BEBPA 2023 U.S. Bioassay Conference

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



Welcome Back & Introduction

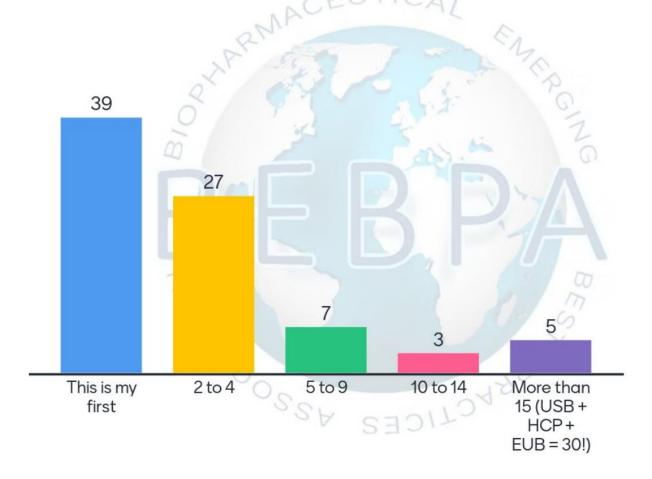
Laureen Little, President of BEBPA

Audience Surveys



i.1 How many BEBPA Conferences have you

attended?

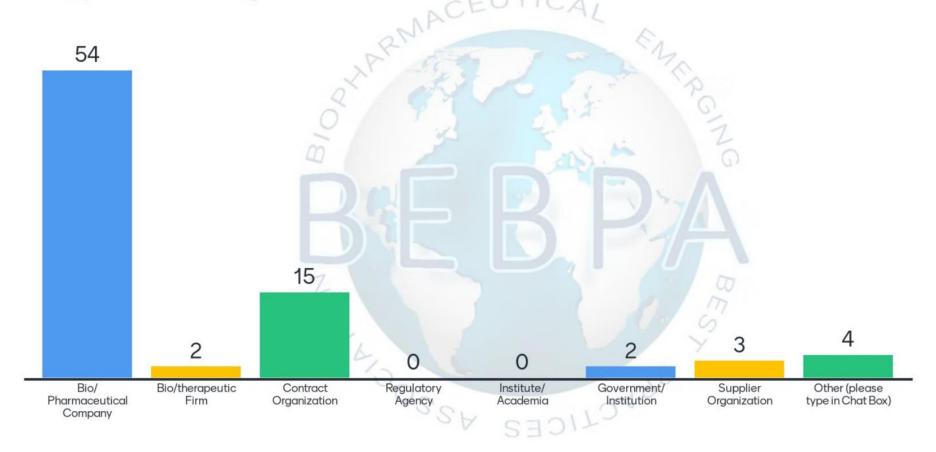






i.2 What type of organization do you work for?

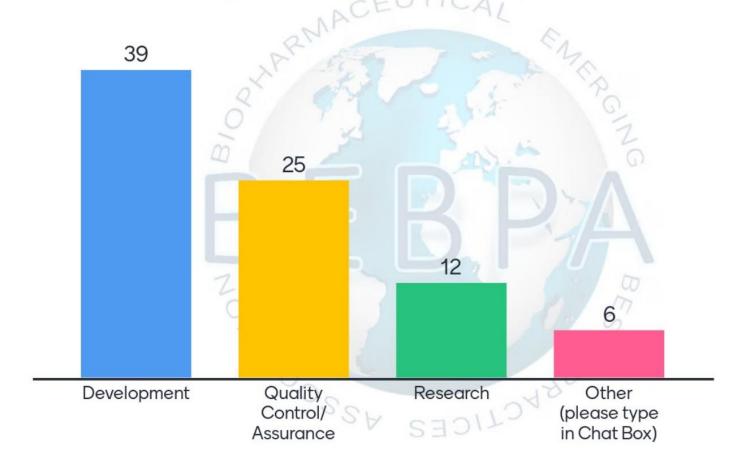






i.3 What part of the organization do your work for?



