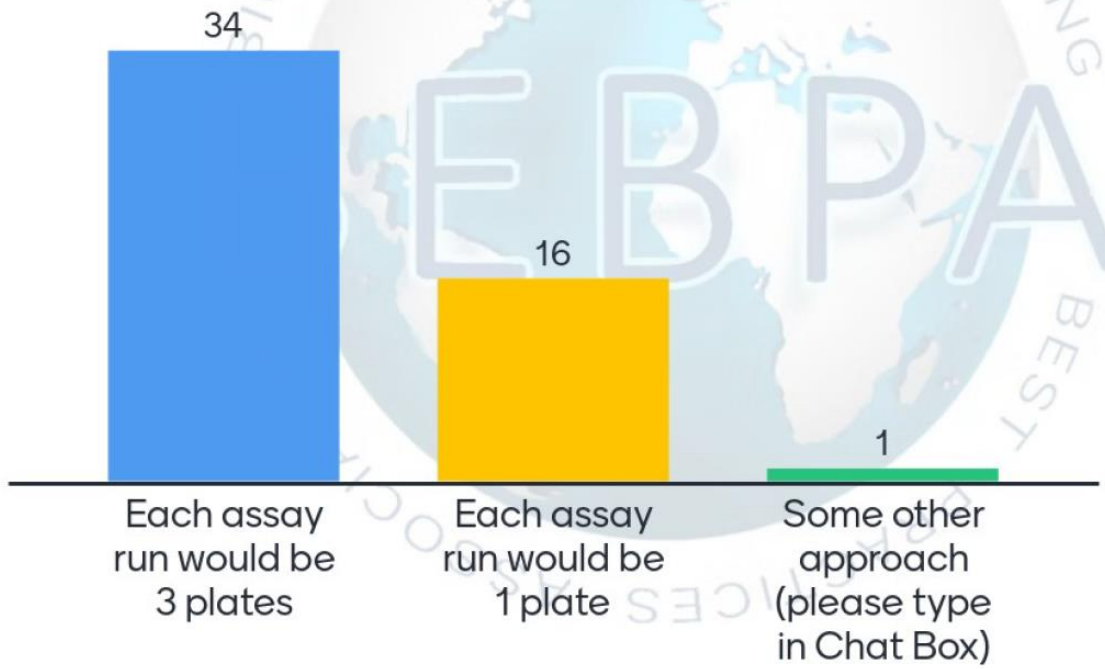
3.1 Which guidances do you use for validation of potency? (Choose all that apply)



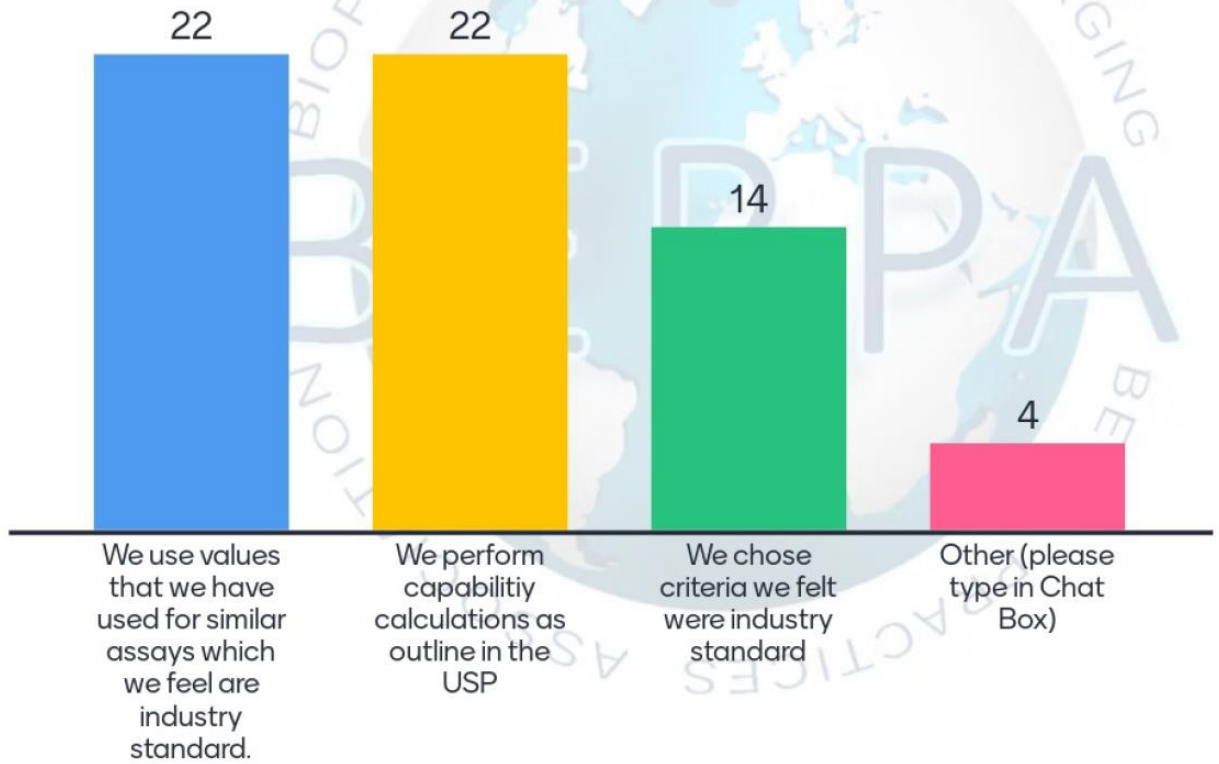
3.2 How familiar are you with USP NF General Chapters on Bioassay (1030, 1032, 1033, 1034)?



