BEBPA 2024 Host Cell Protein Conference

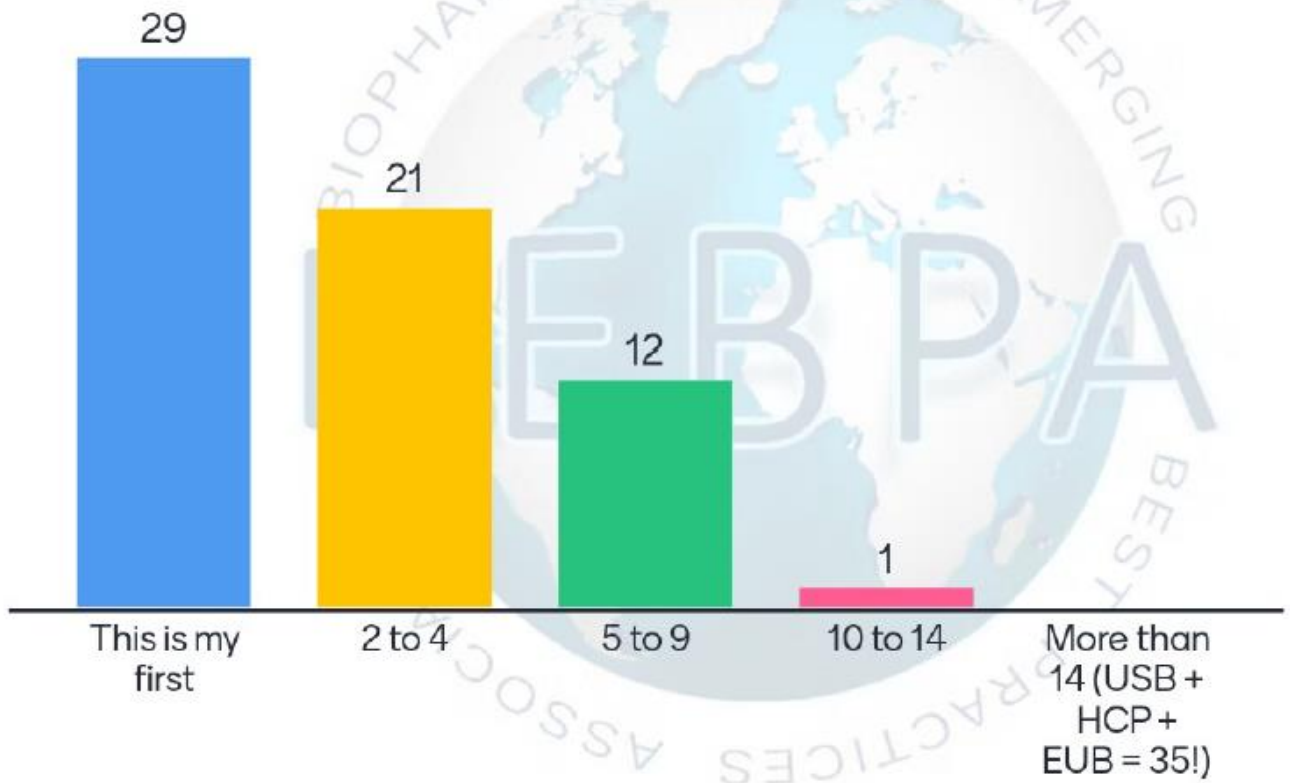
14-16 May 2024
College Park, MD, USA
Hybrid Event

Welcome Back & Introduction

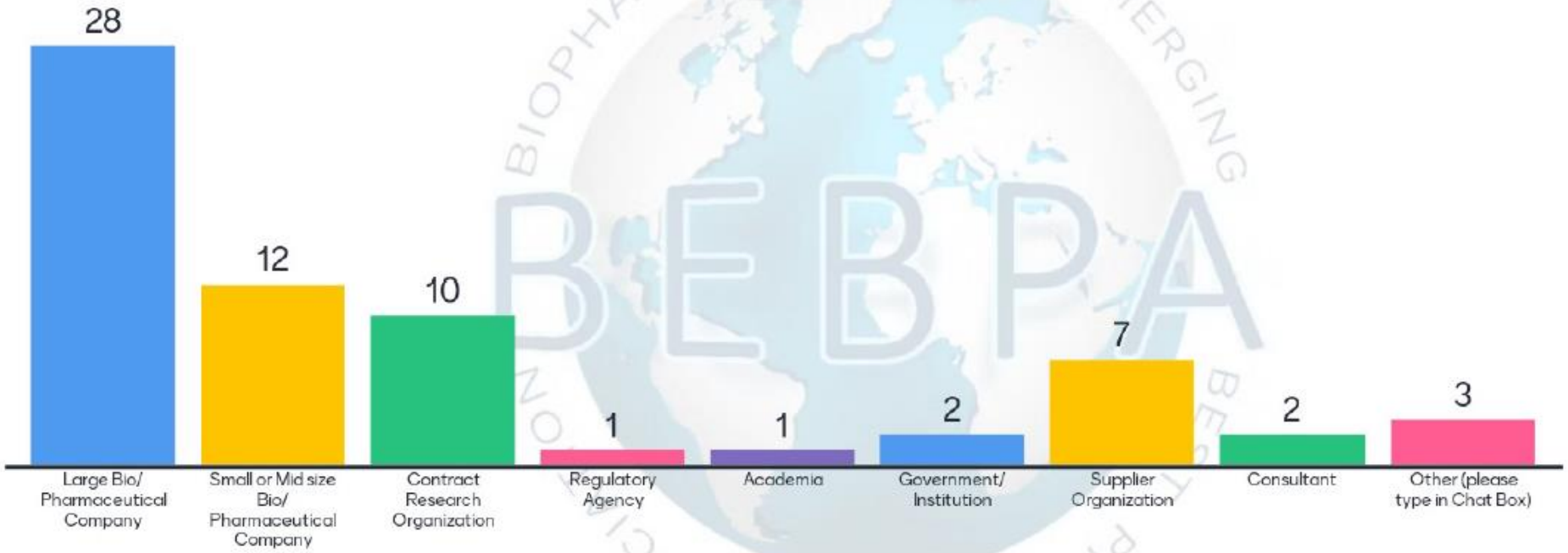
Laureen Little
Principal Consultant
Quality Services
BEBPA President

Audience Surveys

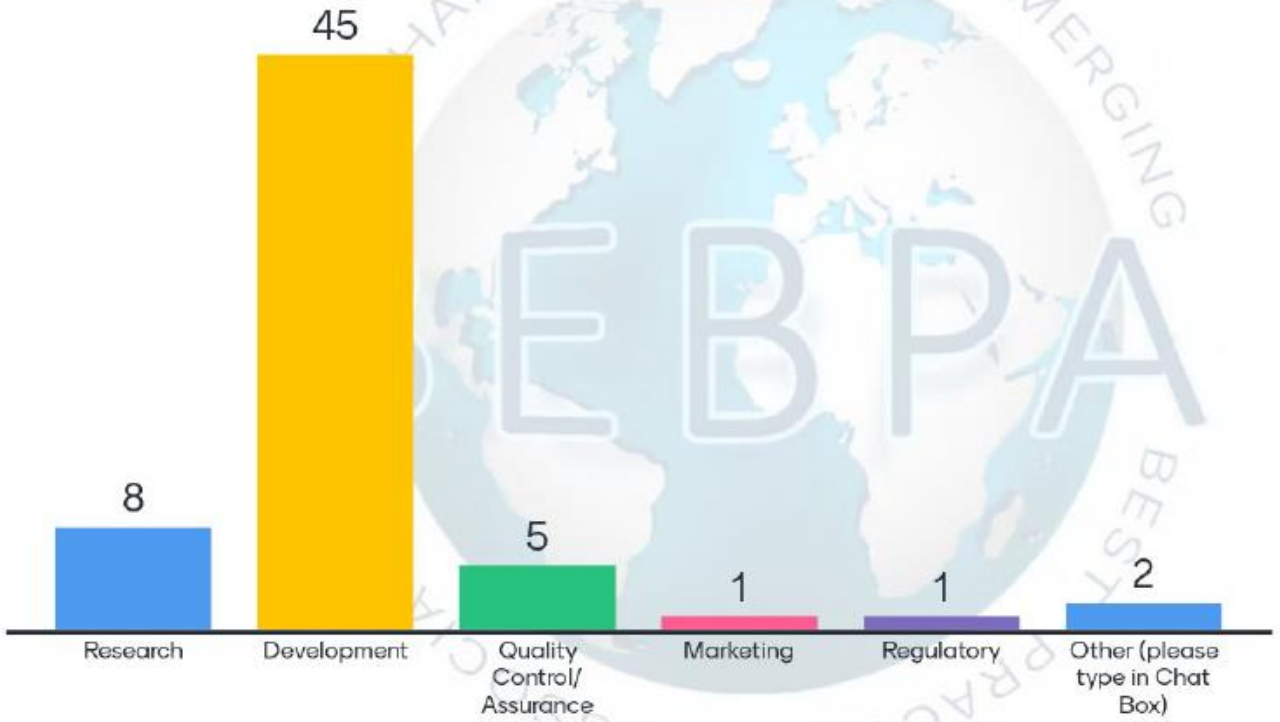
i.1 How many BEBPA Conferences have you attended?



