BEBPA 2022 EUR Bioassay Conference - Day 1

Wednesday, 28 September 2022

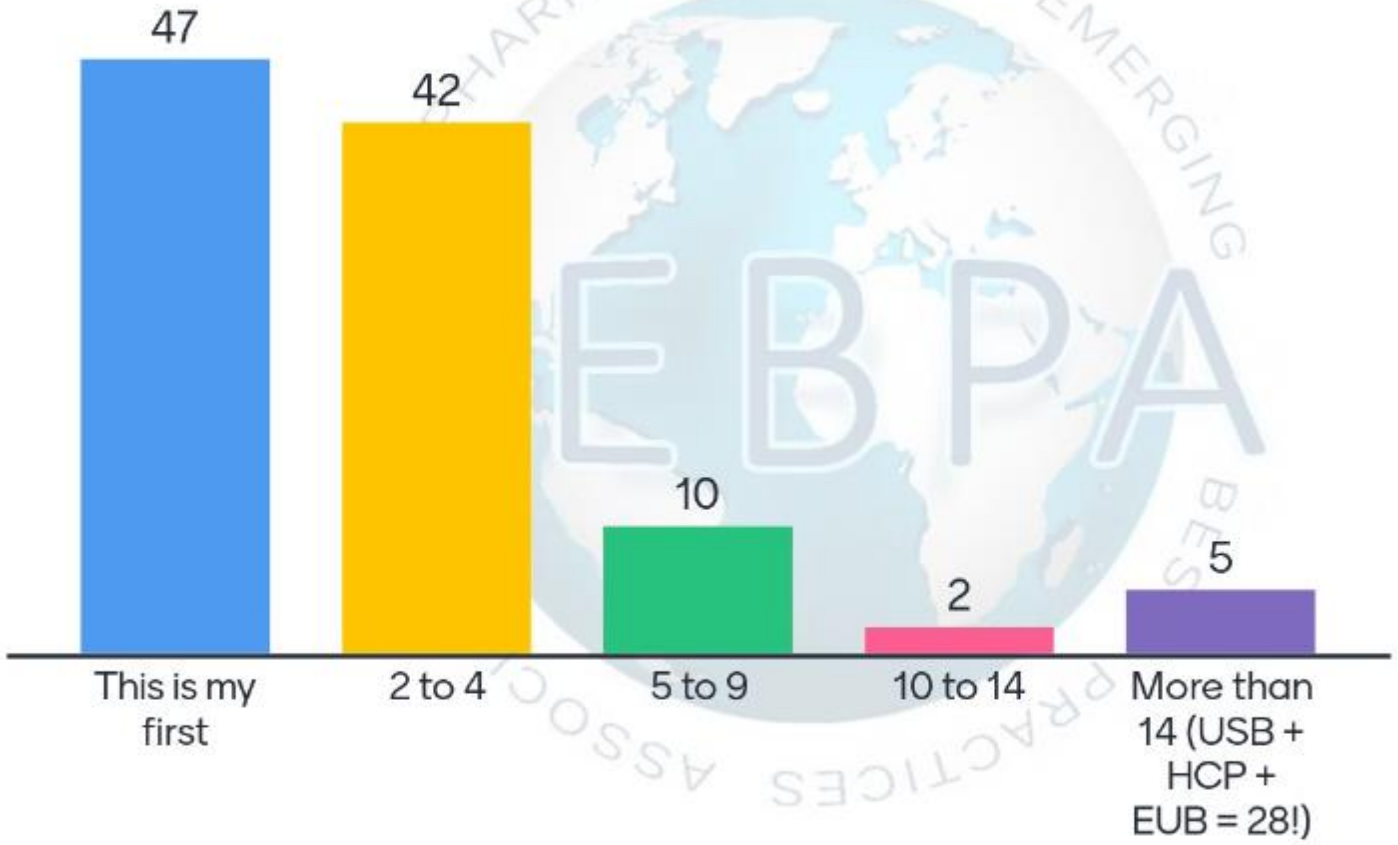
Audience Surveys

Welcome Back & Introduction

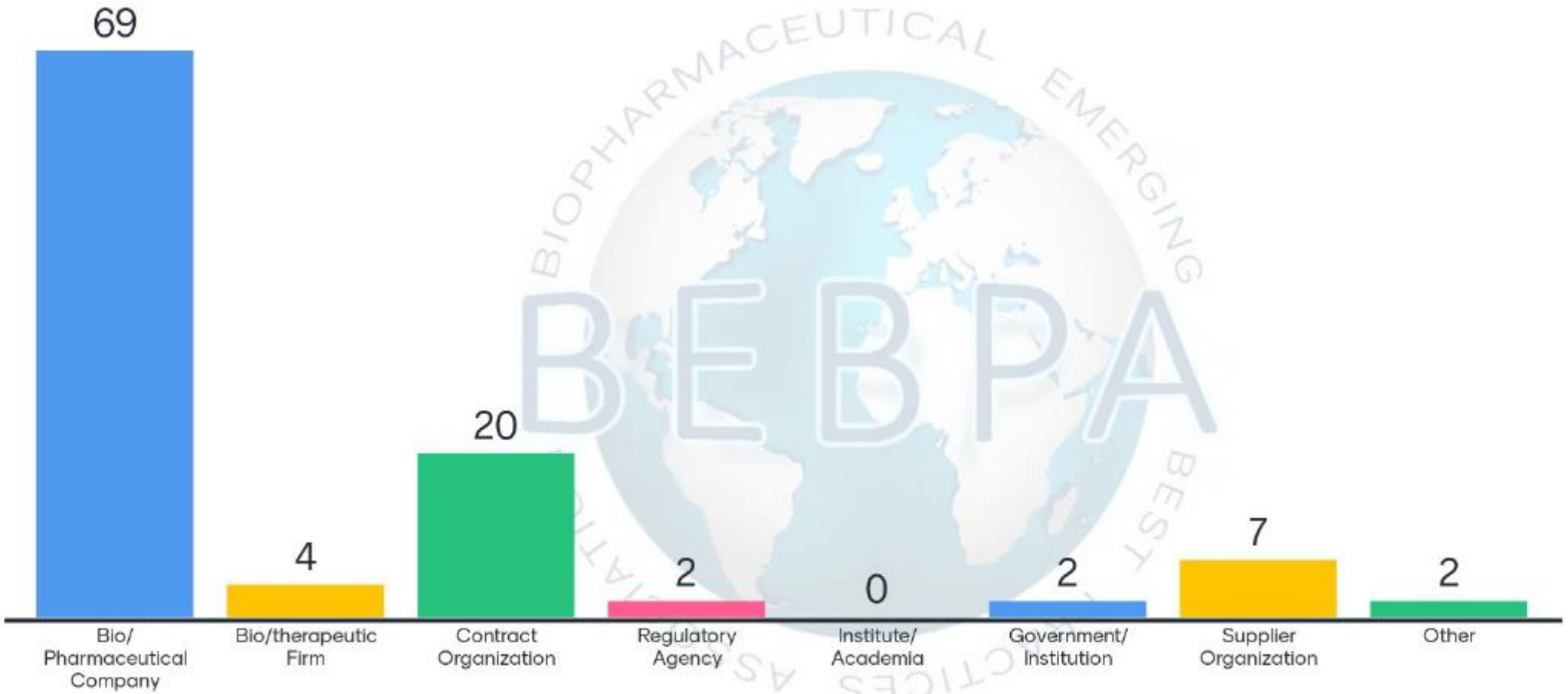
Laureen Little, President of BEBPA

Audience Surveys

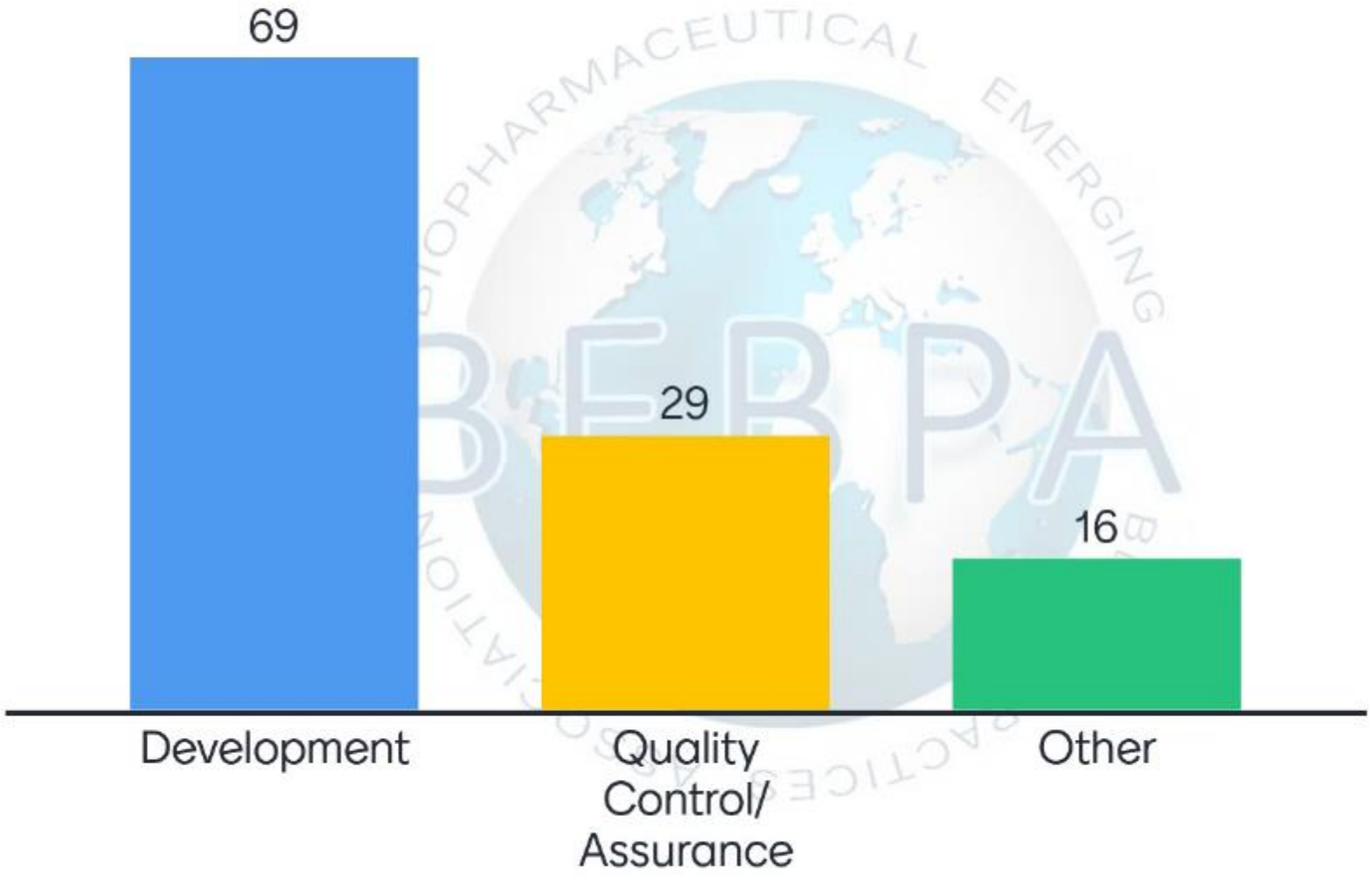
i.1 How many BEBPA Conferences have you attended?



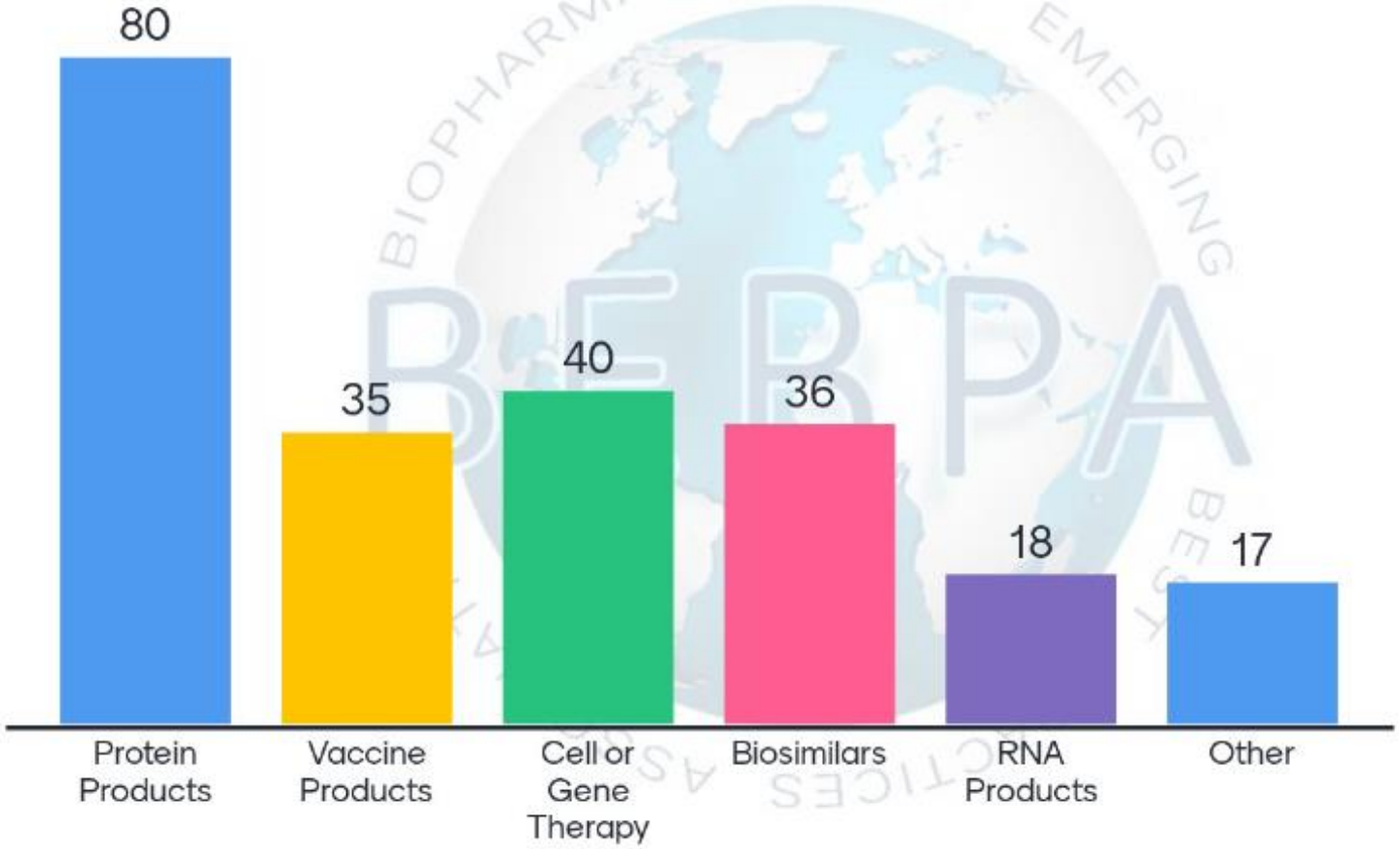
i.2 What type of organization do you work for?



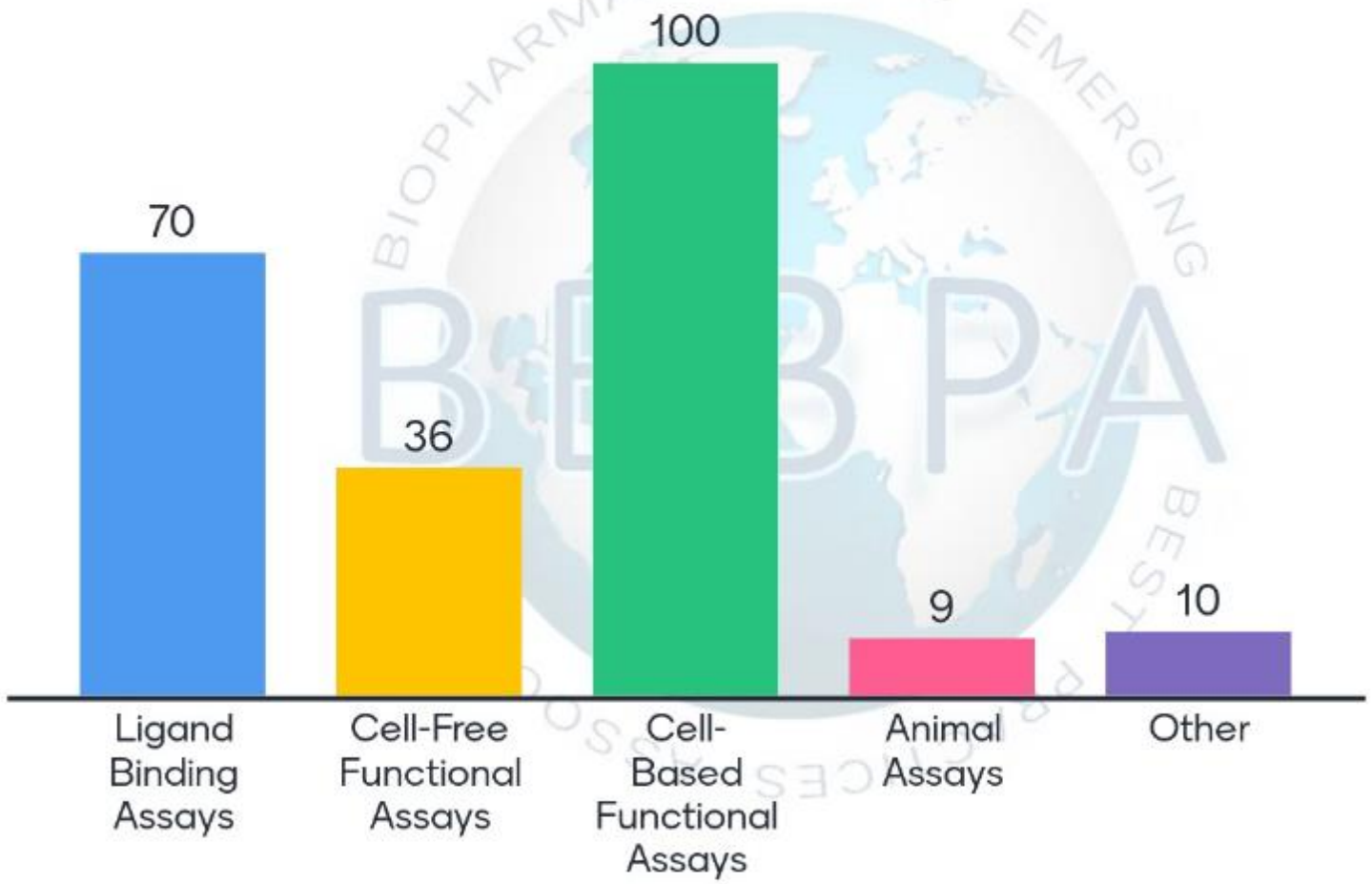
i.3 What part of the organization do your work for?



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)

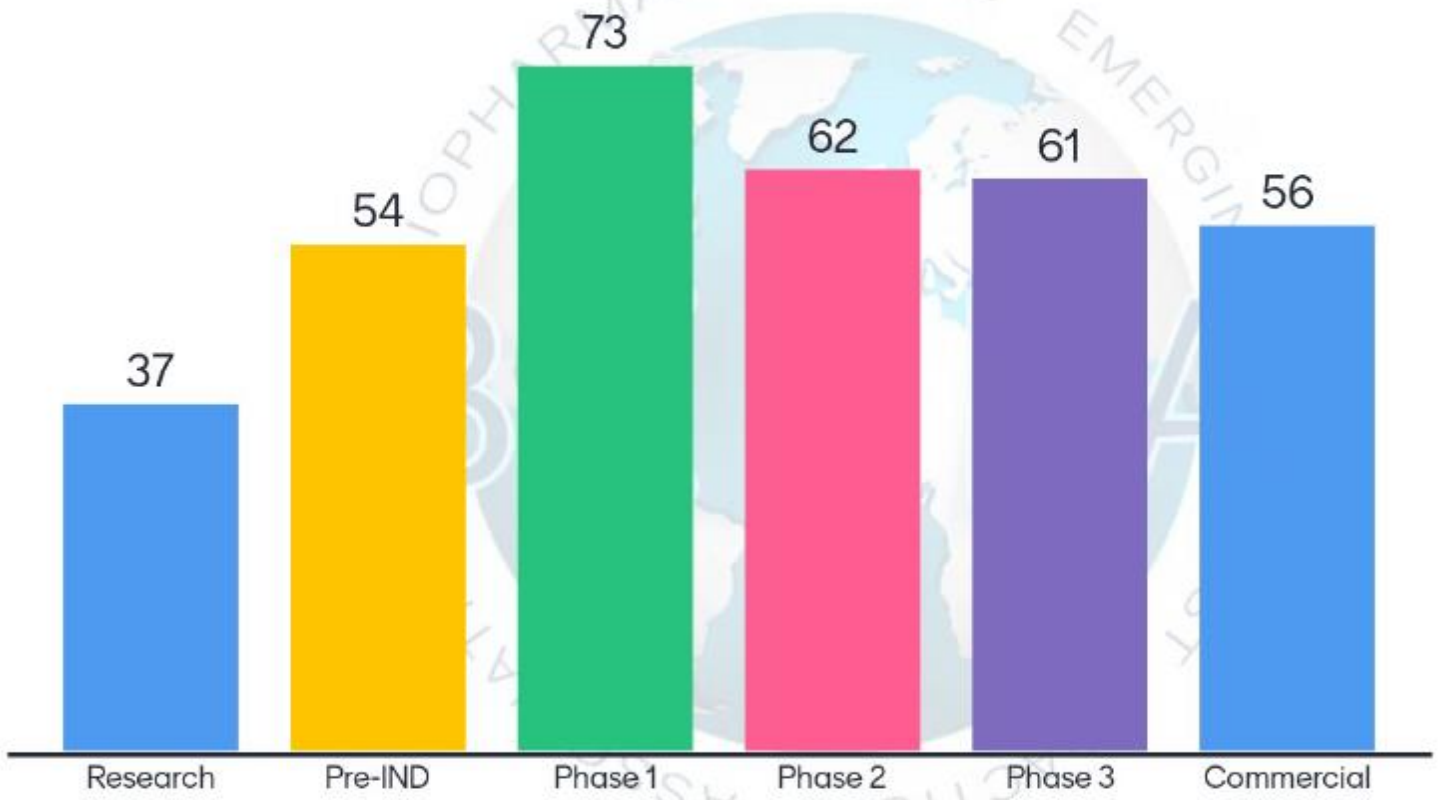


Session 1: Regulatory Issues

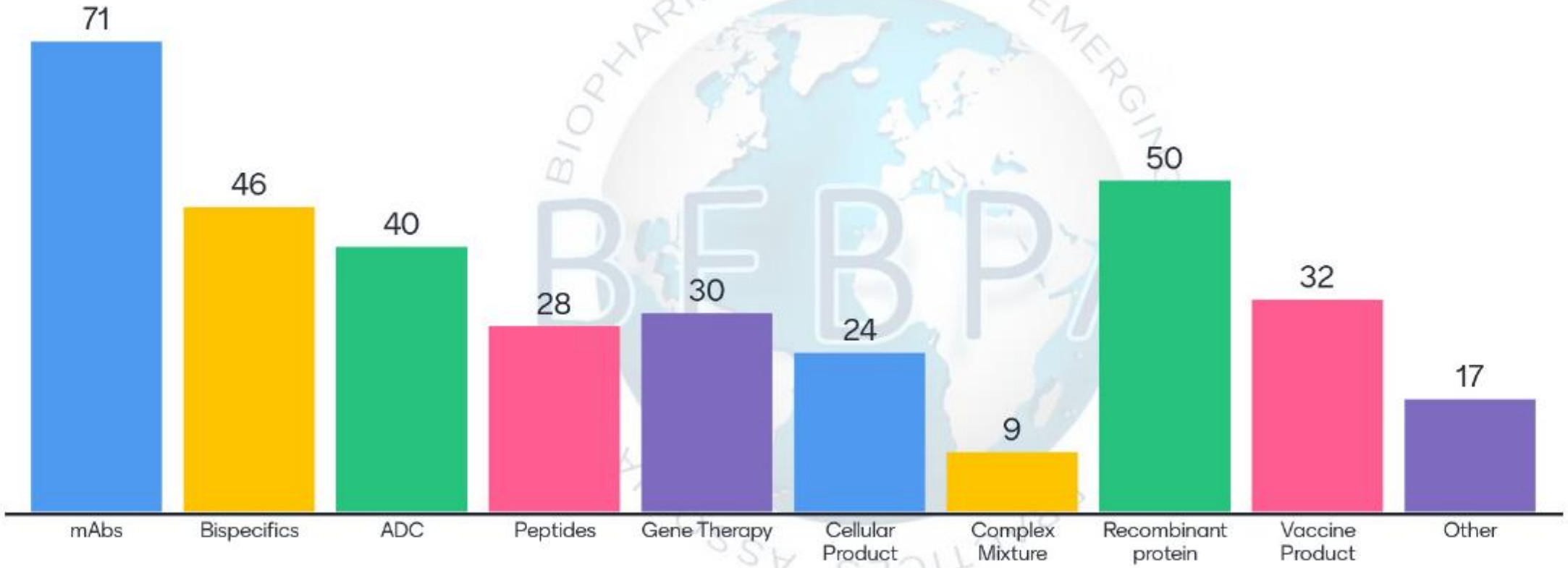
Session Chair: Laureen Little, President of BEBPA

Audience Surveys

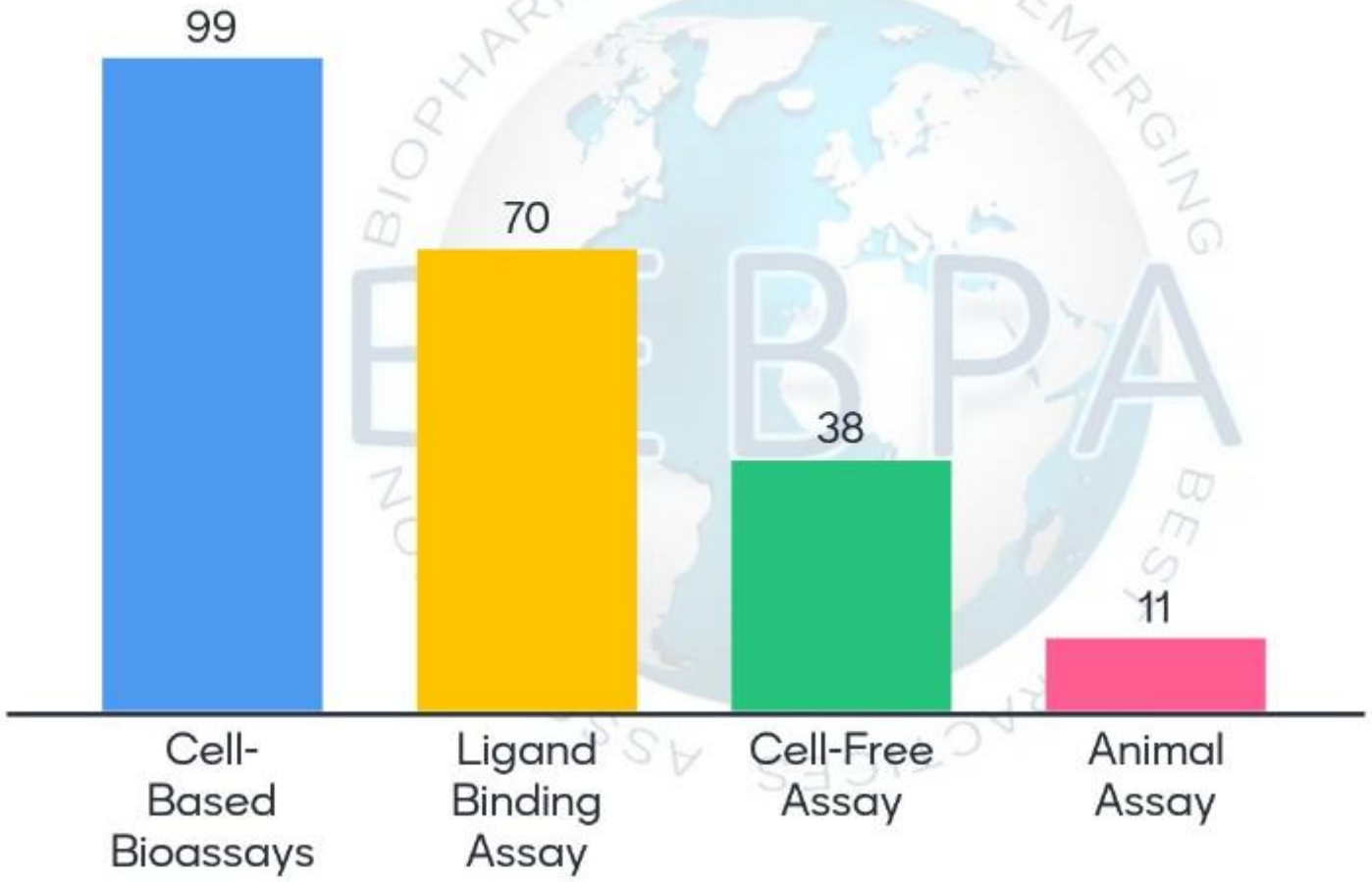
1.1 For what phase of clinical development are you supporting? (Check all that apply)