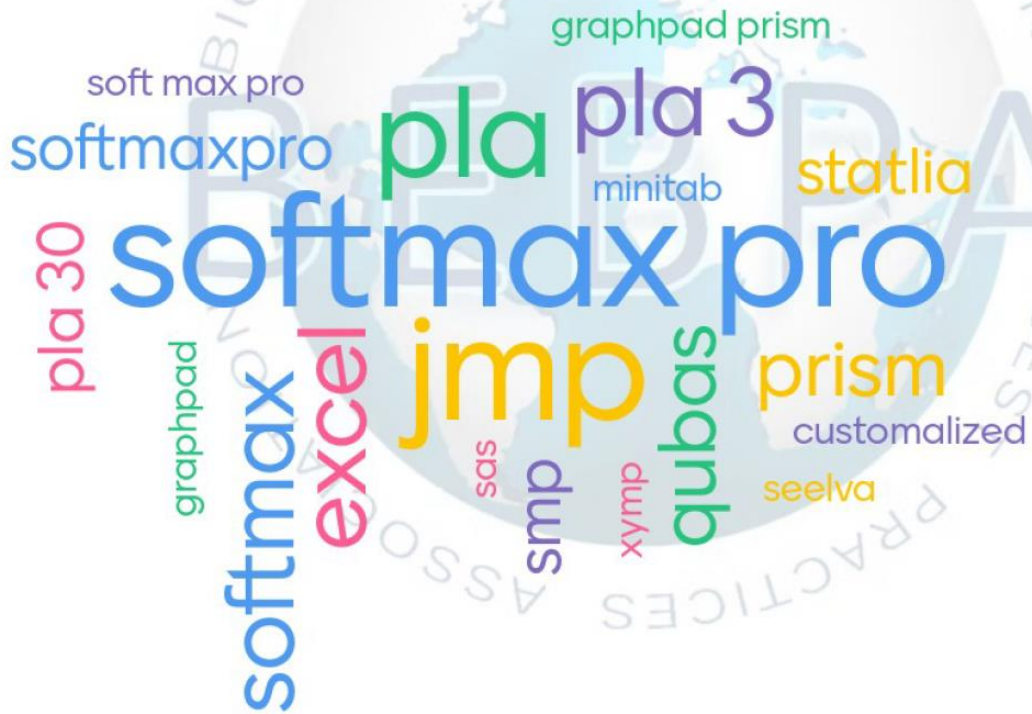
3.3 When you perform a validation for a method which requires a reportable value which is the average of 3 plates. Would you:



3.4 How do you determine your validation acceptance criteria?

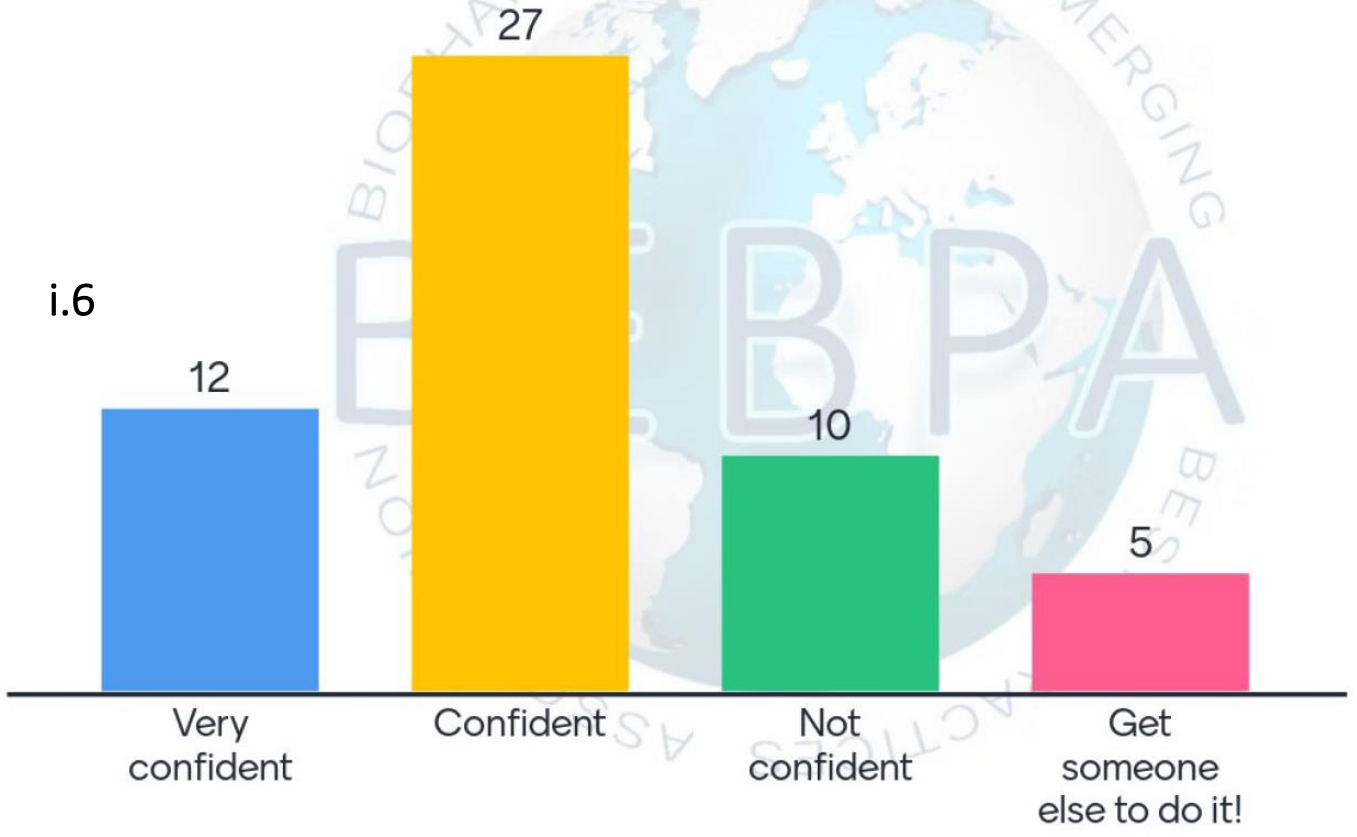


3.5 Which software do you use to analyze your bioassay data?

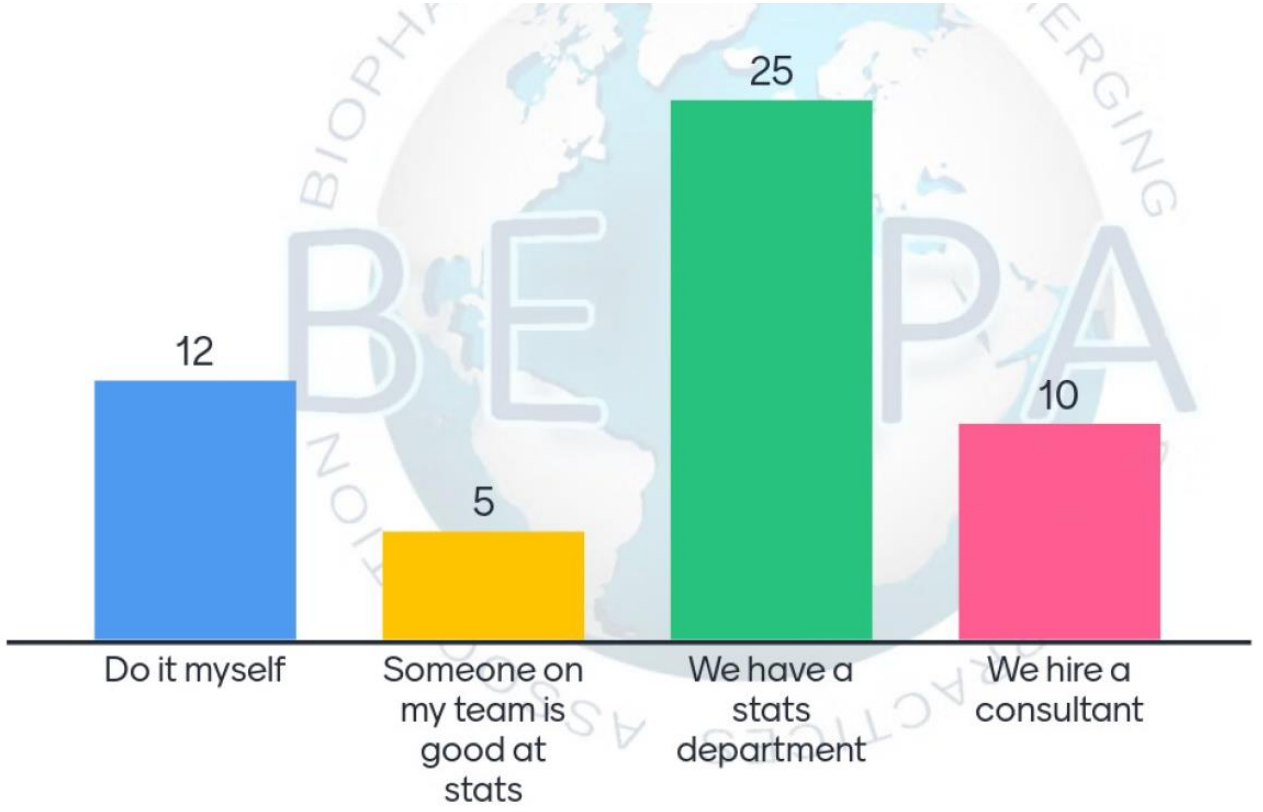