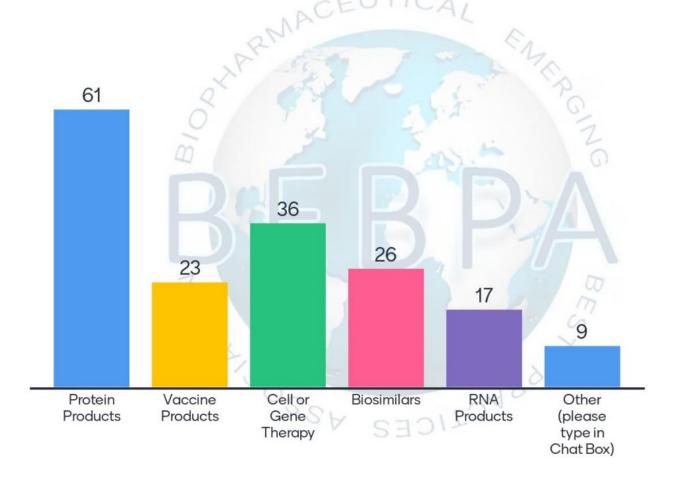




i.4 What type of products do you work with? (Check all that

BEBPA

apply)

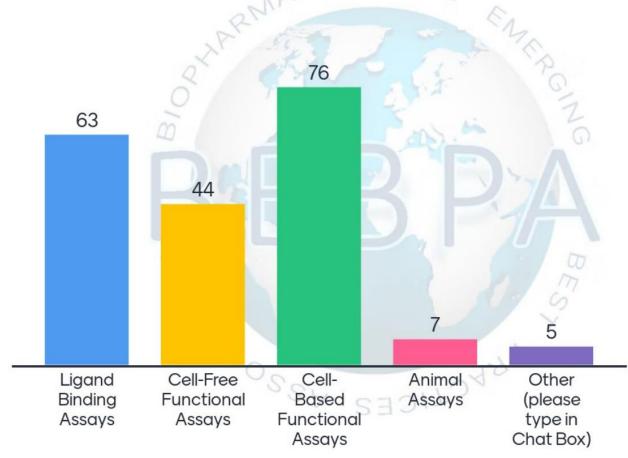




i.5 What type of assays do you develop? (Check all that

apply)





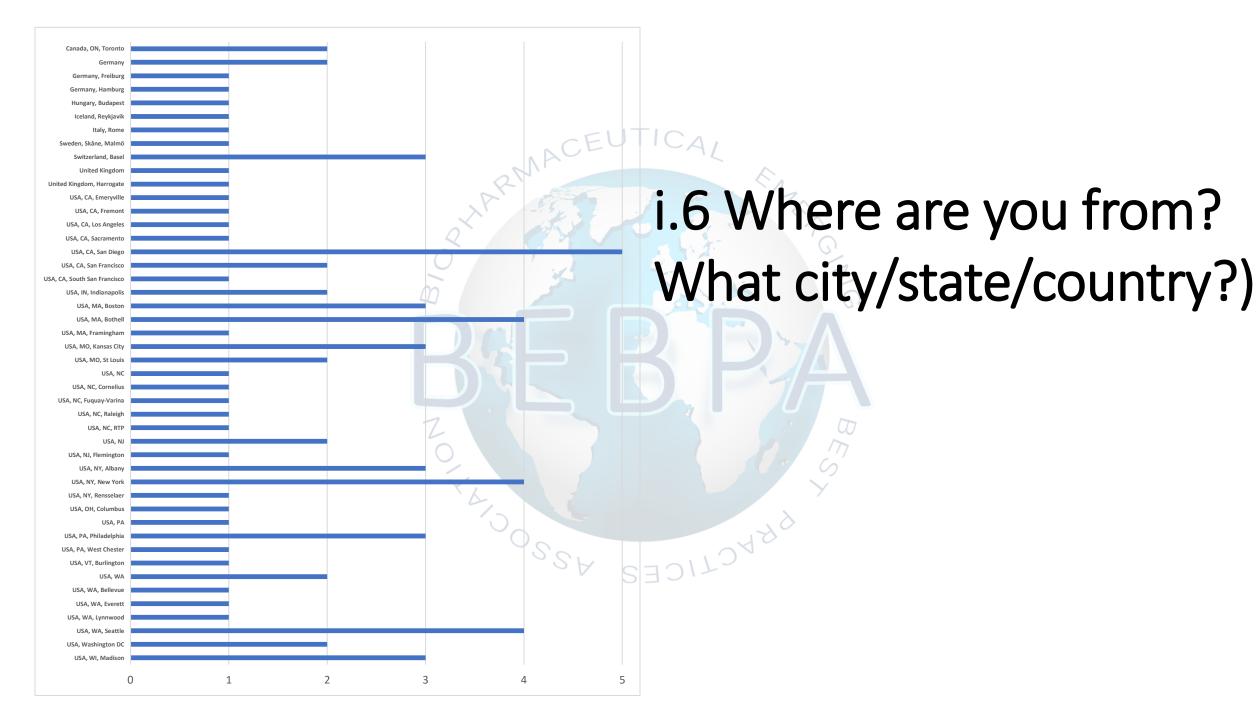


i.6 Where are you from?What city/state/country?)