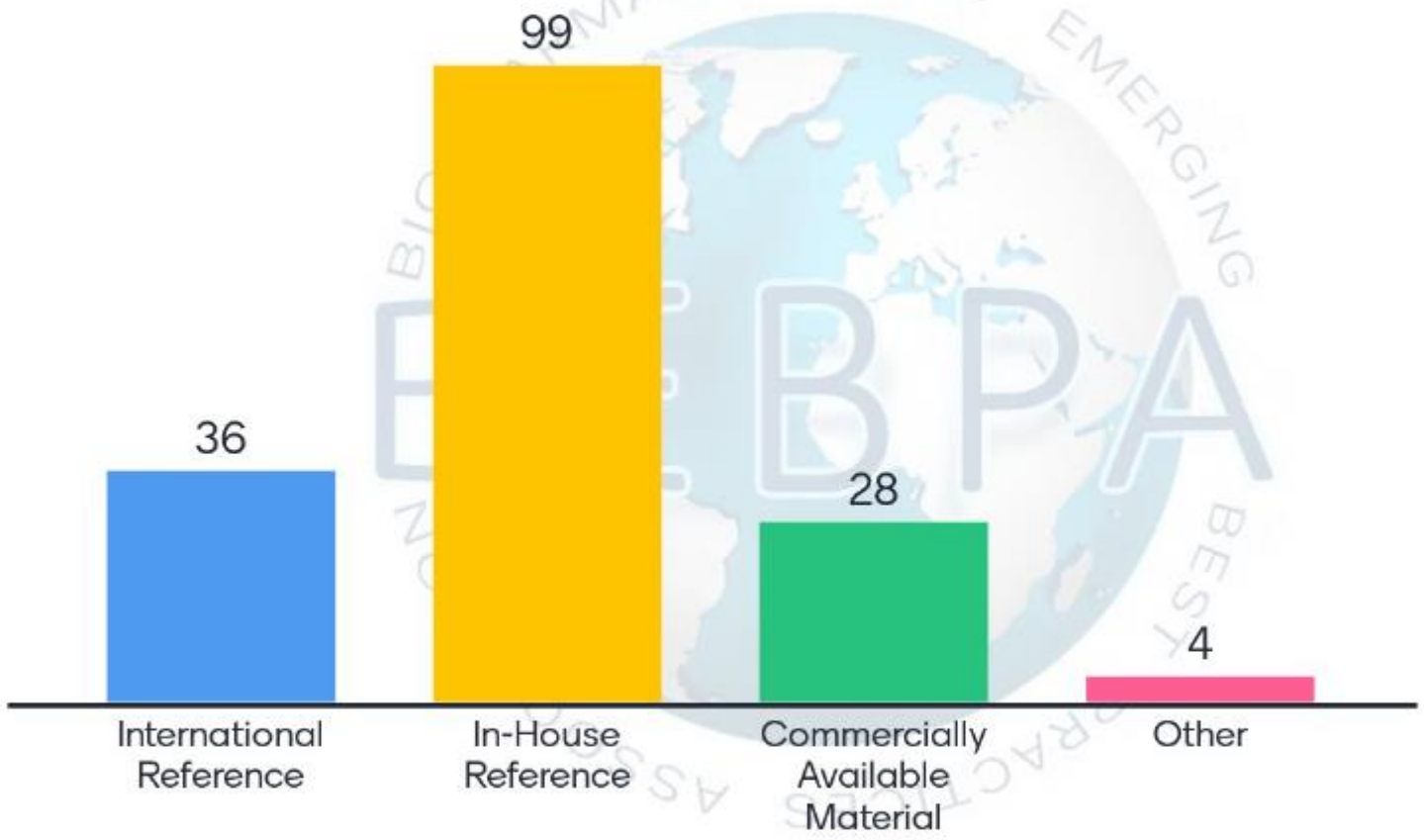
1.2 What kind of products do you work with? (Check all that apply)



1.3 What kind of bioassays do you use? (Check all that apply)

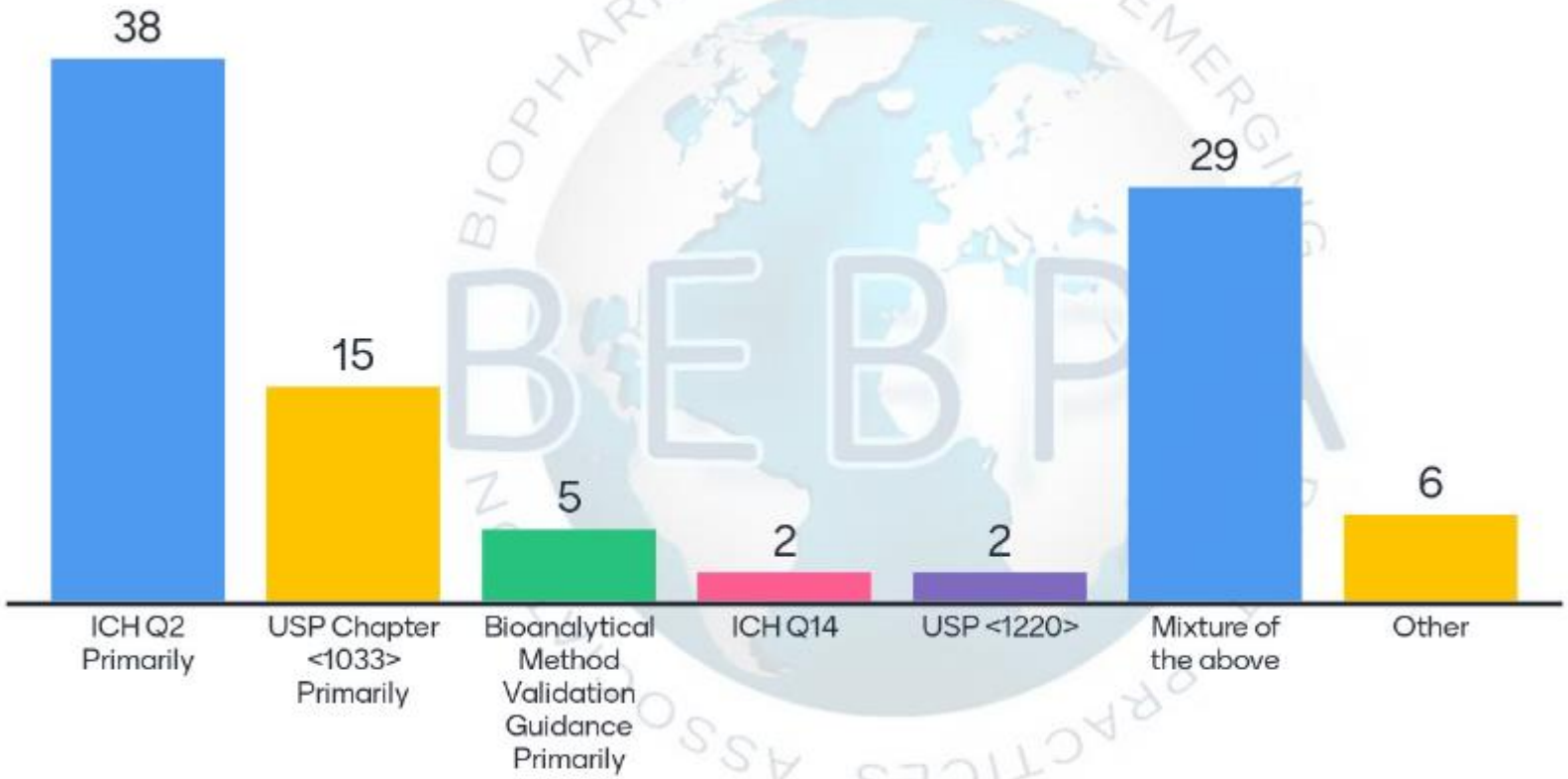


1.4 What type of reference do you use? (Check all that apply)

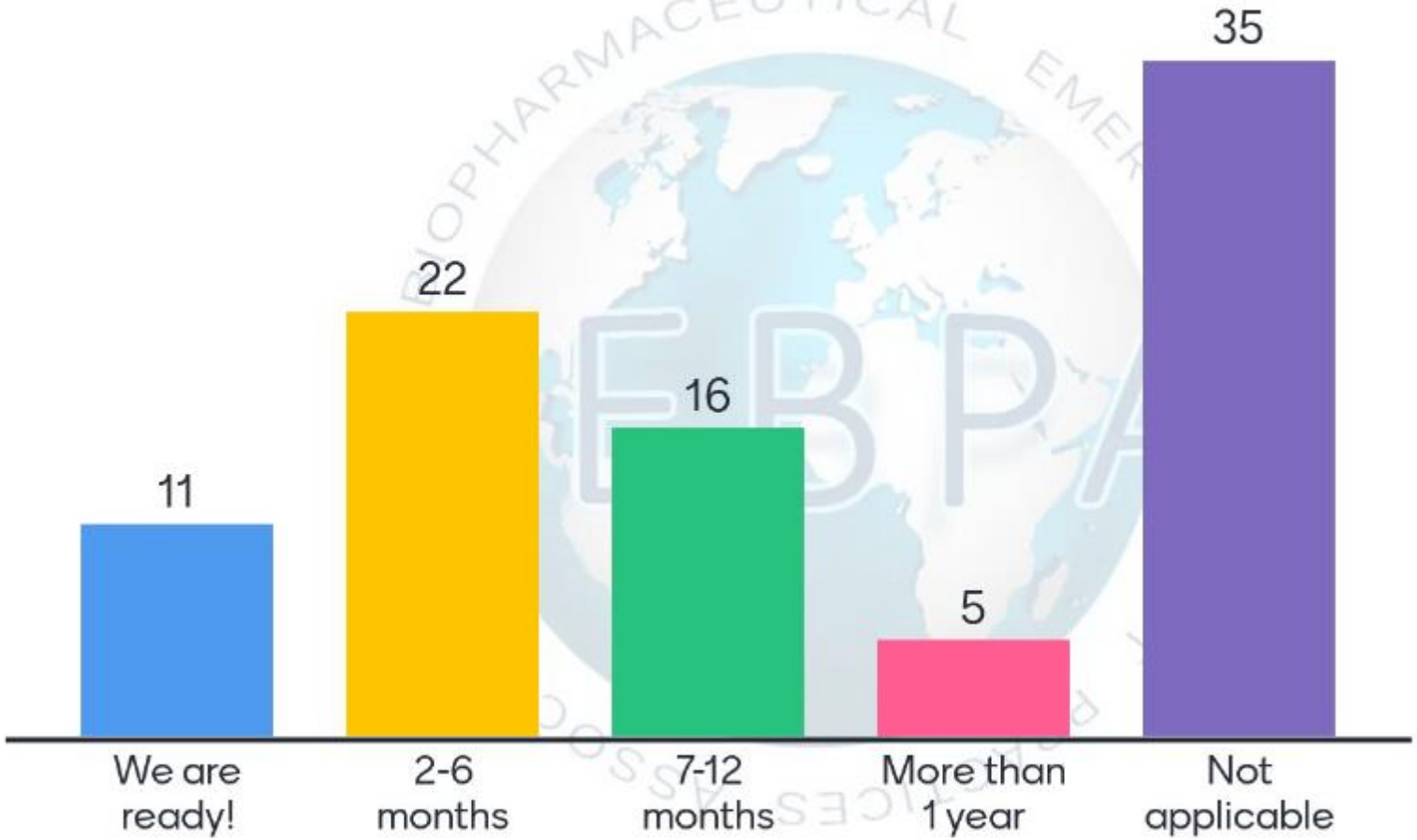


1.5 Do you have a two-tiered reference system?

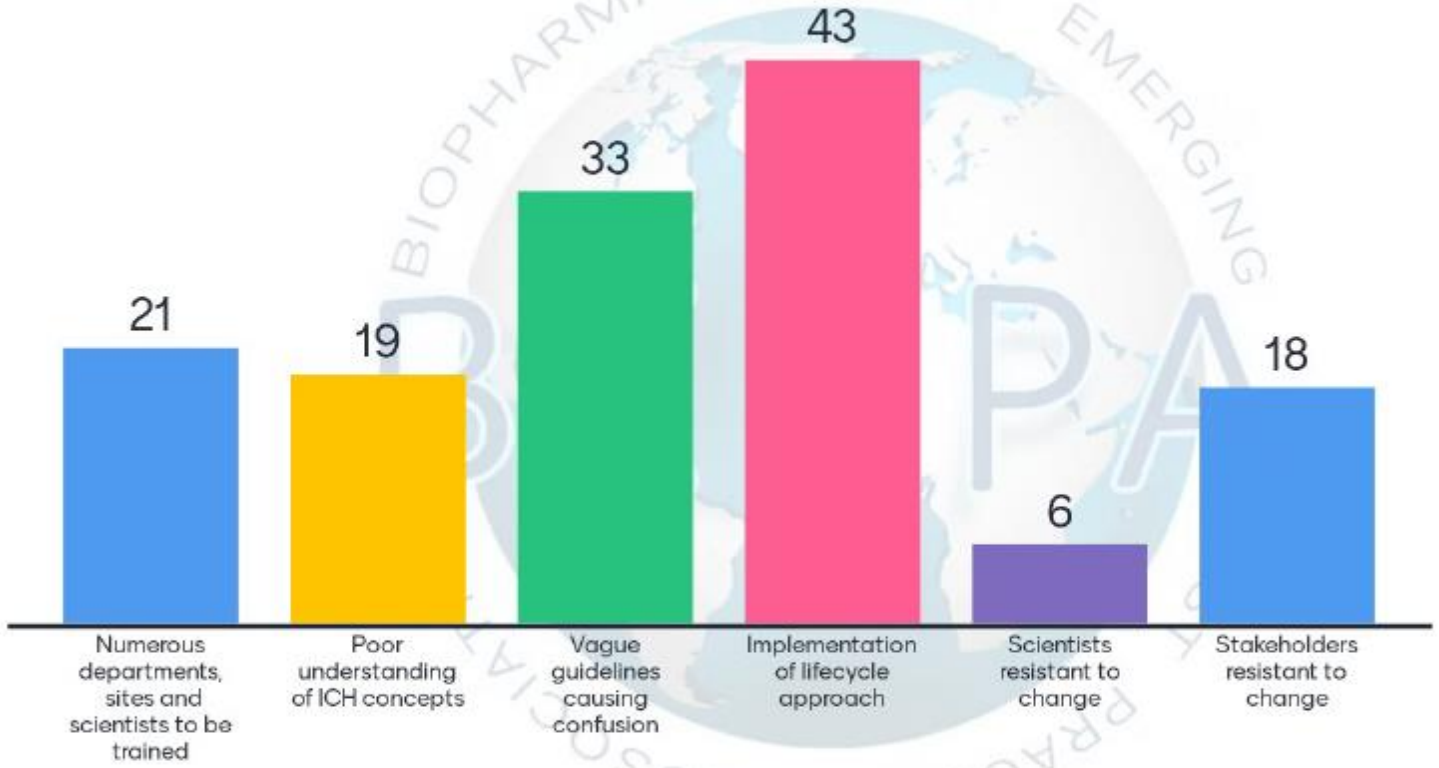
1.6 Which validation guidance do your validations most closely resemble?



1.7 We will submit ICHQ2(R2)/ICHQ14 documents for procedure validations (including, but not only, SOP revisions, trainings etc.) in ____



1.8 The major challenges of ICHQ2(R2)/ICHQ14 implementation are: (Check all that apply)

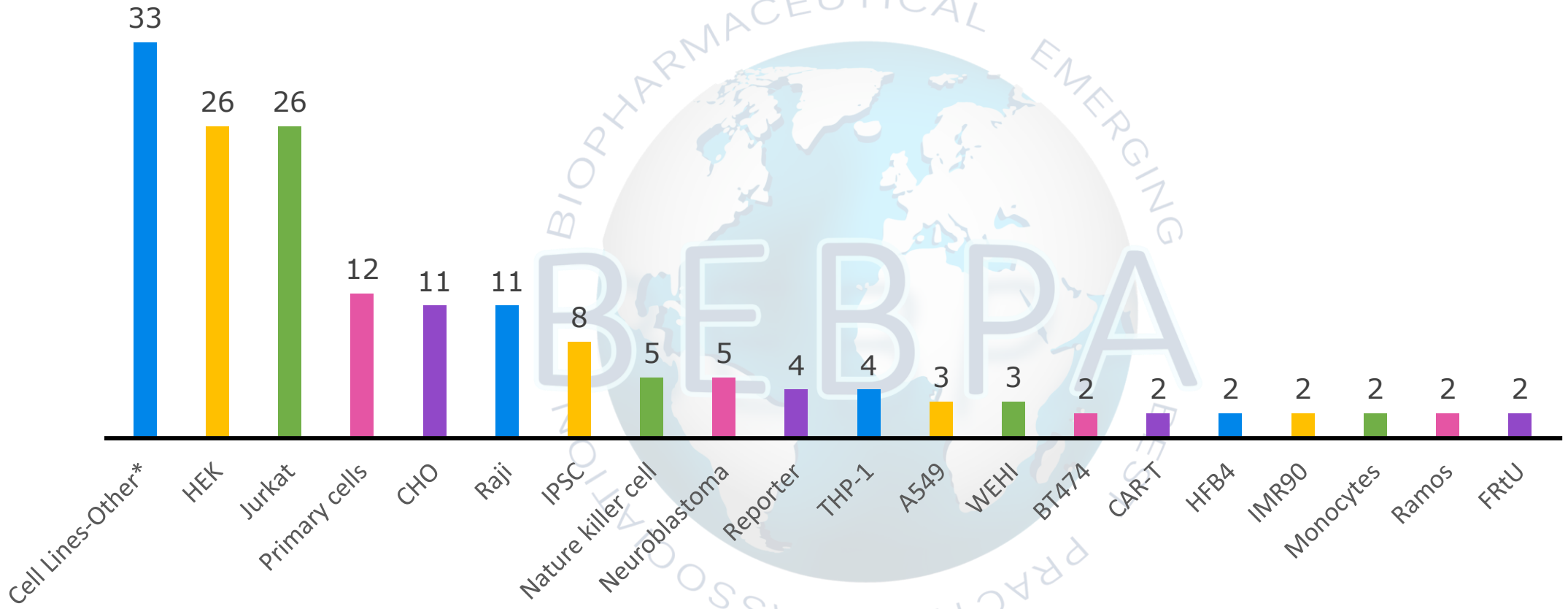


Session 2: Cells for Cell-Based Assays

Session Chair: Laureen Little, President of BEBPA

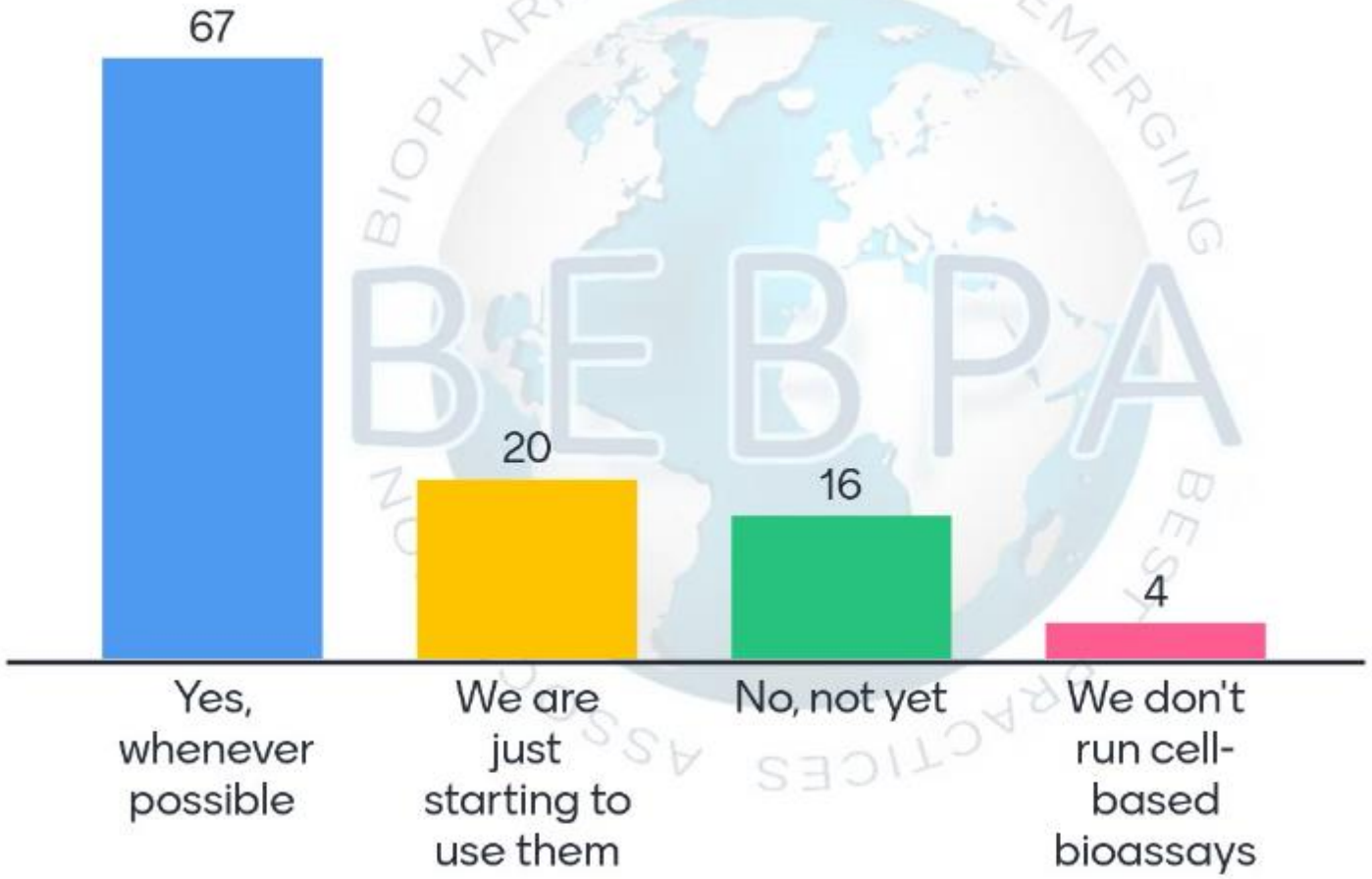
Audience Surveys

2.1 What type of cells in your bioassays?

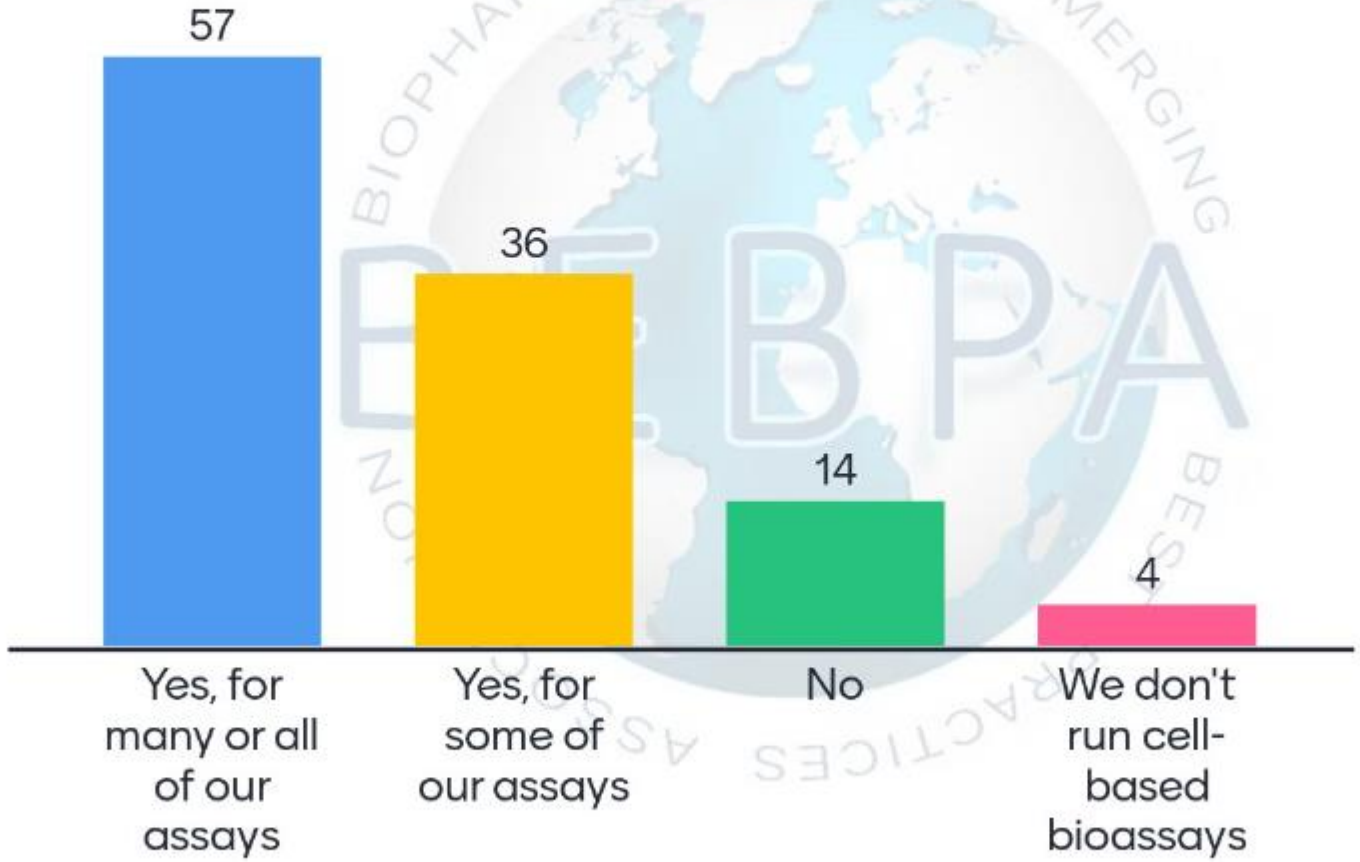


*Cell Lines-Other (single votes)					
A375	HH	HUVEC	SK-N-MC	NCI-H1299	Continuous cell line
A431	Sc	JeKo-1	TD-T cells	Tumor cells	Commercial cell lines
A549	Es2	U937	FPBMCs	Fibroblasts	Murine breast cancer cells
AD293	CTLL	Vero	Epithelial	Engineered	Genetically-modified cell lines
Apac	L929	WILS	Colo205	Immortalized	Mammalian established cell lines
BHK	TF1	Neurons			

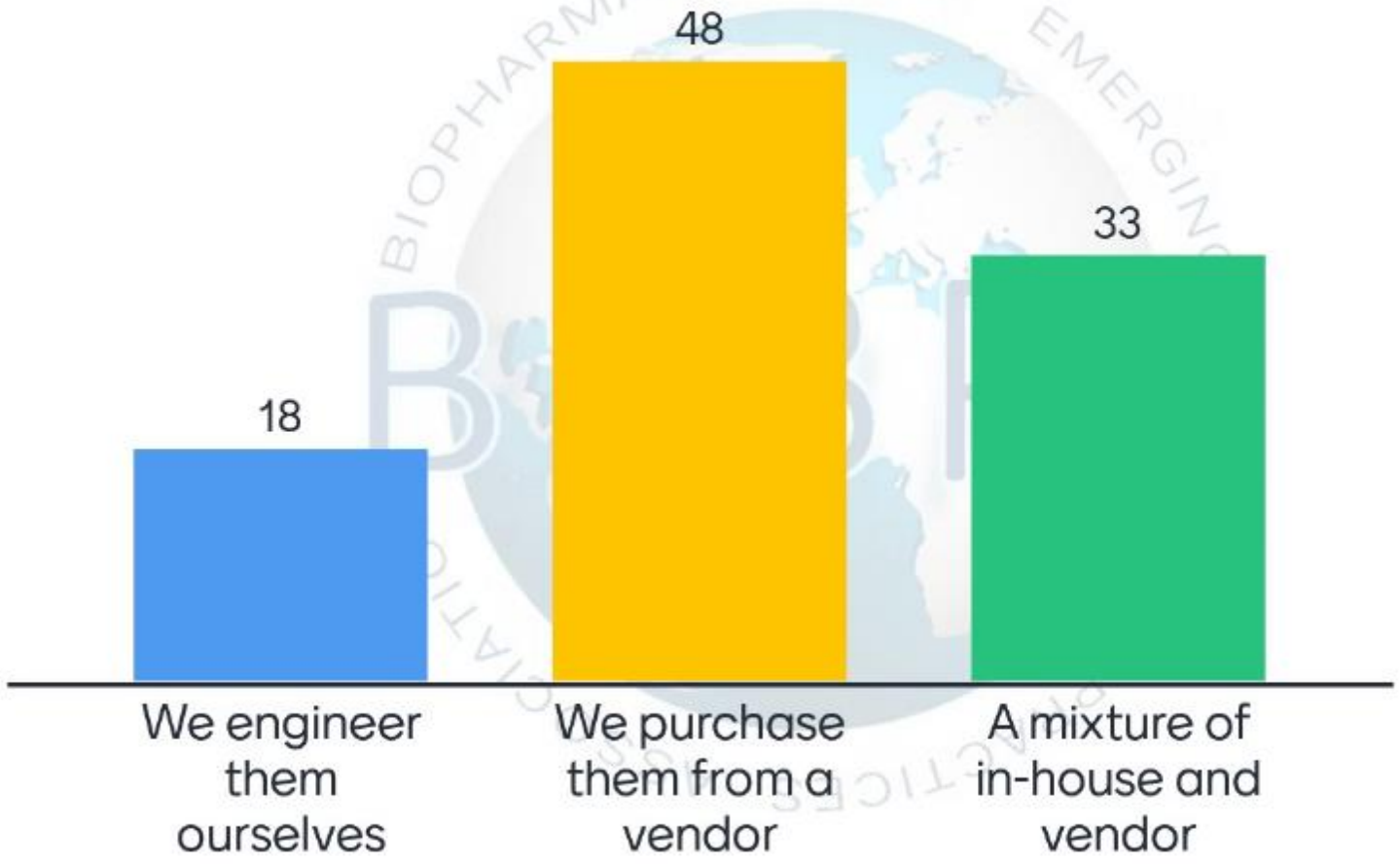
2.2 Do you use Frozen-Ready-To-Use Cells for your potency assays?