3.6 What software do you have available for data exploration and statistics?

3.7 How confident are you when using it?



3.8 When statistical analysis is needed, do you do it yourself or call a statistician?

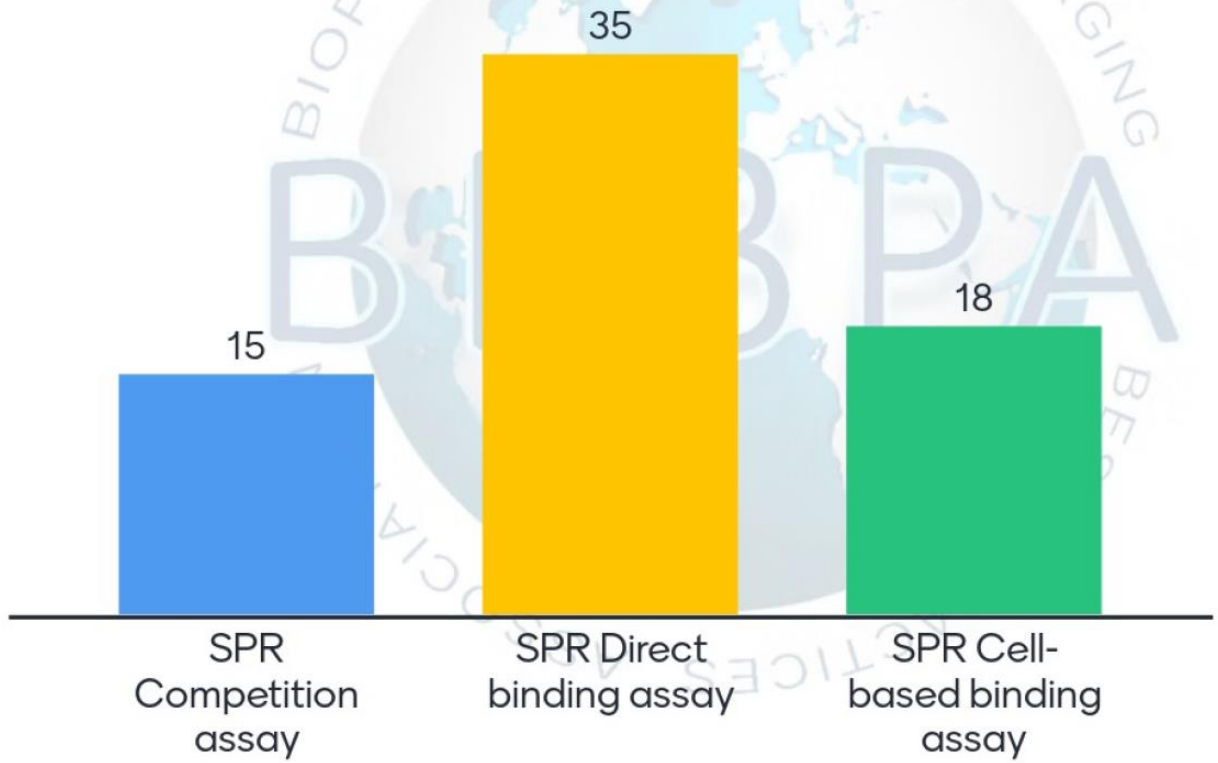


Session 4: Antibody Product Potency Assay Development

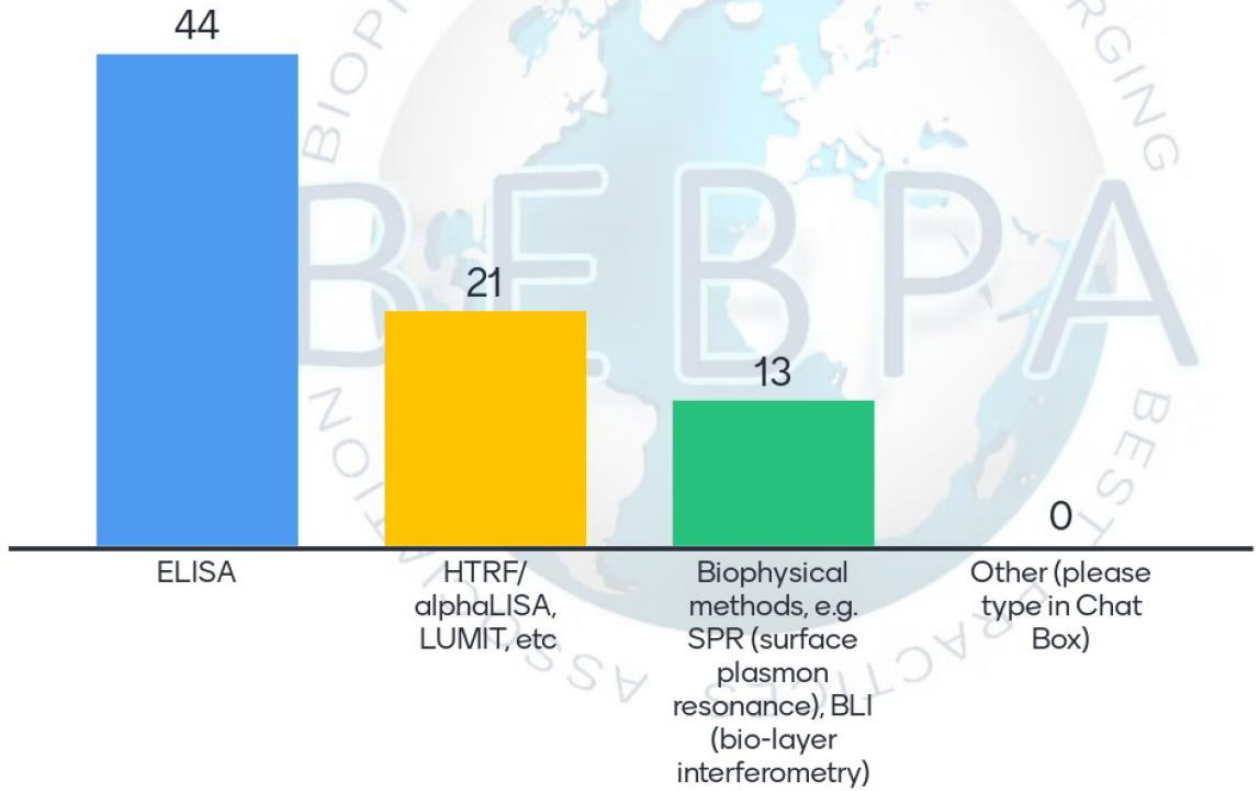
Session Chair: Ulrike Herbrand, Scientific Director, Charles River Labs