Session 1: Assay Lifecycle

Session Chair: Laureen Little, President of BEBPA

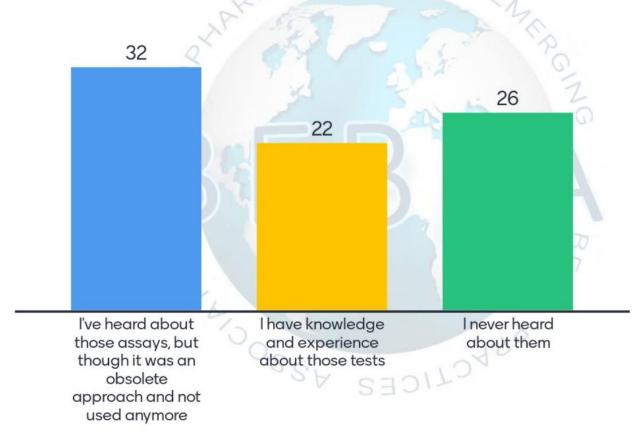
Audience Surveys



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

standard

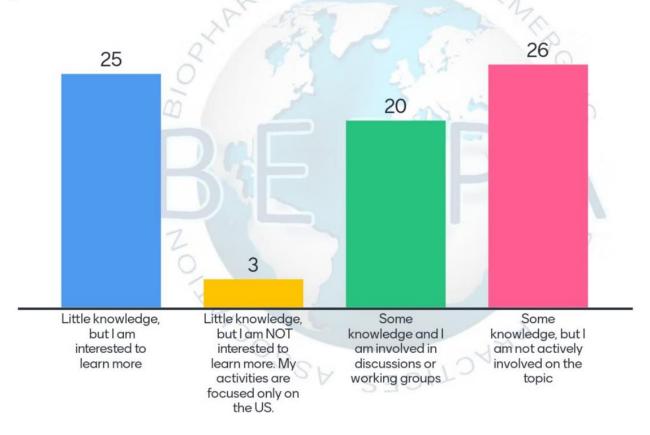


vaccines? Yes, those tests are No, obsolete testing Yes, those tests are strategies are no mandatory and still used even if required by there are longer required and regulations mechanisms to used, even if in remove, replace some cases they and refine them remain the



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



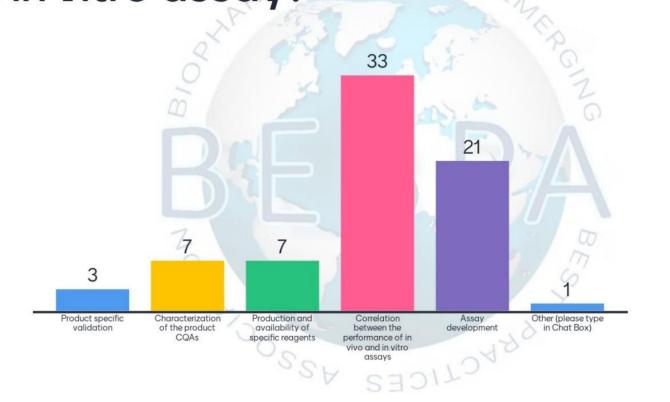




1.4 What are the main technical challenges in

implementing in vitro assay?



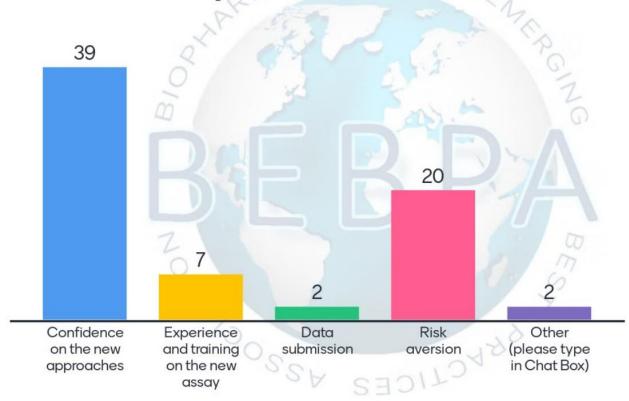




1.5 What are the main regulatory challenges in the

acceptance of in vitro assay?