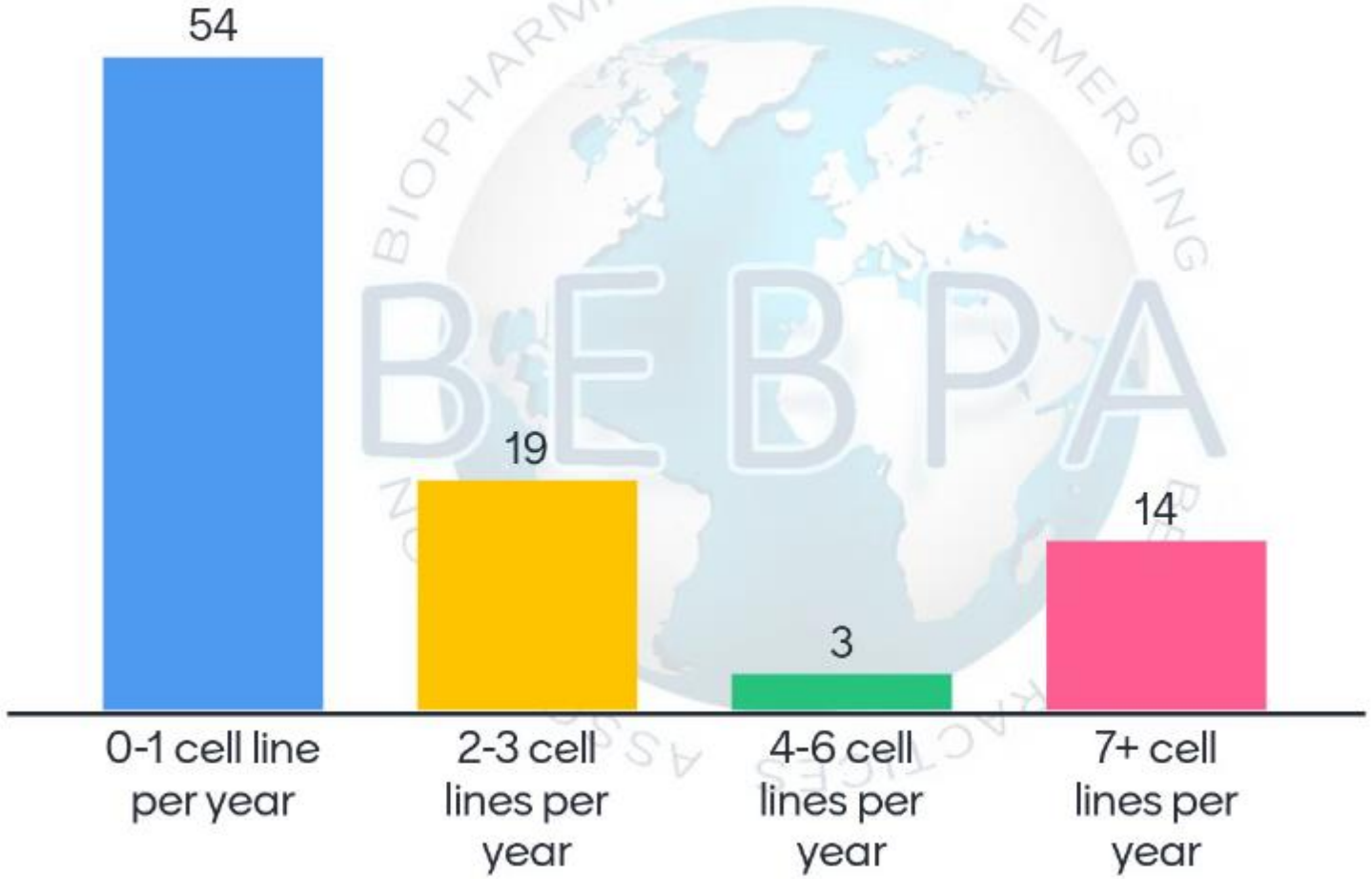
2.3 Do you use engineered cell lines for your bioassays?



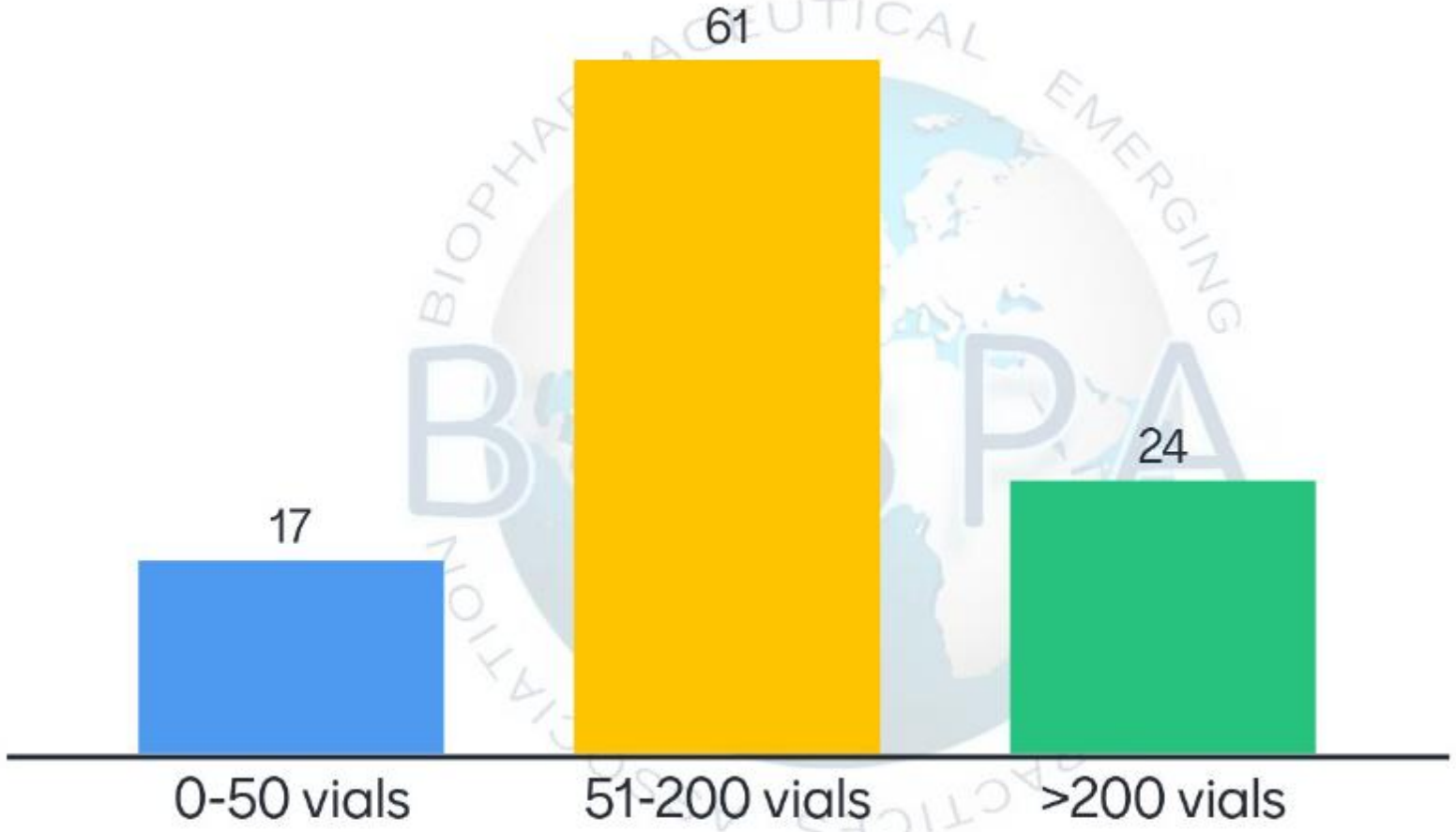
2.4 Do you develop your own engineered cells lines or purchase them from a 3rd party/vendor?



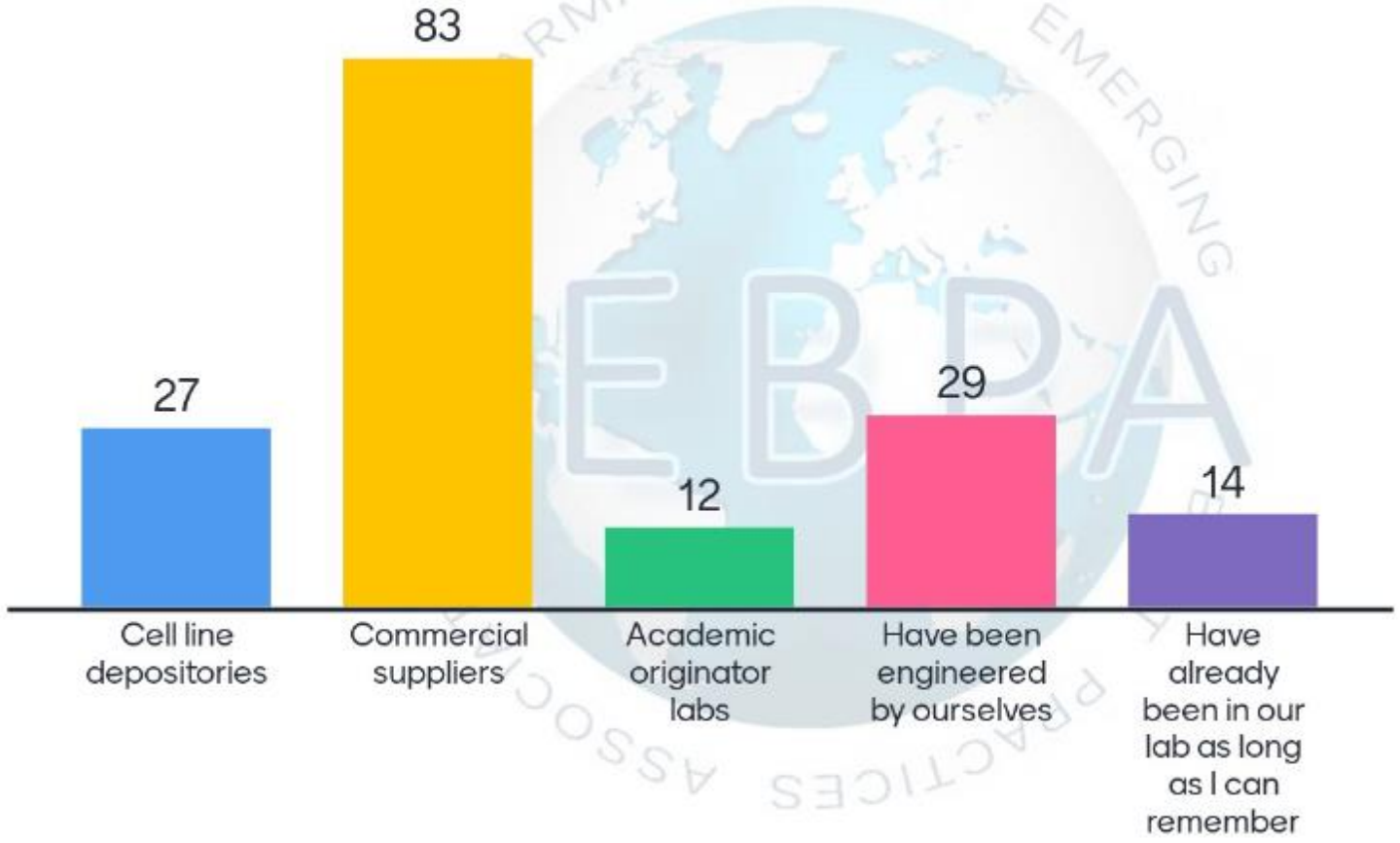
2.5 How frequently does your company create in-house engineered cell lines for bioassays?



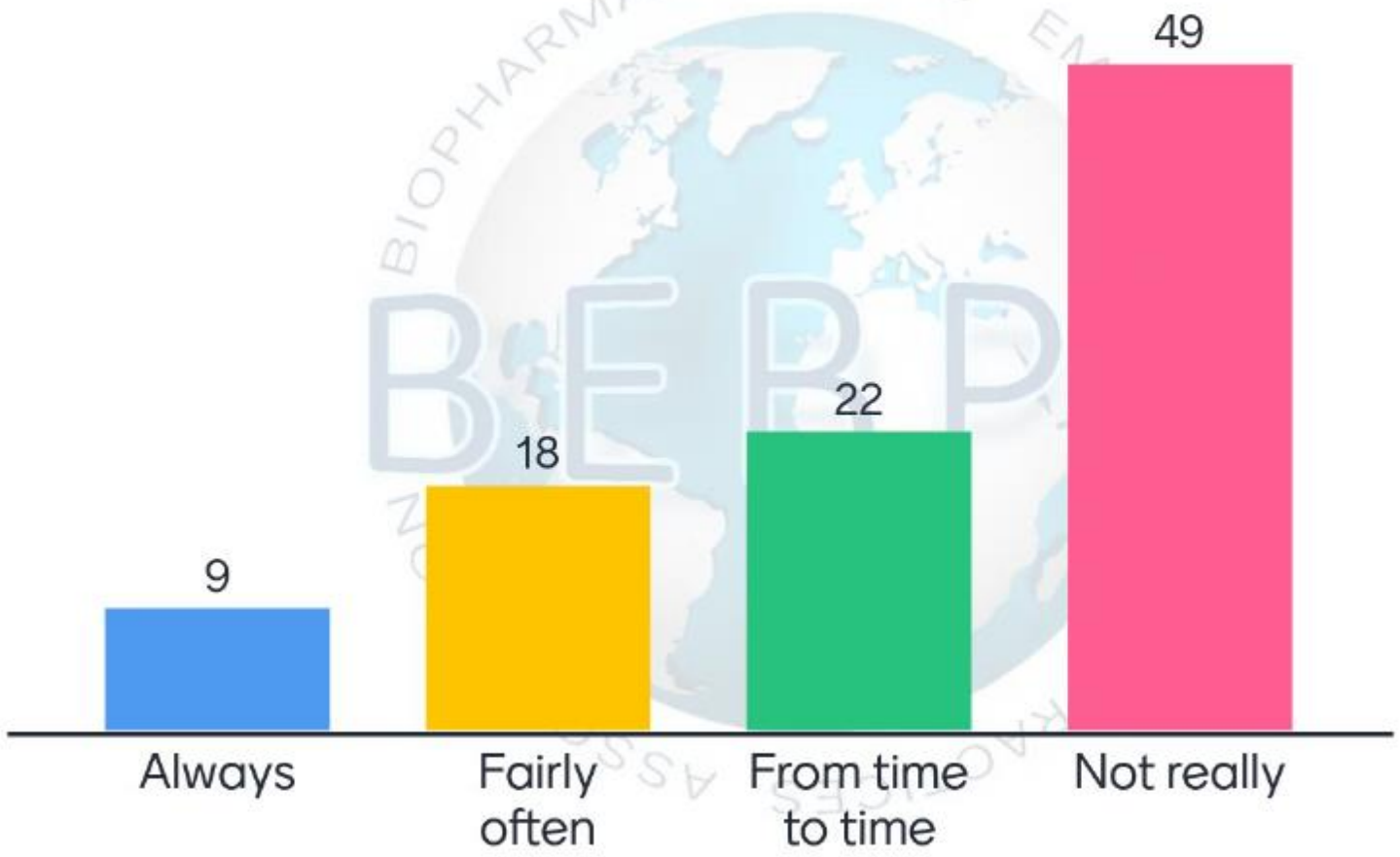
2.6 What size is your working assay cell bank?



2.7 Where did you source your (engineered) bioassay cells from? (Check all that apply)



2.8 When you develop a bioassay, do you consider serum replacement or reduction?

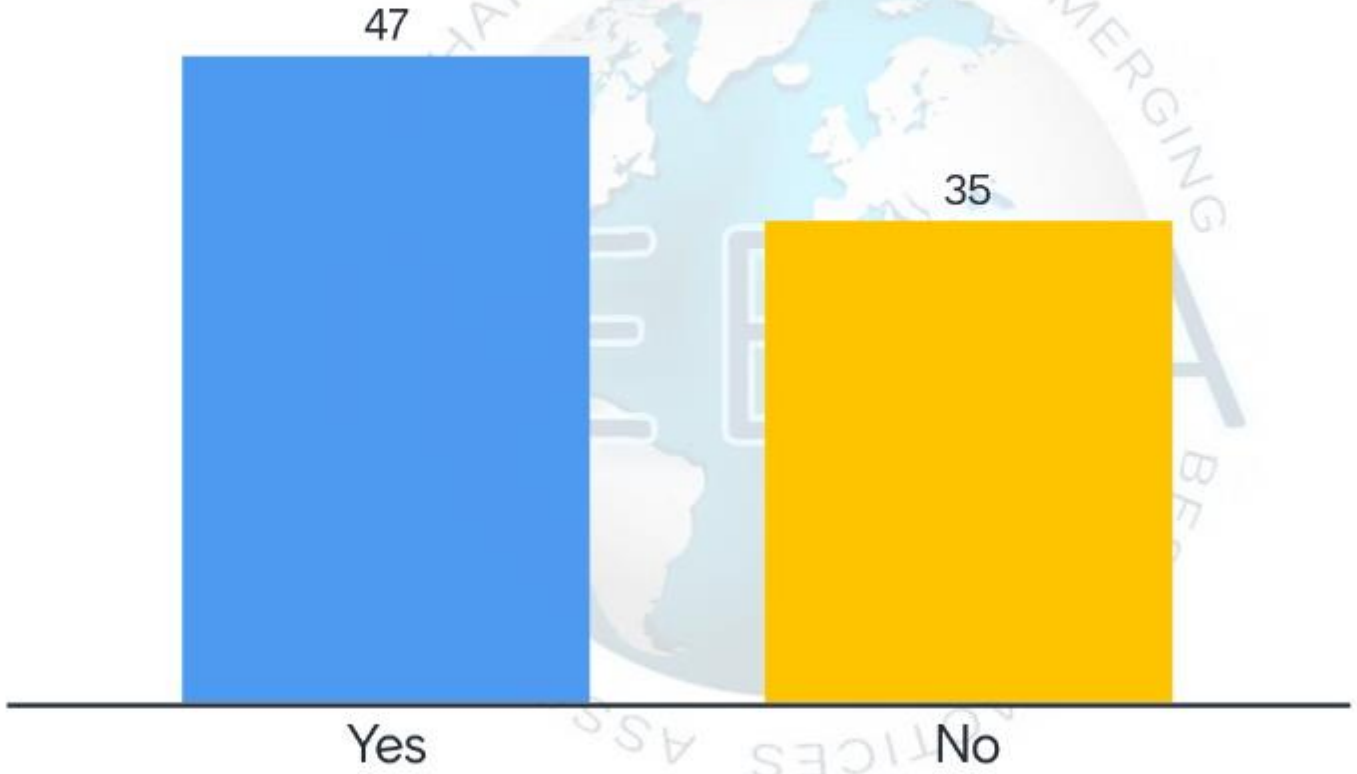


Session 3: Potency Assay Development Case Studies

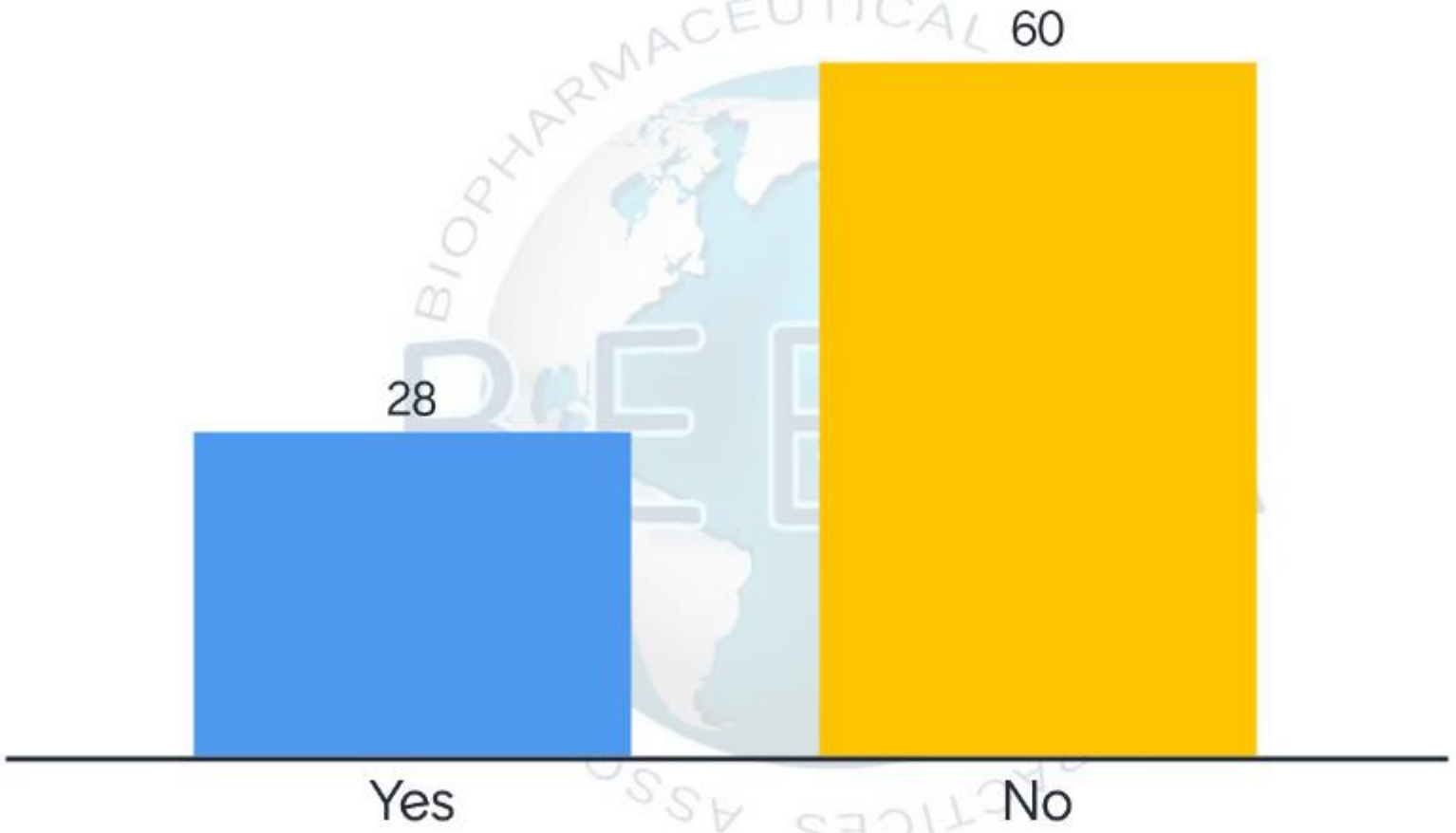
Session Chair: Hans-Joachim Wallny, Executive Director, Novartis Pharma

Audience Surveys

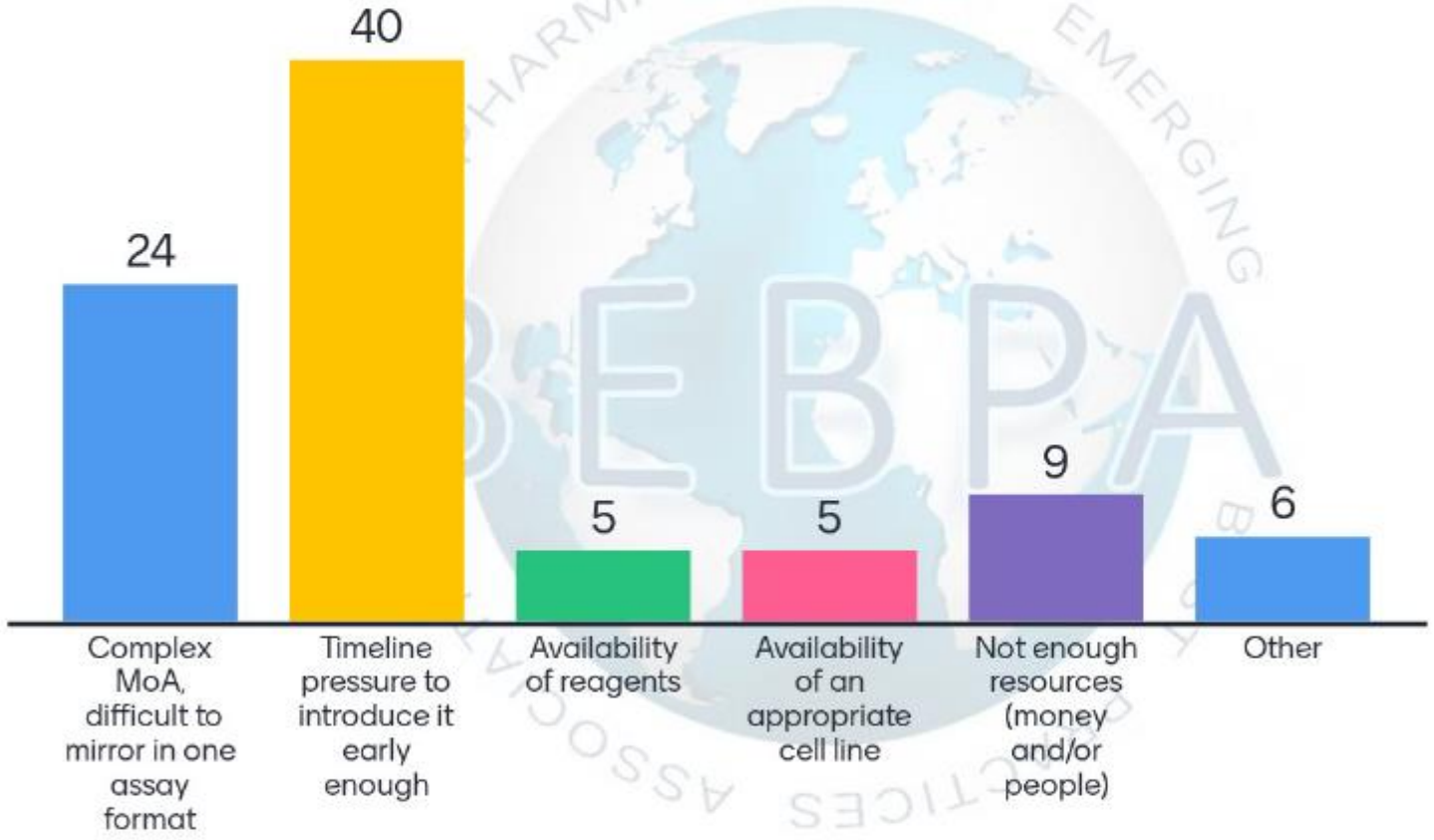
3.1 Do you work with multi-specific drug products?



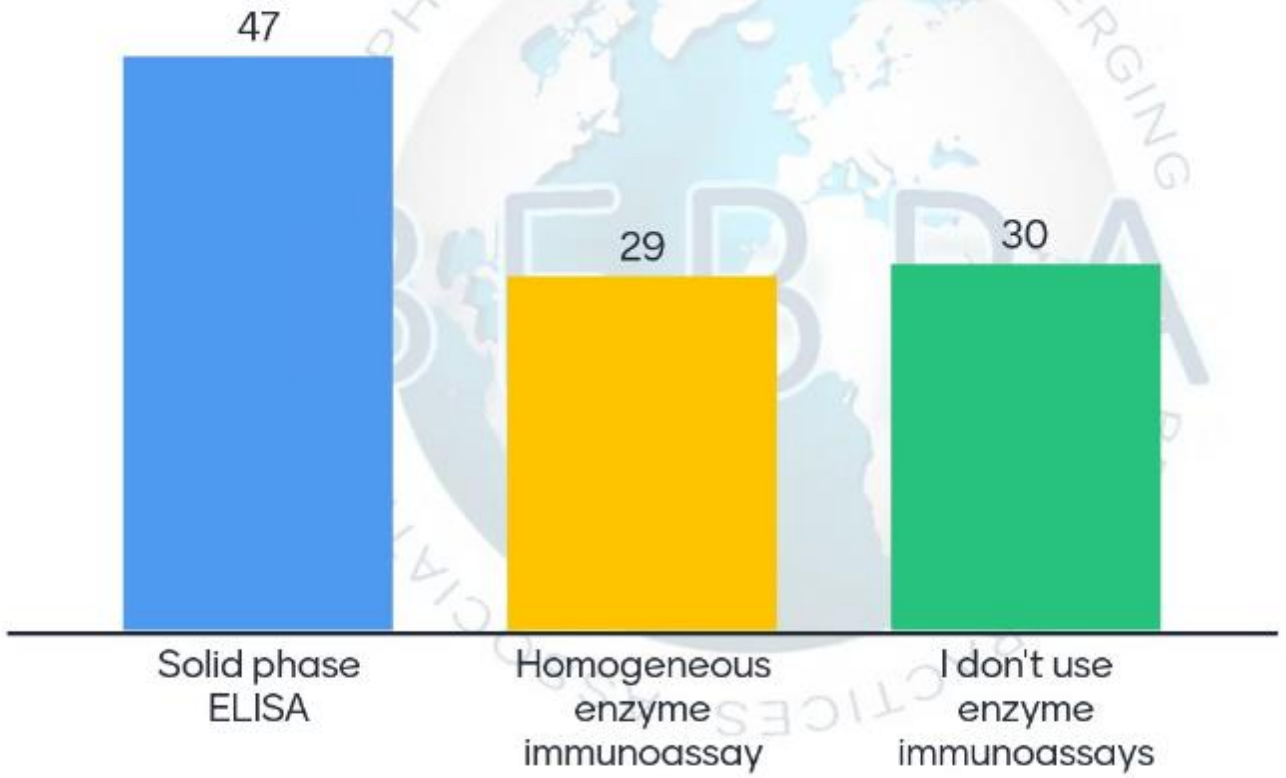
3.2 Do you develop multiplex assays?