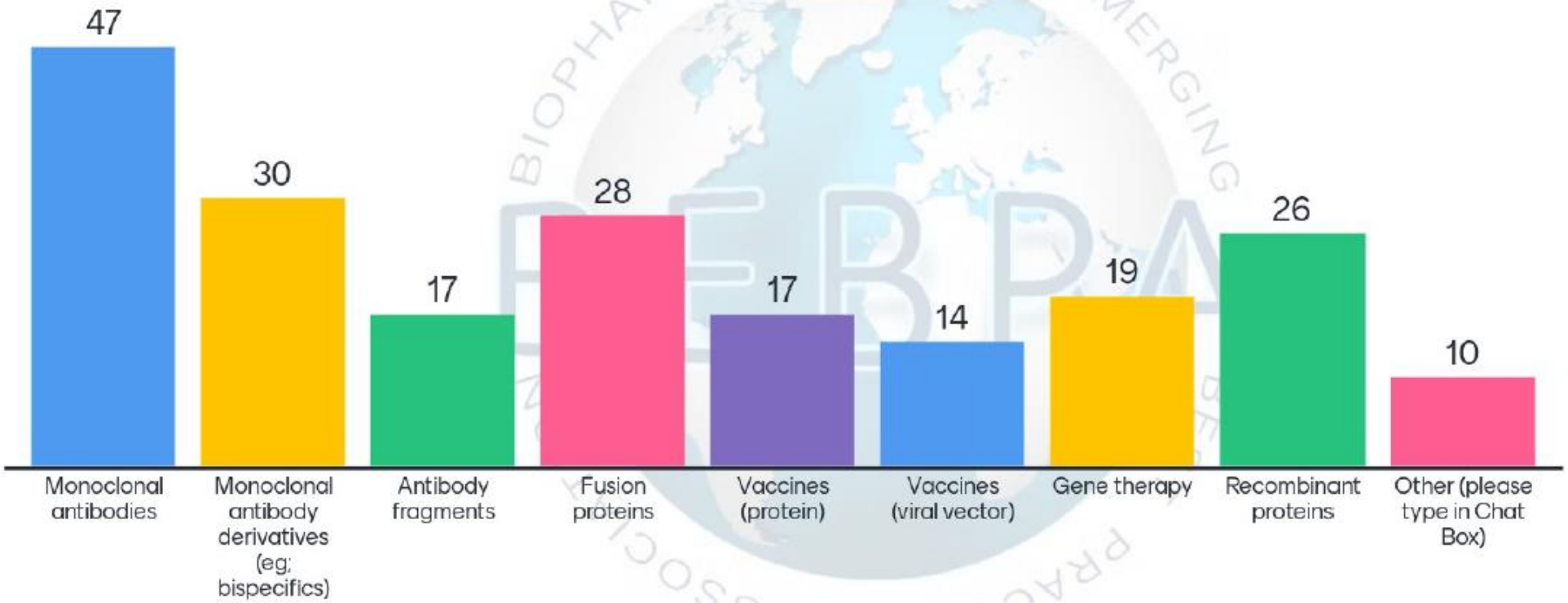
i.2 What type of organization do you work for?



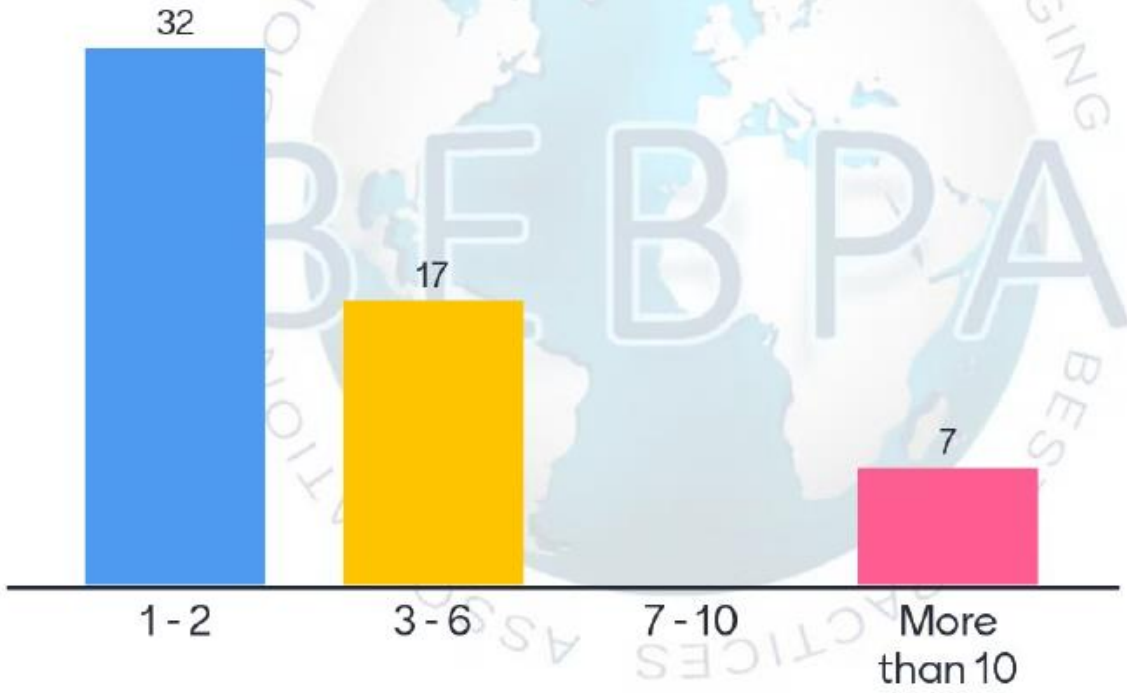
i.3 What part of the organization do your work for?



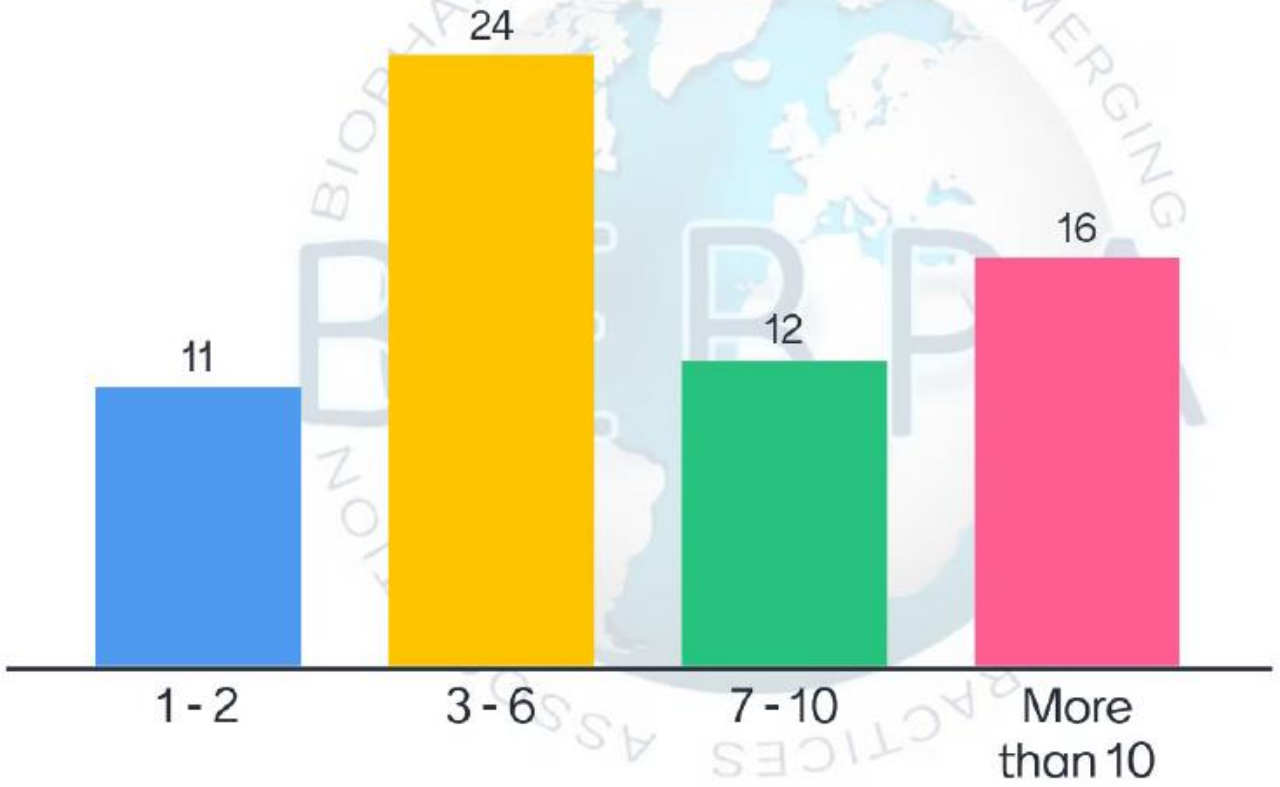
i.4 What product modalities do you work to develop?