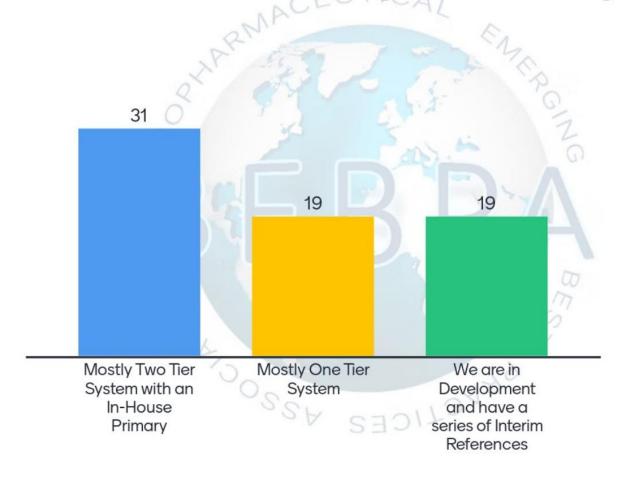




1.6 What type of Reference System do you



have?

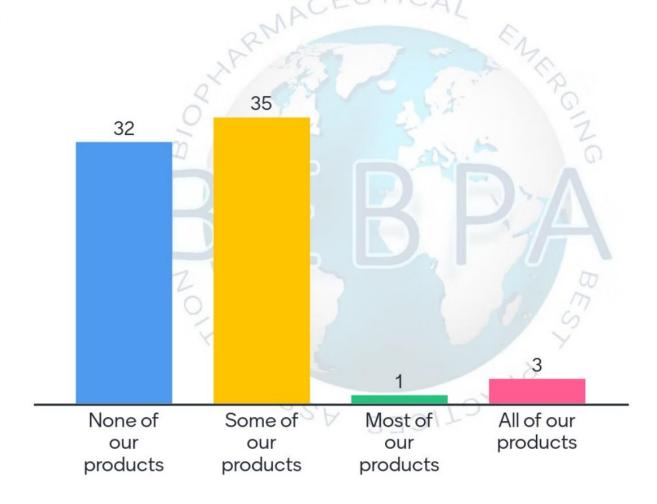




1.7 Is there an International reference available for

BEBPA

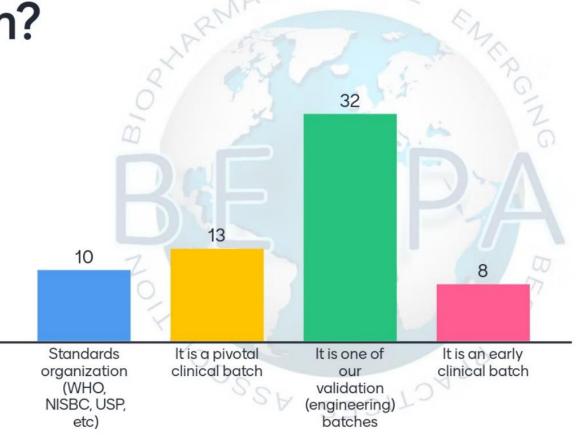
you product?





1.8 Where do you source your primary

reference from?









Session 2: Potency Assay Development for Complex Products

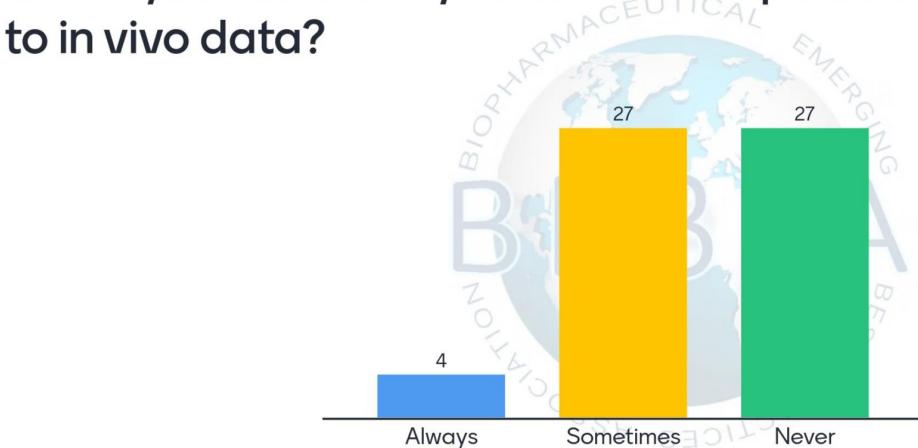
Session Chair: Hans-Joachim Wallny, Executive Director, Novartis Pharma AG Switzerland & Kristin Clement, Principal Consultant, Bio-Val Consulting