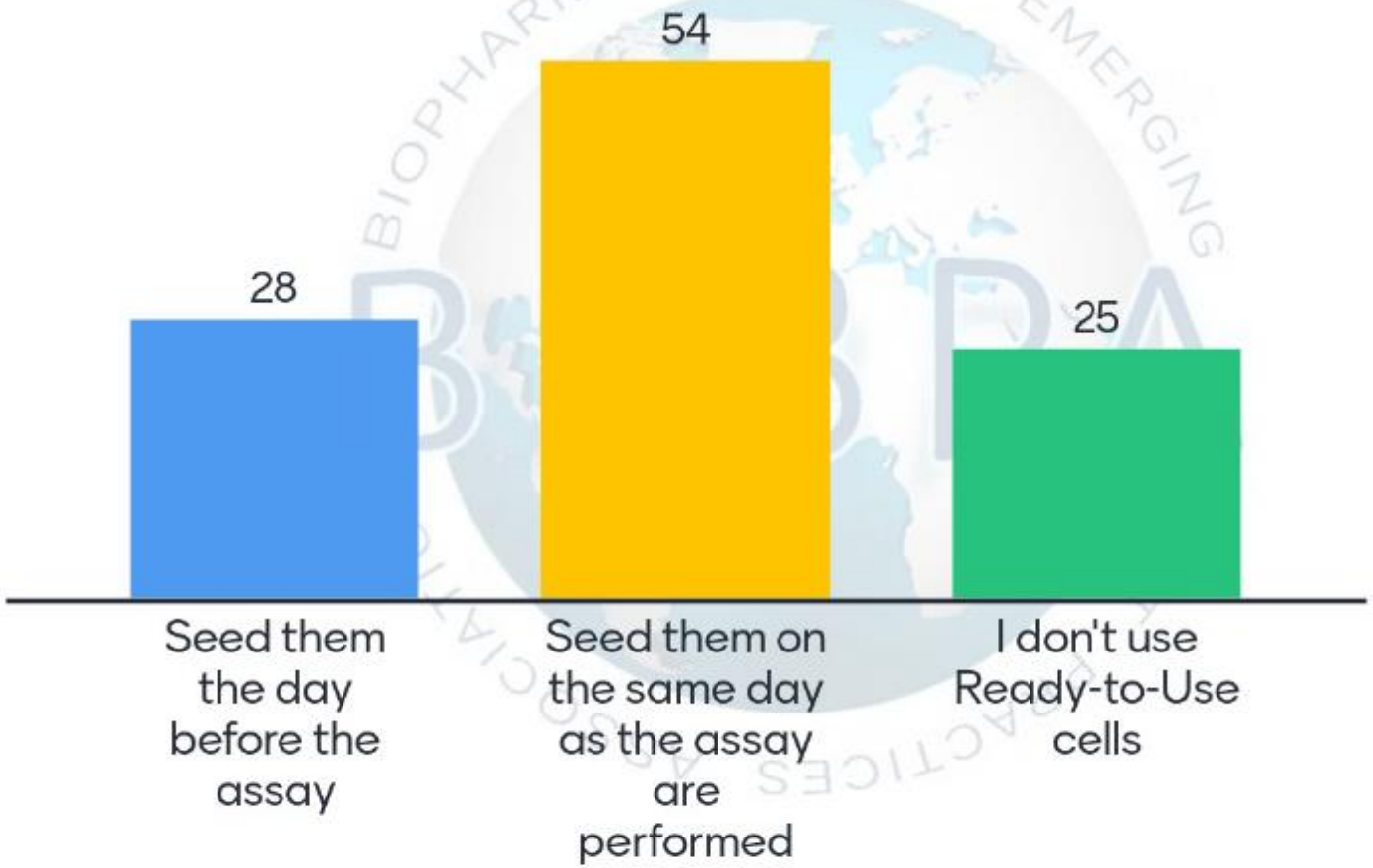
3.3 What is your biggest challenge today to develop a good potency assay for BLA submission?



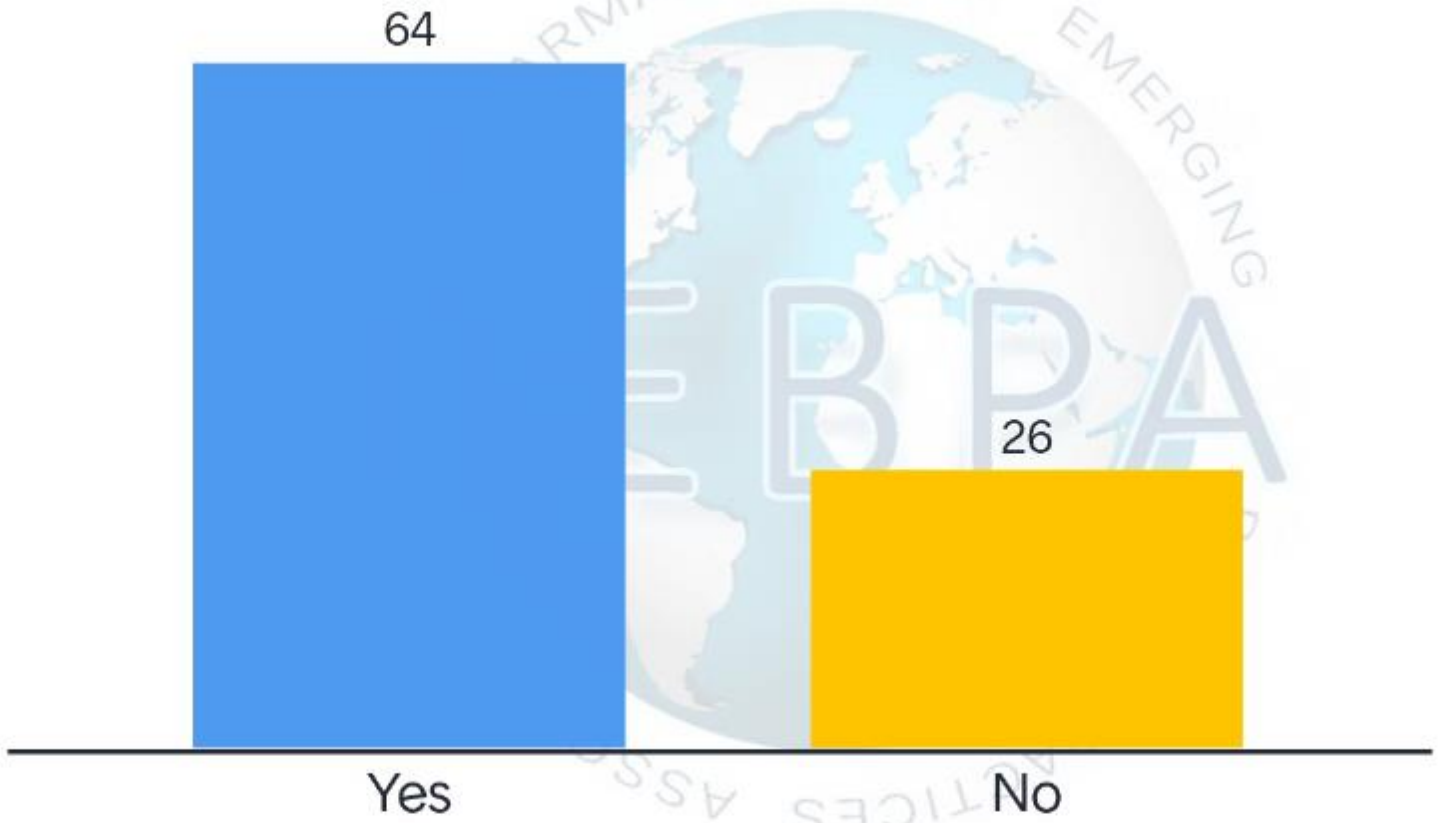
3.4 Which enzyme immunoassay technique are you using for quantification of an antigen in a potency assay? (Check all that apply)



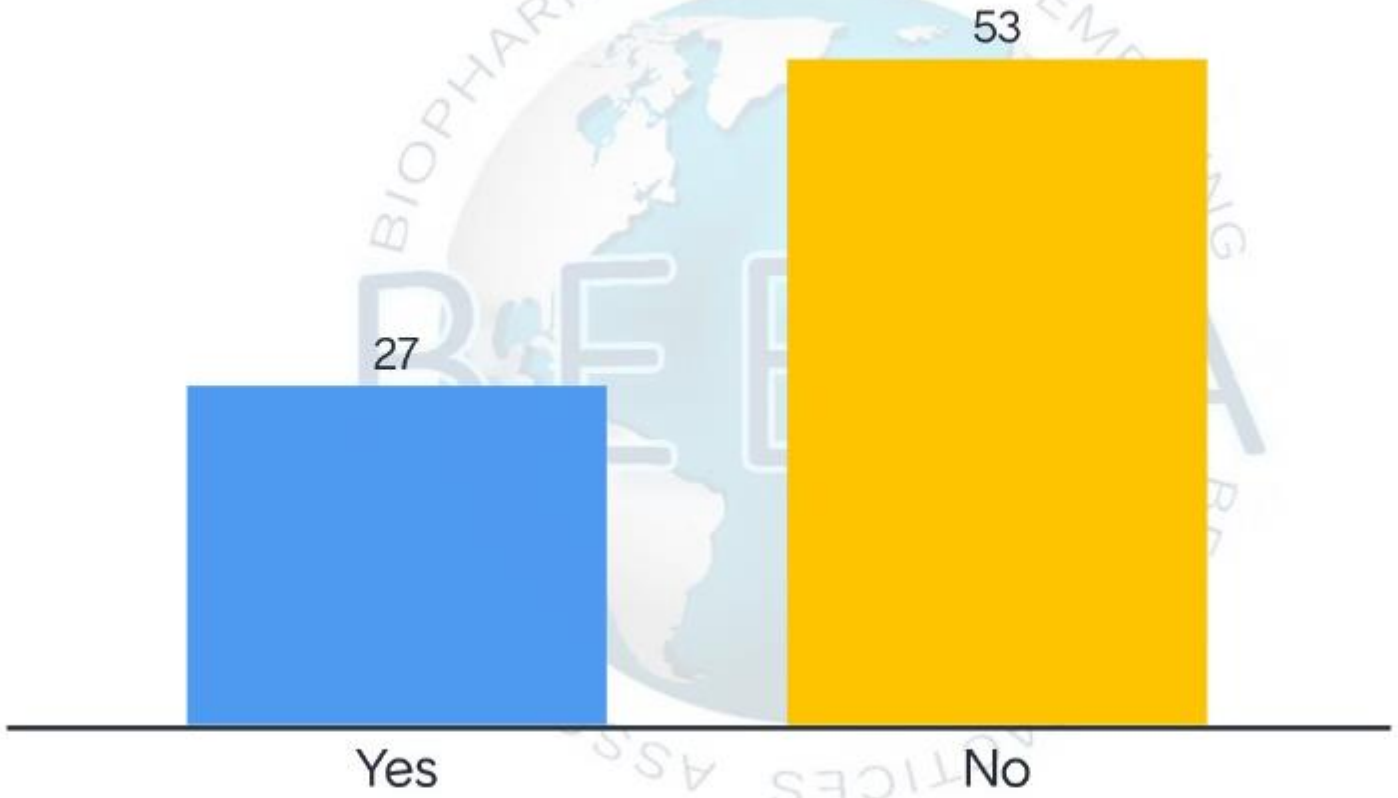
3.5 How are you using Ready-to-Use cells? (Check all that apply)



3.6 Do you have a System Suitability Test requirement for the response ratio of the cells?



3.7 Do you use homogeneous enzyme immunoassay for QC testing?

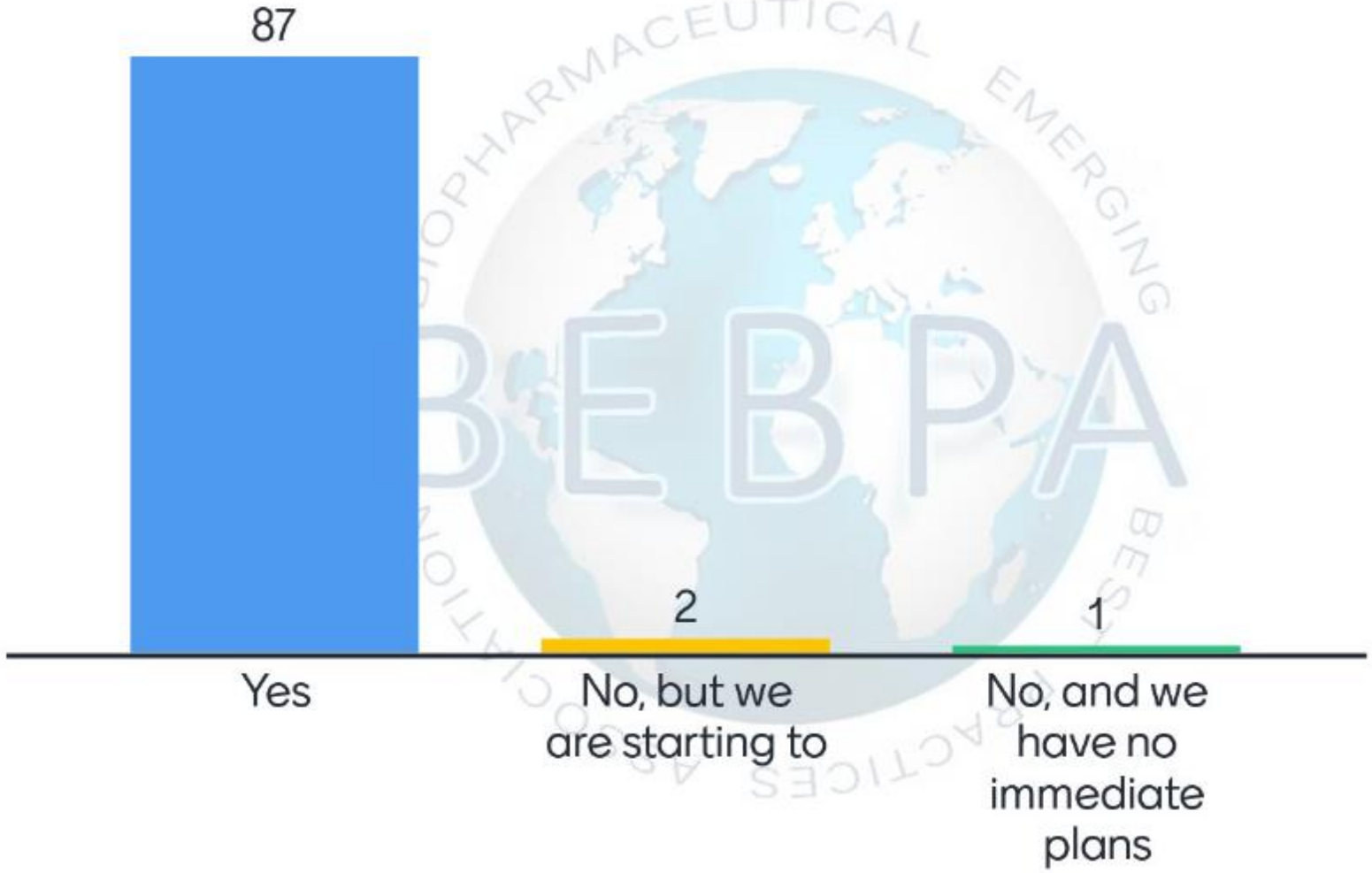


Session 4: Statistical Tools for Method Development

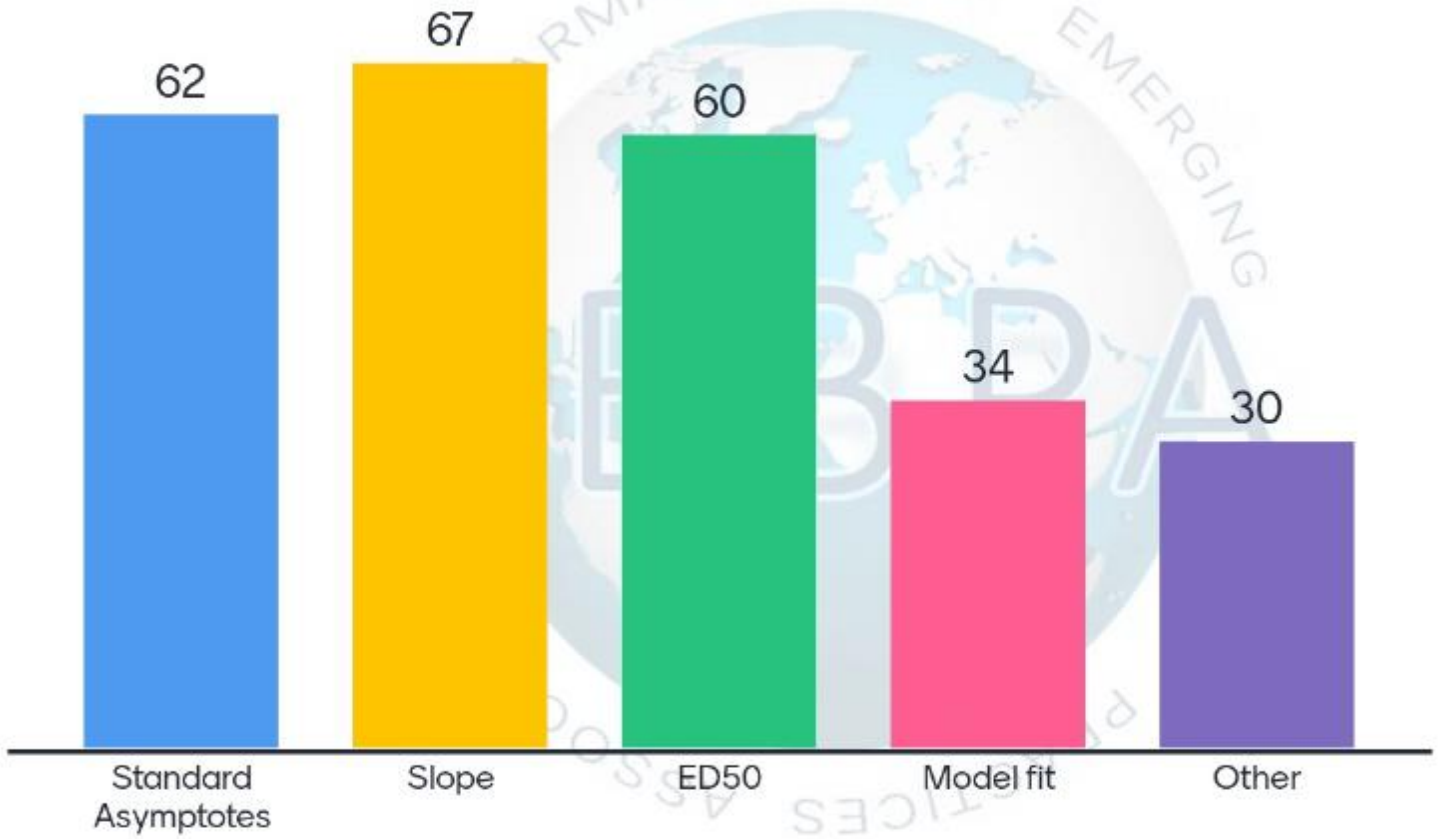
Session Chair: Perceval Sondag, Senior Director, Novo Nordisk

Audience Surveys

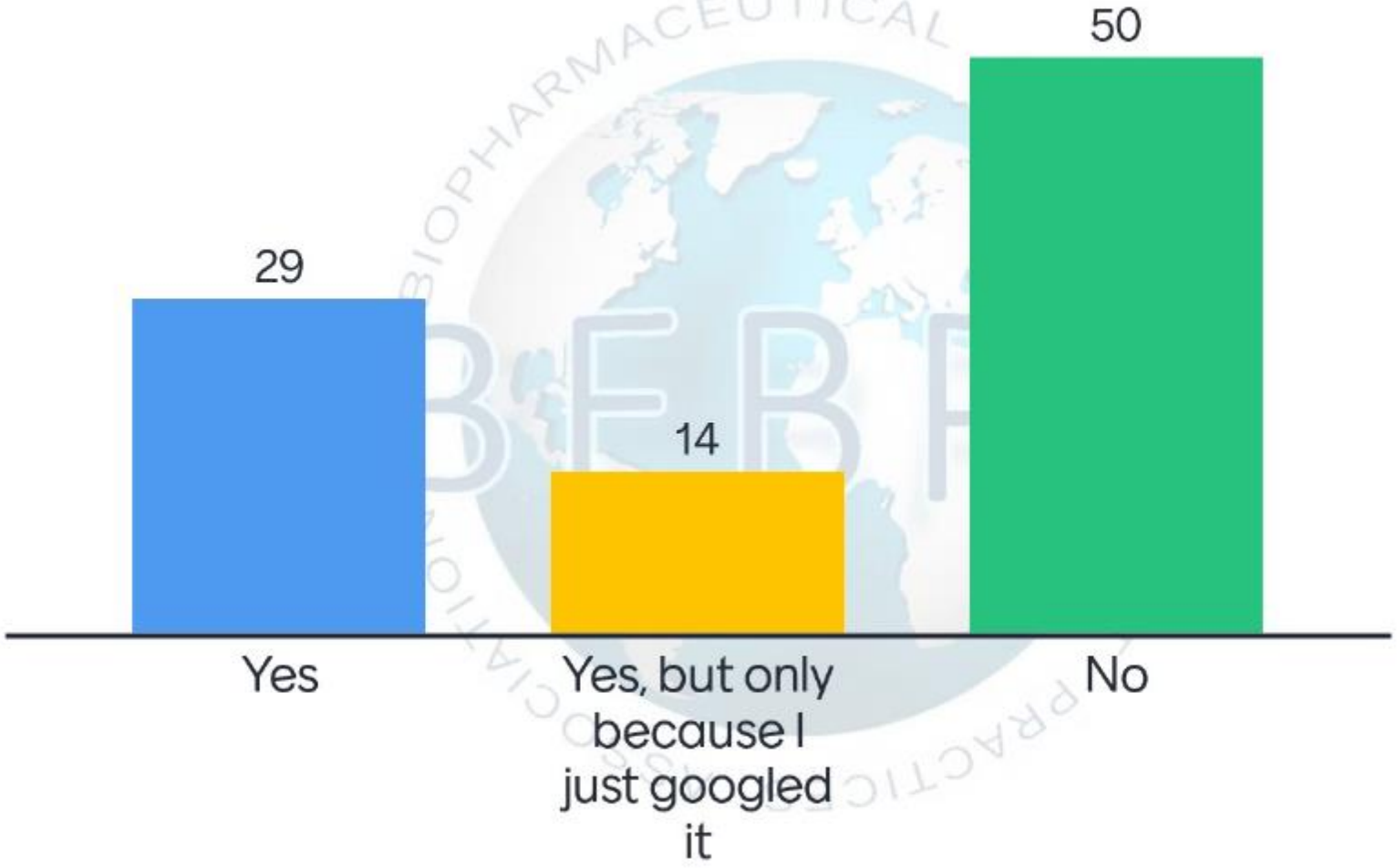
4.1 Do you trend your assay performance?



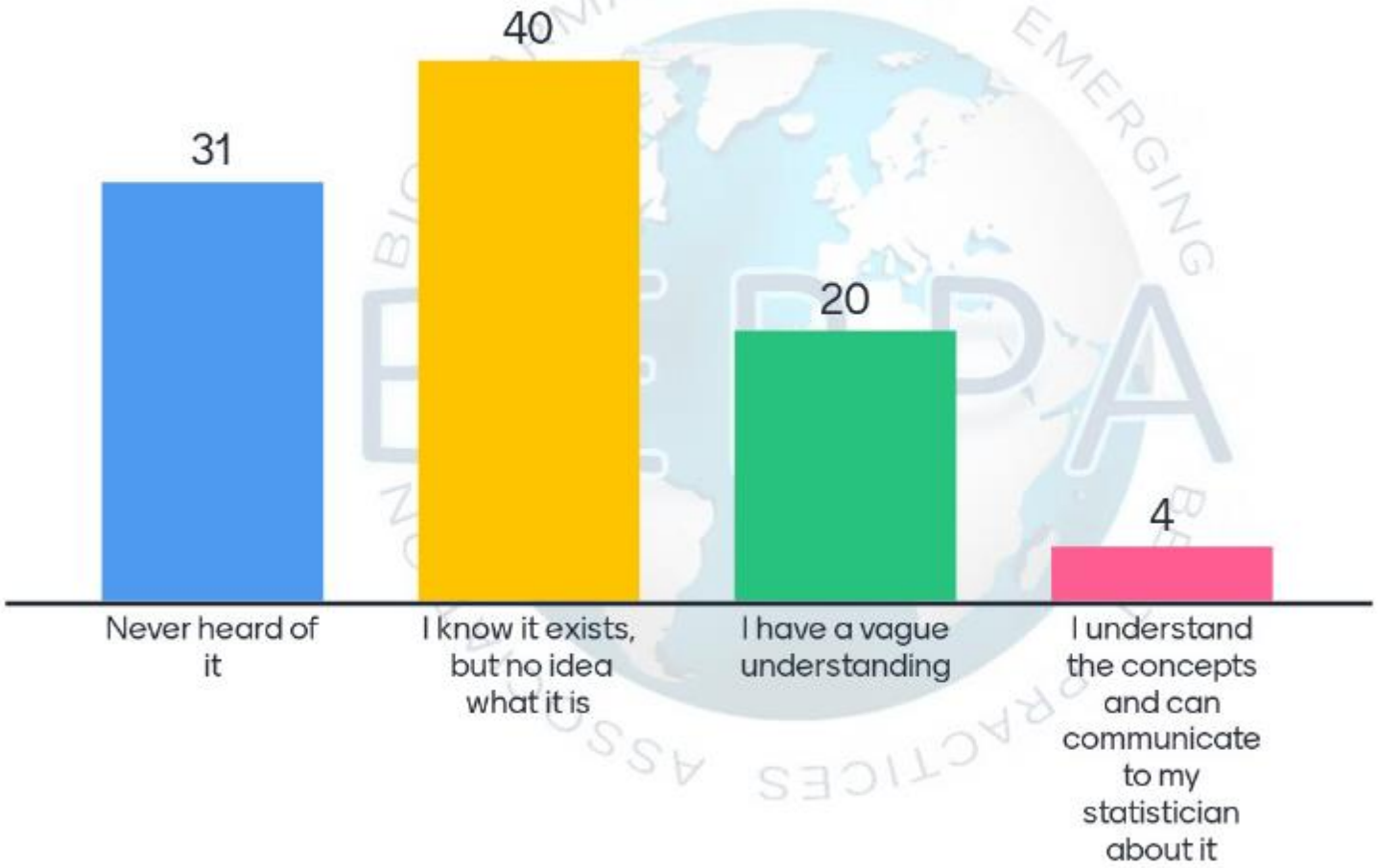
4.2 What parameters do you trend for the reference samples? (Check all that apply)



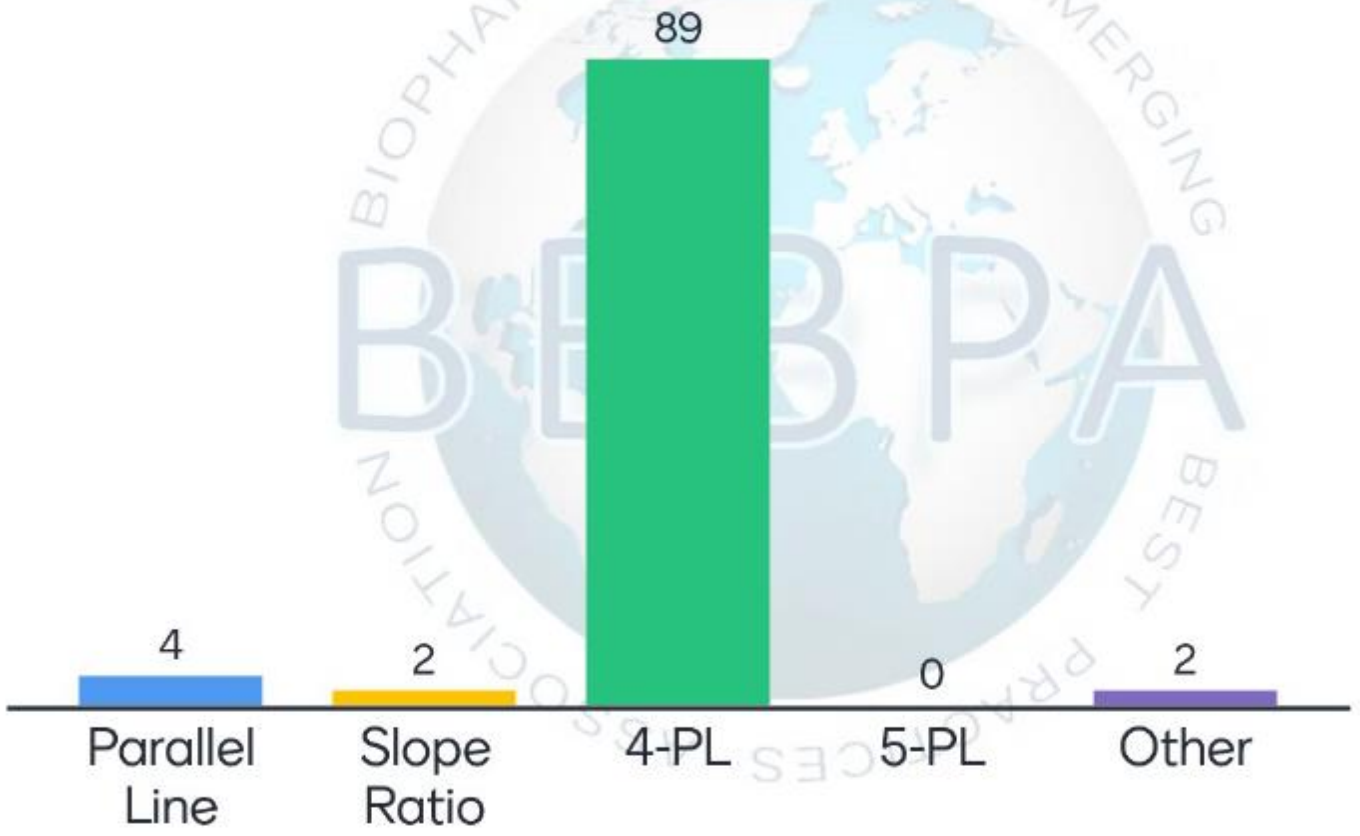
4.3 Do you know what TOST is?