i.5 How many products that you have worked on are affected by HCP-related setbacks?



i.6 How many years have you worked with HCP assays?



i.7 Where are you from (what city/state/country)?

67 responses

16 67

DAY 1 Audience Surveys

Introduction: Kevin Van Cott, Associate Professor, Univ of Nebraska, Lincoln

Session 1A: Regulatory Perspective

Session Chair: Alexey Khrenov, Branch Chief, CBER, FDA

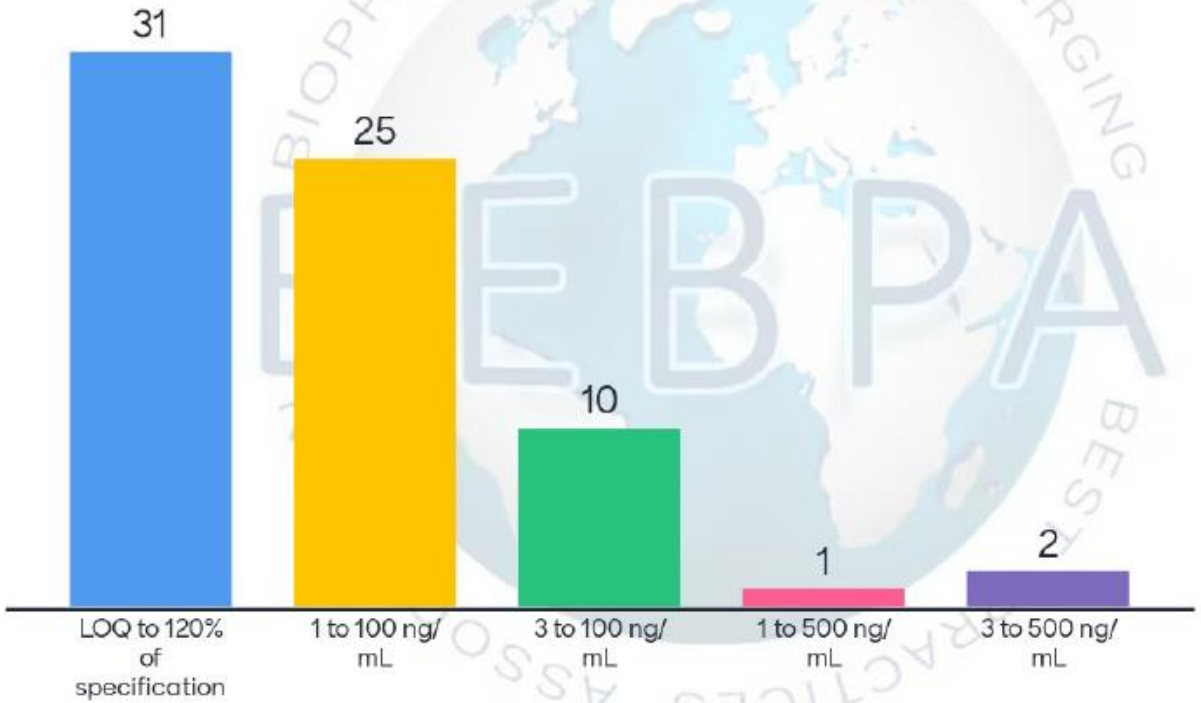
Session 1B: ELISA Development

Session Chair: Catherine Shoemaker-Ramsey, Associate Director, Biogen

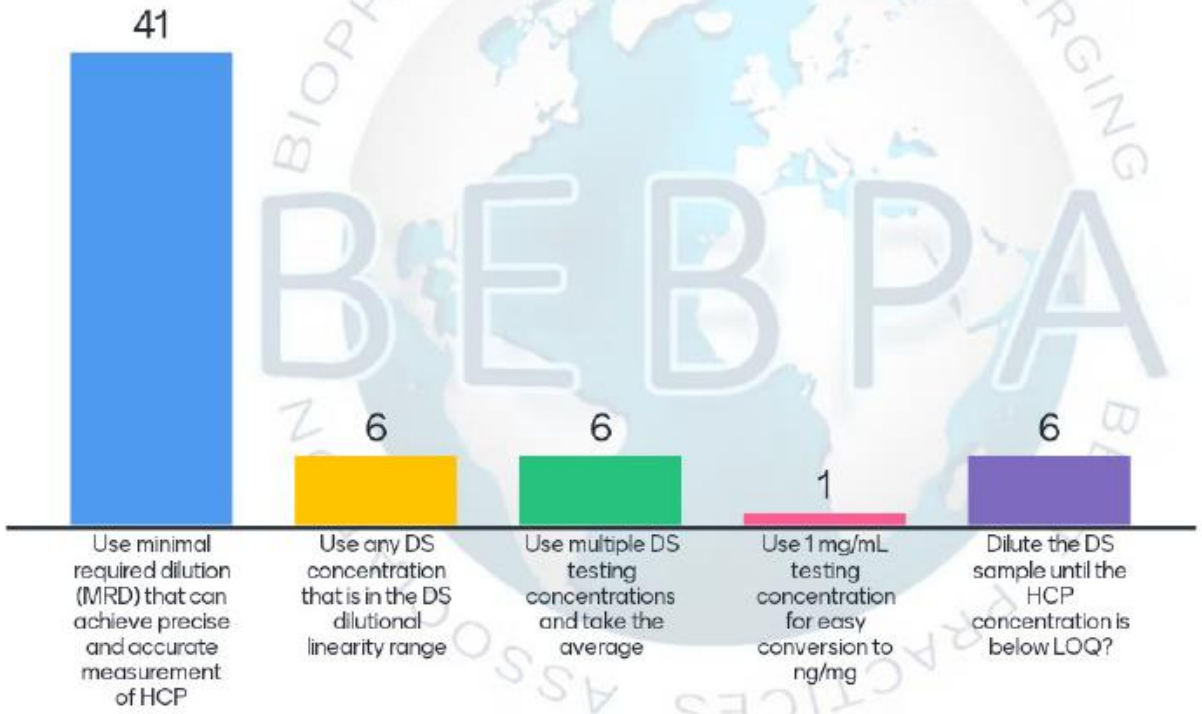
Session 1C: HCP and Product Stability

Session Chair: Ned Mozier, Retired, Pfizer

1a.1 What would be a reasonable reportable range of HCP ELISA assay according to ICH Q2(R2) guidelines?