Audience Surveys



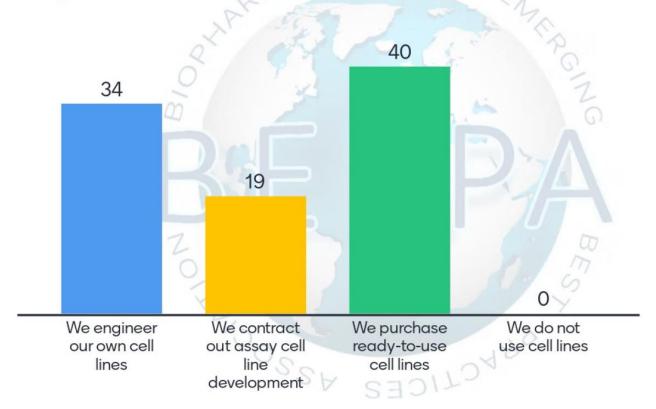
2.1 Do you correlate your functional potency assays





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



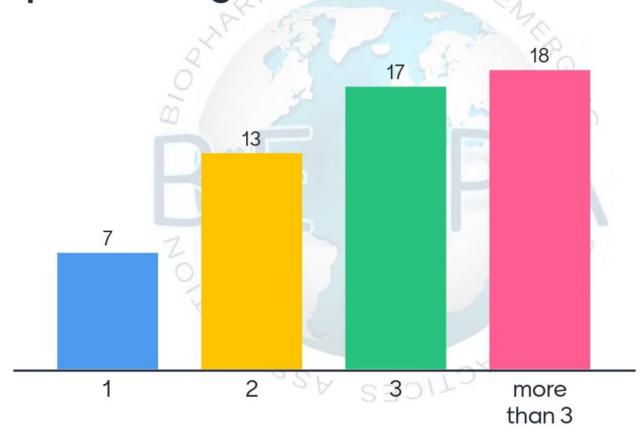




2.3 How many different potency assays do you develop (on

average) for complex biologics?

