16th Annual EUR Bioassay Conference

27-29 September 2023

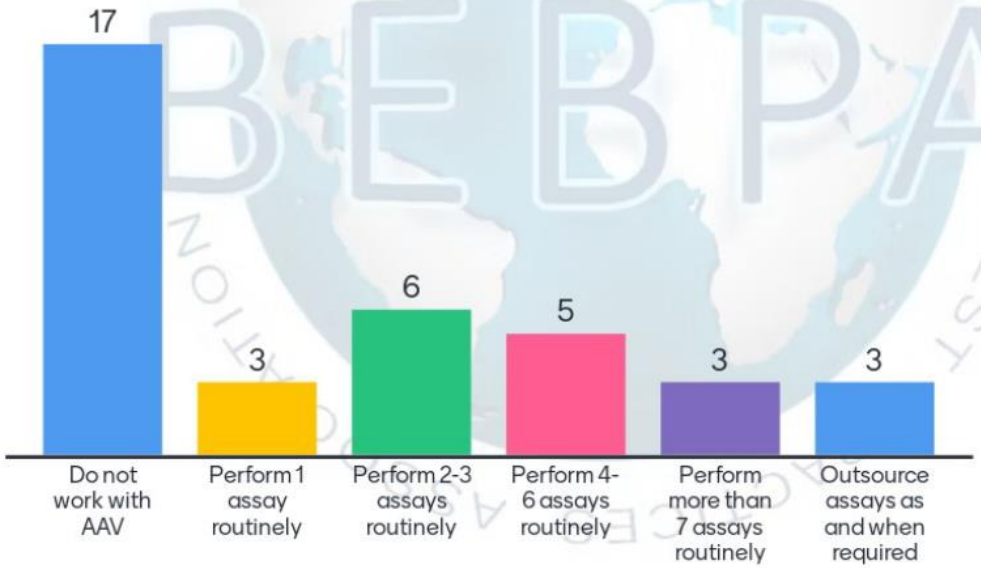
Bled, Slovenia

Interest Group 1: Gene Therapy

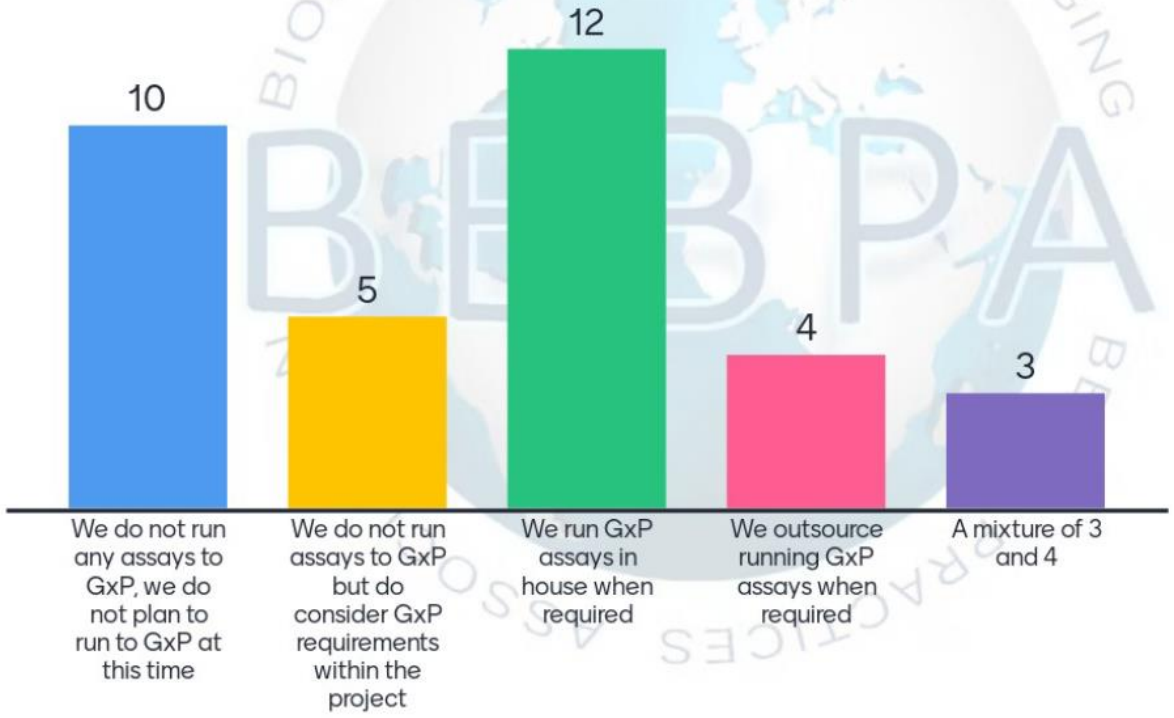
Interest Group 1 Leaders:
Anton Stetsenko, Director, Orca Bio
Sian Estdale, Head of Scientific Affairs, Labcorp

Audience Surveys

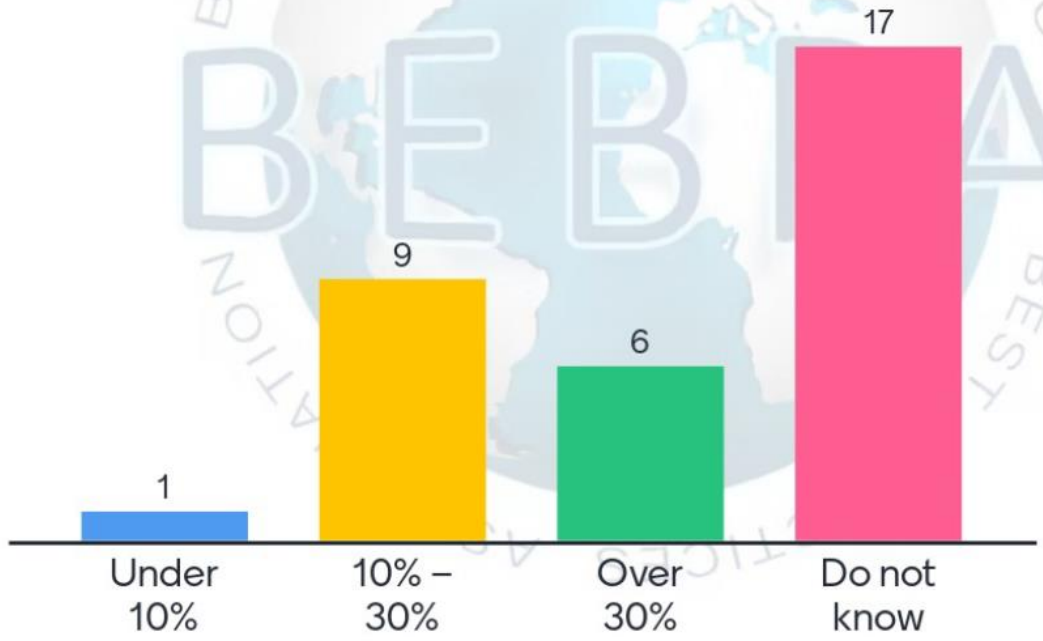
IG1.1 Do you work with AAV in house, if so how many routine analytical assessments do you perform?