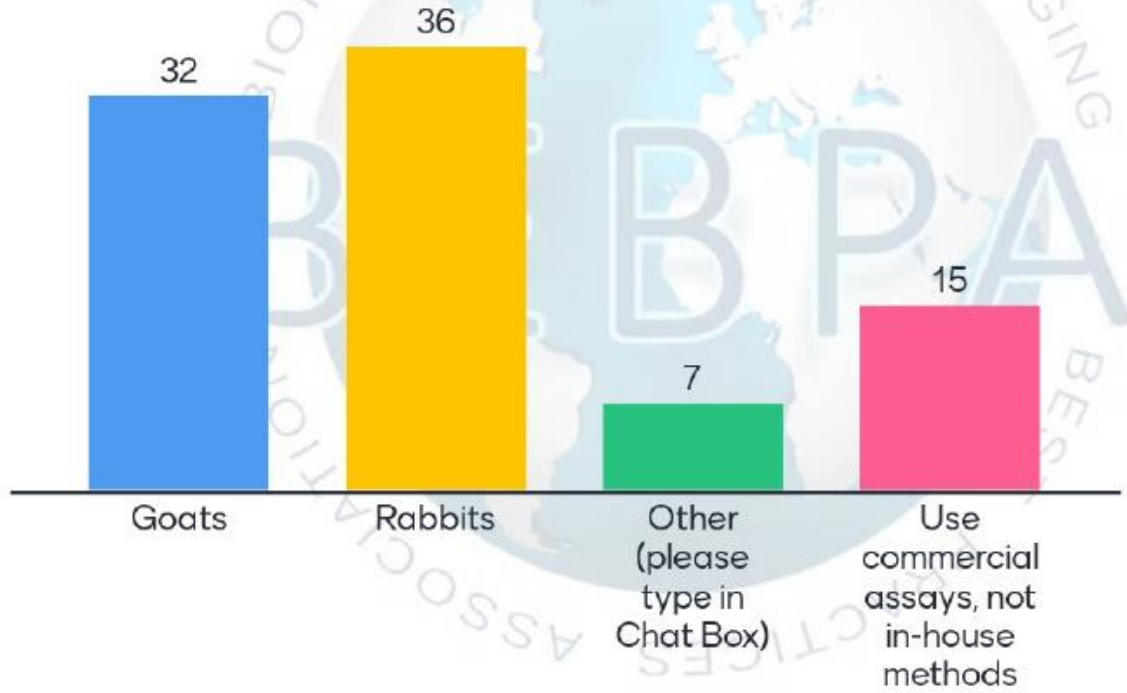


1a.2 How do you determine the appropriate drug substance (DS) testing concentration for your HCP ELISA assay during development?

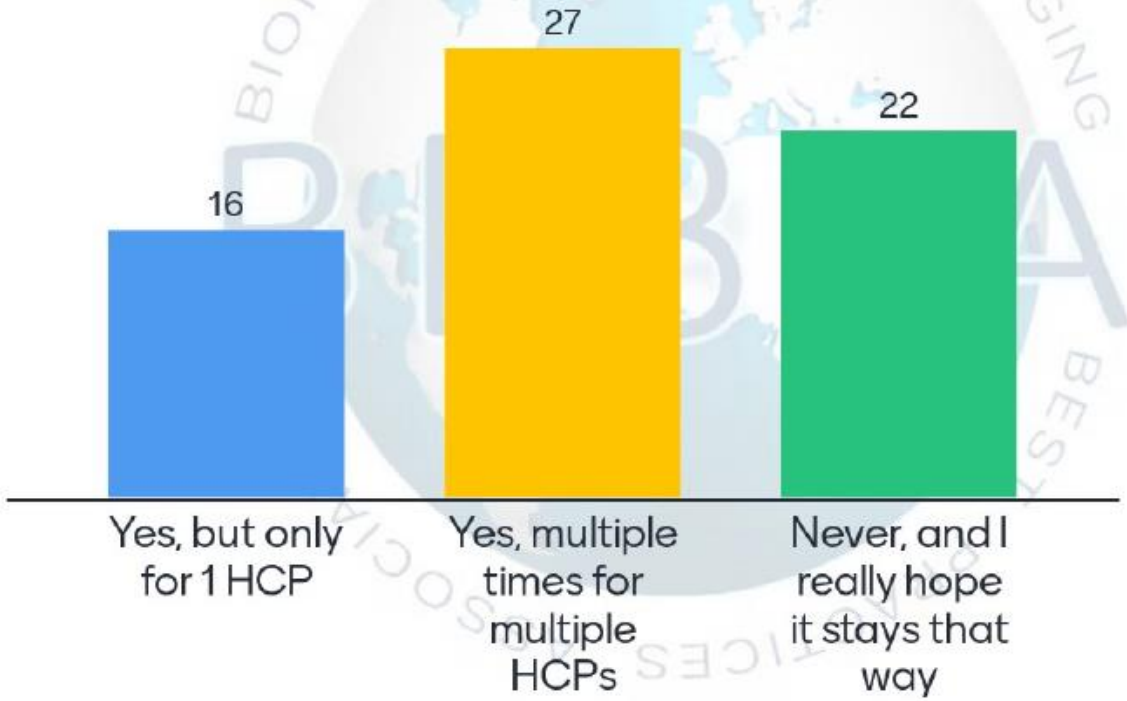


5 60

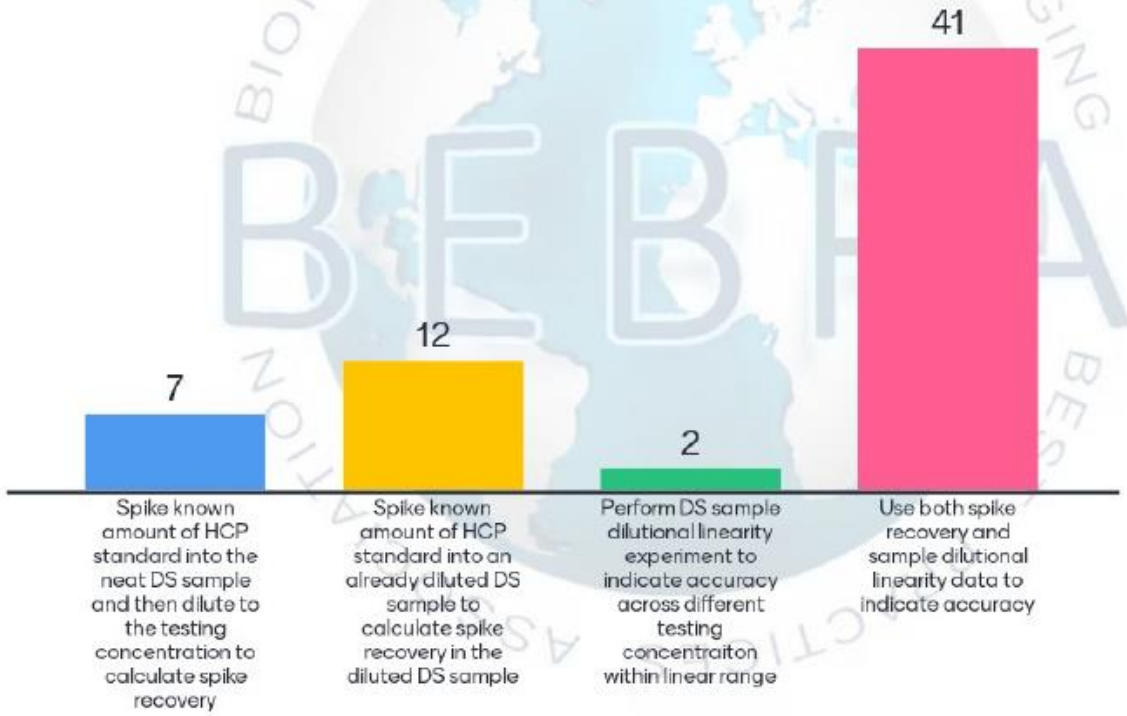
1b.1 What animal species does your company use to generate antibodies for your in-house HCP assay?