Audience Surveys

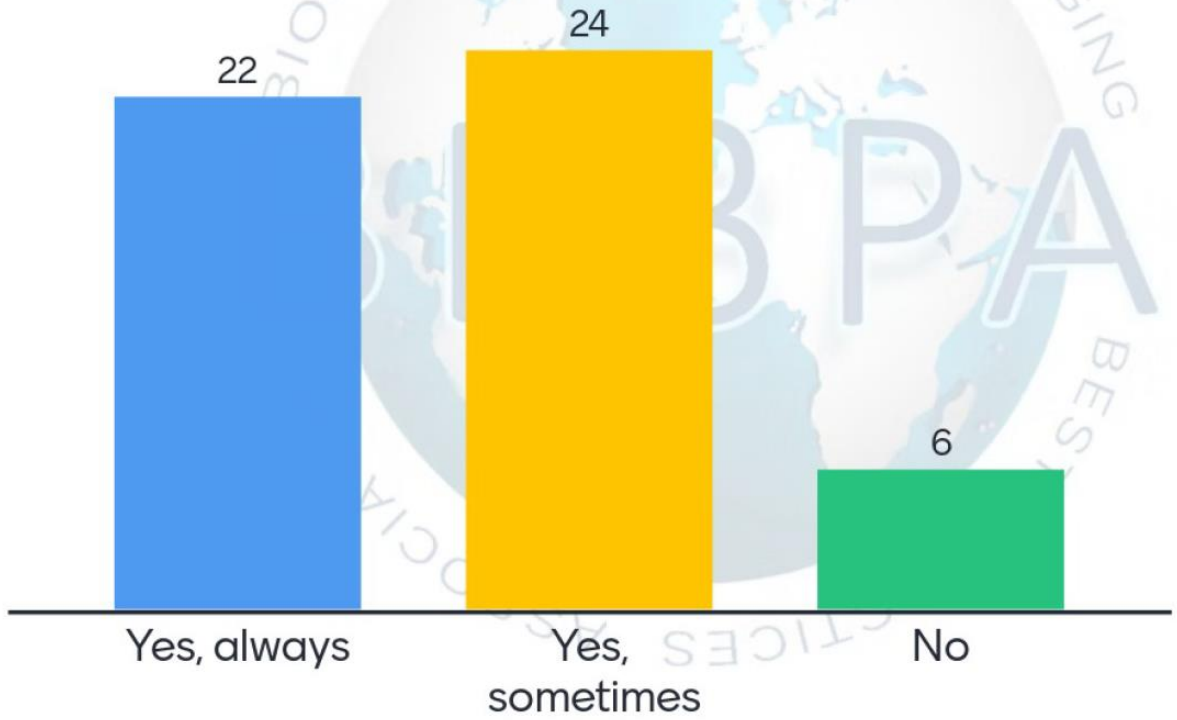
4.1 Which type of SPR assay do you use to support mAb process development?



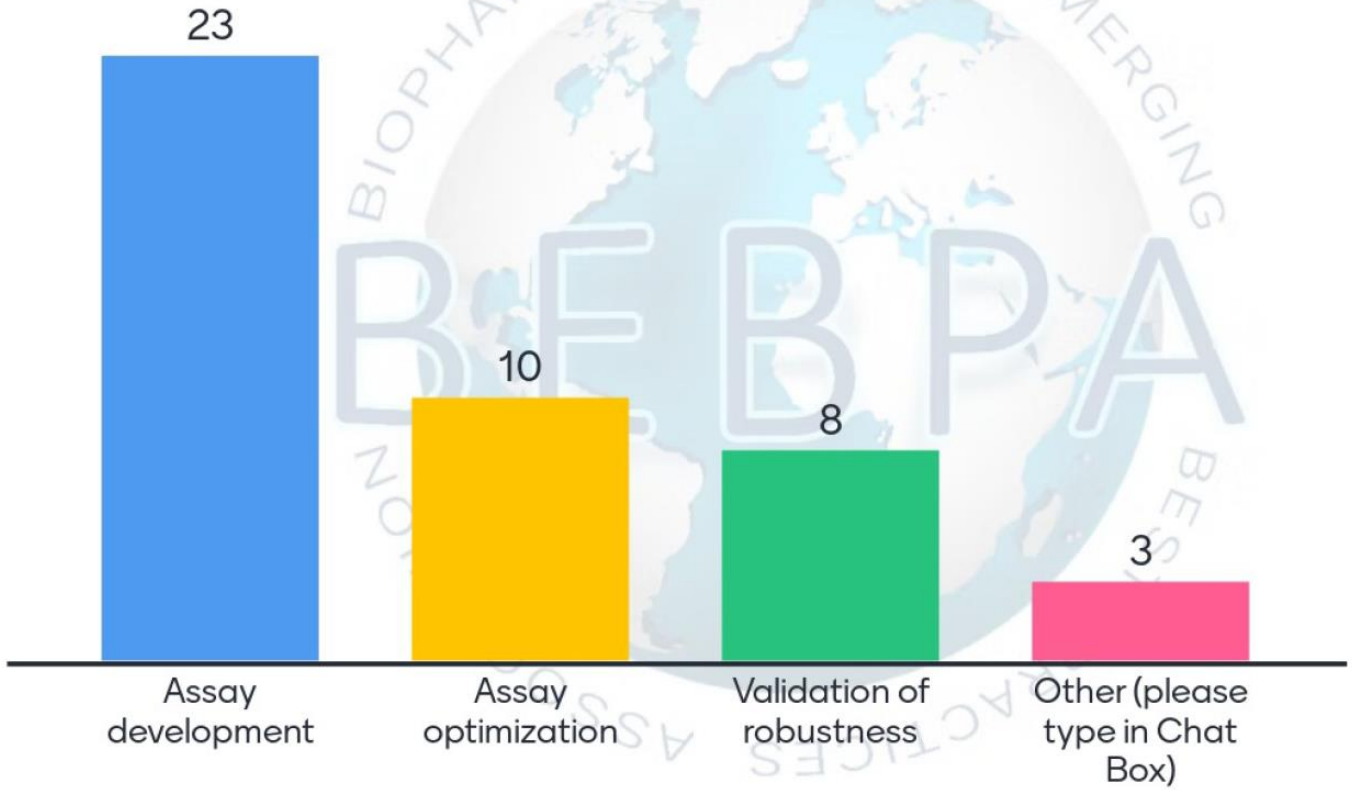
4.2 Have you considered or do you use cell-free potency strategies for your test items? Which ones?