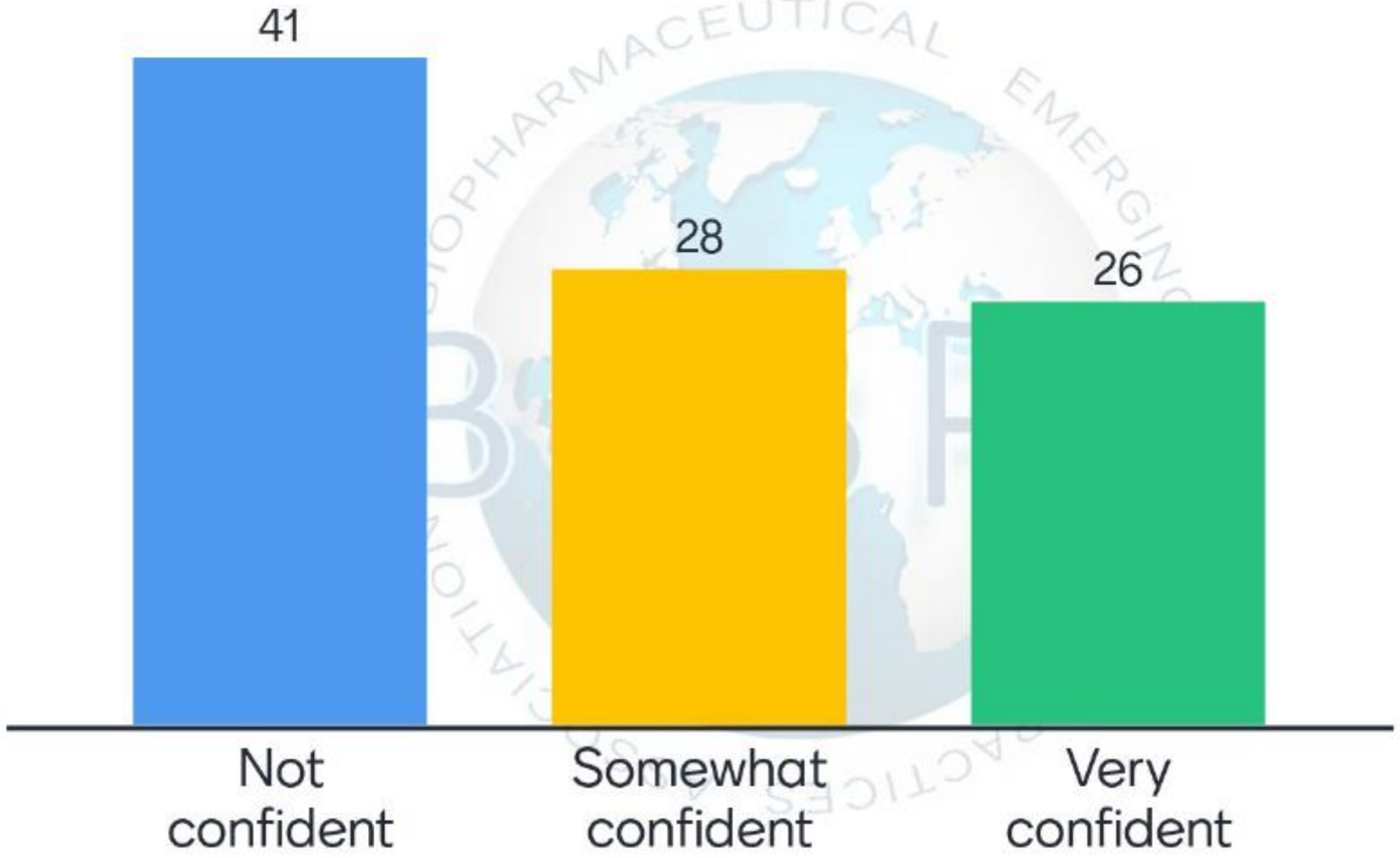
4.4 (For non-statisticians only) Do you know Bayesian statistics?



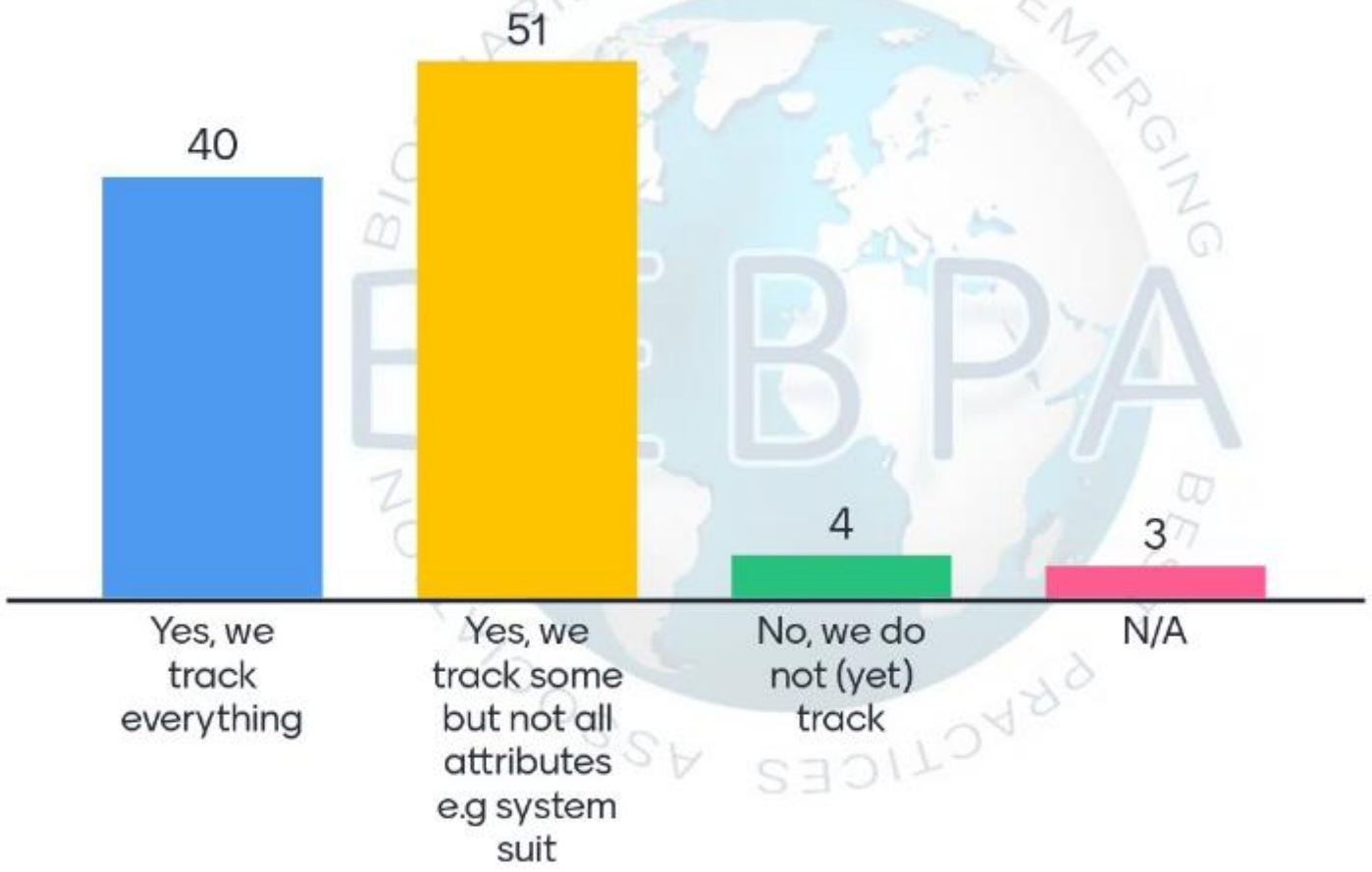
4.5 Which bioassay model do you use most often?



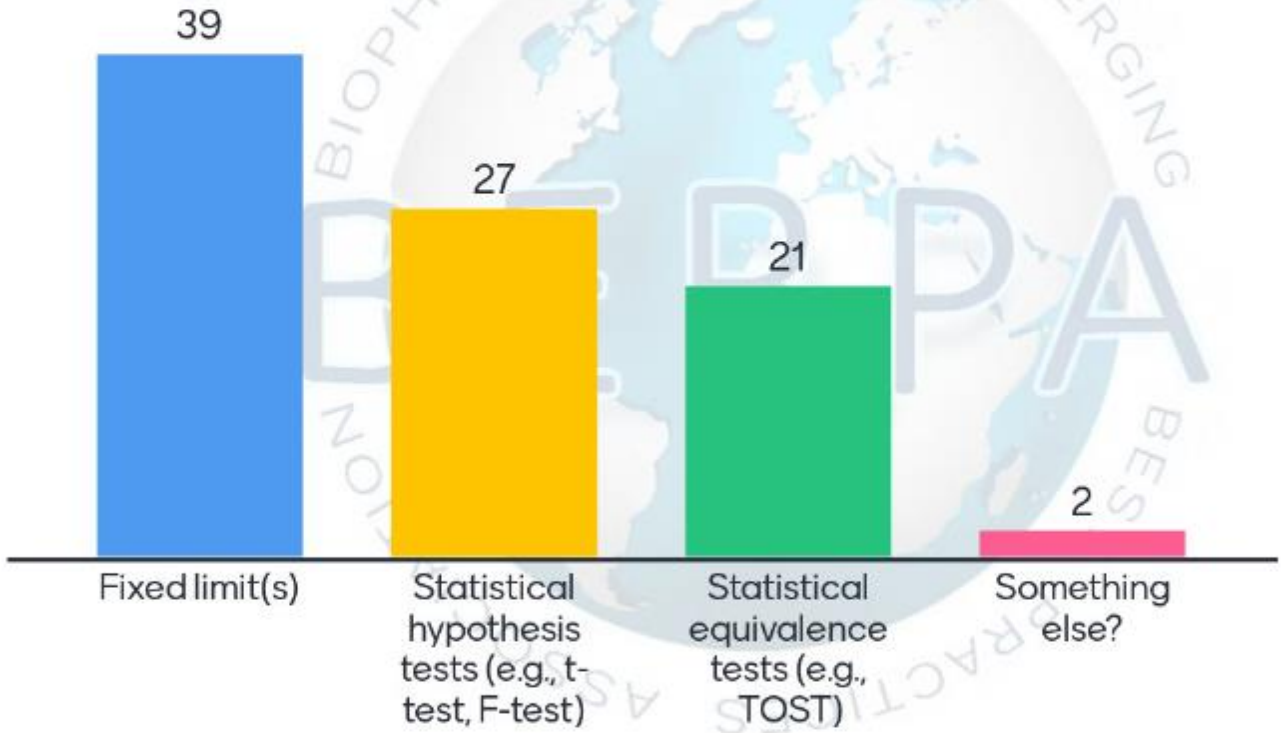
4.6 How confident are you with SPC charts?



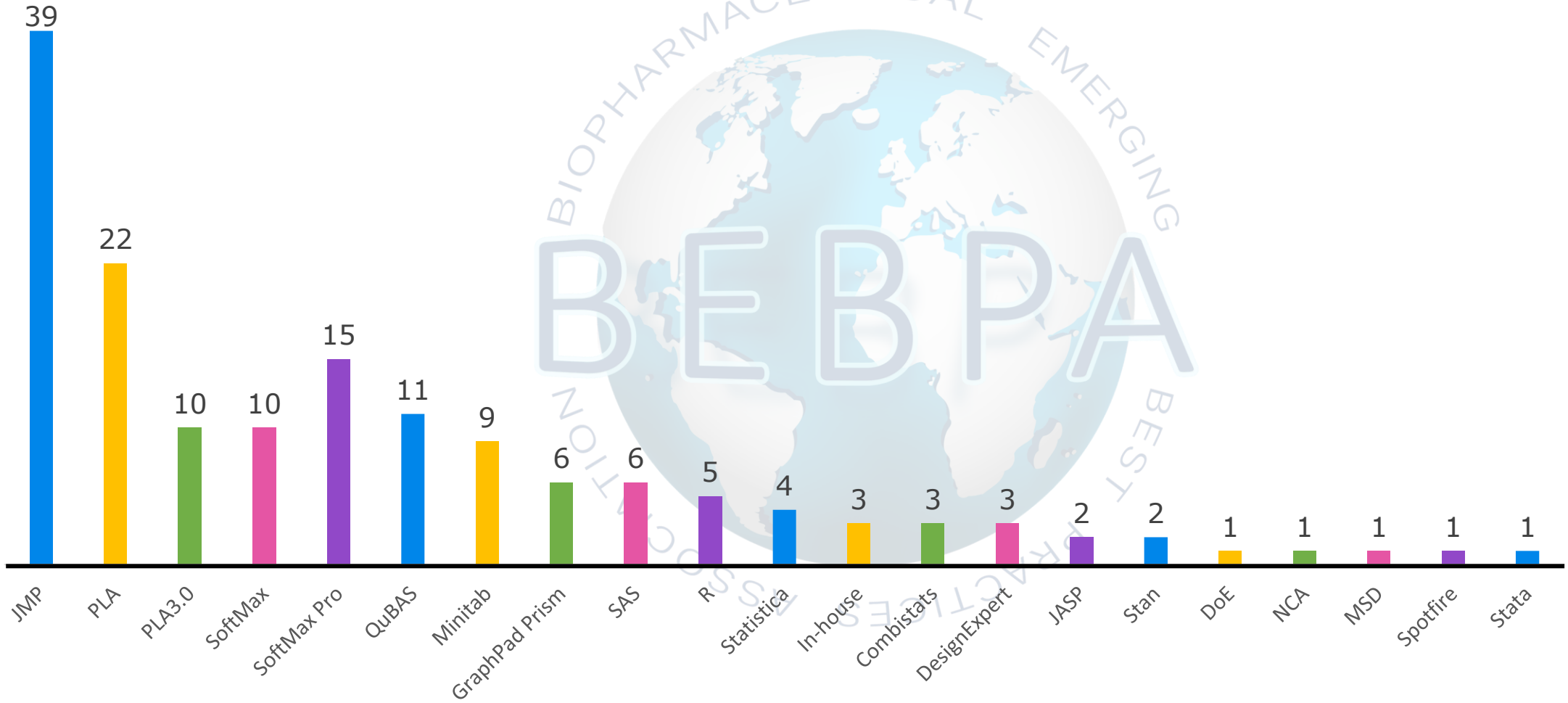
4.7 Do you trend/track/monitor all aspects/ attributes of your assays?



4.8 What method do you use most often to assure conformance to specifications (e.g., assay suitability, batch release, bridging)?



4.9 What statistical program do you use?



BEBPA 2022 EUR Bioassay Conference - Day 2

Thursday, 29 September 2022

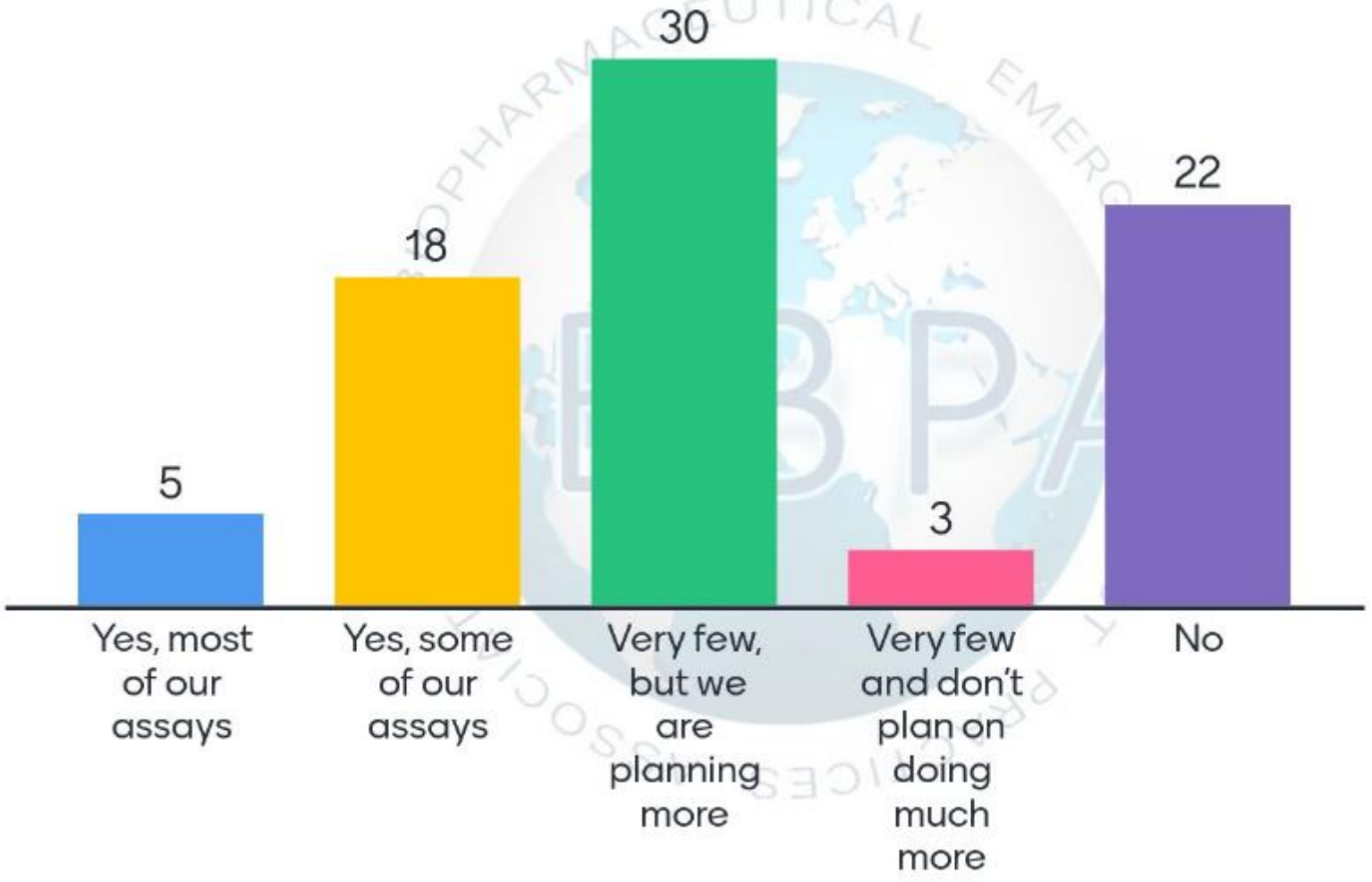
Audience Surveys

Session 5: Automating Potency Assays

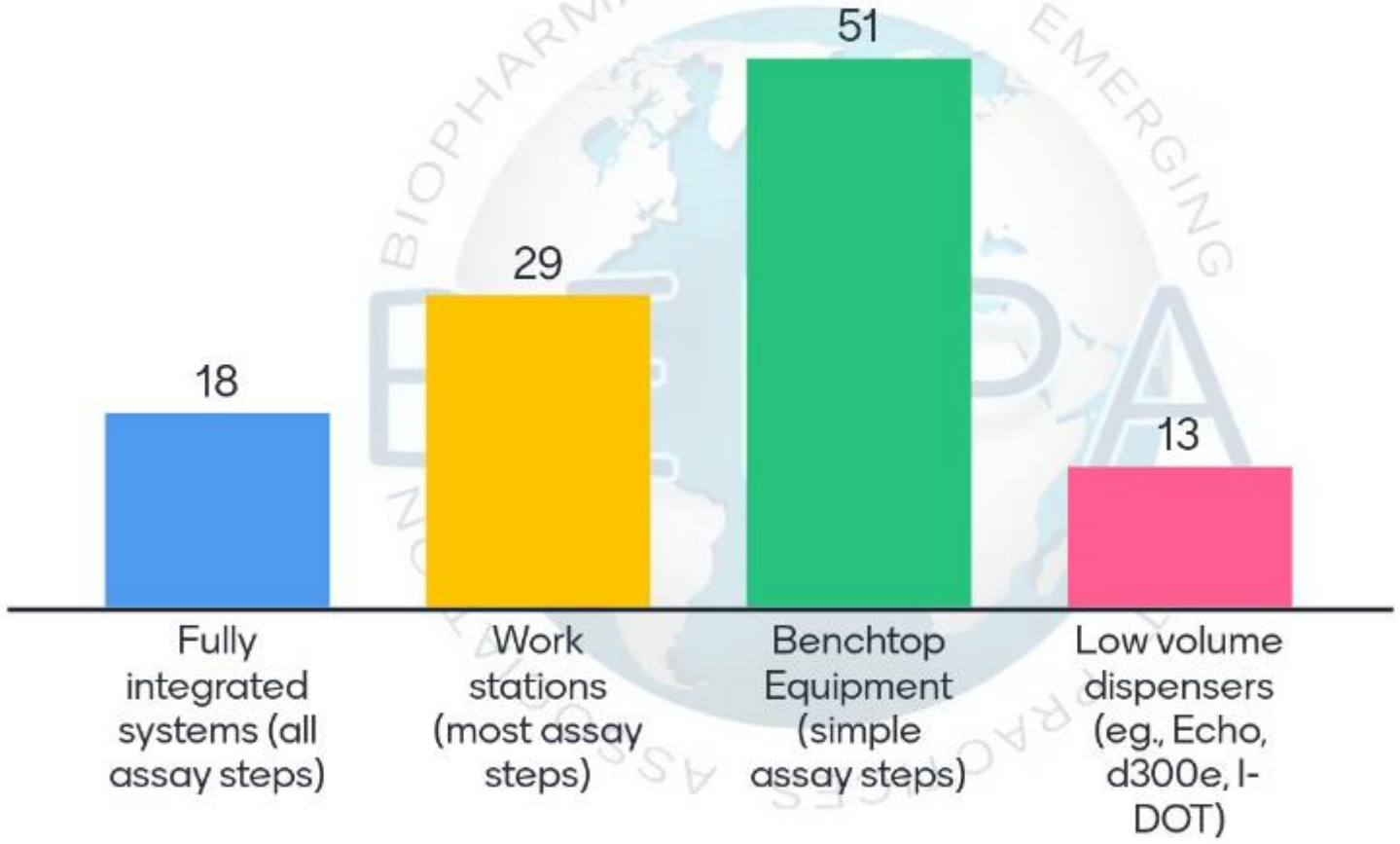
Session Chair: Siân Estdale, Head of Scientific Affairs, Labcorp

Audience Surveys

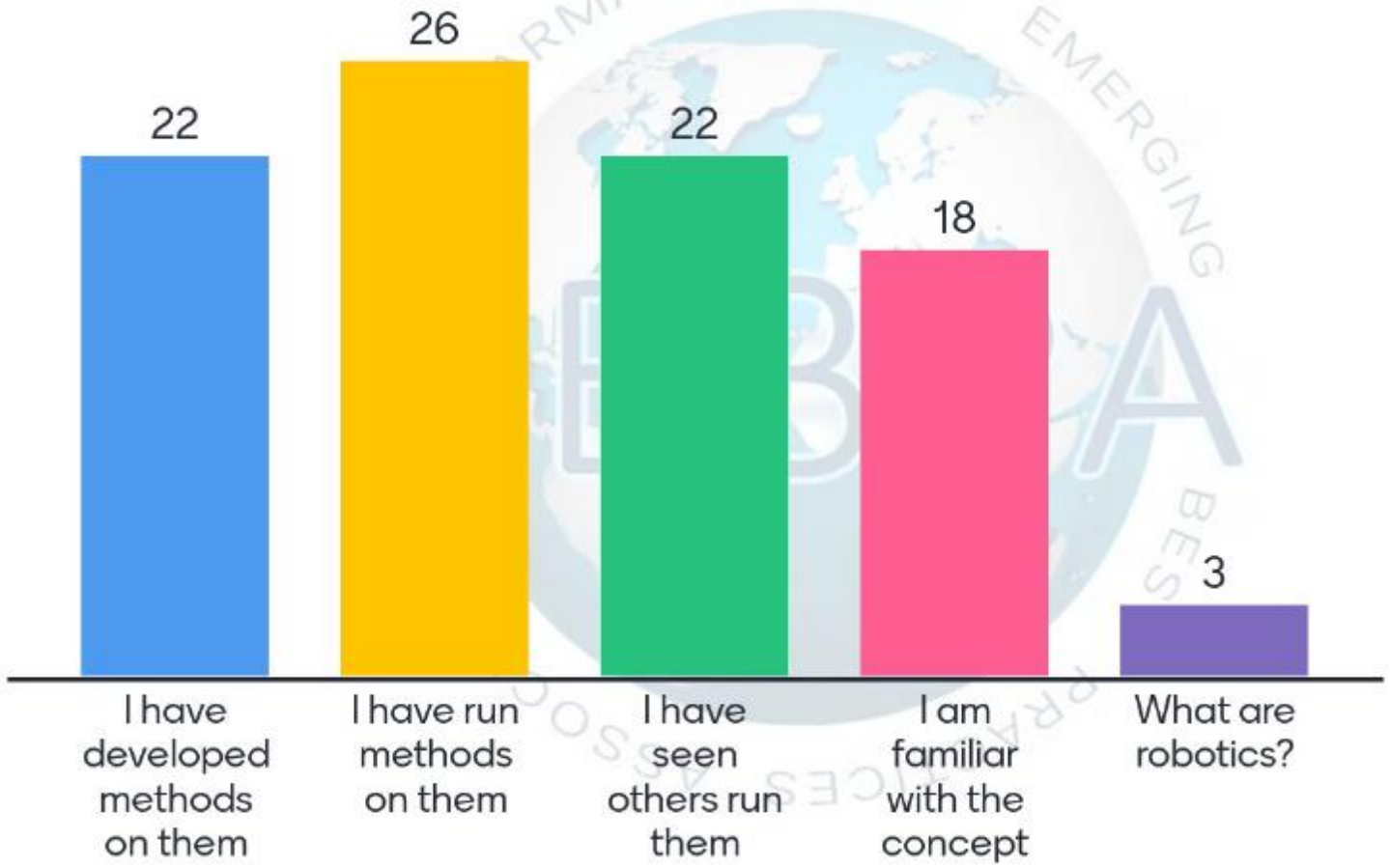
5.1 Have you automated your assays?