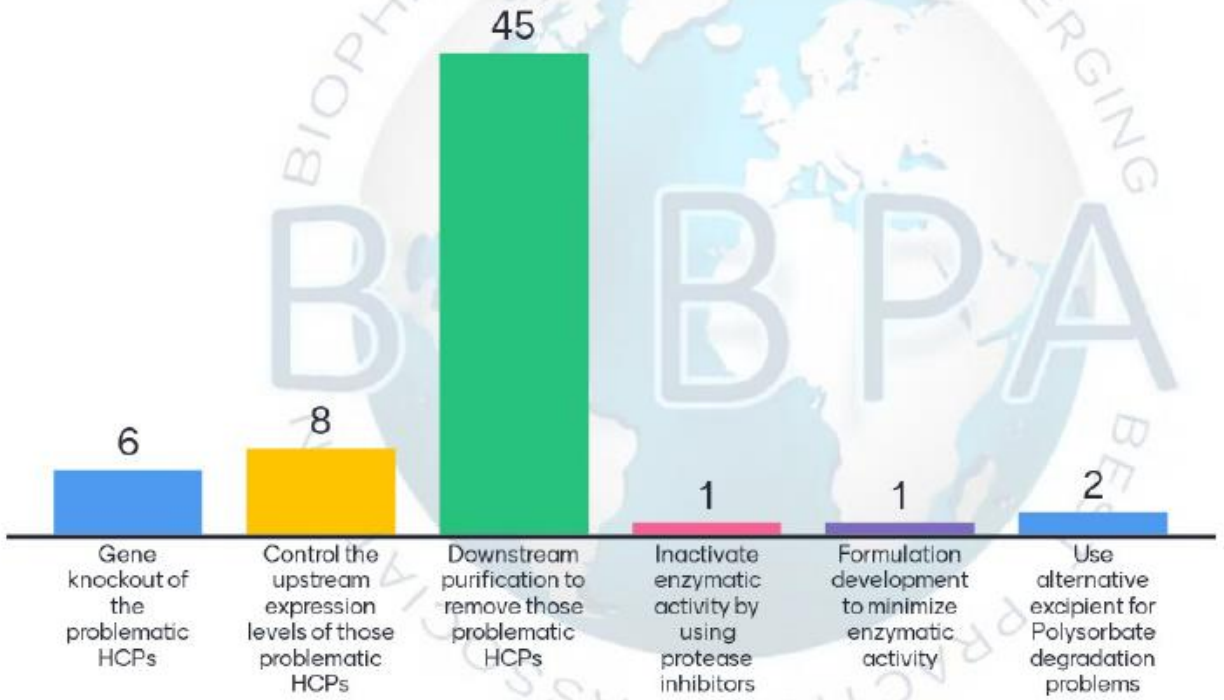
1b.2 Has your company had to develop/ use an assay for detection of a specific, high risk HCP?



1b.3 How do you demonstrate accuracy during your HCP ELISA method validation?



1c.1 From control strategy perspective, what do you think is the most effective approach to control low abundance HCPs that impact product stability?



DAY 2 Audience Surveys

Session 2A: Bioprocessing

Session Chair: : Denise Krawitz, Principal Consultant, CMC Paradigms LLC

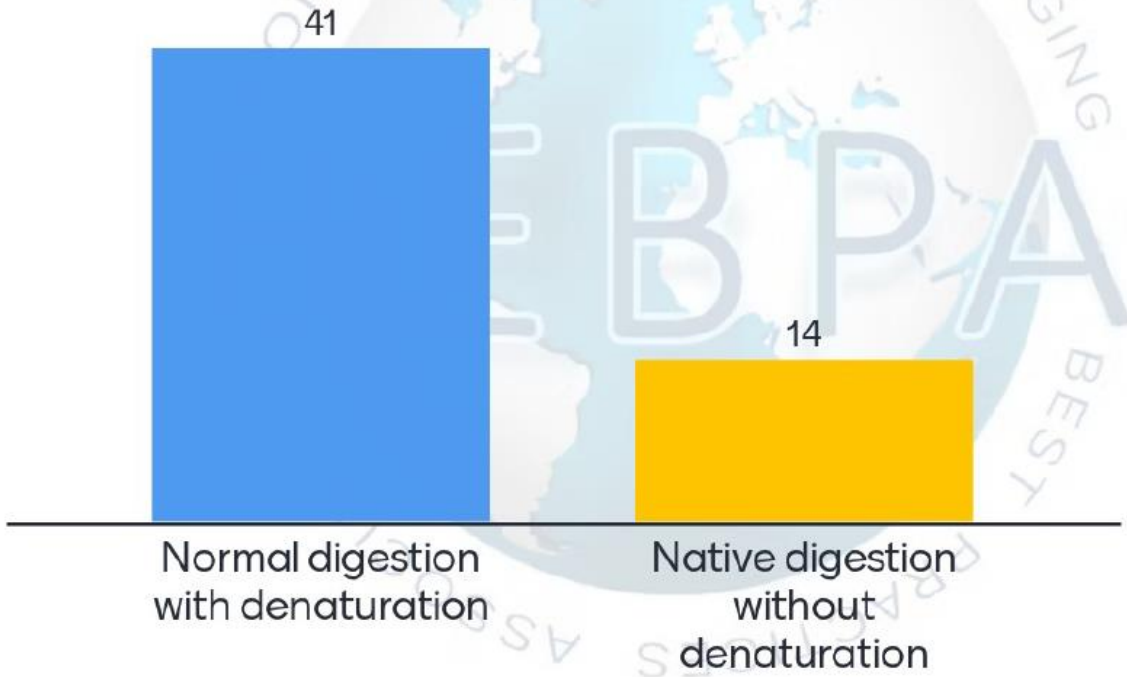
Session 2B: HCP Analysis

Session Chair: Alexey Khrenov, Branch Chief, CBER, FDA

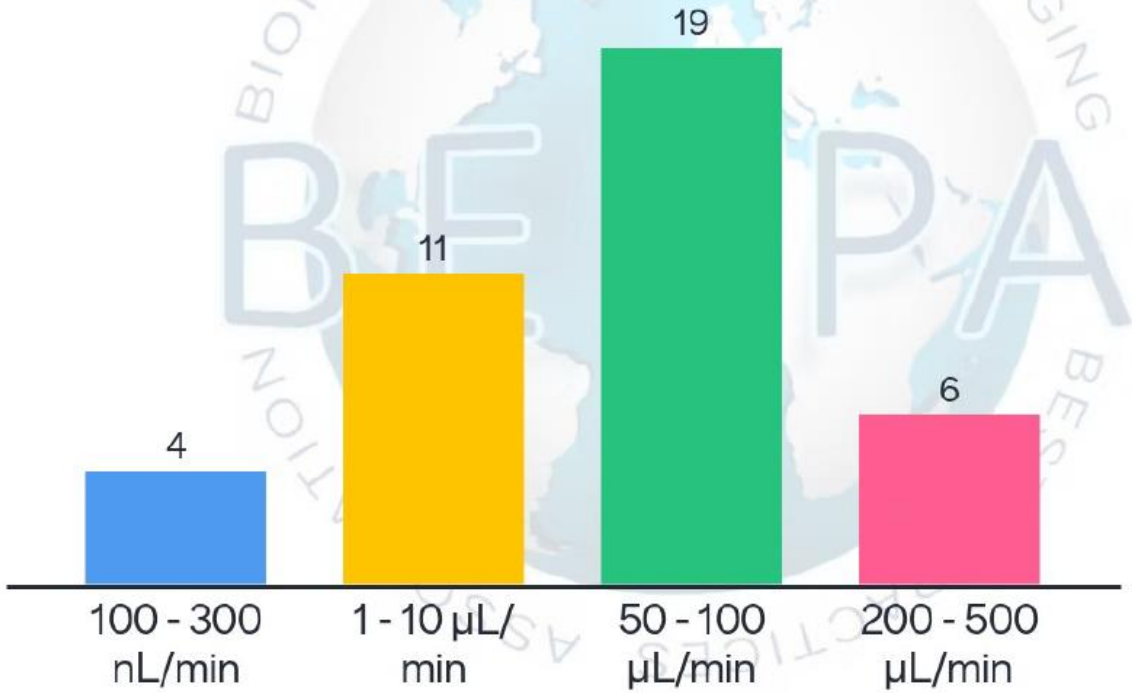
Session 2C: HCP Challenges

Session Chair: Catherine Shoemaker-Ramsey, Associate Director, Biogen

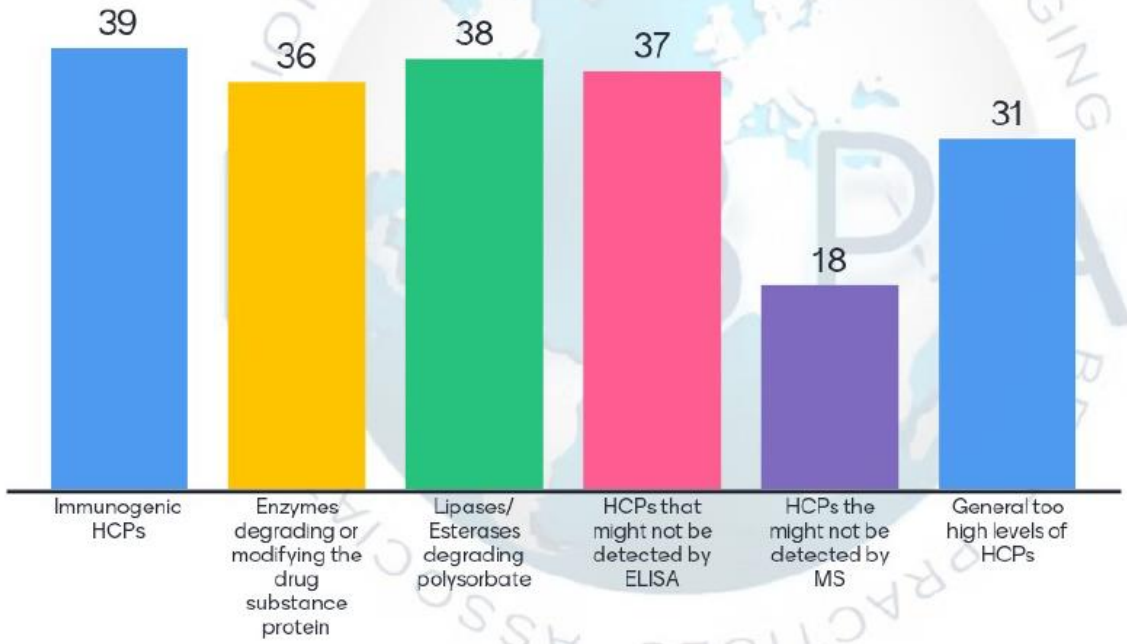
2a.1 What type of Trypsin digest condition you use for HCP analysis using LC MS approach?