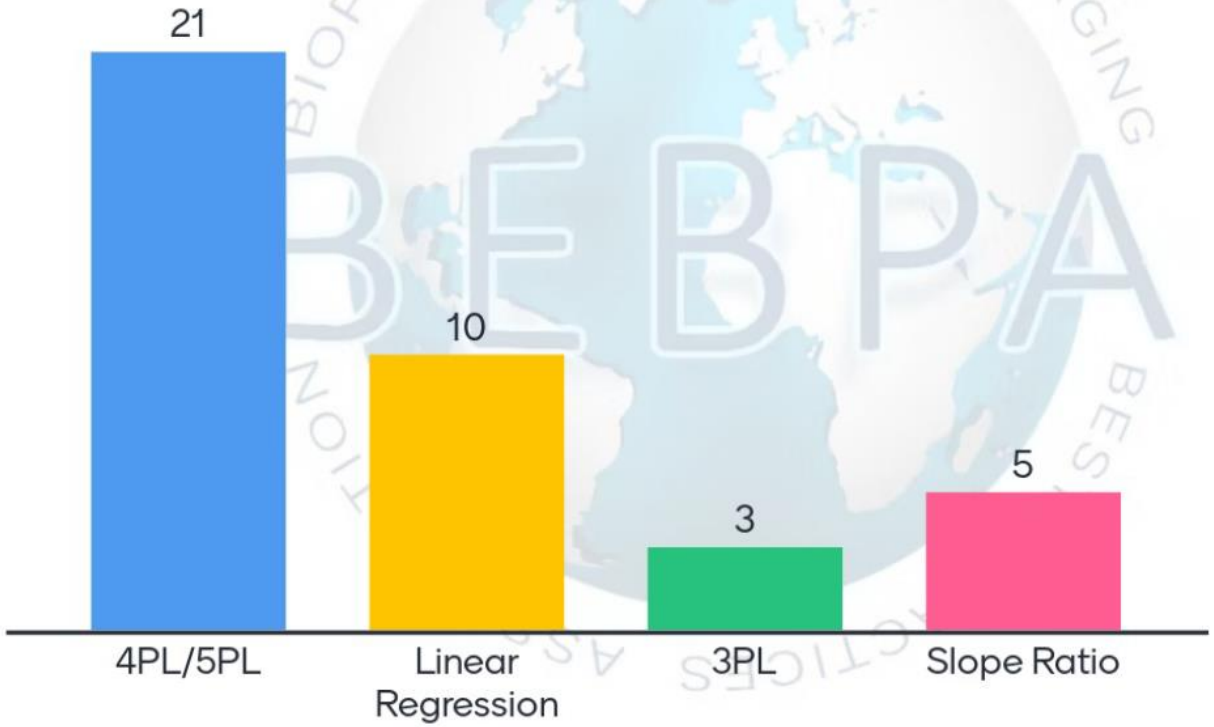
IG1.2 When performing analytical assays on your AAV samples are they performed to GxP?



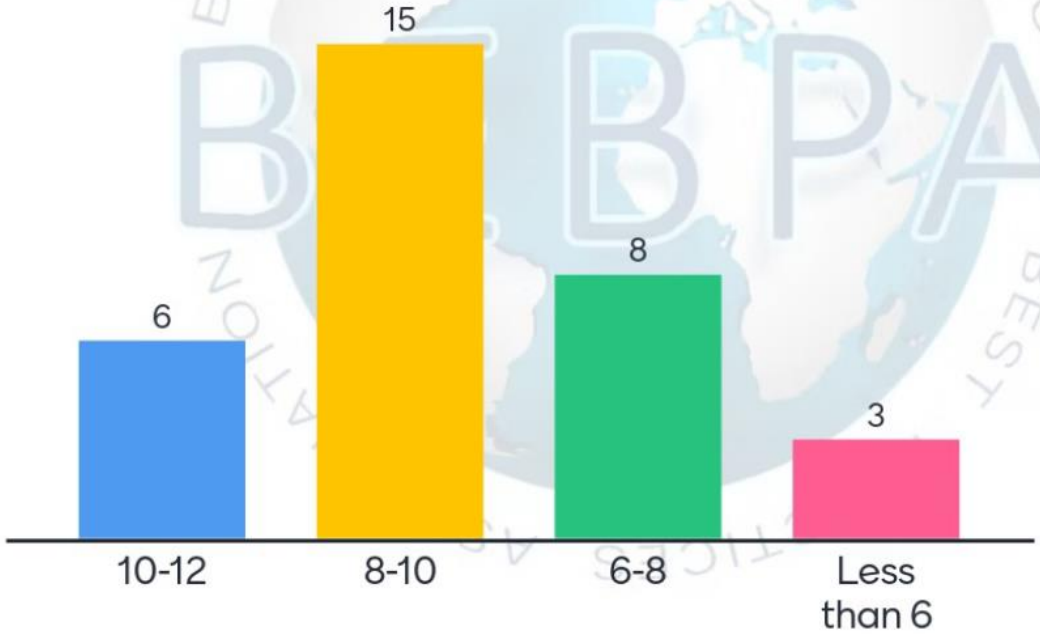
IG1.3 How variable, as a percent geometric coefficient of variation (%GCV), are your potency assays for gene therapy products?



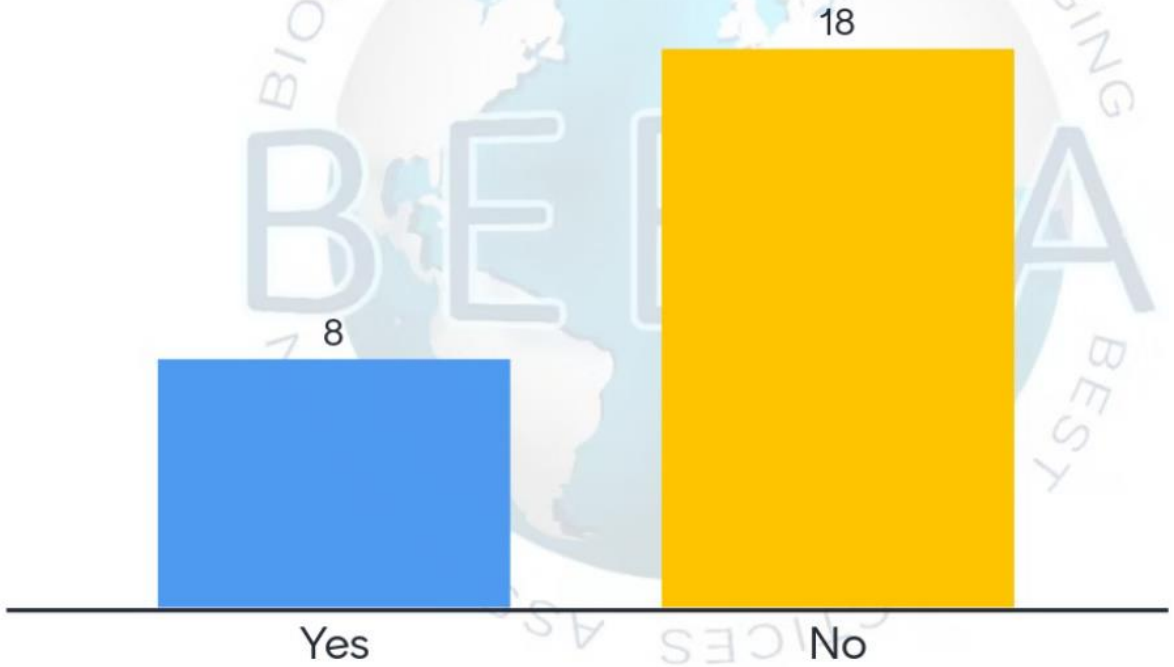
IG1.4 Which statistical model do you use to analyze data from your potency assays for complex products



IG1.5 For your potency assays for complex products, how many data points define your reference standard curve?



IG1.6 Are you using a "matrix" approach for your release assays?



IG1.7 If yes to the previous question, which steps are you including in your matrix?