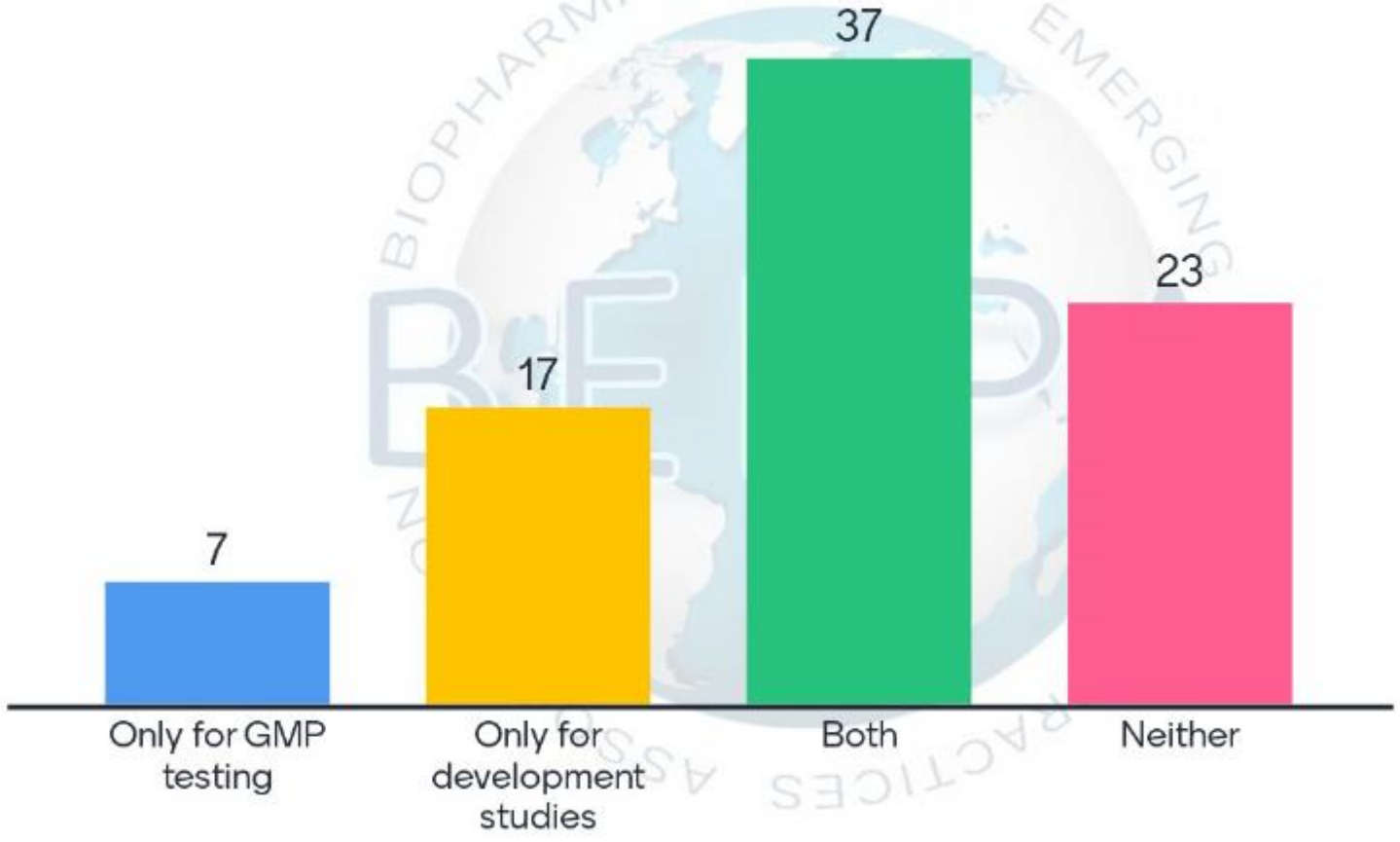
5.2 Do you use automated liquid handling and laboratory robotics? (Check all that apply)



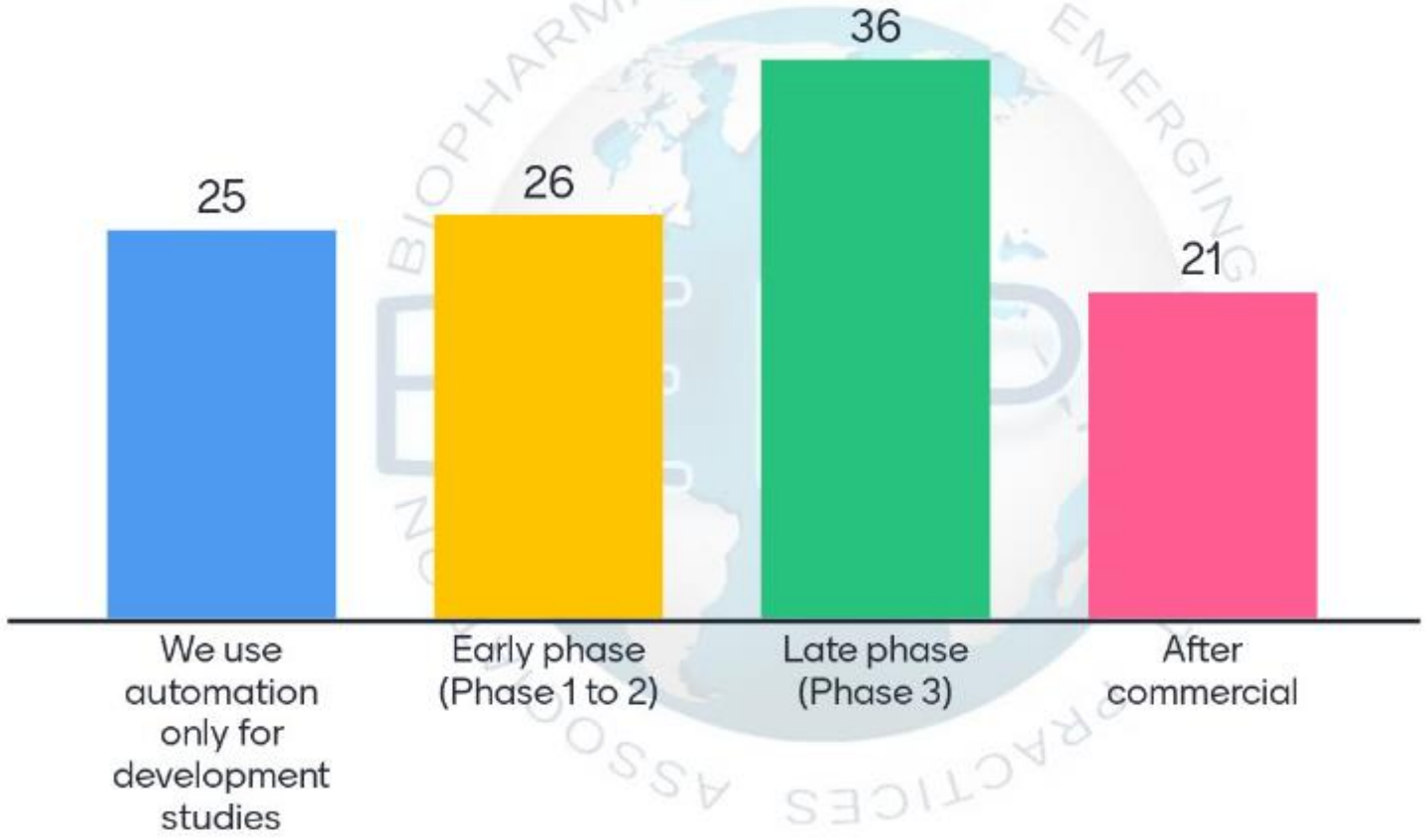
5.3 Do you have personal experience with liquid handlers and laboratory robotics?



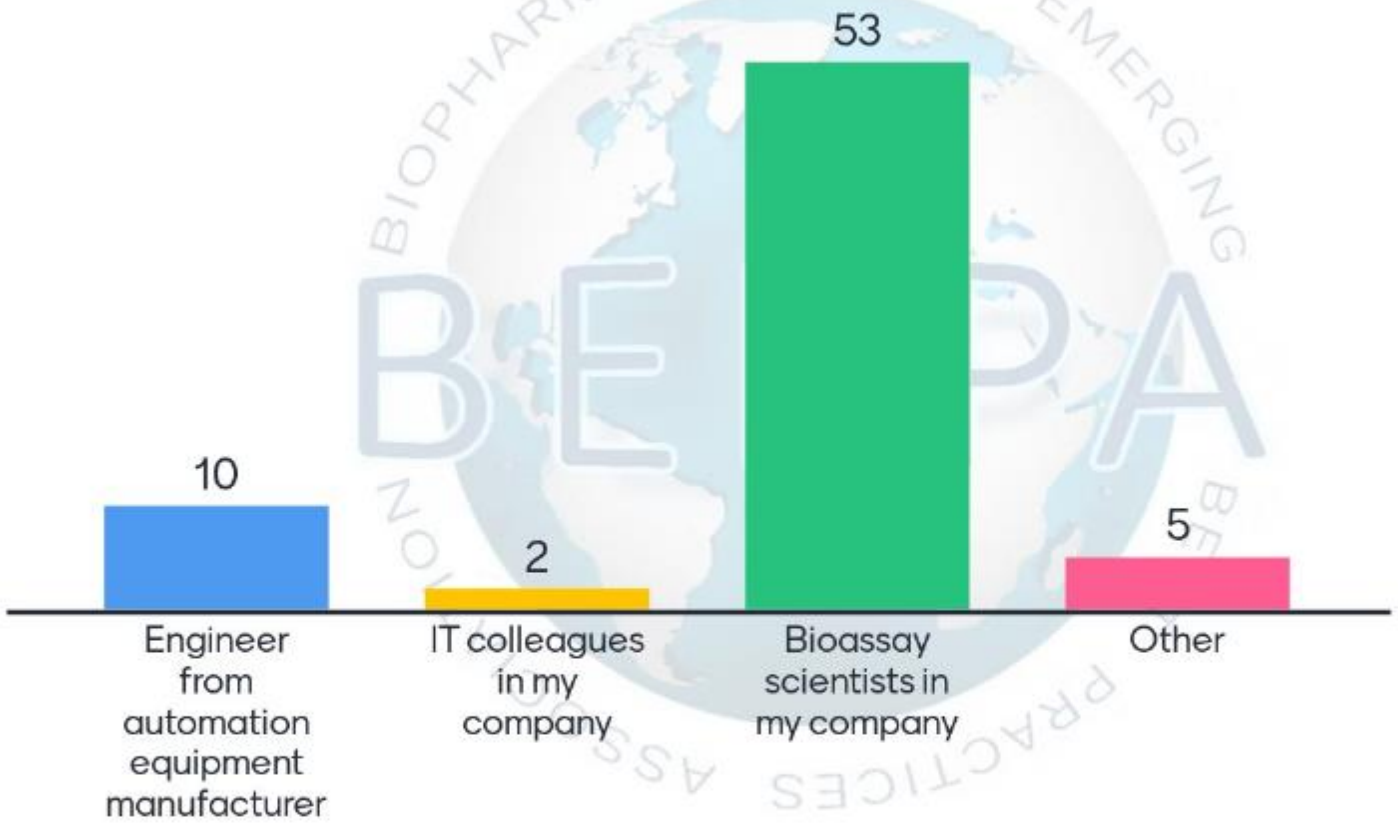
5.4 Do you use bioassay automation systems in GMP testing or in development studies?



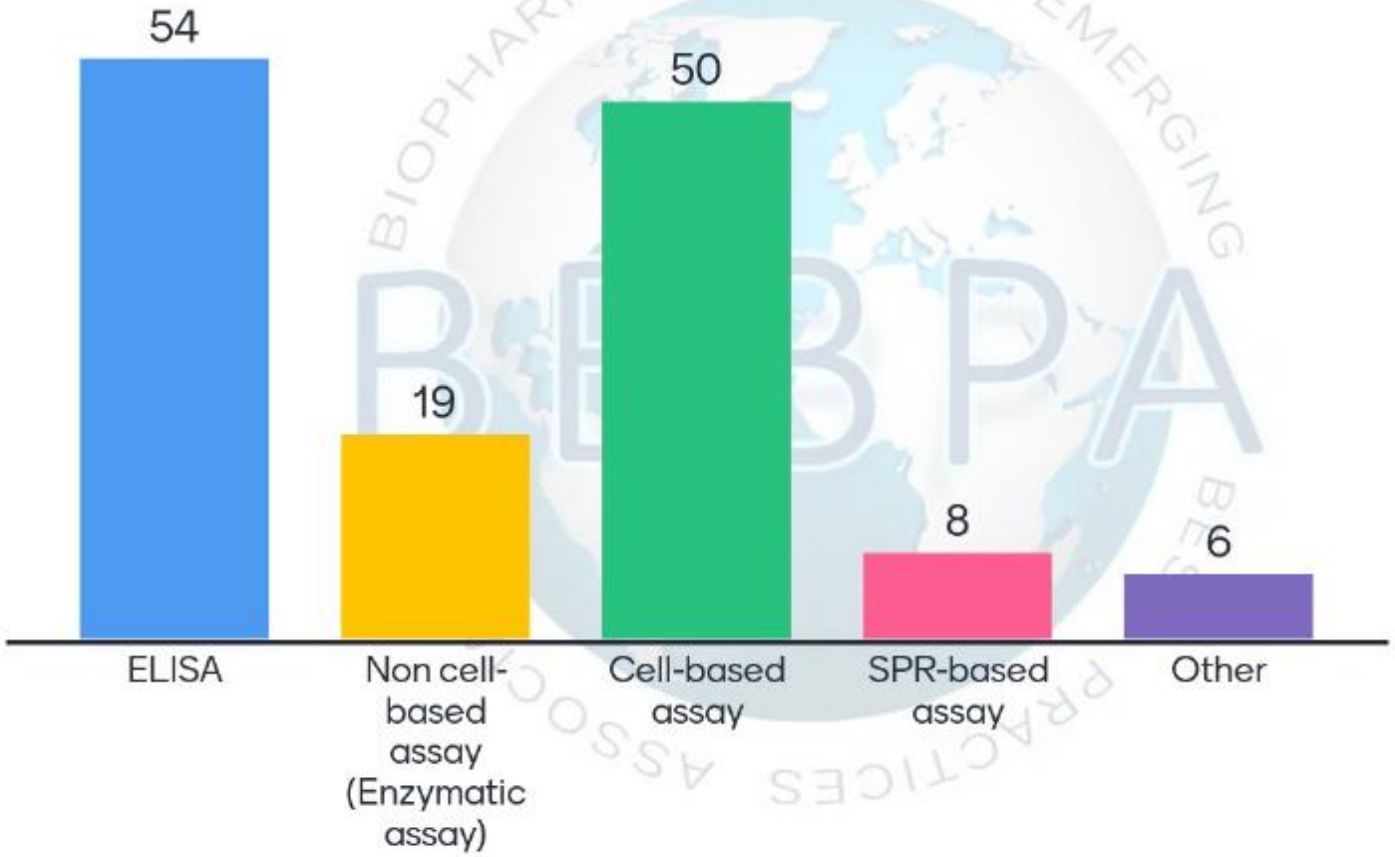
5.5 In which phase do you implement automation under GMP conditions? (Check all that apply)



5.6 Who establishes the programs for your bioassay automation?



5.7 Which type of bioassay do you apply automation to? (Check all that apply)

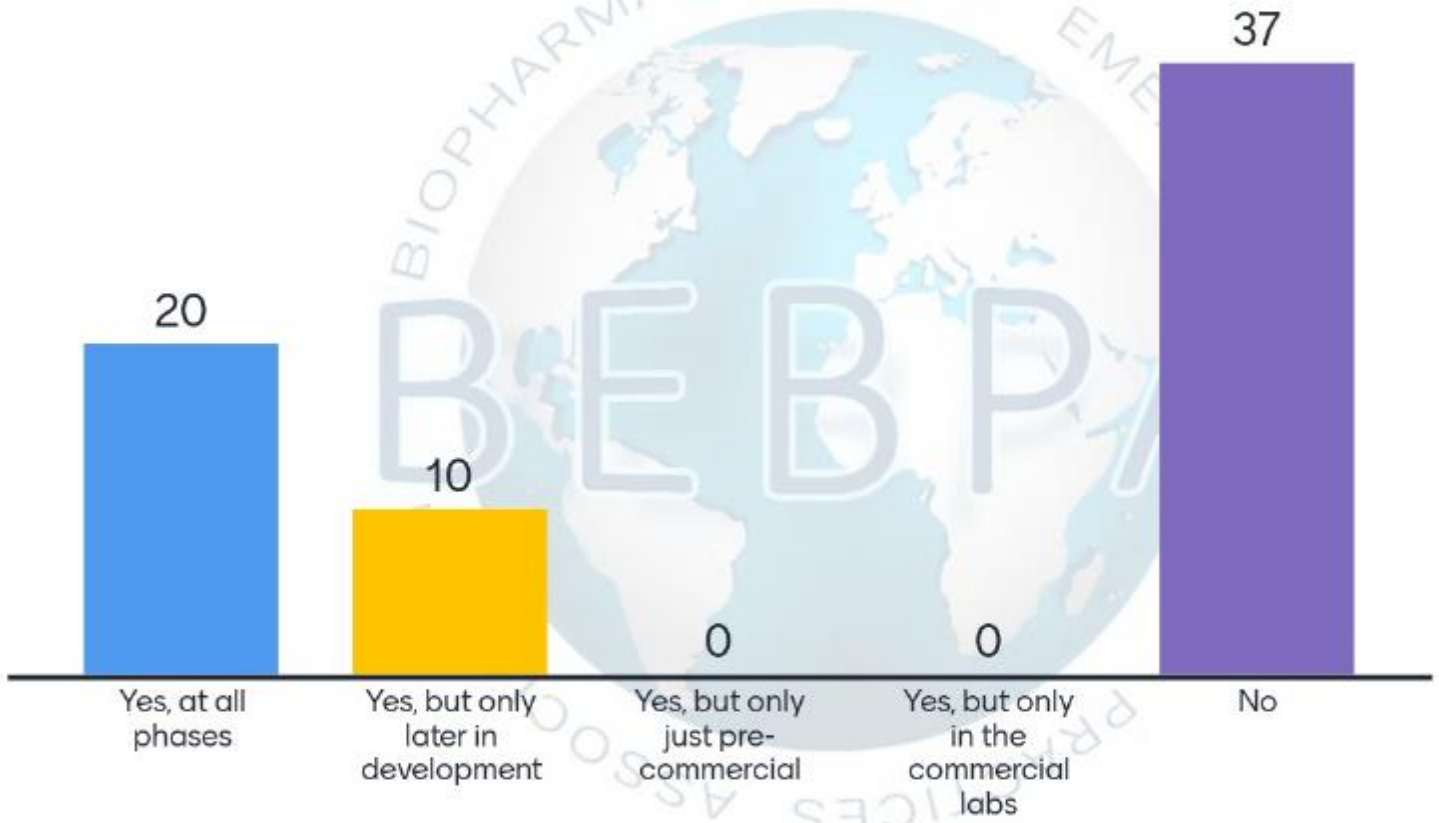


Session 6: Potency Assay Development

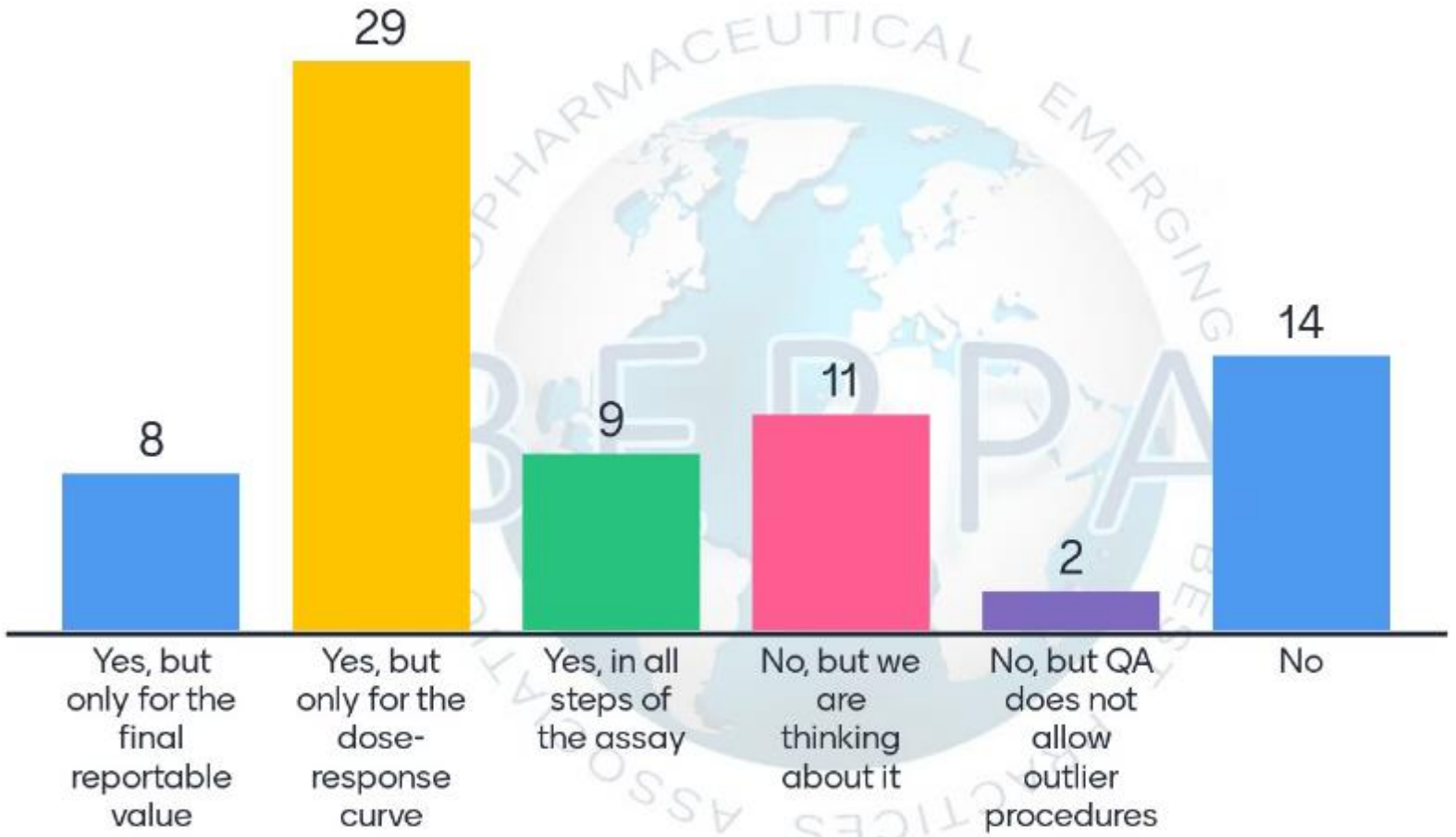
Session Chair: Ulrike Herbrand, Scientific Director Global, Charles River

Audience Surveys

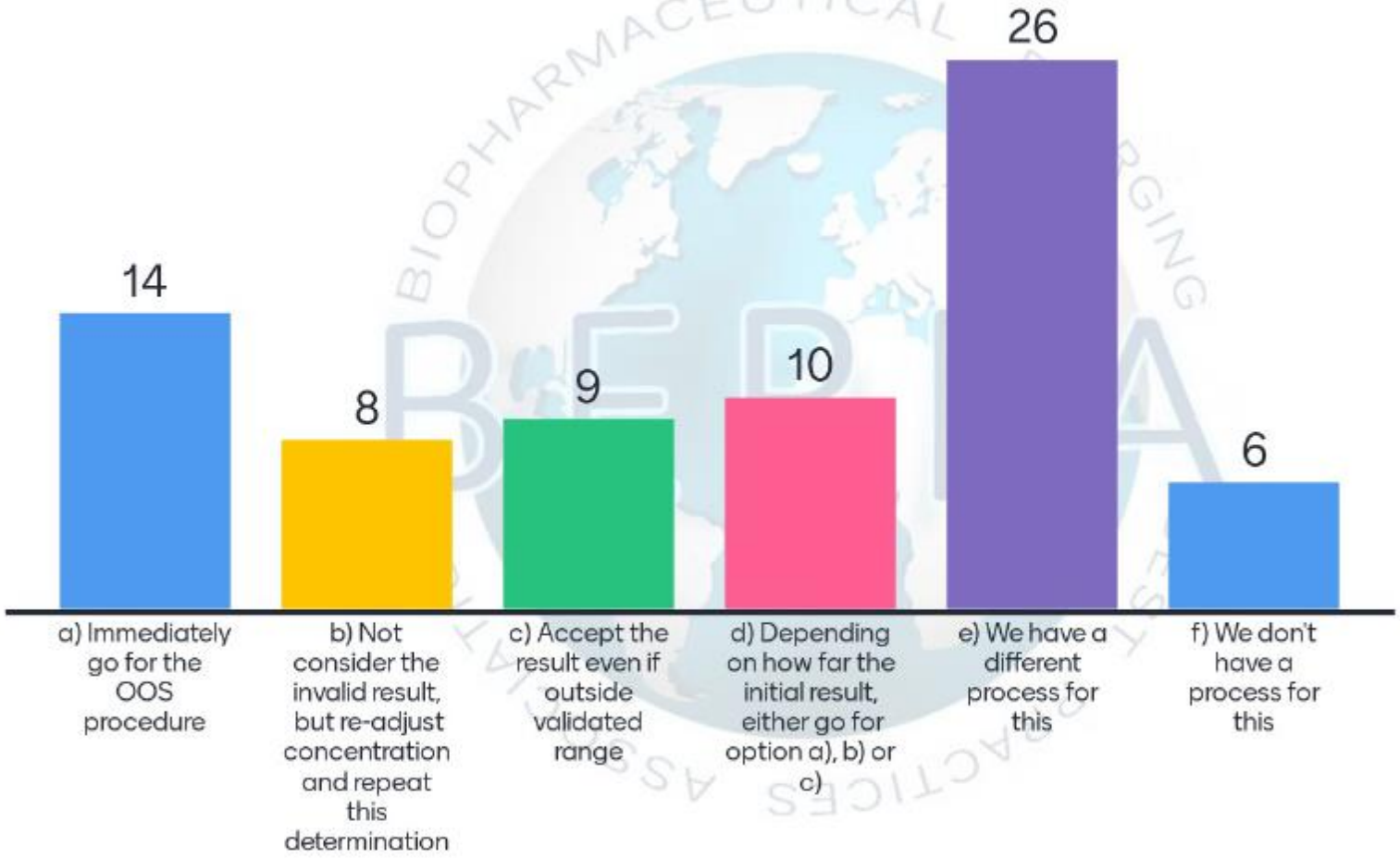
6.1 Do you work with a statistician when developing the assay?



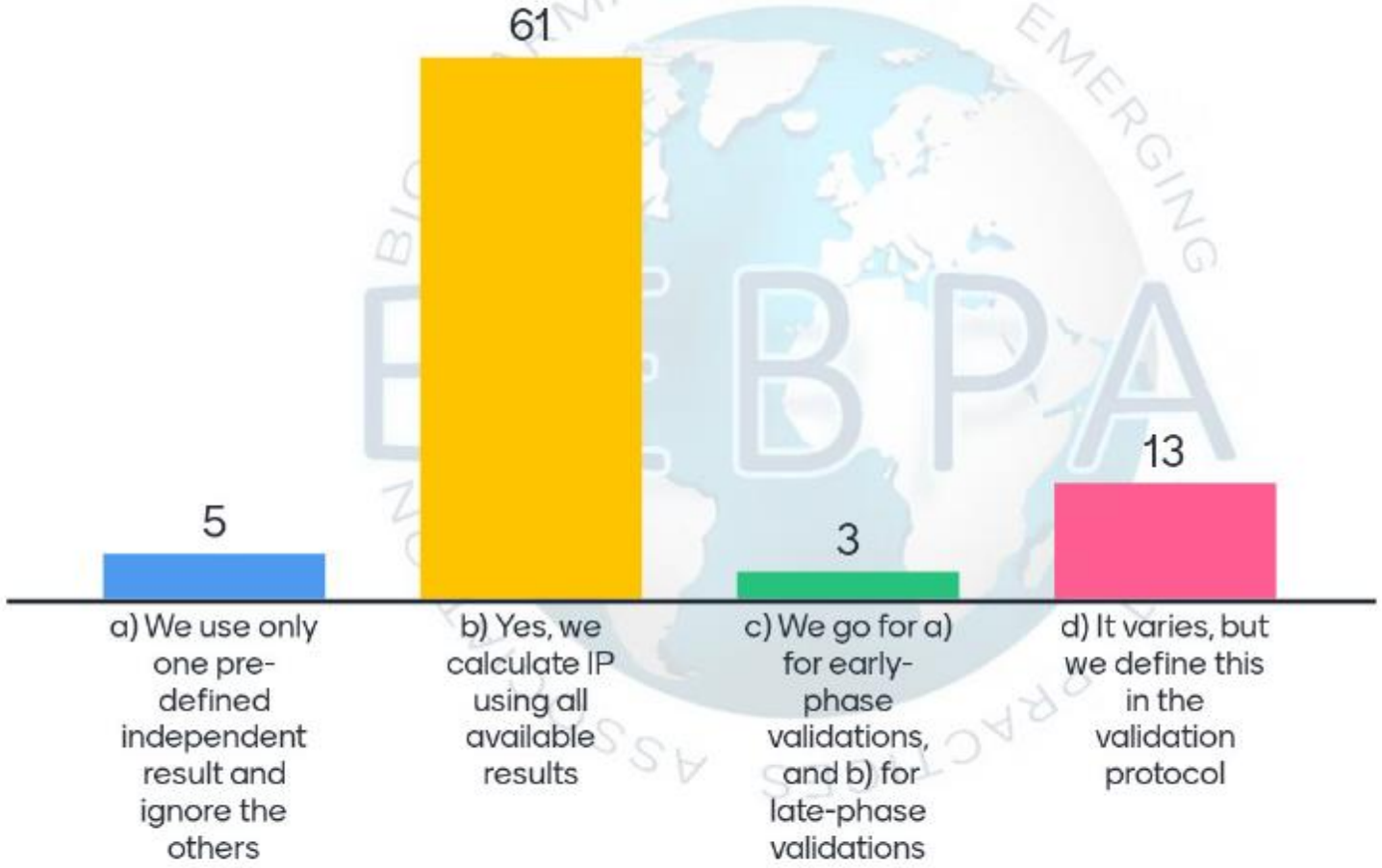
6.2 Do you use an outlier analysis in your bioassay?