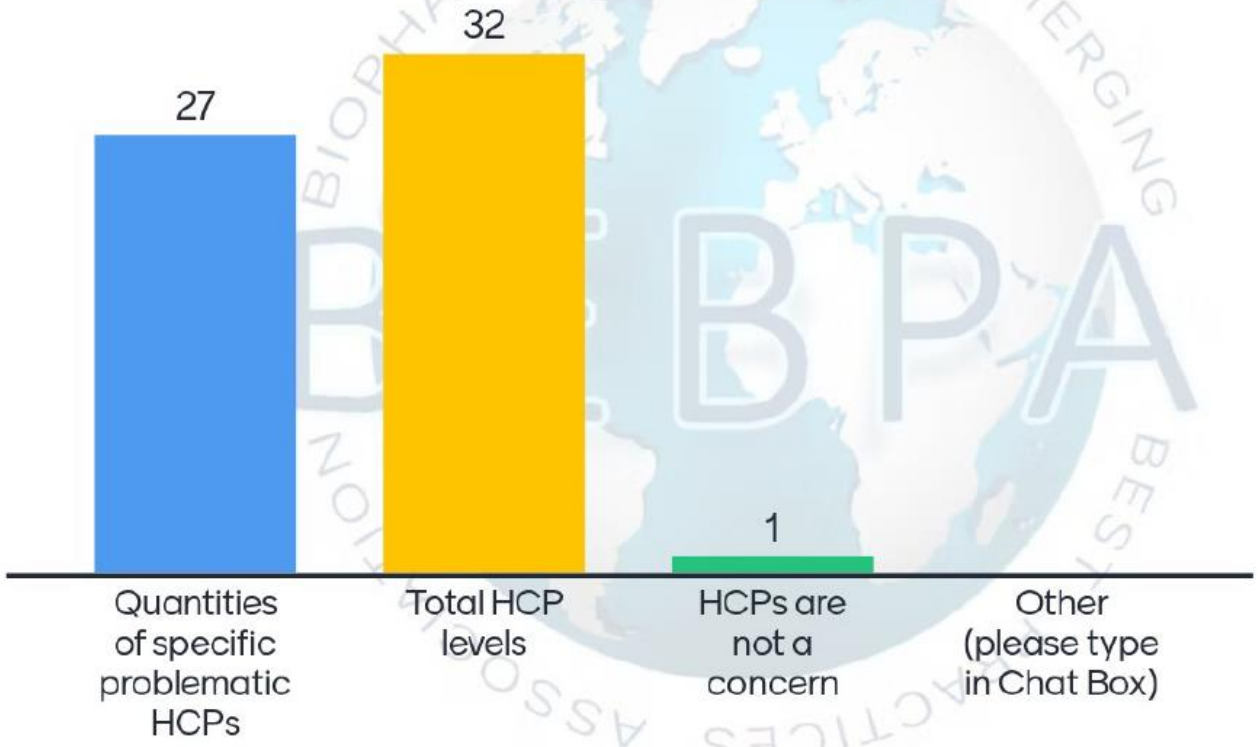
2a.2 What flow rate you use in your LC MS method for HCP analysis?



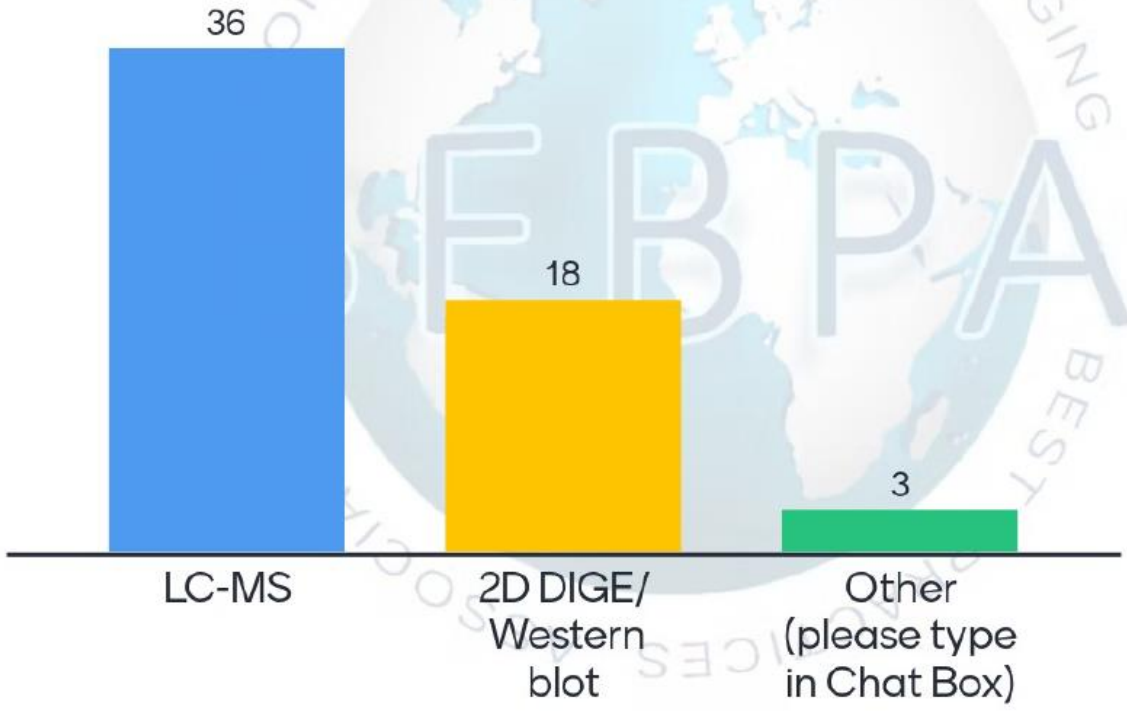
2a.3 What HCPs are typically of concern for your projects?



2a.4. What is your main HCP related concern:



2c.1 What orthoganol methods does your company use to confirm HCP levels measured by ELISA?