14 responses

	qPCR	
MOA level	qPCR	Protein
MOA	dPCR	Protein level
MOI	PCR	Protein level
MOI	Infectious titer	Protein Expression
mRNA	Infectious titer	Protein expression
Reporter Gene	Infectivity	Protein Expression by fluorescence
Reporter Gene	Infectivity MOA	Test
	Integrity	

Interest Group 2: Monoclonal Ab

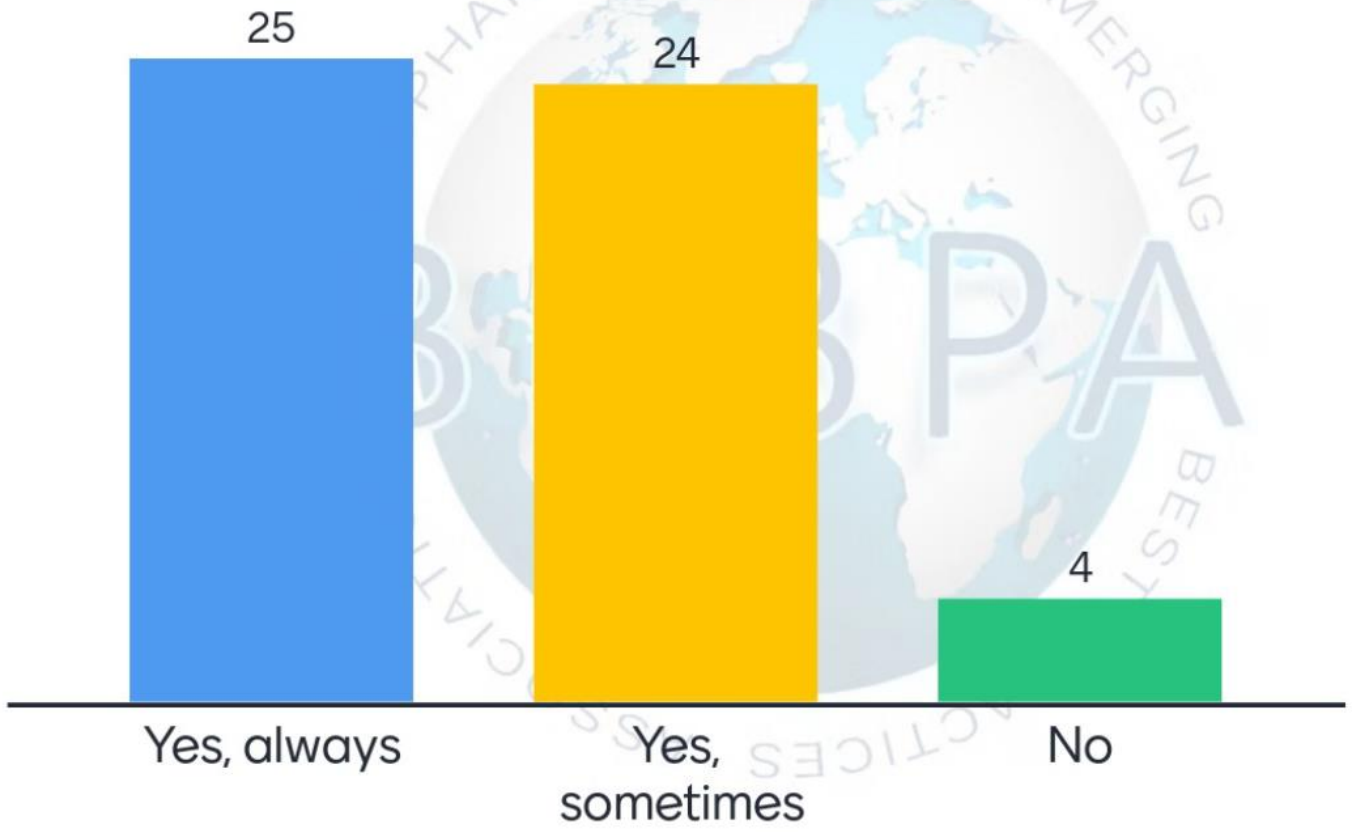
Interest Group 2 Leaders:

Ulrike Herbrand, Scientific Director, Charles River Labs

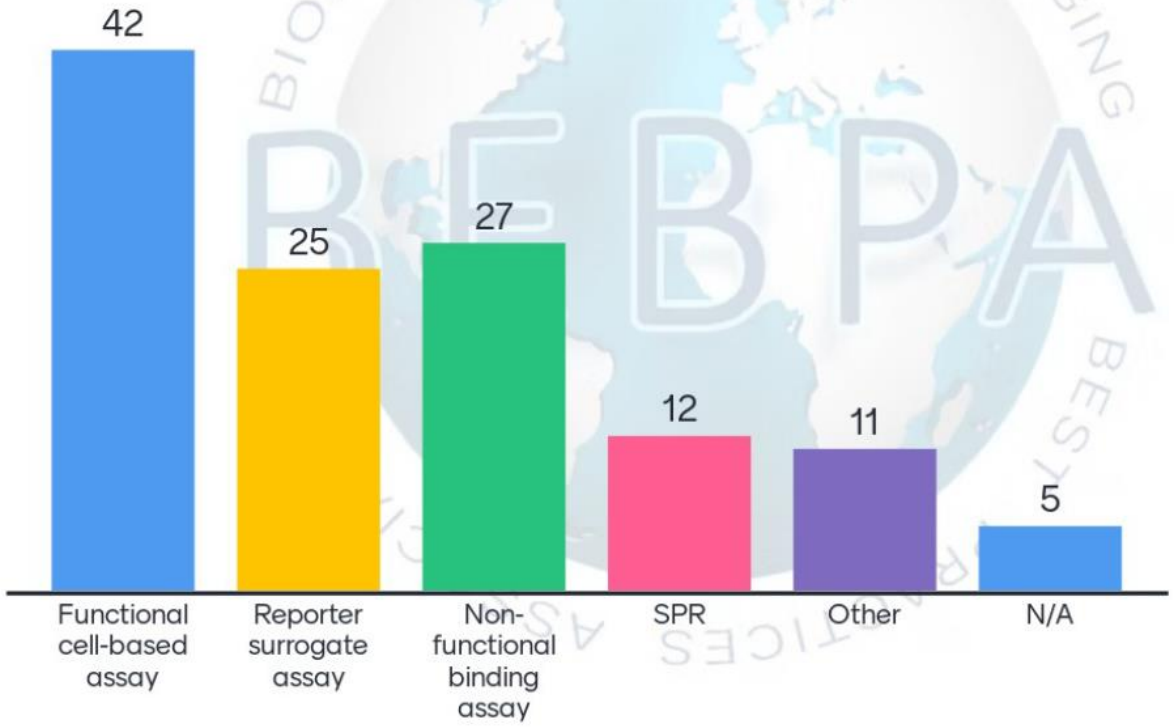
Hans-Joachim Wallny, Executive Director, Novartis Pharma AG

Audience Surveys

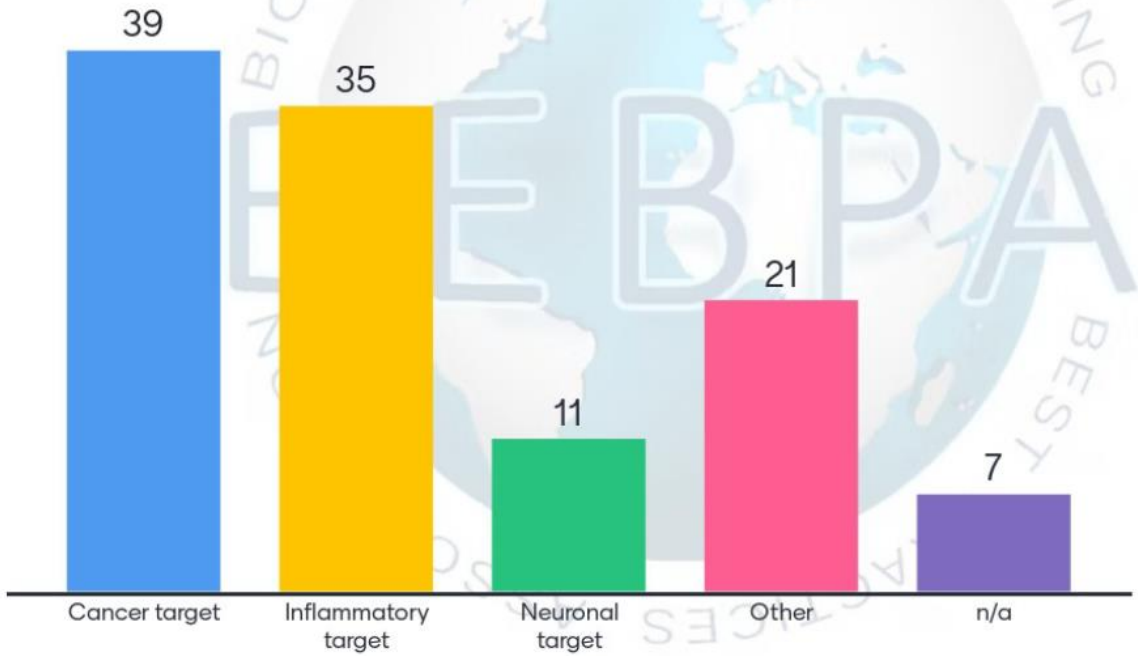
IG2.1 Do you work with mAbs?