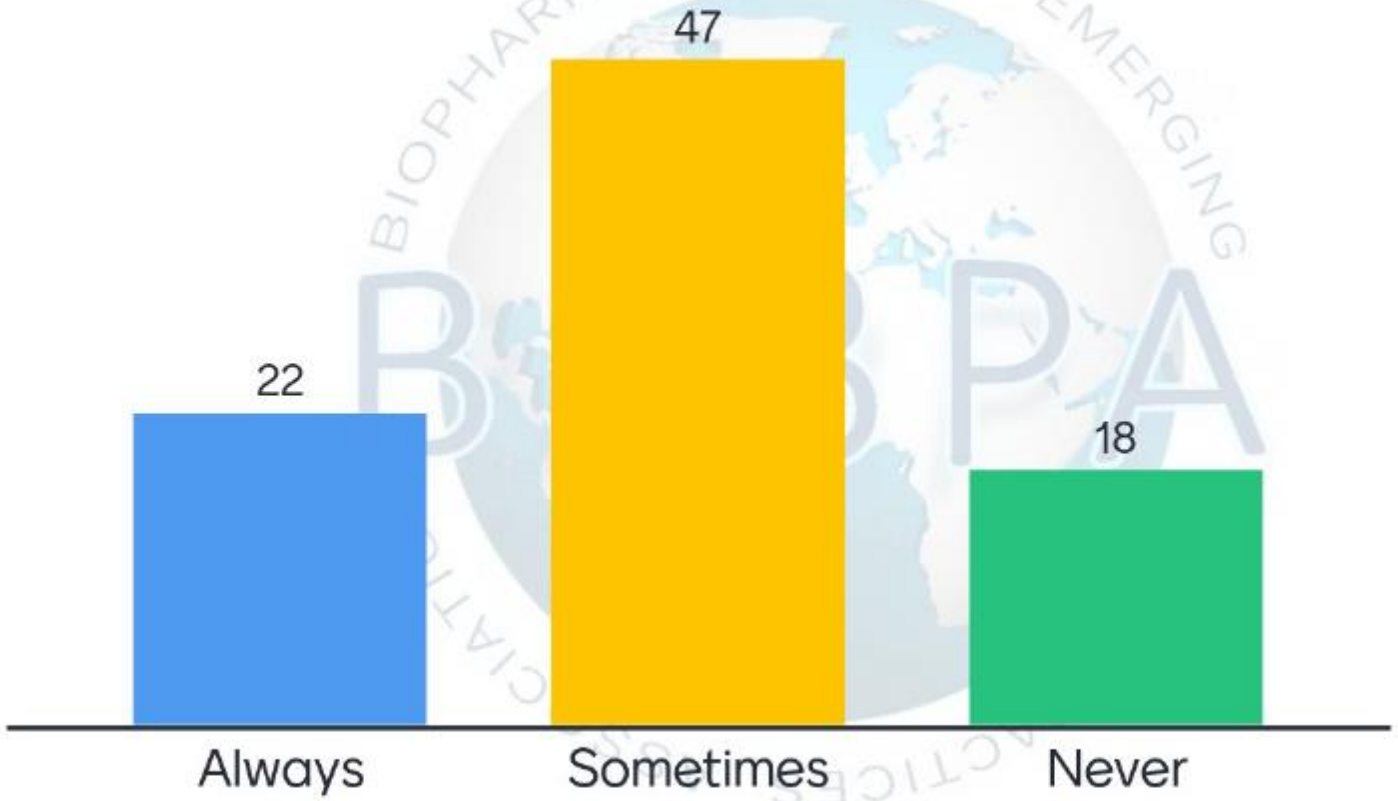
6.3 For a GMP result with multiple determinations/reportable result, one determination is outside the validated range of the method. What do you do?



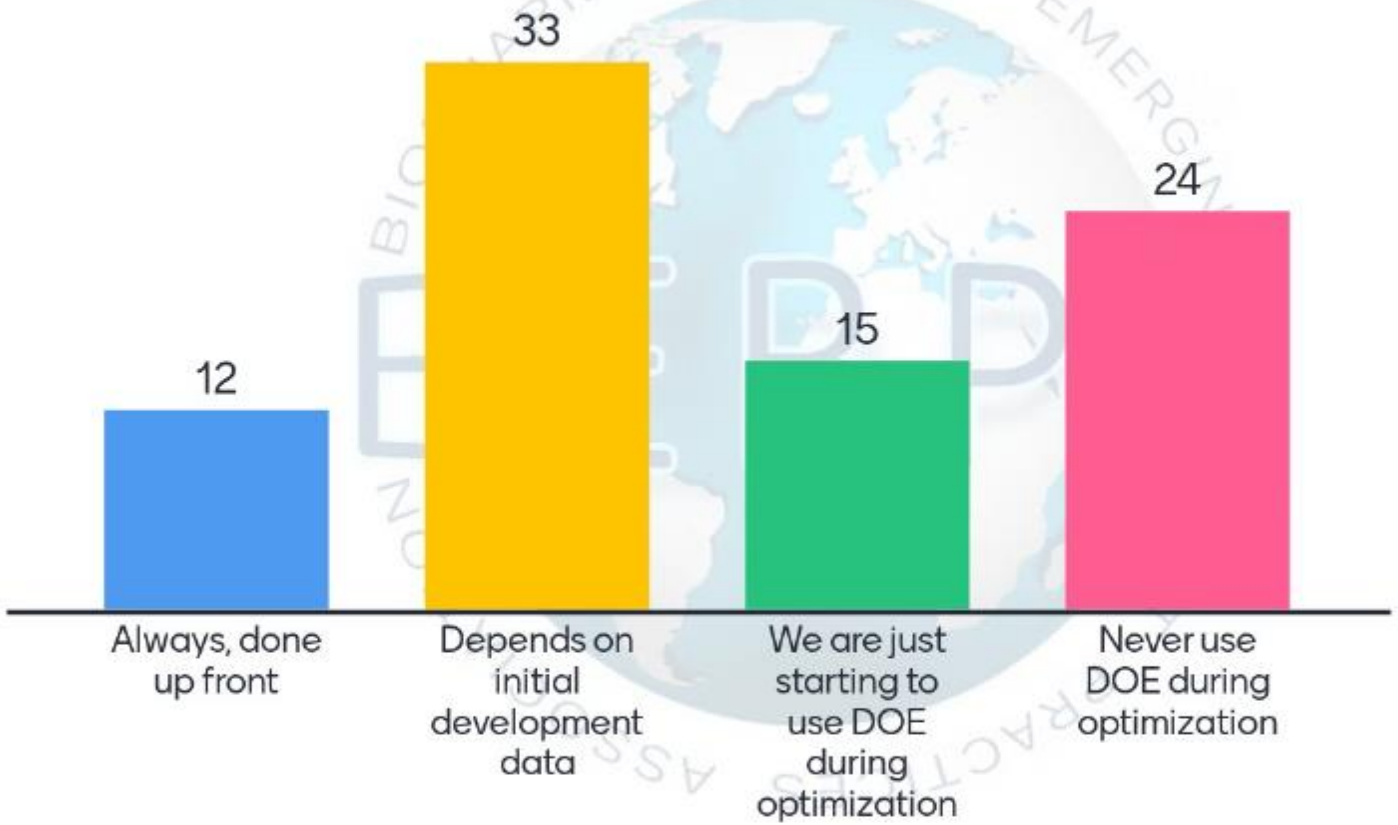
6.4 For method validations, do you use all repeatability results for calculation of intermediate precision (IP)?



6.5 Do you use DOE for the development of your potency assay?



6.6 Do you use DOE for the optimization of your potency assay?

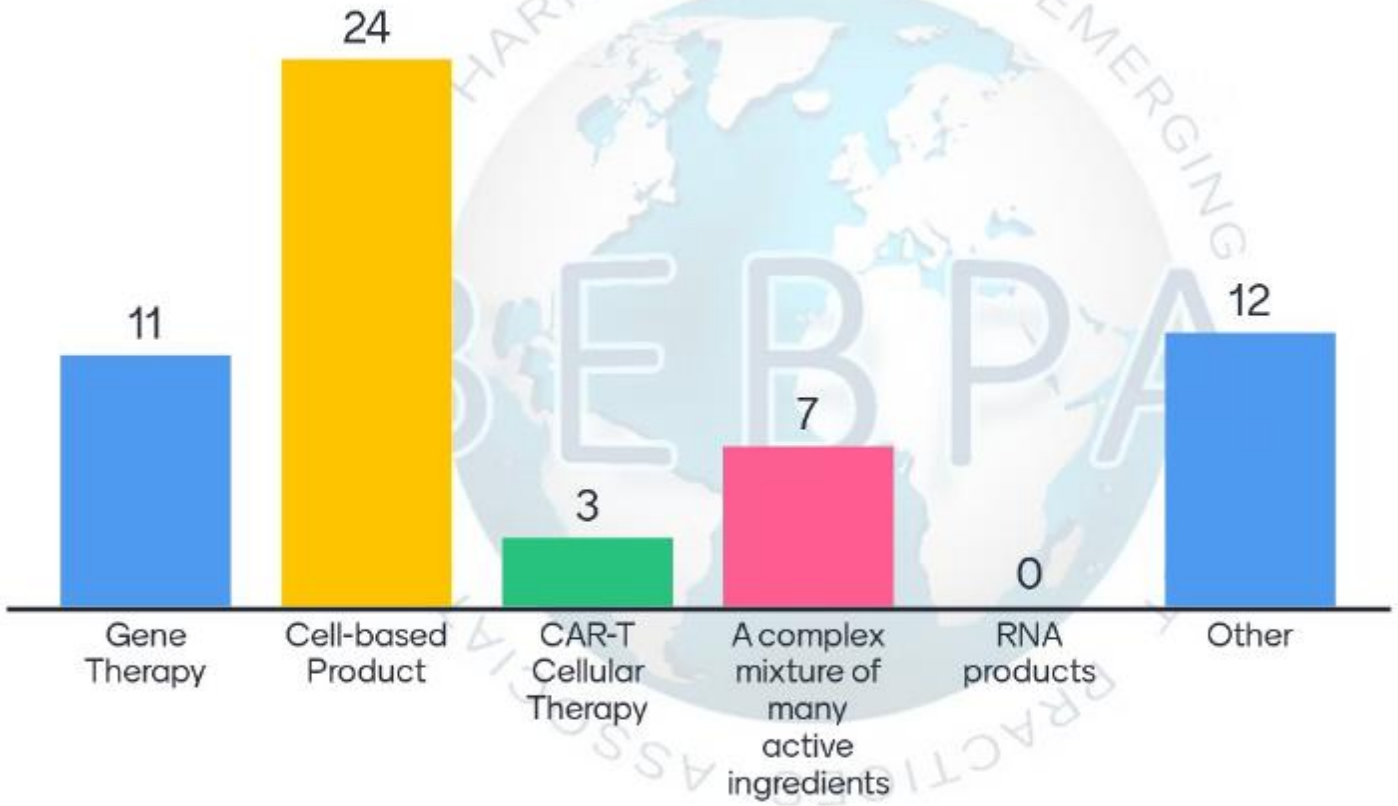


Session 7: Cell and Gene Therapy

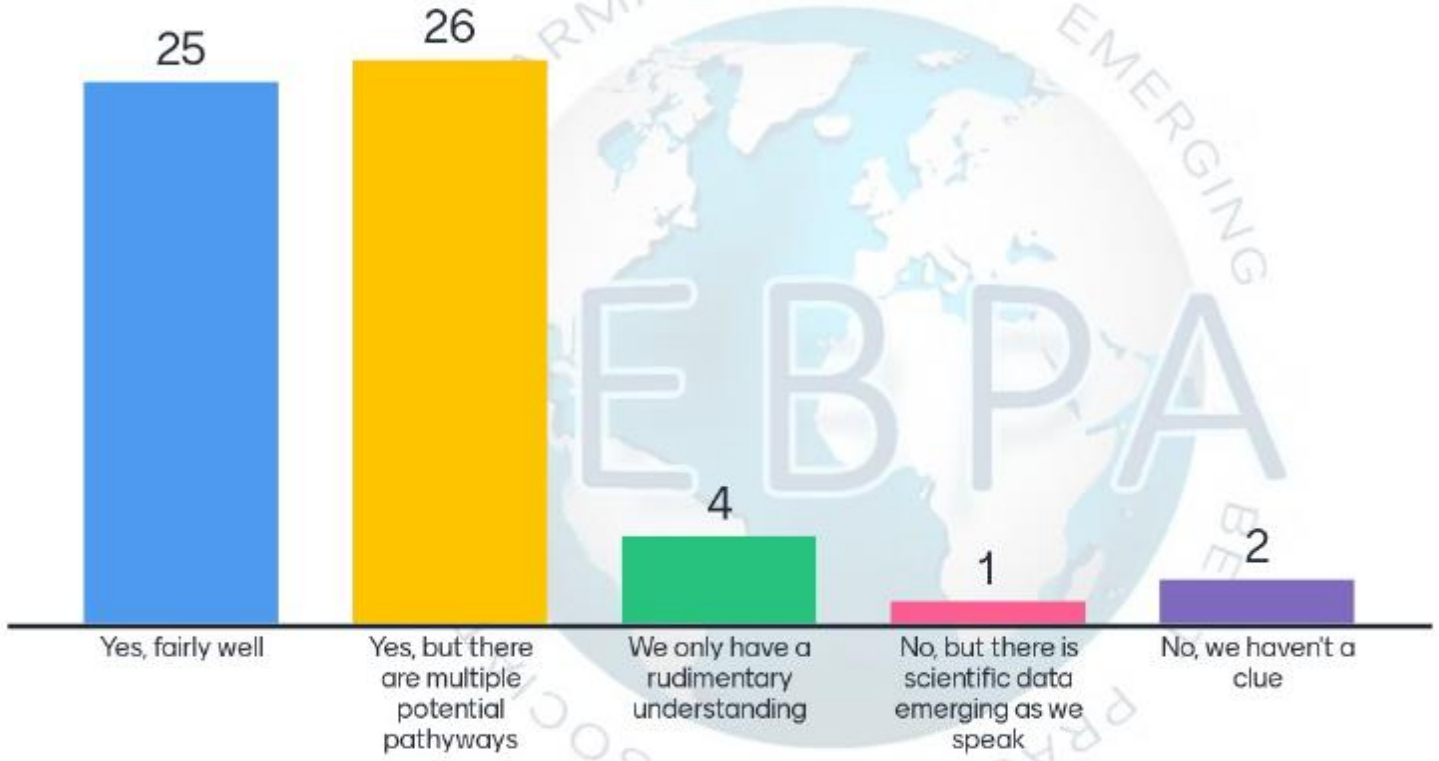
Session Chair: Roger Grau, NBE/Biosimilar CMC Expert, Solvias

Audience Surveys

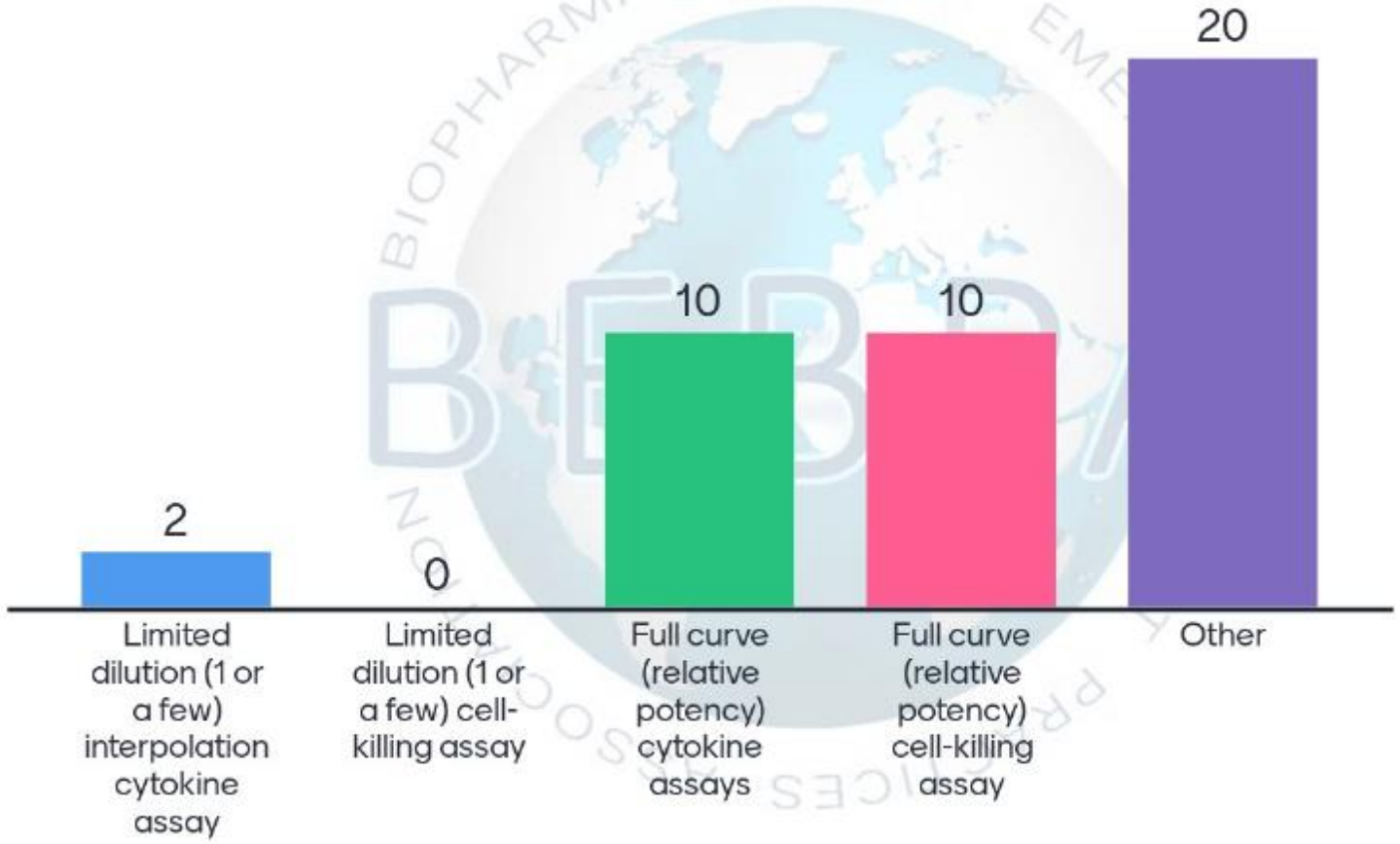
7.1 If you are developing a "complex" product, what type is it?



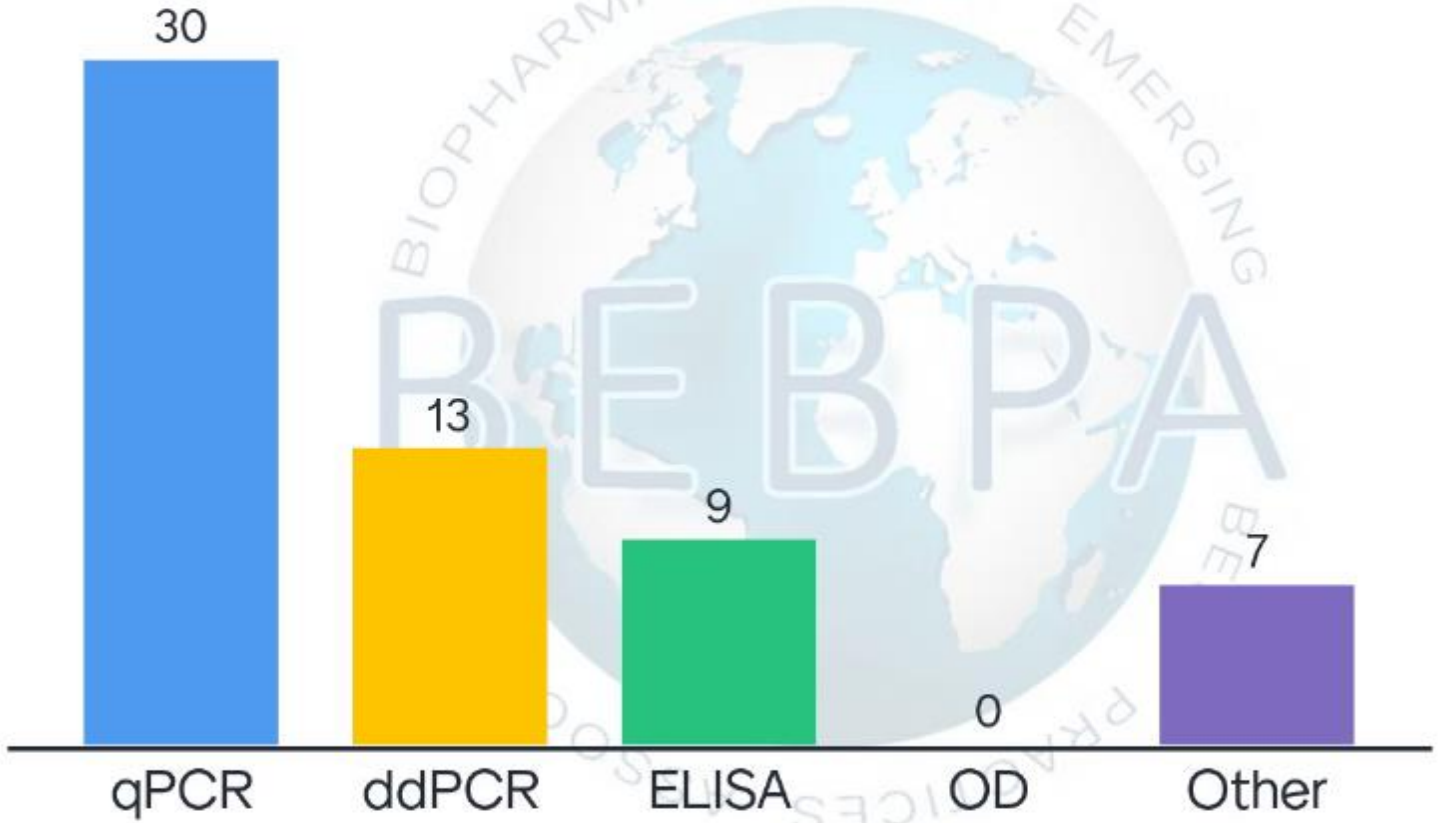
7.2 If you are developing a complex product -- do you understand the Mechanism of Action?



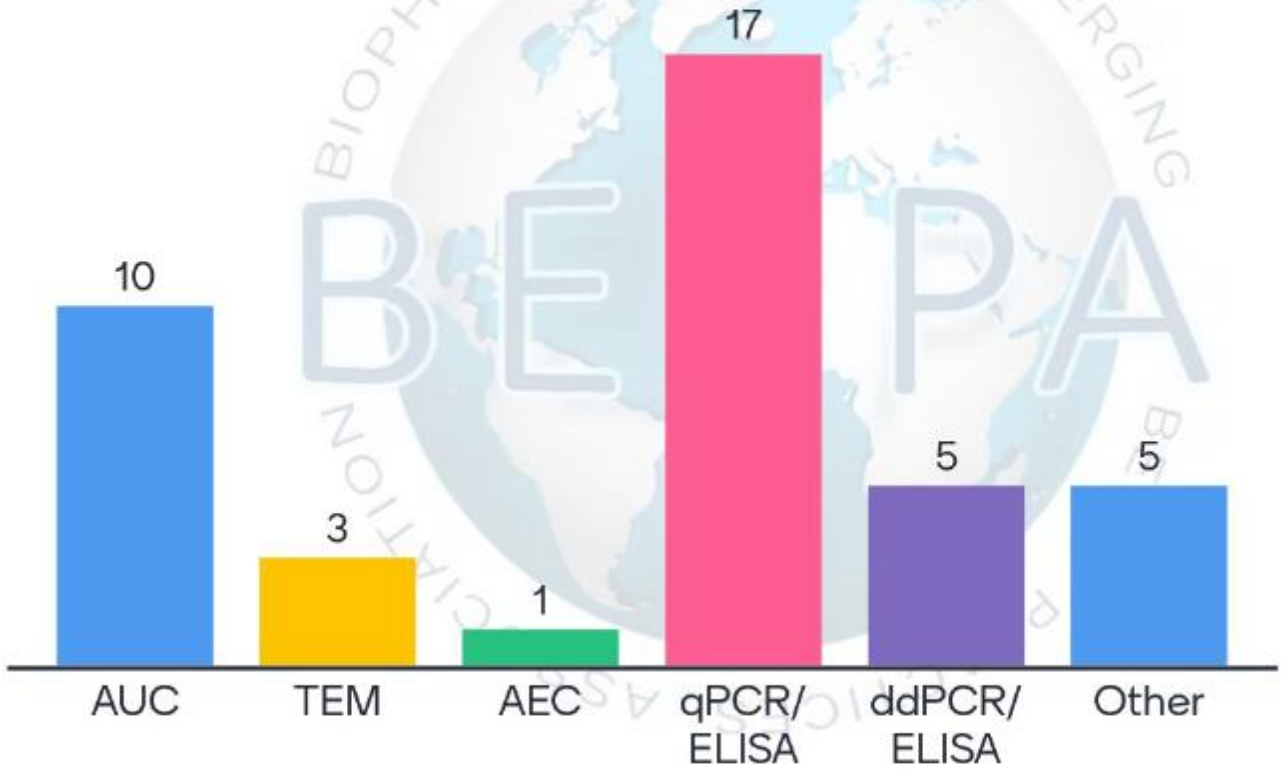
7.3 How do you assess potency for your CTx (e.g., CAR-T) Therapeutic? (Check all that appy)



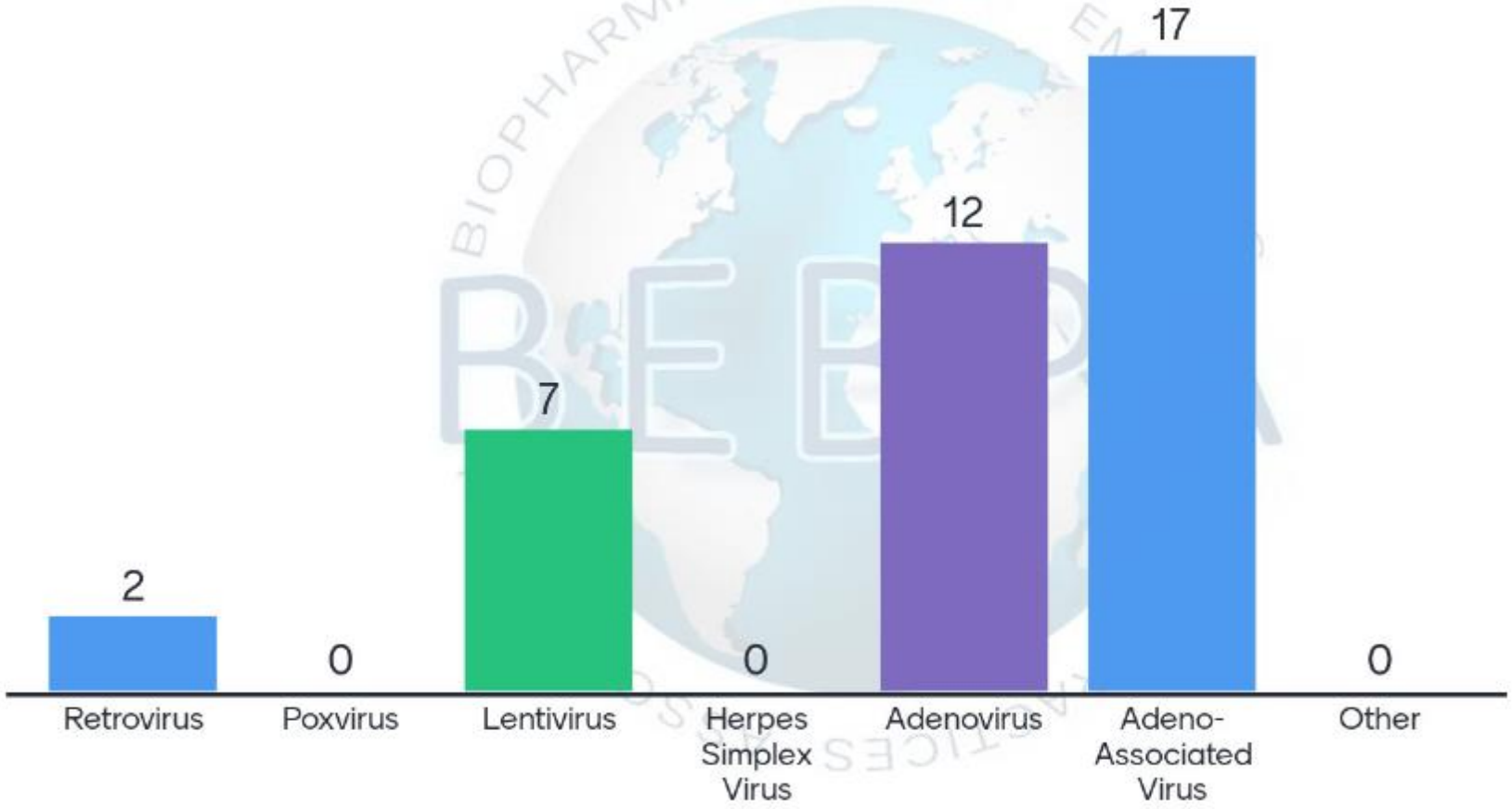
7.4 What methods do you use to assess viral genomic or capsid titer? (Check all that apply)