DAY 3 Audience Surveys

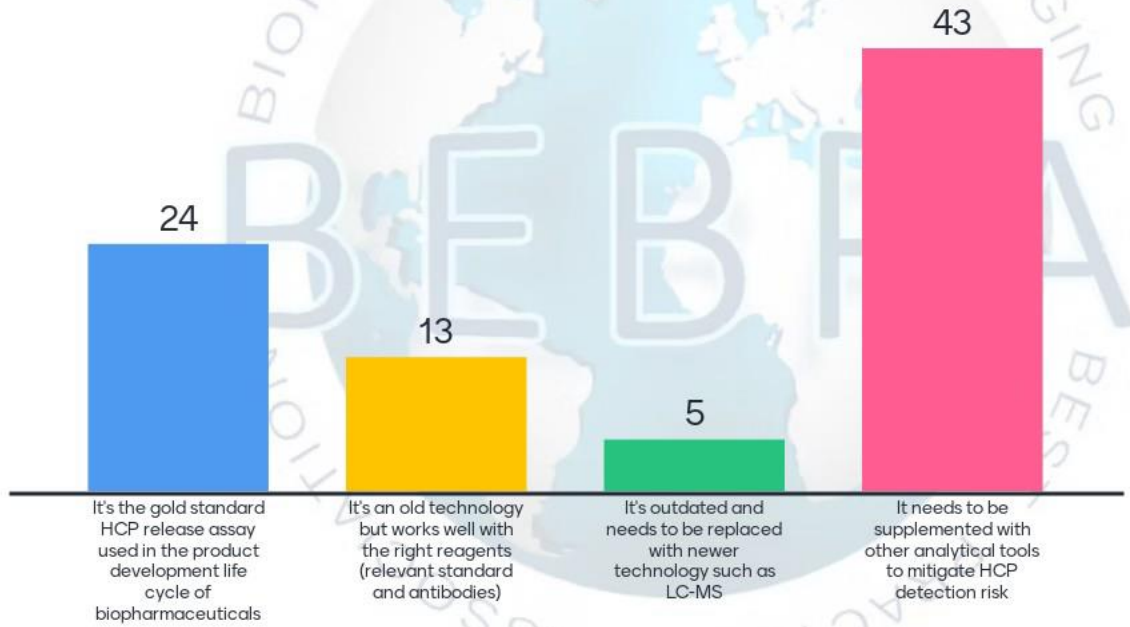
Session 3A: Mass Spectrometry

Session Chair: Ying Zhang, Director, Sarepta Therapeutics

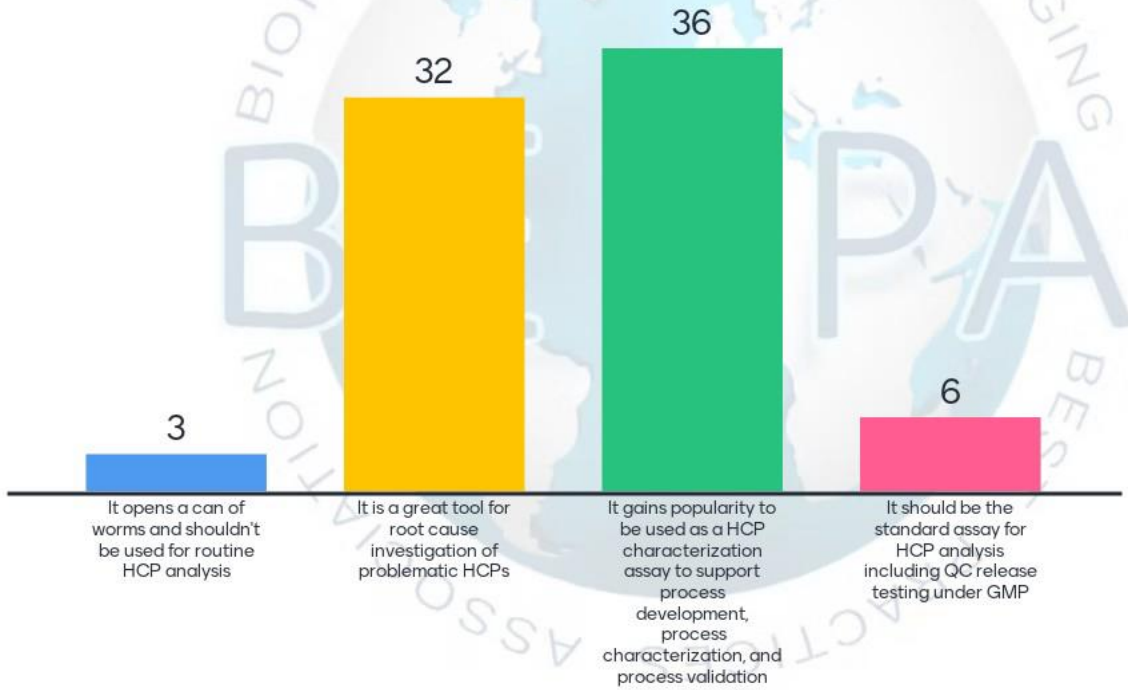
Session 3B: Regulatory Discussion

Session Chairs: Alexey Khrenov, Branch Chief, CBER, FDA
and Ying Zhang, Director, Sarepta Therapeutics

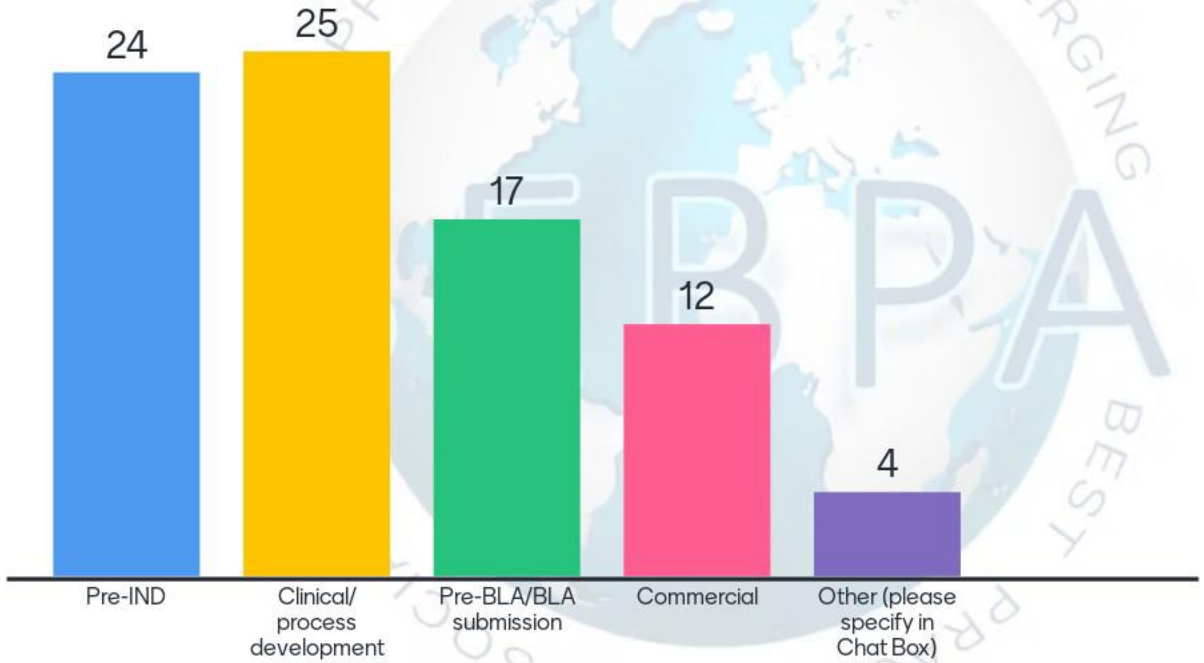
3a.1 What's your view on the ELISA method used for HCP measurement?



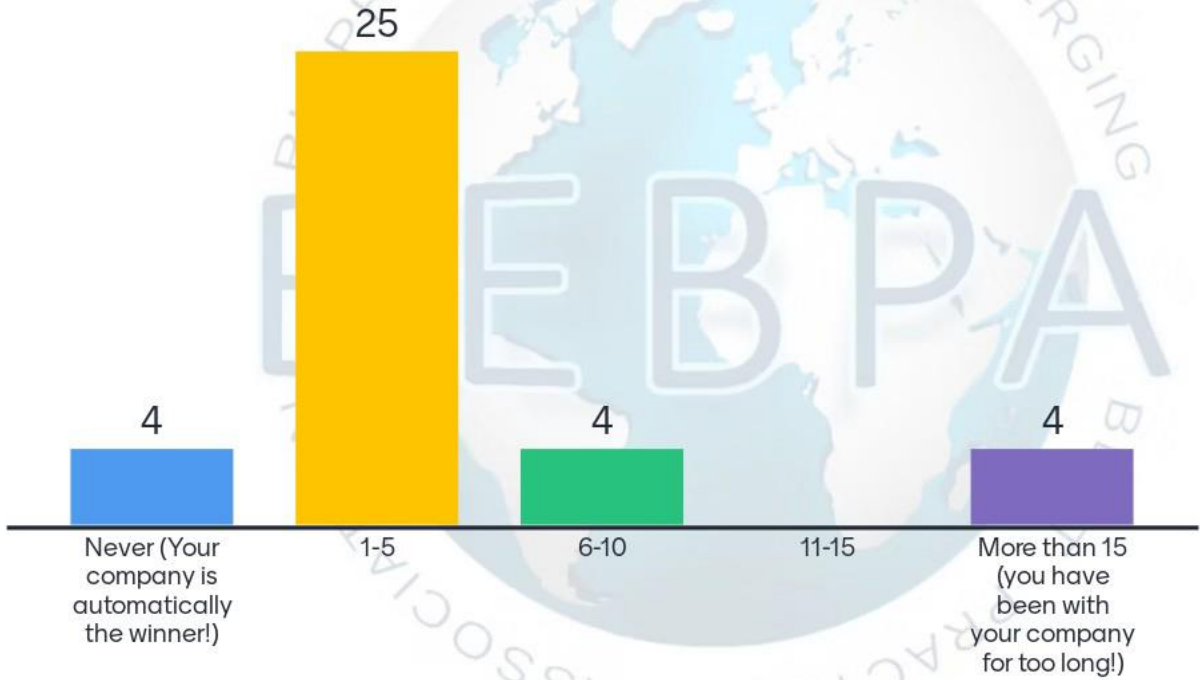
3a.2 What's your view on the LC-MS method used for HCP analysis?