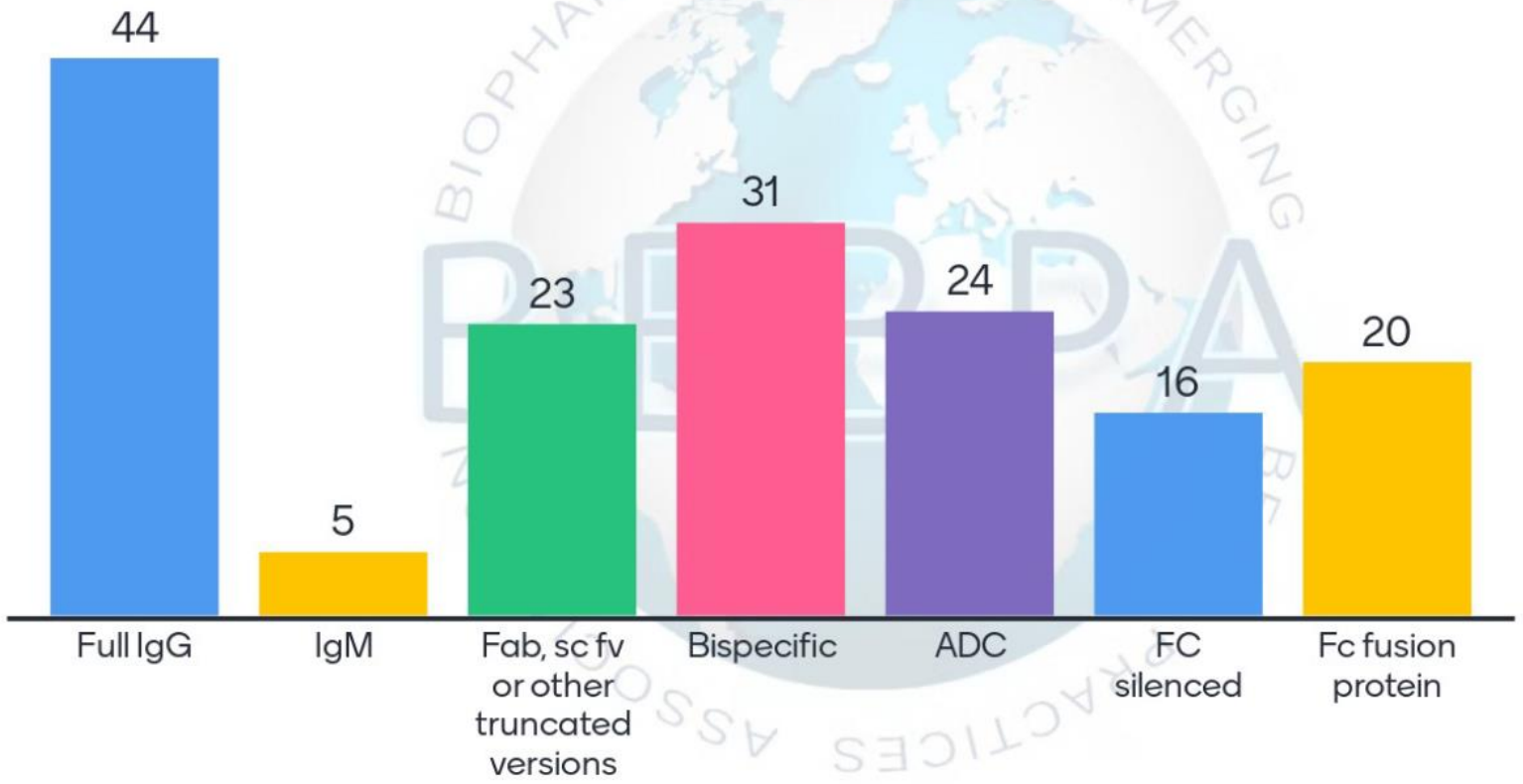
IG2.2 Which assay do you use for release purposes of mAb products?



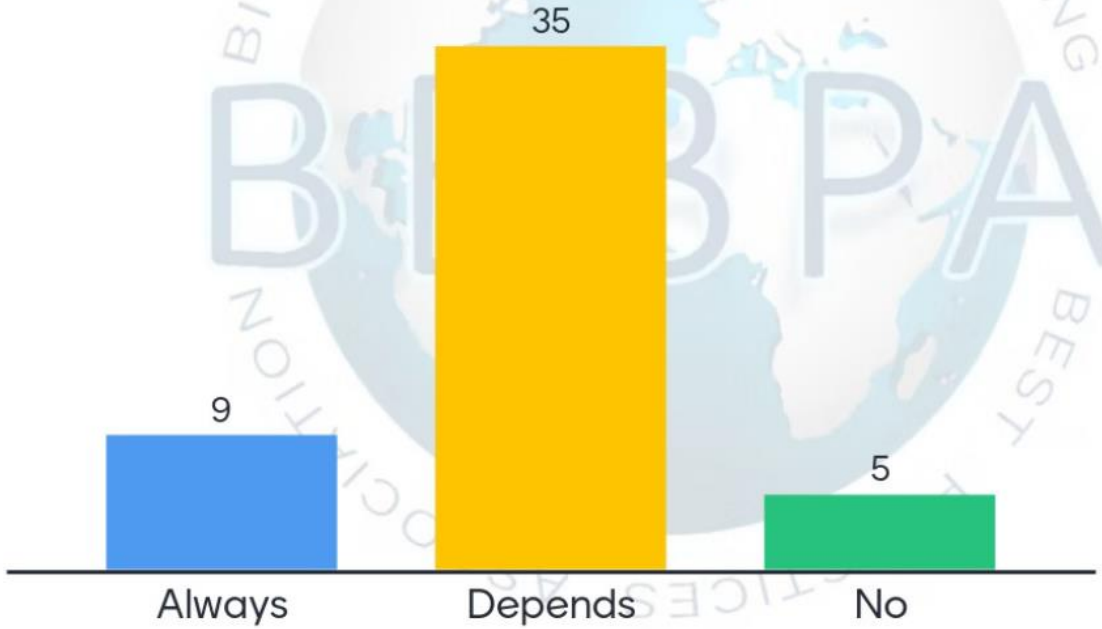
IG2.3 What is the target of your mAb product?



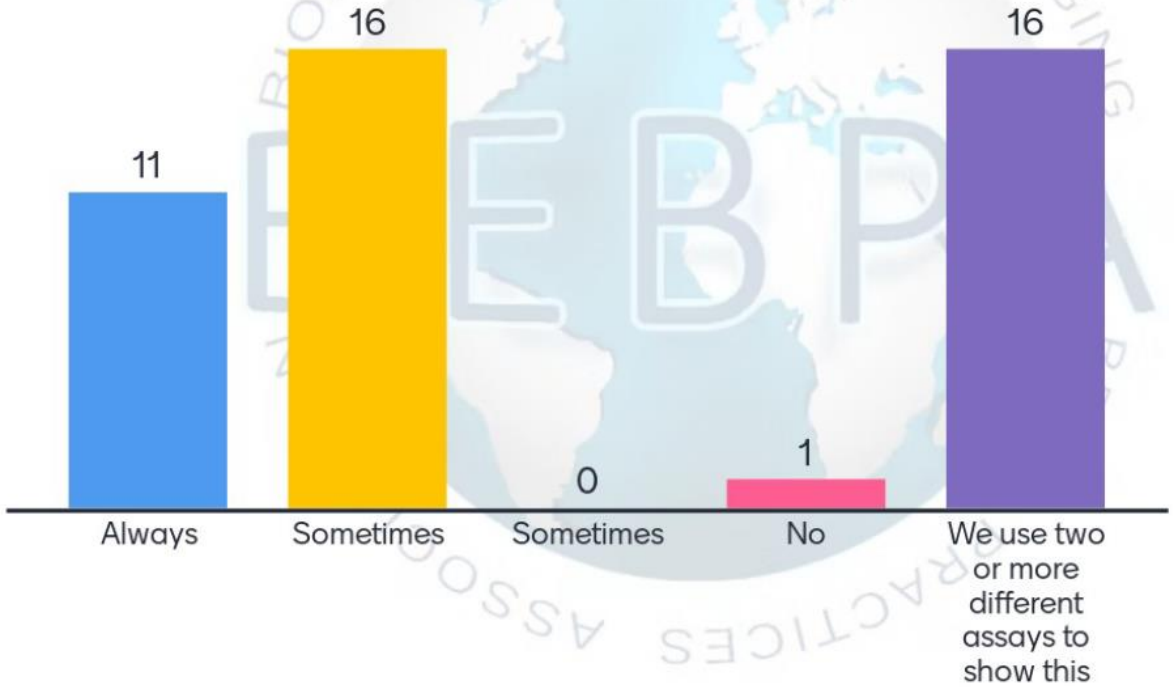
IG2.4 what type of mAb do you work with?