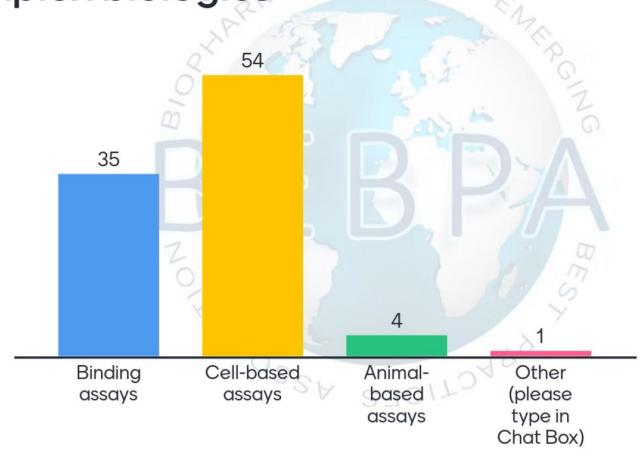




2.5 Which assay formats do you use for determination of

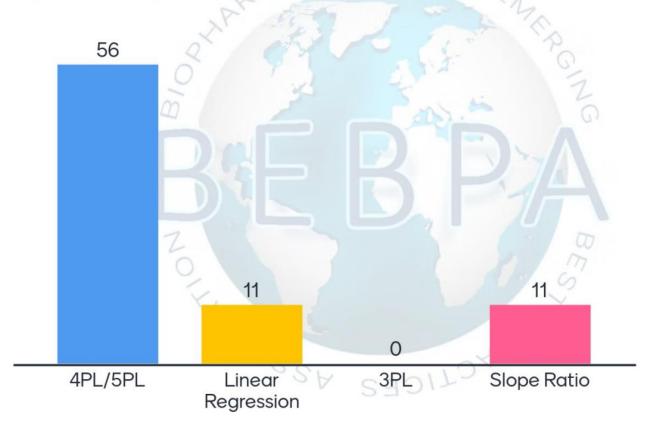
potency for complex biologics





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

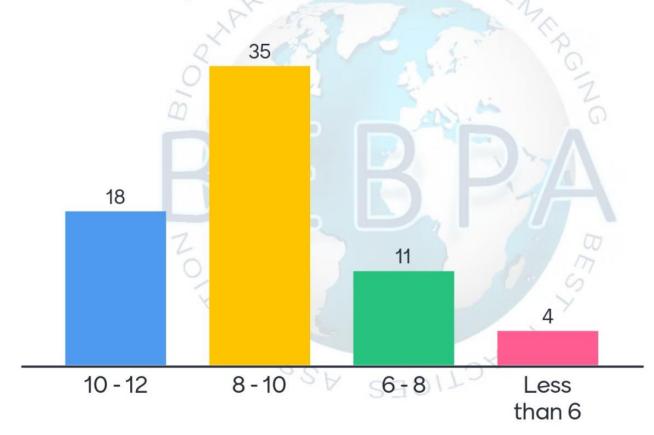






2.7 For your potency assays for complex products, how many data points define your reference standard curve?

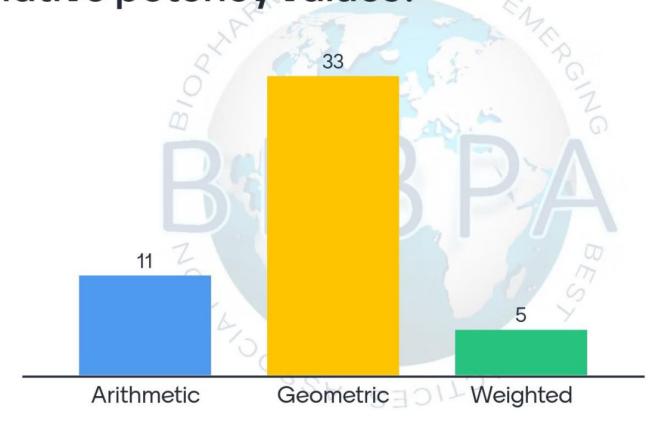






2.8 What method does your laboratory use to combine independent relative potency values?

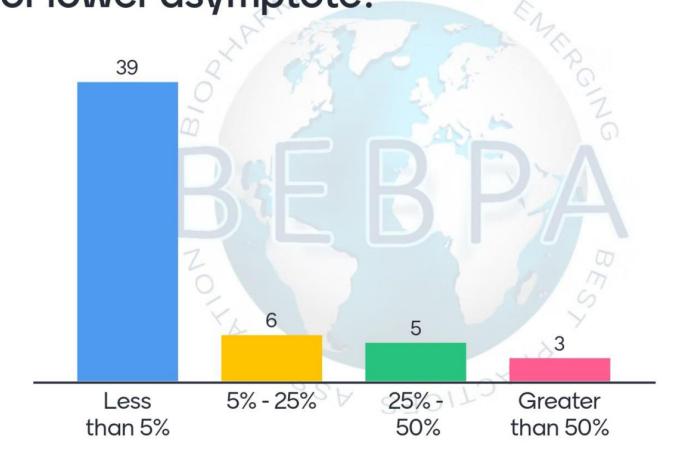






2.9 What percentage of your assays do not have a well defined upper or lower asymptote?









Session 3: Statistical Tools

Session Chair: Nancy Niemuth, Consultant, Act Two Consulting

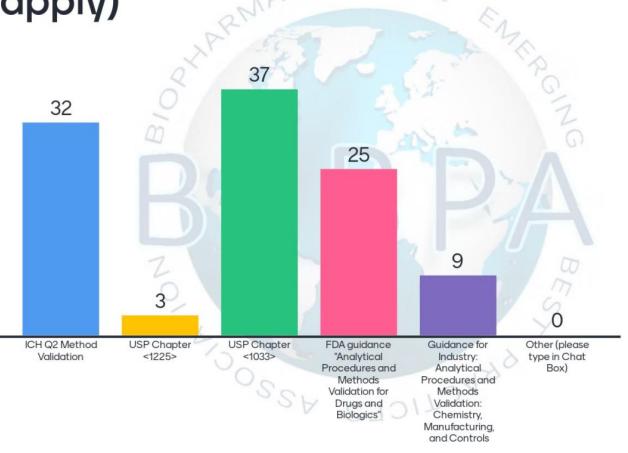
Audience Surveys



3.1 Which guidances do you use for validation of potency?

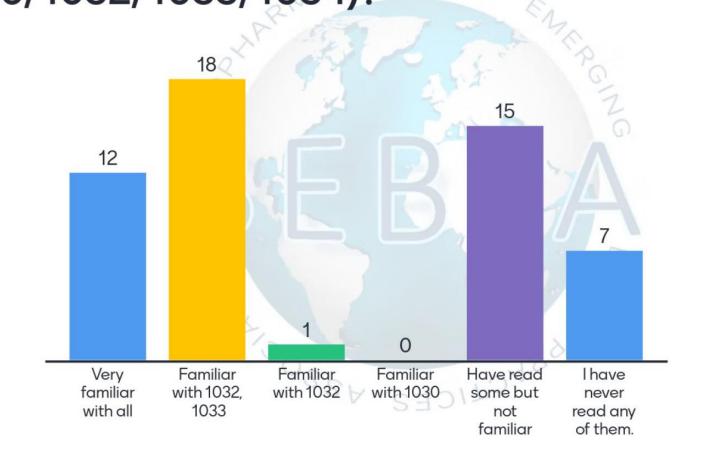
(Choose all that apply)