4.3 Do you use DOE in the lifecycle of your bioassay?



4.4 If you use DOE, at which stage?

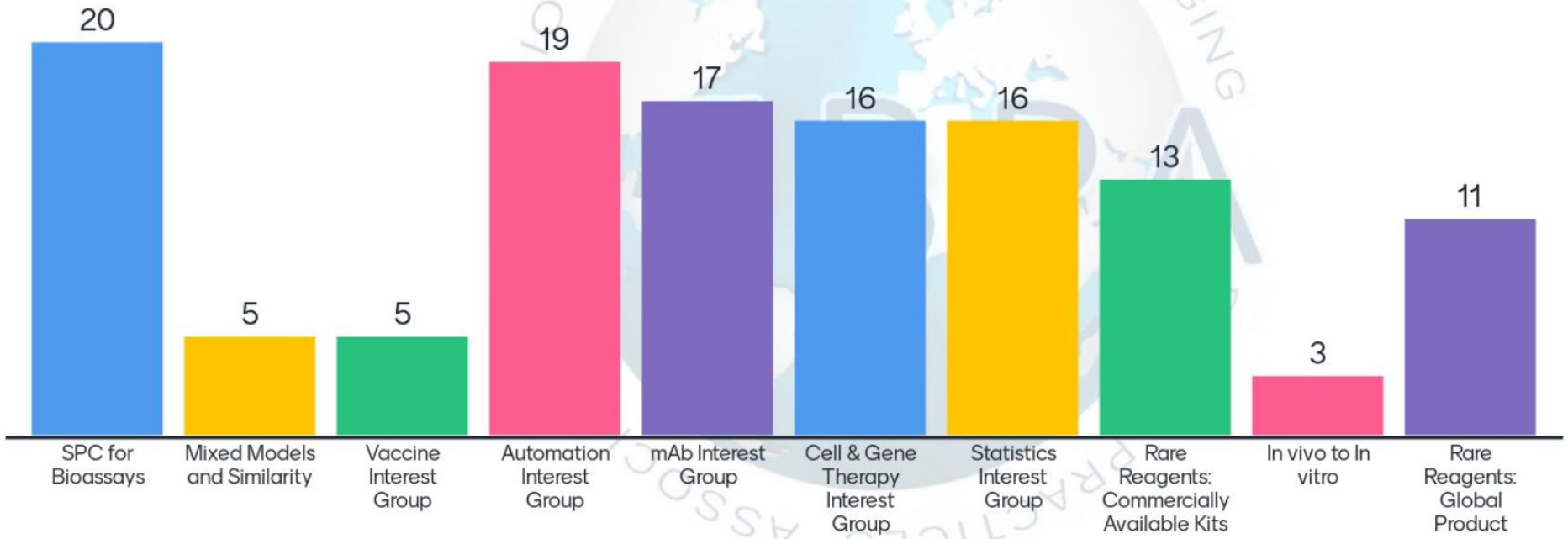


Session 5: Workshop Summaries

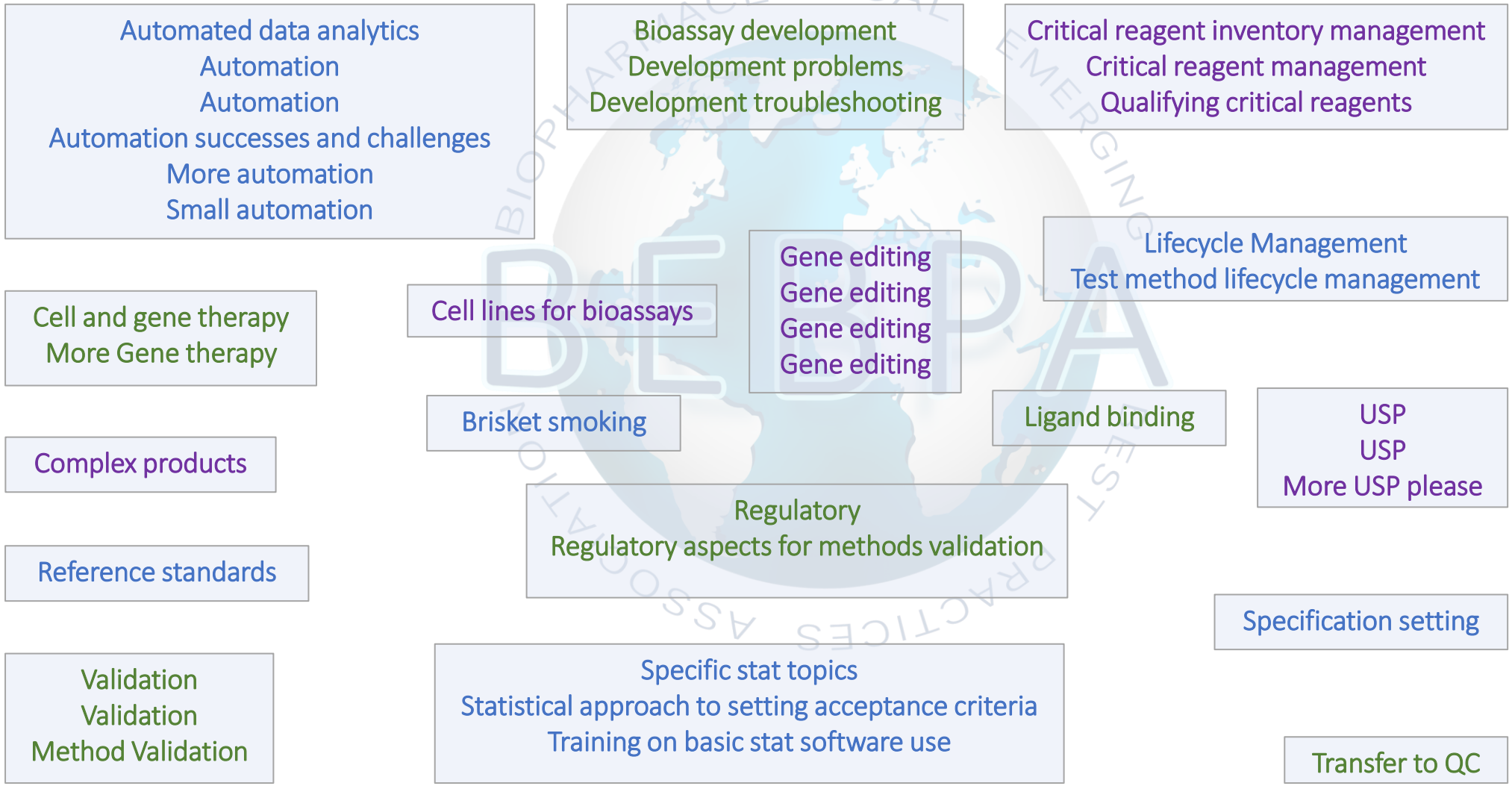
Session Chair: Bassam Hallis, Interim Deputy Director, Research & Evaluation, UK Health Security Agency and Laureen Little, President, BEBPA

Audience Surveys

5.1 Which Workshop(s) did you attend? (In-person audience)



5.2 What topics do we need for interest groups in the future?




BIOPHARMACEUTICAL EMERGING BEST PRACTICES ASSOCIATION
BEBPA

Thank you!!