IG2.5 When developing bioassays for mAbs and comparable product do you start with binding assay and then switch to more functional assays for phase 3?



IG2.6 If your mAb has FcR function as part of the MoA, does your bioassay reflect this?

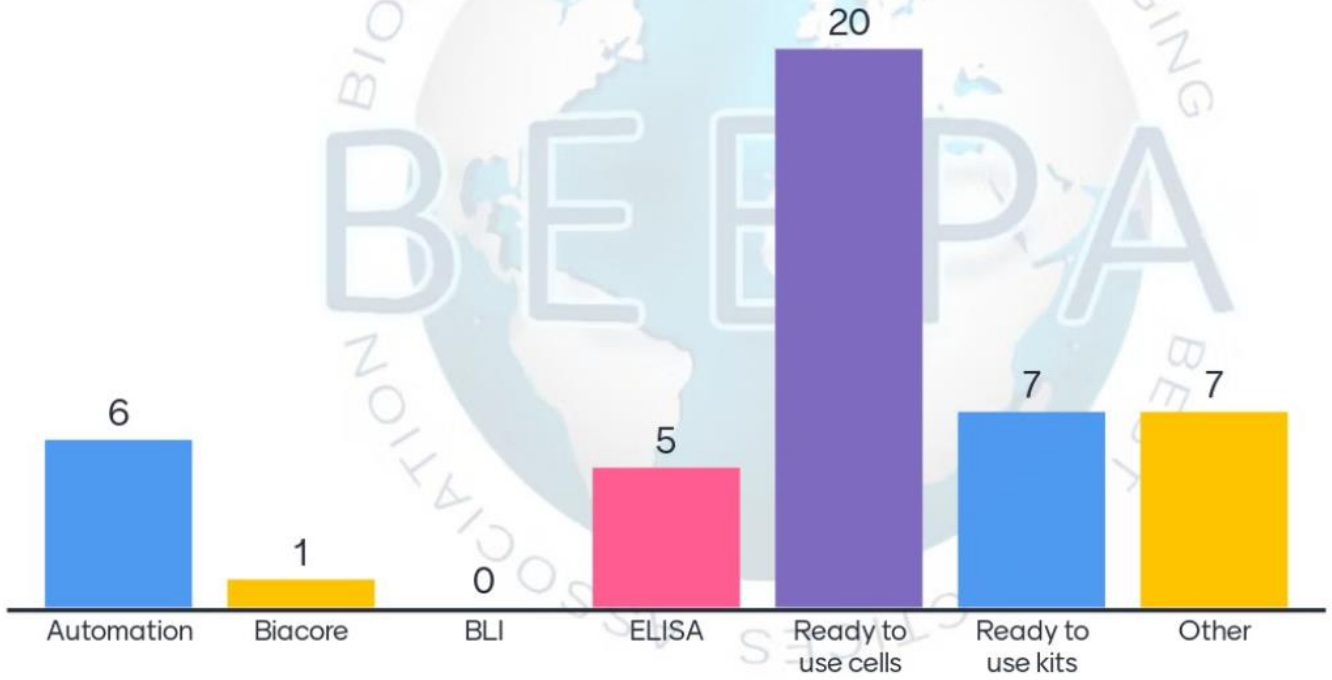


Interest Group 3: Data Analysis

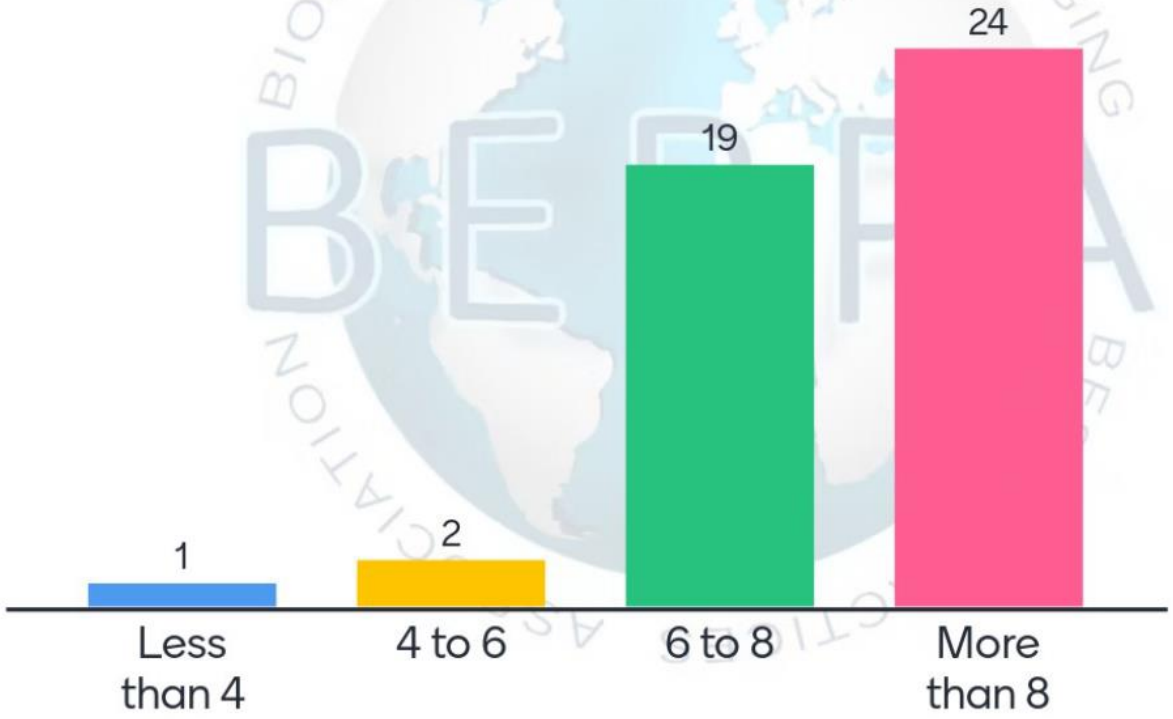
Interest Group 3 Leaders:
Nancy Niemuth, Statistical Consultant, Act Two Consulting
Anton Stetsenko, Director, Orca Bio