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

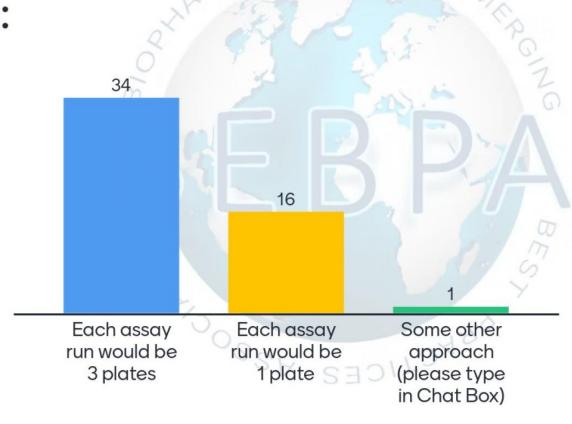






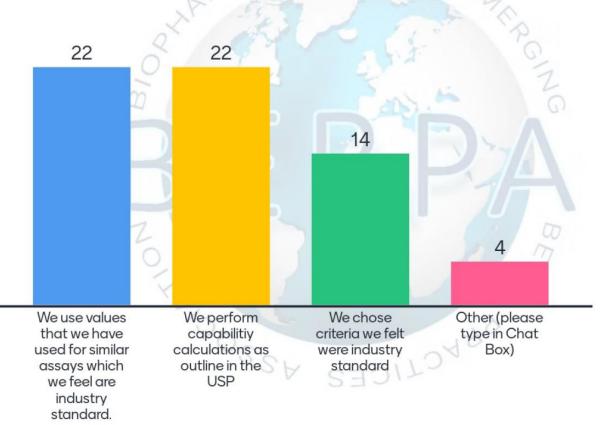
3.3 When you perform a validation for a method which requires a reportable value which is the average of 3 plates. Would you:





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?