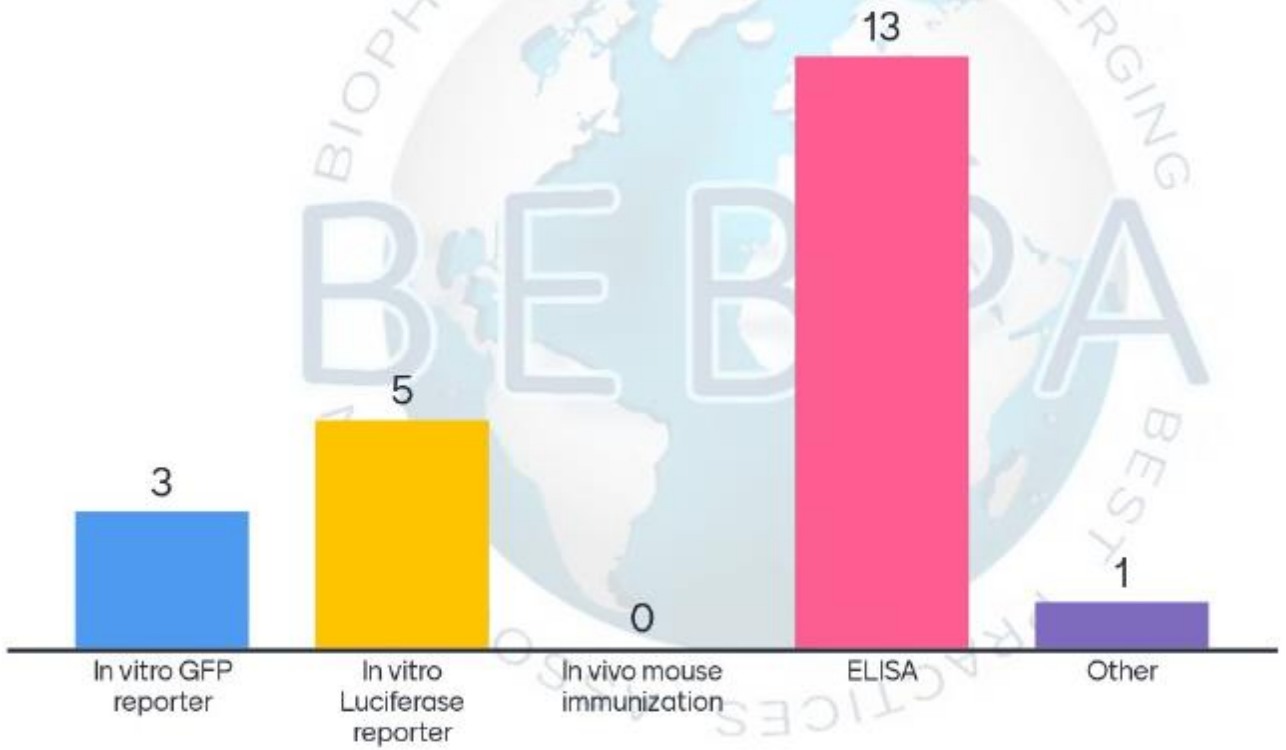
7.5 What methods do you use to assess the fraction of viral capsids with a complete genome (content ratio)? (Check all that apply)



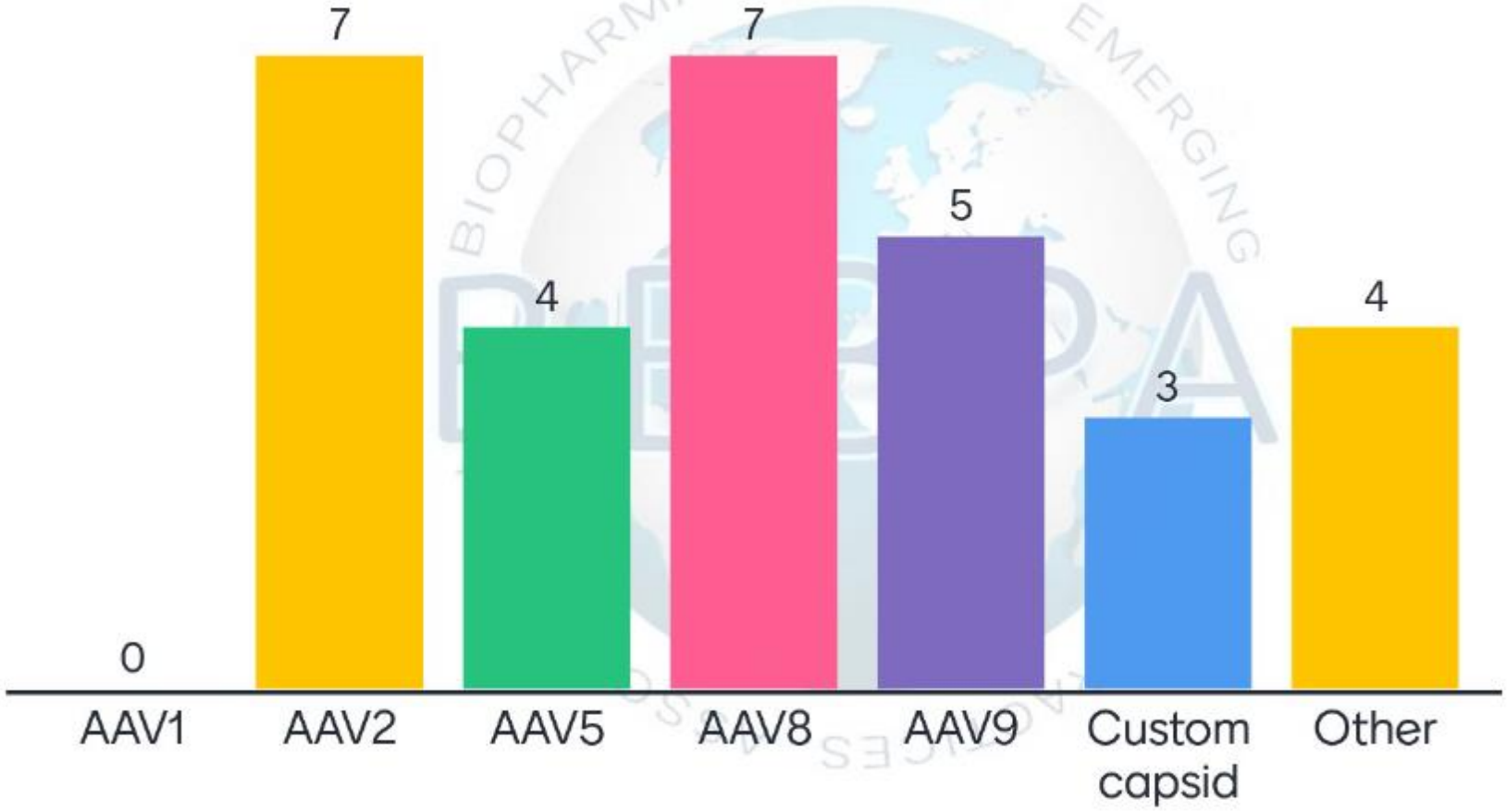
7.6 What viral vectors do you use for your gene therapy delivery? (Check all that apply)



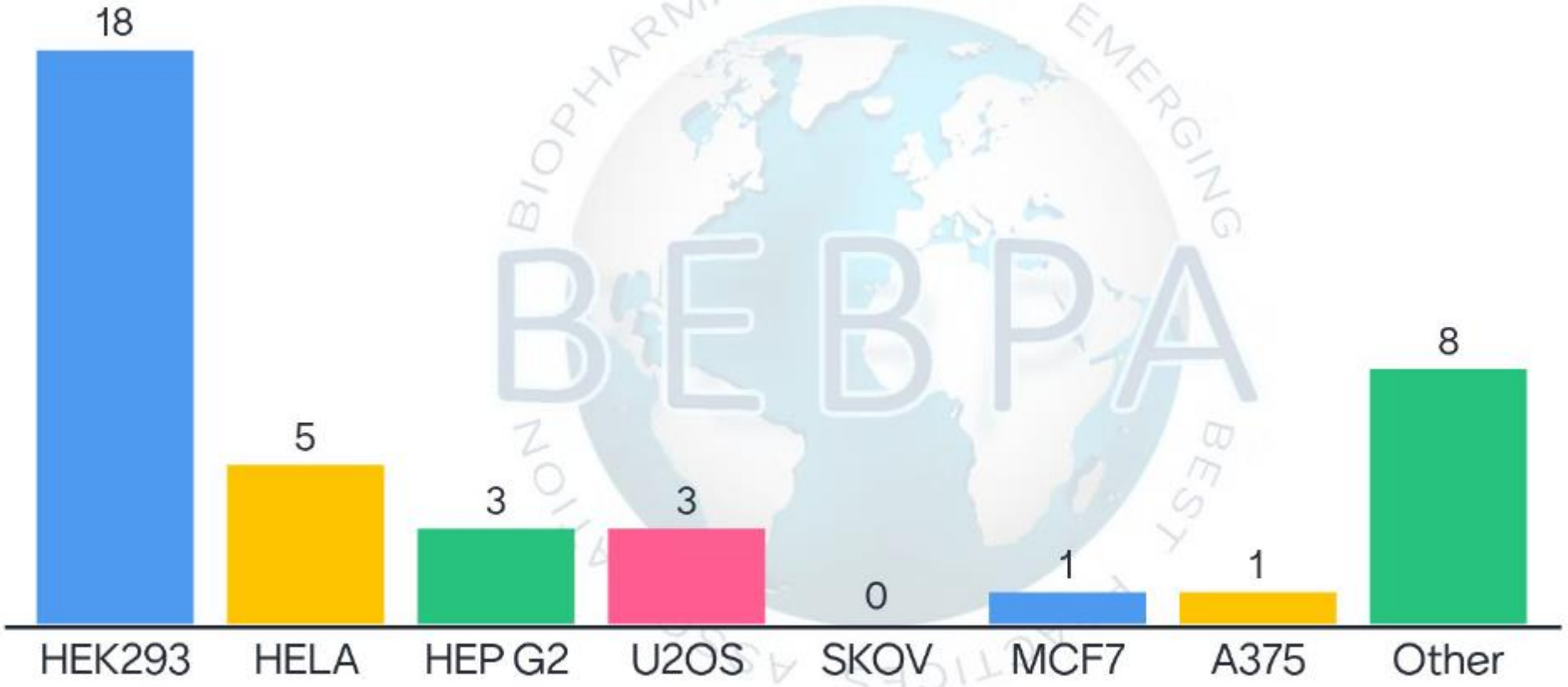
7.7 What methods do you use for assessement of neutralizing antibodies against your gene therapy vector? (Check all that apply)



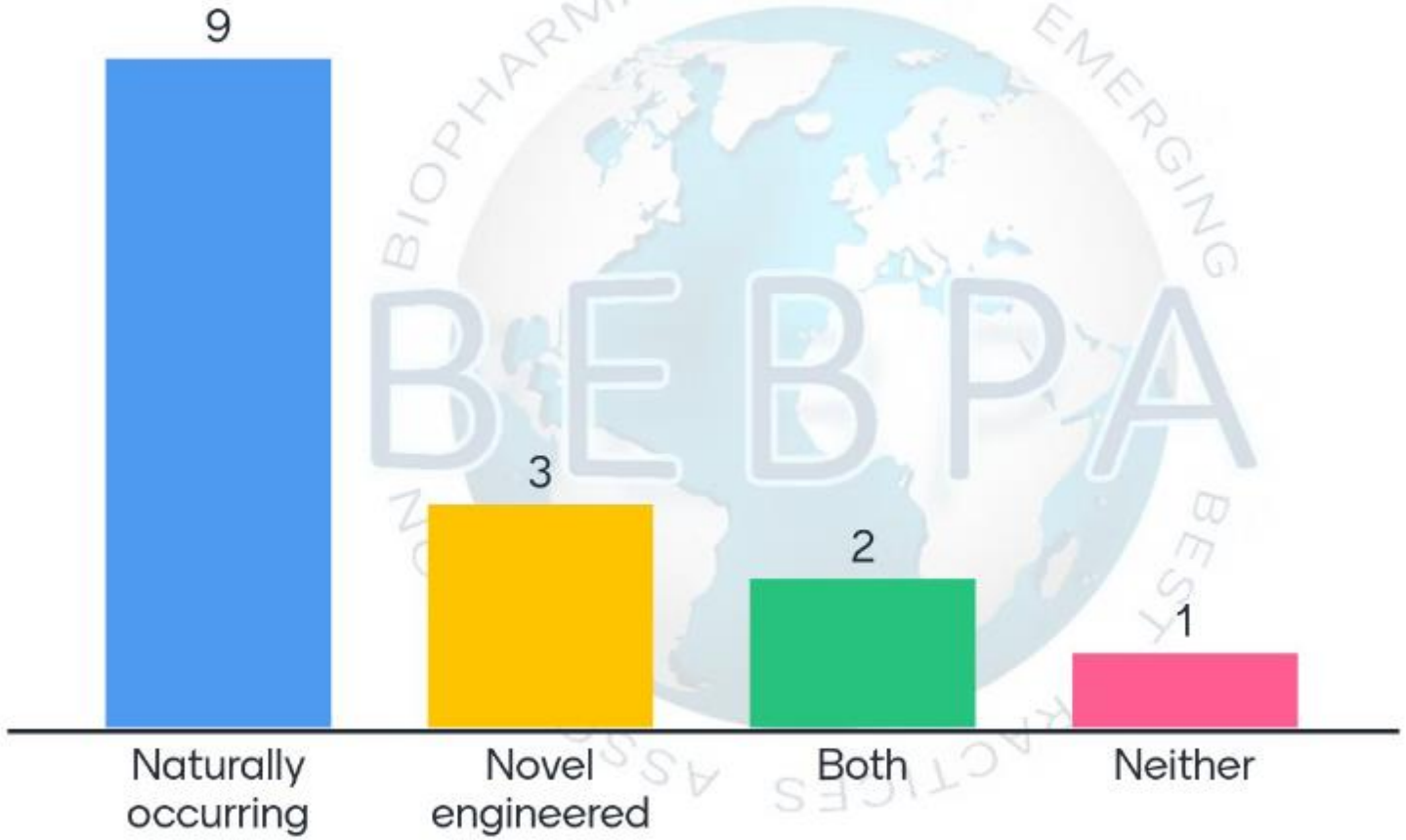
7.8 If working with AAV, what serotypes are you utilizing? (Check all that apply)



7.9 What cell lines are you utilizing in your gene therapy assay development? (Check all that apply)



7.10 If working with AAV, are you developing with naturally occurring capsids or novel engineered capsids?

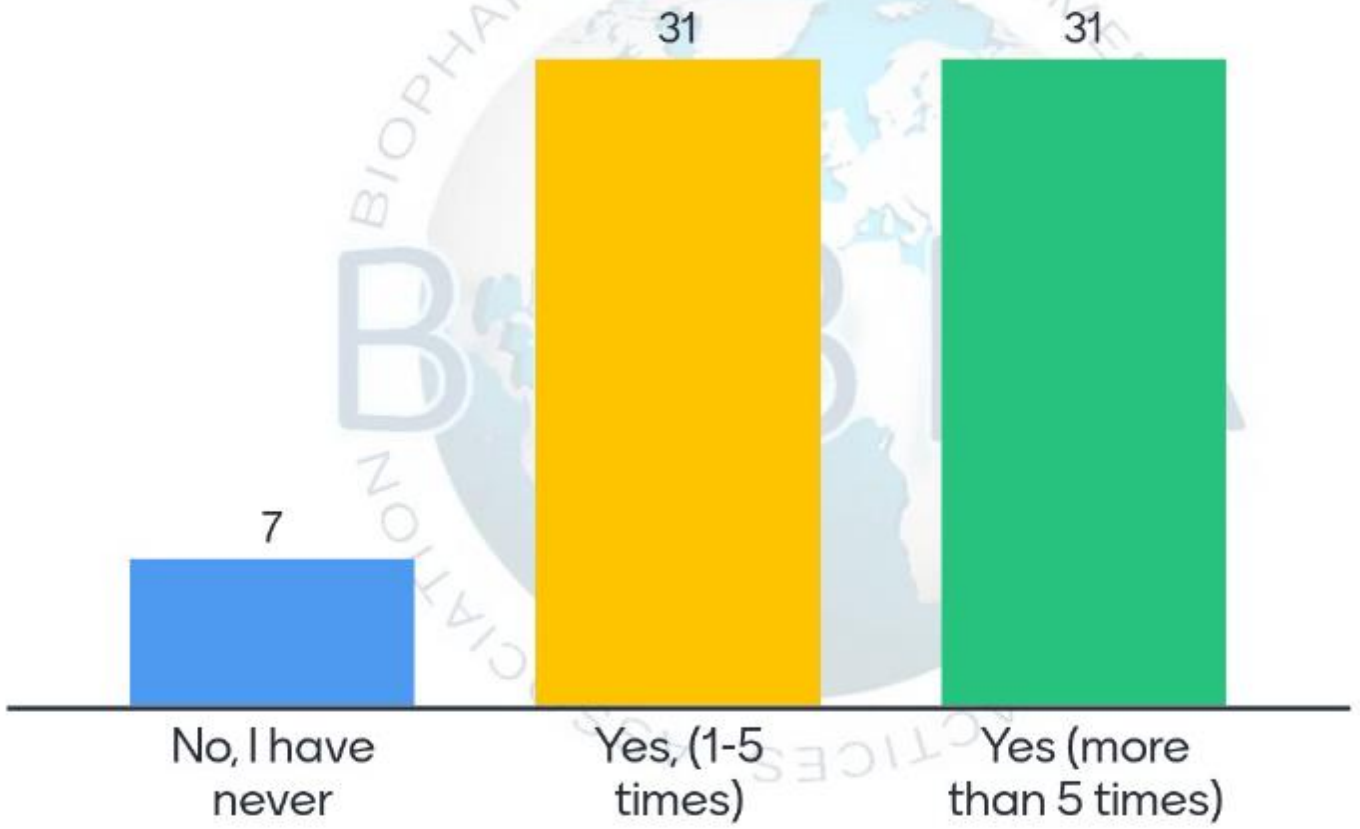


Session 8: Special Topics During the Bioassay Lifecycle

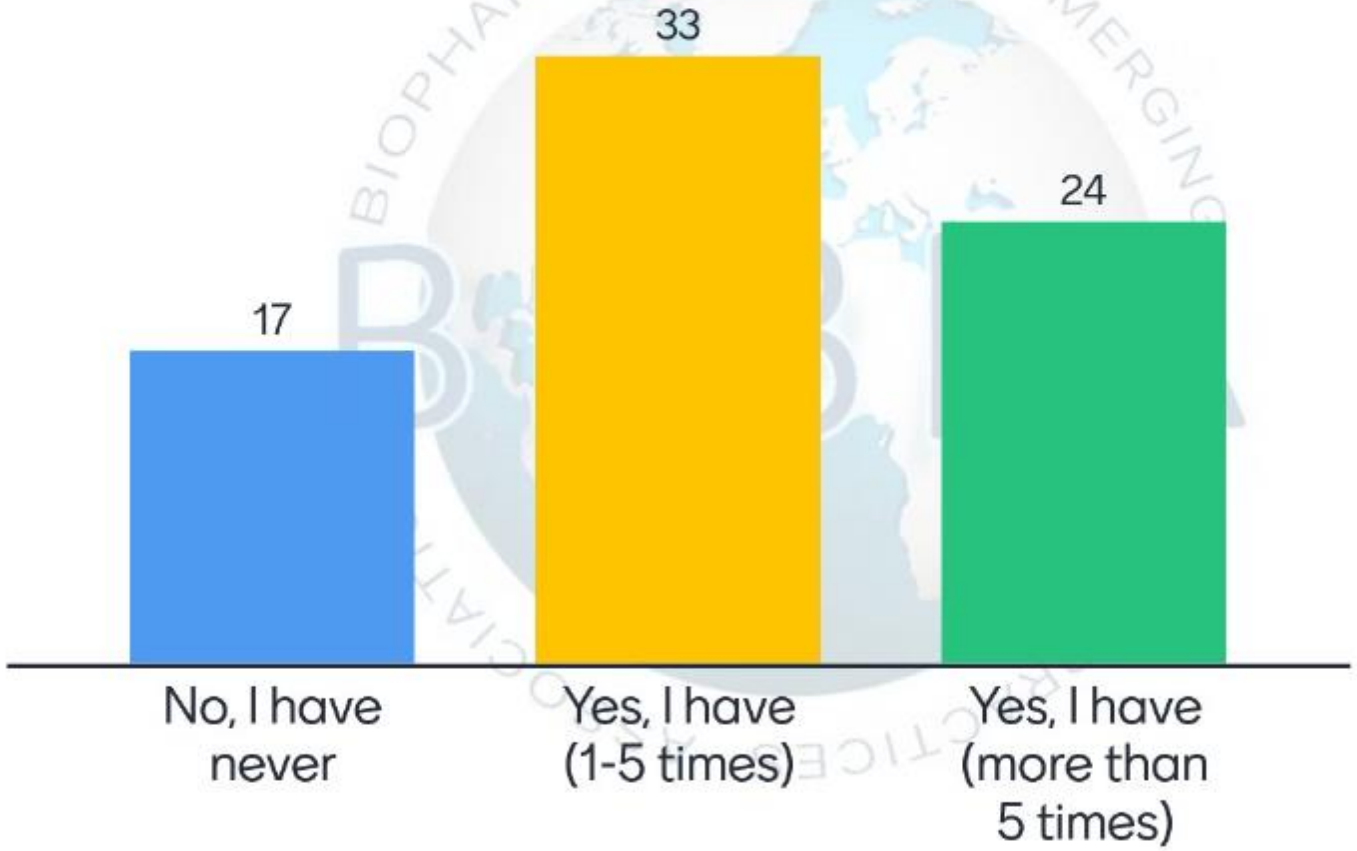
Session Chair: Siân Estdale, Head of Scientific Affairs, Labcorp

Audience Surveys

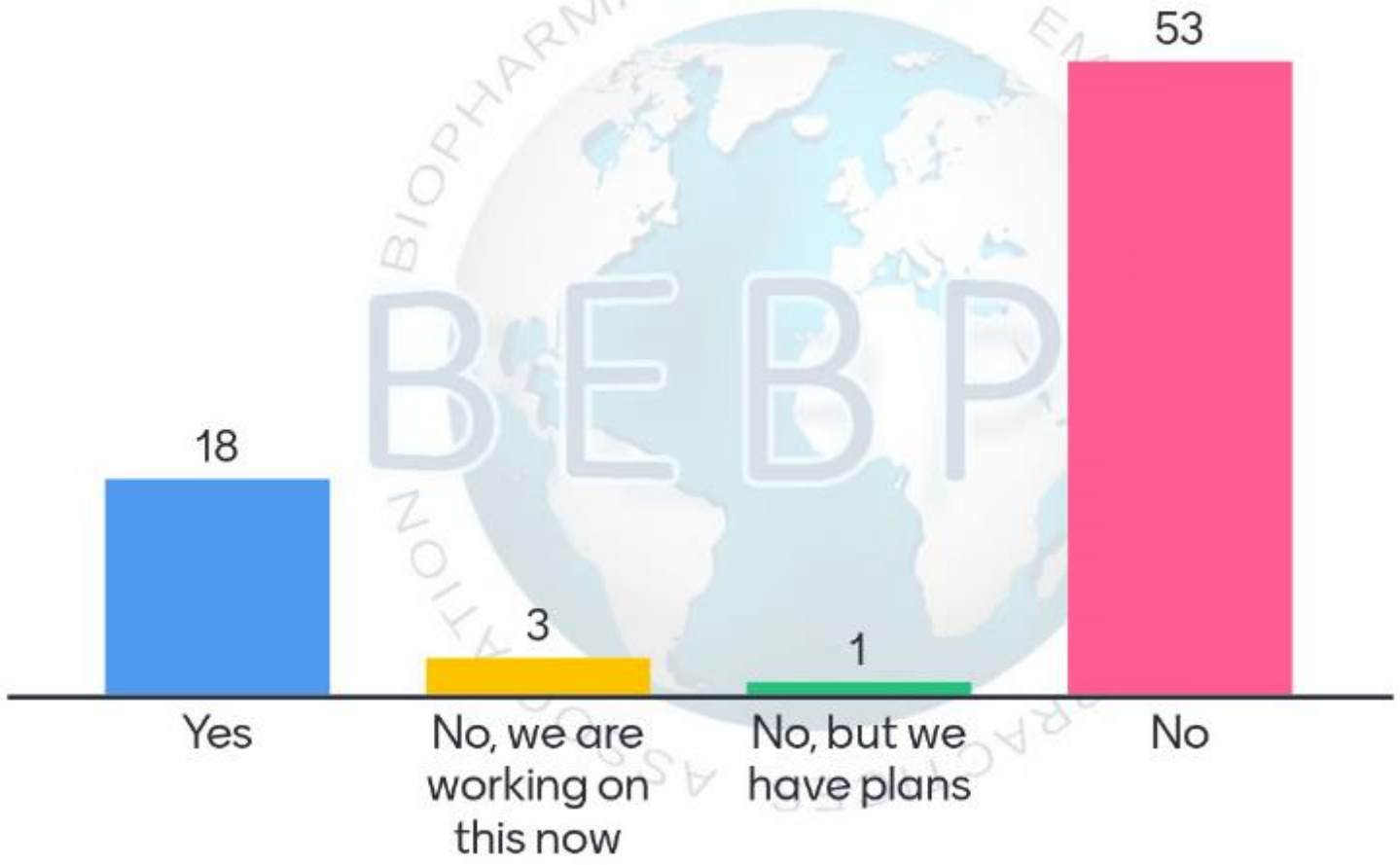
8.1 Have you optimized a potency assay before?



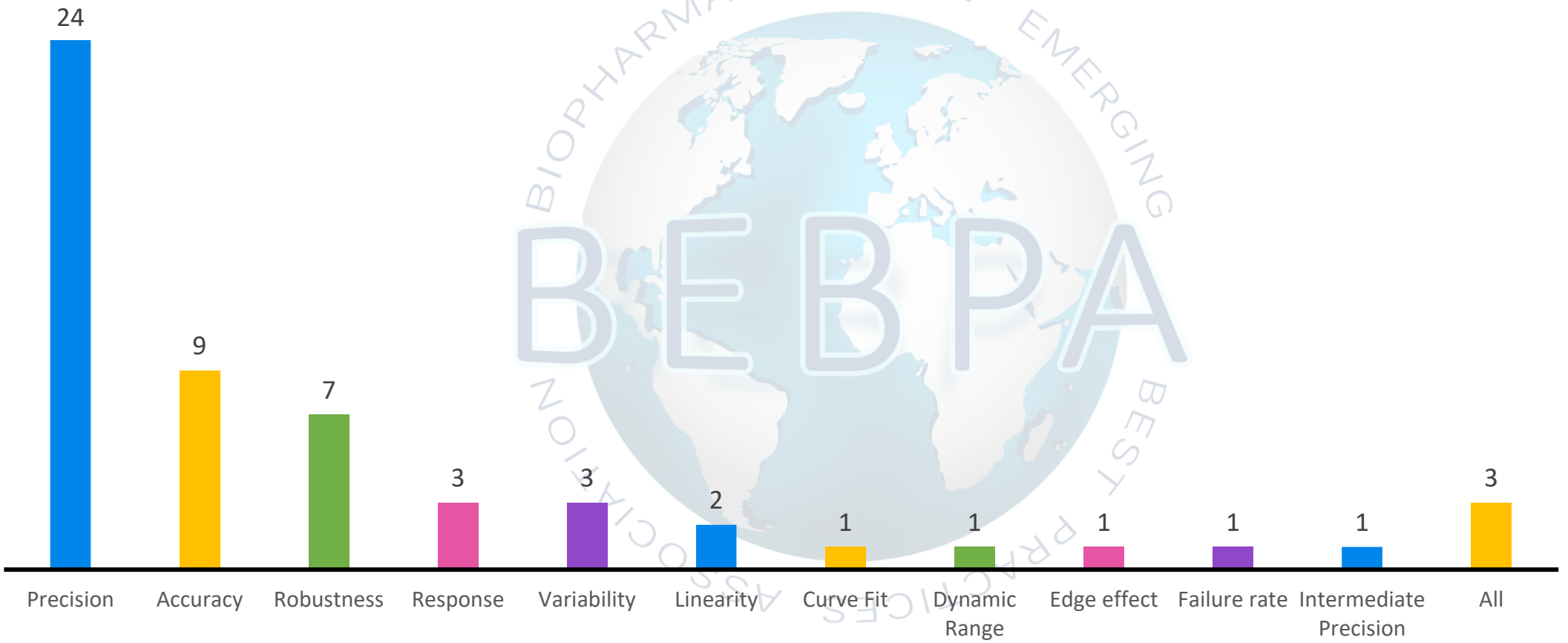
8.2 Have you validated a potency assay before?



8.3 Have you ever been involved in replacing an in-vivo with an in-vitro assay?



8.4 What assay characteristic improves the most as you complete assay development? (e.g., precision, accuracy, etc.)




BIOPHARMACEUTICAL EMERGING BEST PRACTICES ASSOCIATION
BEBPA

Thank You!!