Audience Survey

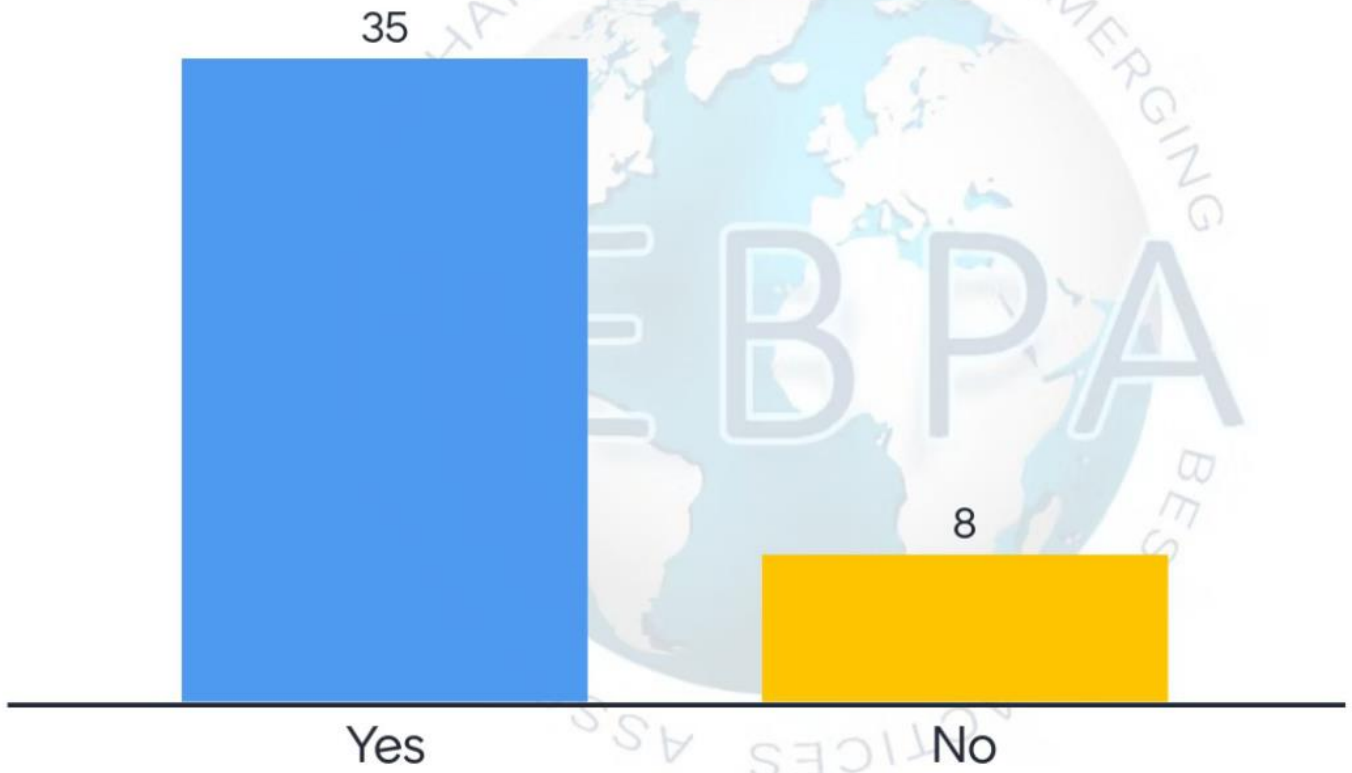
IG3.1 Preferred mode of bioassays to reduce variability and increase precision ?



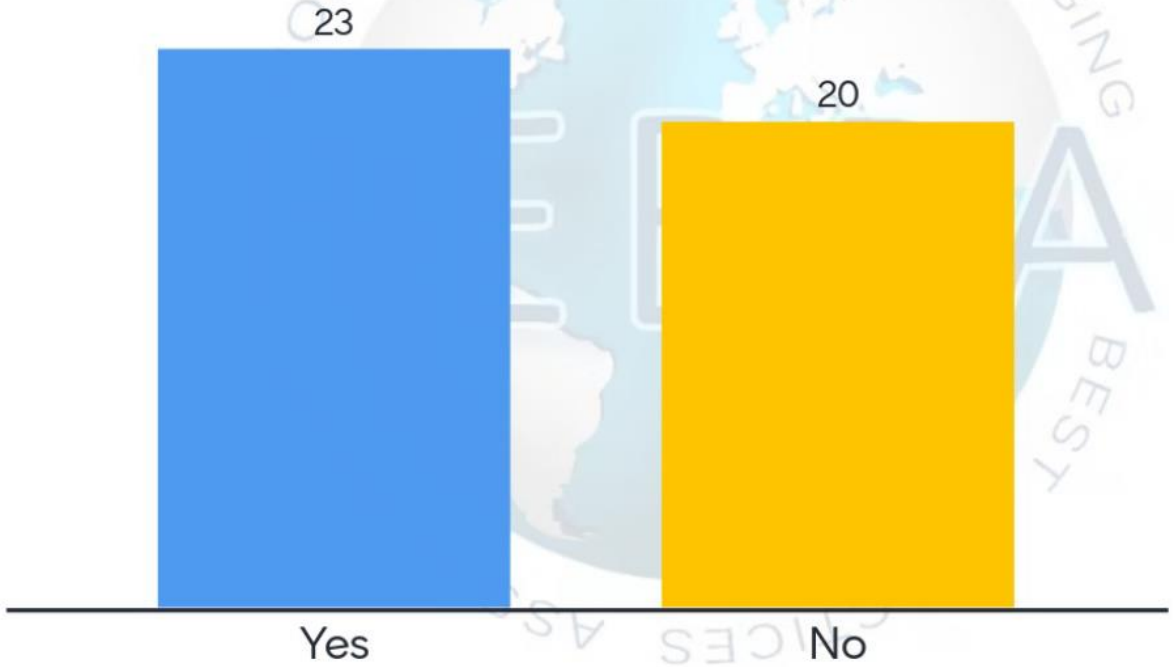
IG3.2 How many concentration points do you use in a typical bioassay dose-response curve?



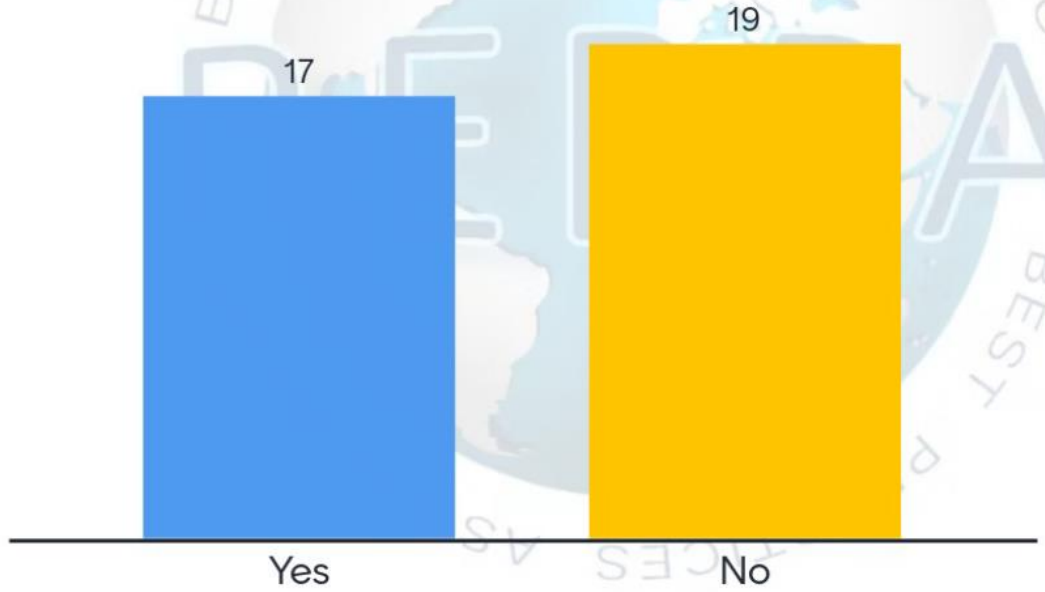
IG3.3 Do you use technical duplicates?