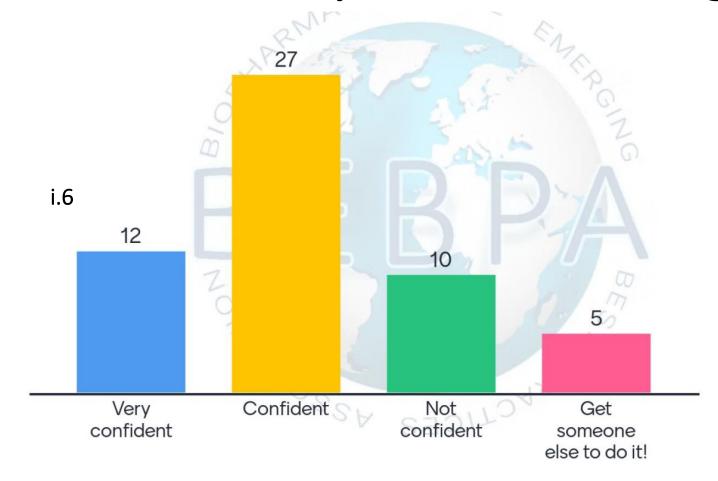






3.7 How confident are you when using it?

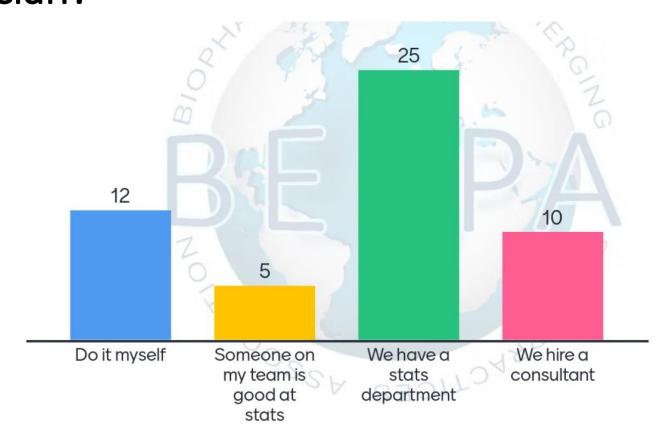






3.8 When statistical analysis is needed, do you do it yourself BEDA or call a statistician?









Session 4: Antibody Product Potency Assay Development

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

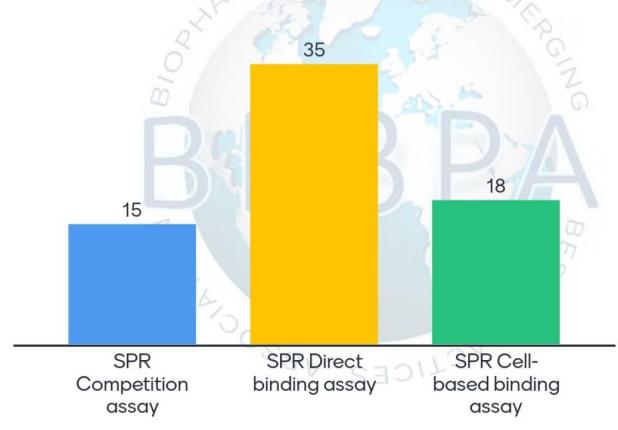
Audience Surveys



4.1 Which type of SPR assay do you use to support



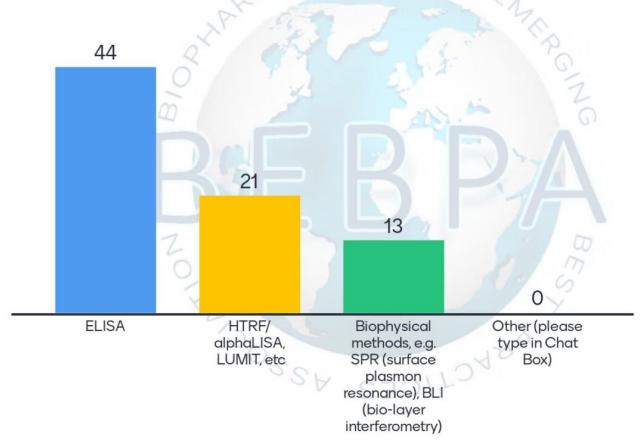
mAb process development?





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

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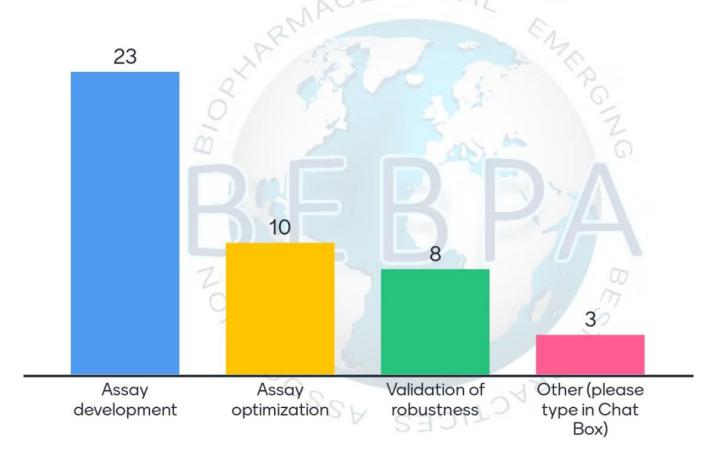
bioassay?





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

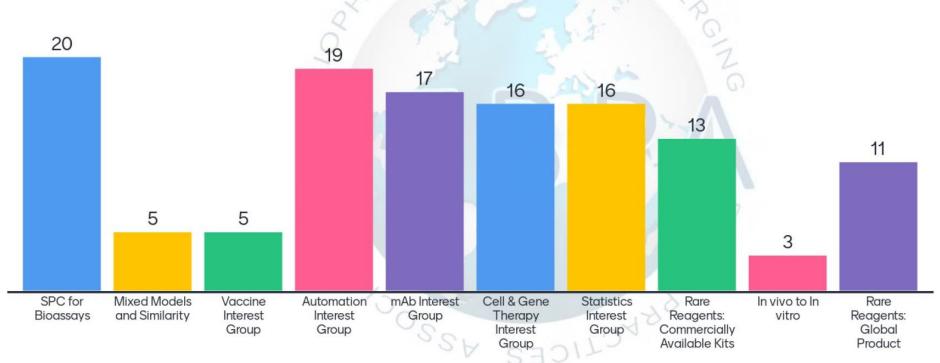
Audience Surveys



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



person audience)



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



Automated data analytics
Automation
Automation
Automation successes and challenges
More automation
Small automation

Bioassay development
Development problems
Development troubleshooting

Critical reagent inventory management
Critical reagent management
Qualifying critical reagents

Cell and gene therapy
More Gene therapy

Cell lines for bioassays

Gene editing Gene editing Gene editing Gene editing Lifecycle Management
Test method lifecycle management

Complex products

Brisket smoking

Ligand binding

USP USP More USP please

Reference standards

Validation Validation Method Validation Regulatory
Regulatory aspects for methods validation

Specific stat topics
Statistical approach to setting acceptance criteria
Training on basic stat software use

Specification setting

Transfer to QC