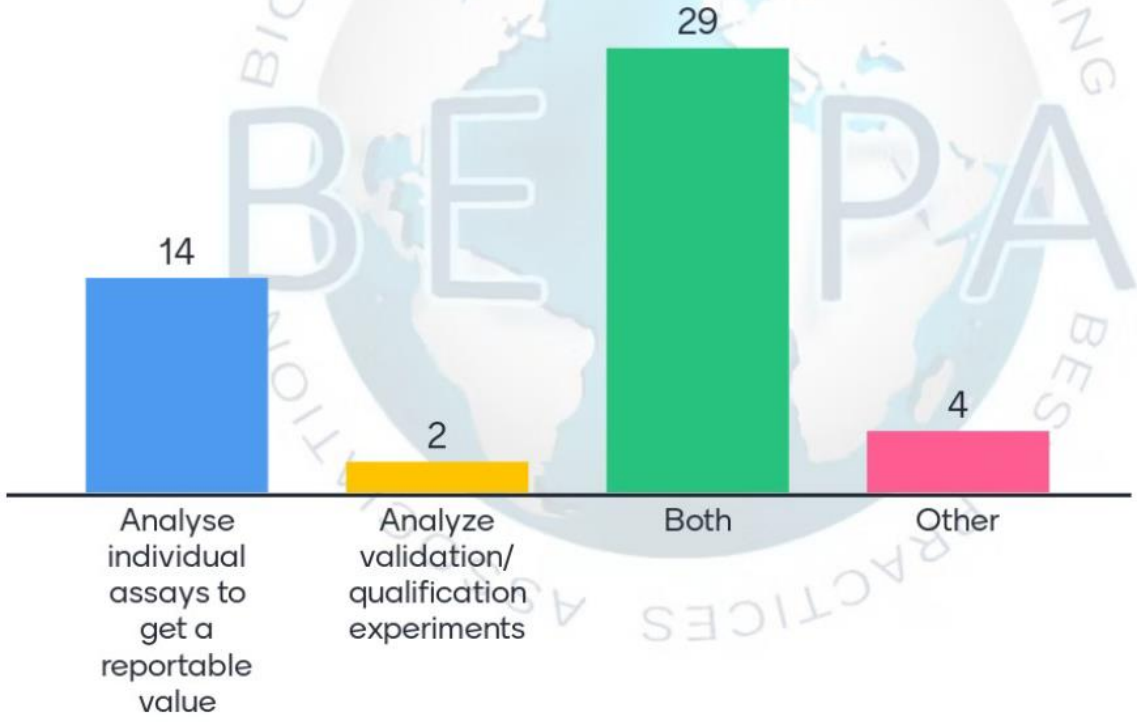
IG3.4 In the past 3 years have you had to deal with a partial dose-response curve?



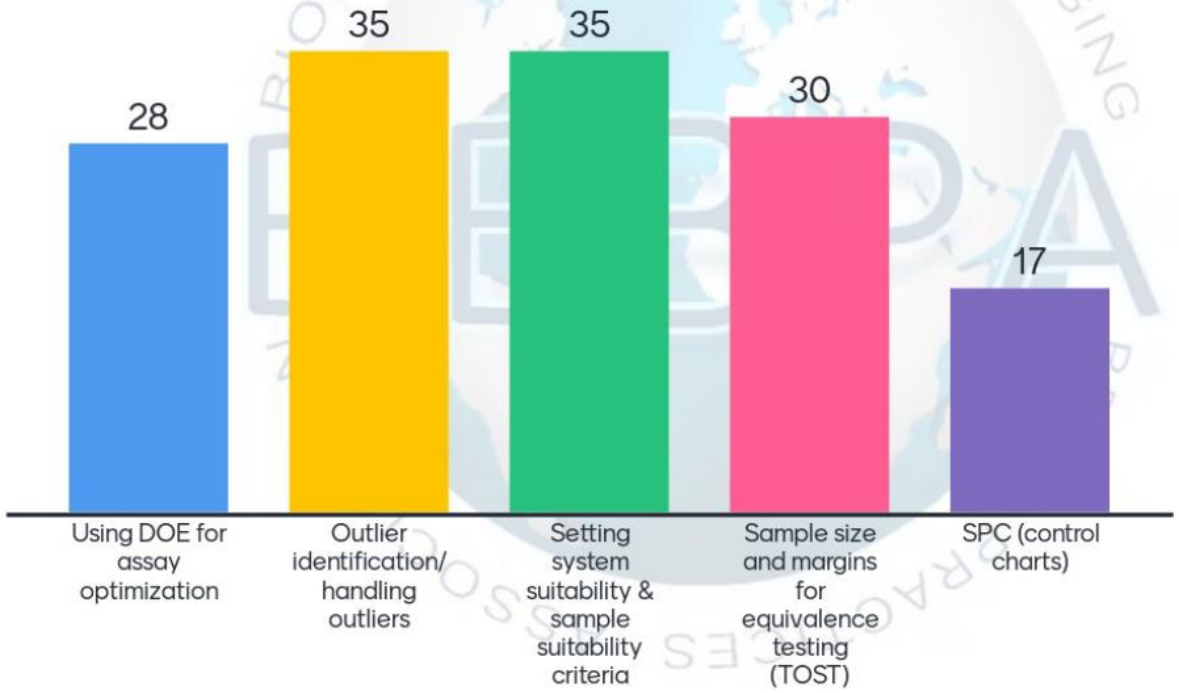
IG3.5 Have you every had a partial dose-response curve cause a "similarity" failure for dose-response curves which appear similar?



IG3.6 What types of data analysis do you do?



IG3.7 Which potential topic areas are you interested in for future meetings?



IG3.8 Please suggest potential topics for the data analysis interest group for future meetings

21 responses

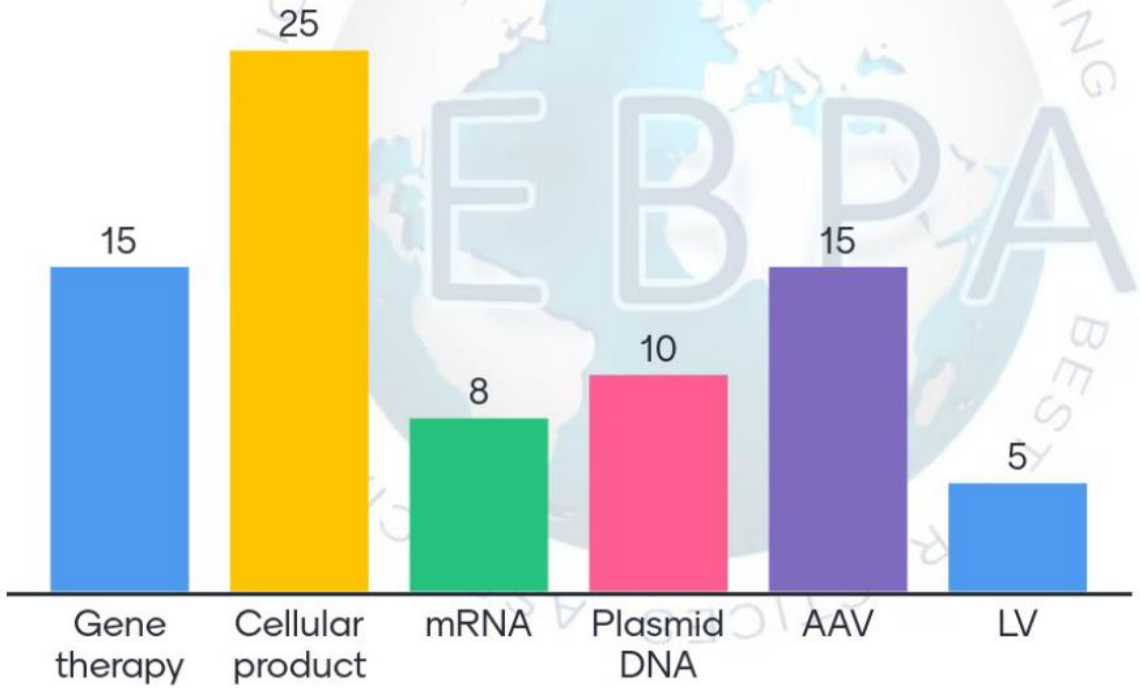
Assay monitoring	Simulations	Comparison SoftMax Pro/PLA
Assay monitoring	Simulations	Bayesian methods
Assay trending	Rescue failed validations	4PL model
Trending	Reduce CV	5PL model
Relevant assay parameters	Implementation of ELN	Data trends
Working with primary cells	Testing similarity	Smart SST for bioassays
Weighting of dose-response curves	Flow cytometric	Setting SSTs
Full curve vs. Parallel line model	Nonlinear mixed models	

Interest Group 4: Stage-Appropriate Potency Assays

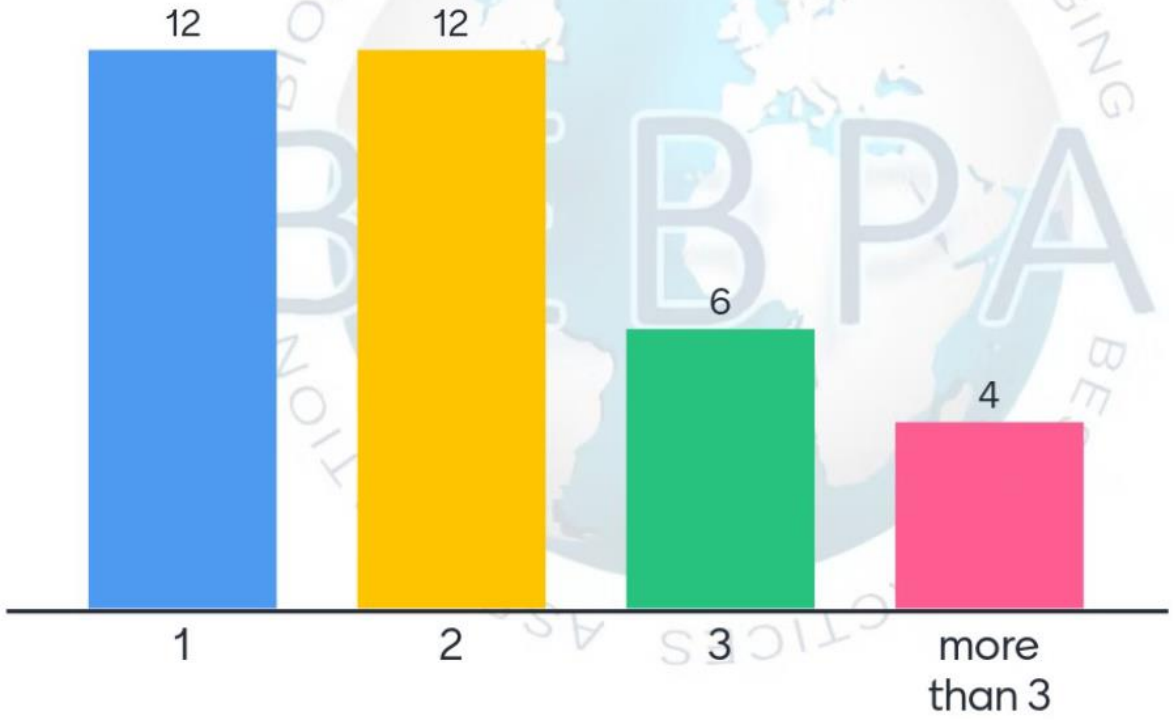
Interest Group 4 Leaders:
Sonja Klingelhöfer, Director , Richter-Helm BioLogics GmbH
Alex Knorre, Senior Scientific Director, Eurofins BioPharma Product Testing Munich GmbH

Audience Survey

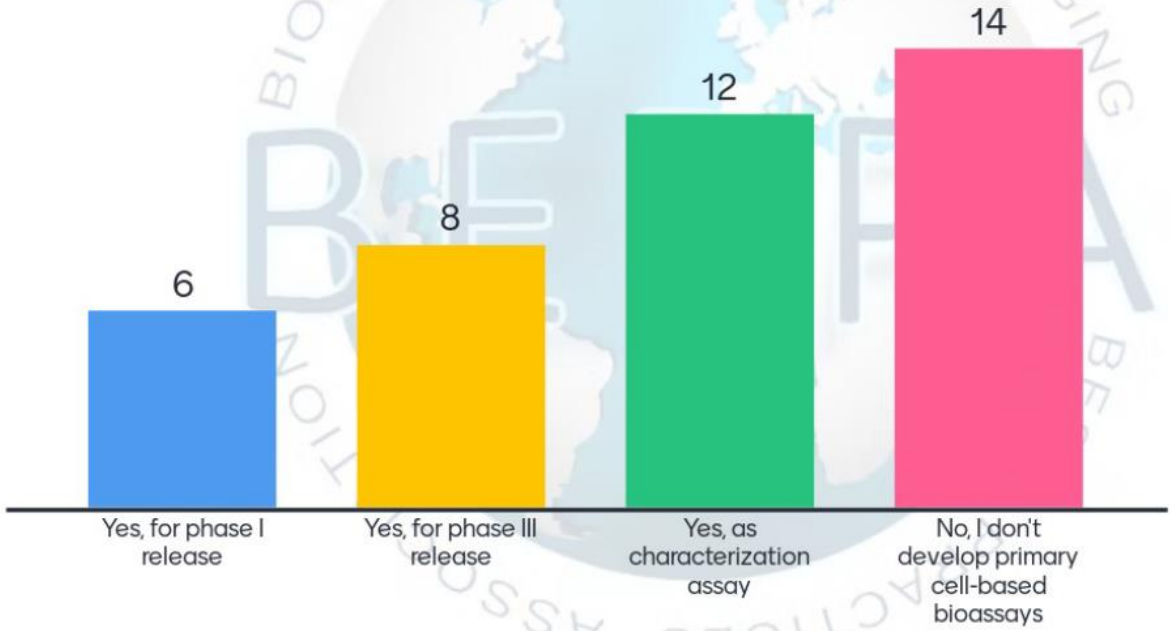
IG4.1 What type of products do you work with?



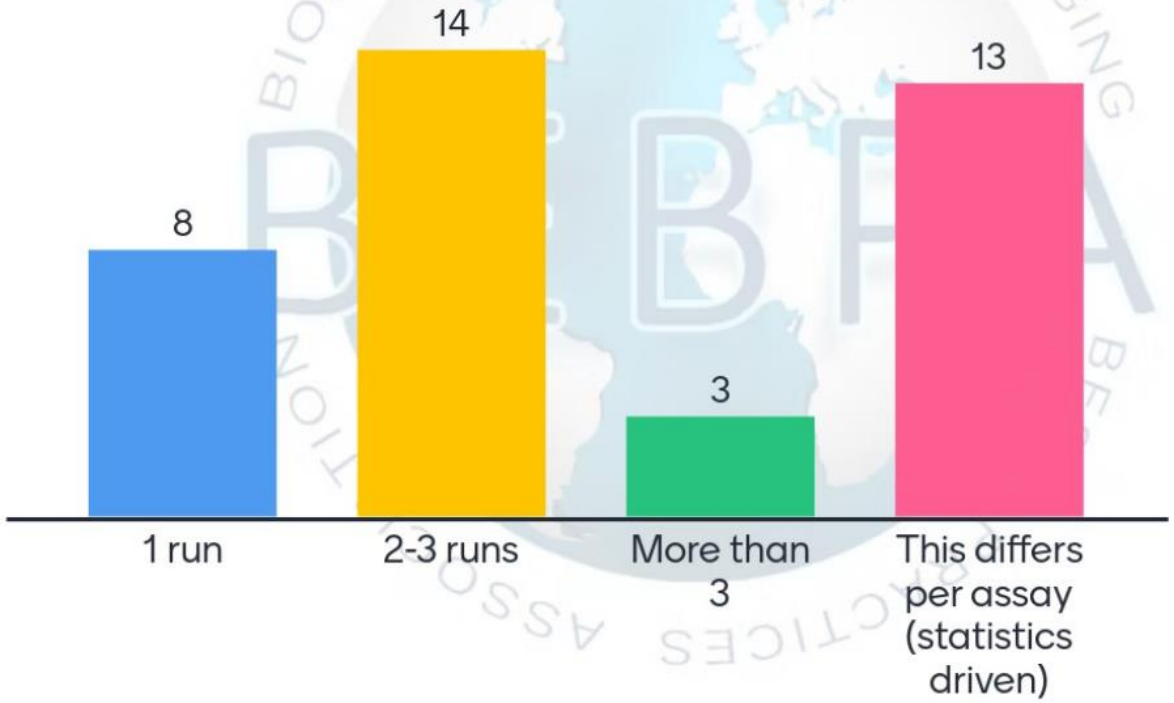
IG4.2 How many different potency assay do you develop (on average) for a product?



IG4.3 Do you develop primary cell-based bioassays for your product?



IG4.4 How many runs do you include for a reportable result?




BIOPHARMACEUTICAL EMERGING BEST PRACTICES ASSOCIATION
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Thank You!!