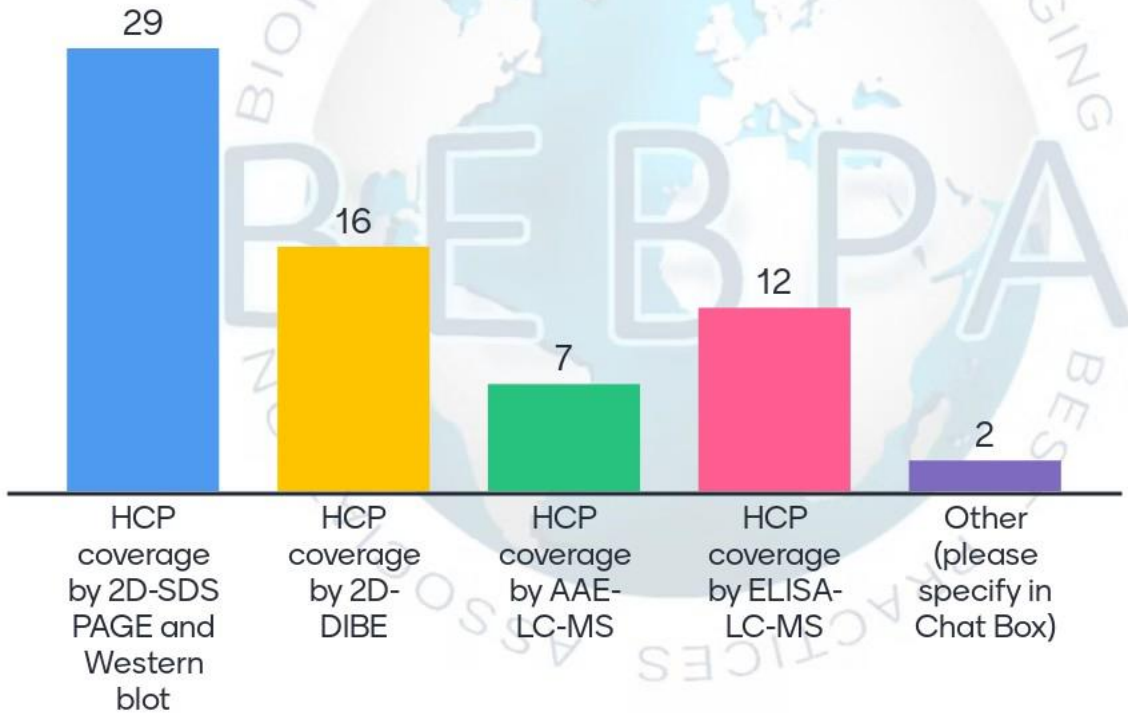
3a.3 At what phase would your company utilizes mass spectrometry for detection and quantitation of HCPs?



3b.1 How many times have your company received queries from regulatory agencies regarding HCP strategies/assay development/assay validation?



3b.2 What type of HCP coverage data do you provide in regulatory submissions (BLA/MAA)?

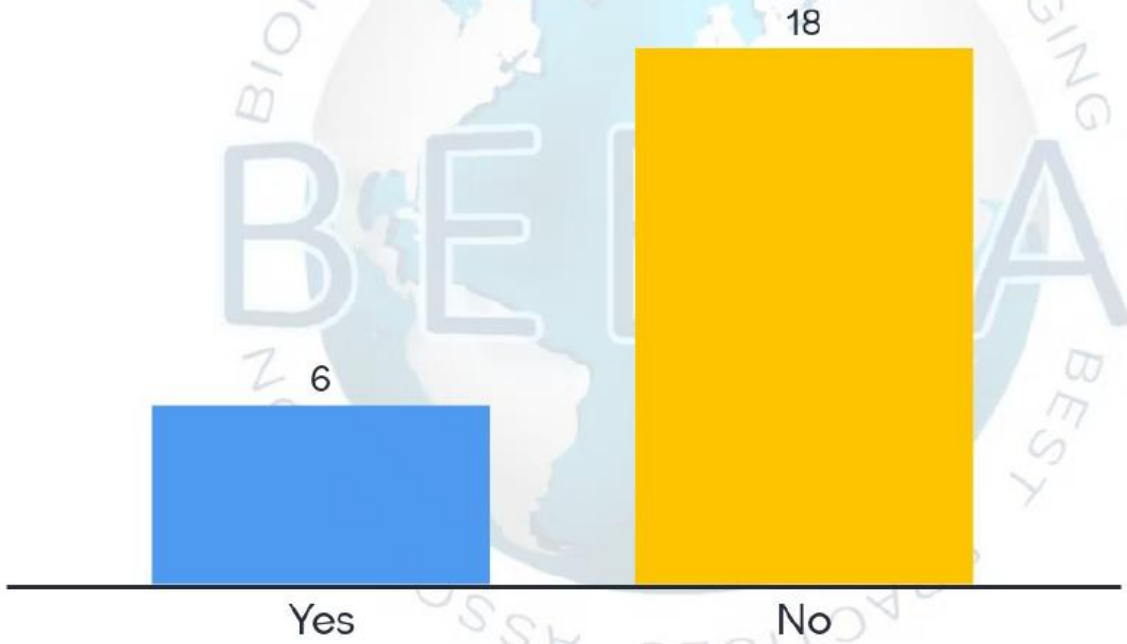


Interest Group 2 Audience Surveys

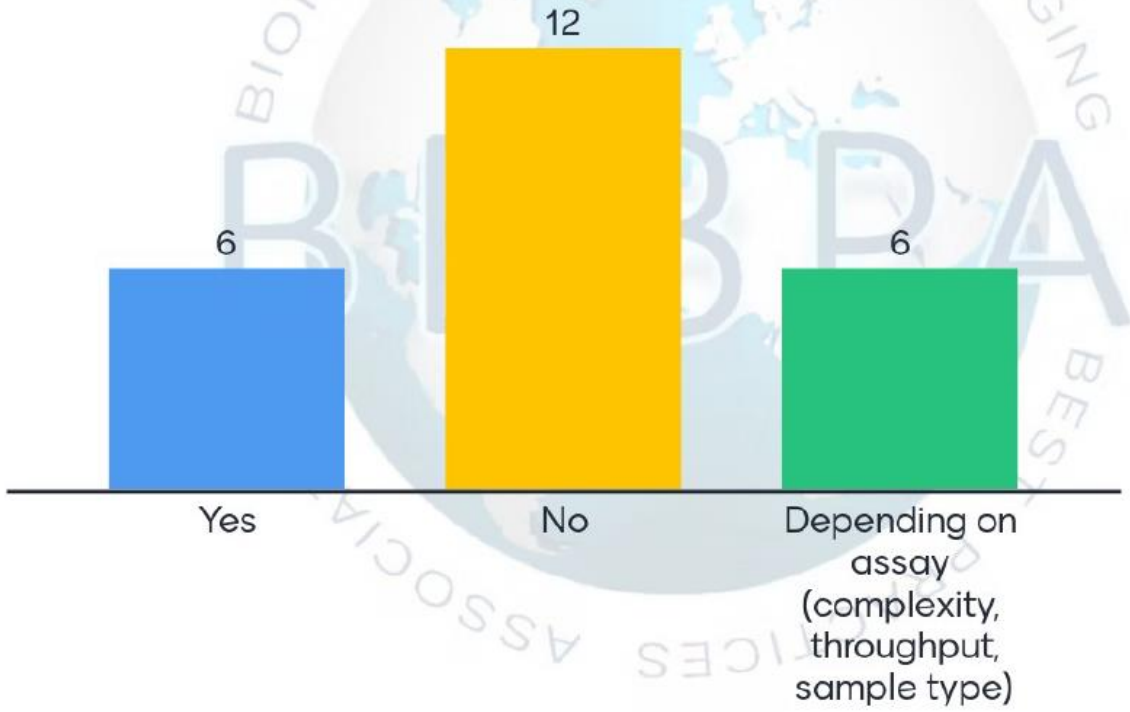
ELISA Development

Session Chair: Catherine Shoemaker-Ramsey, Associate Director, Biogen

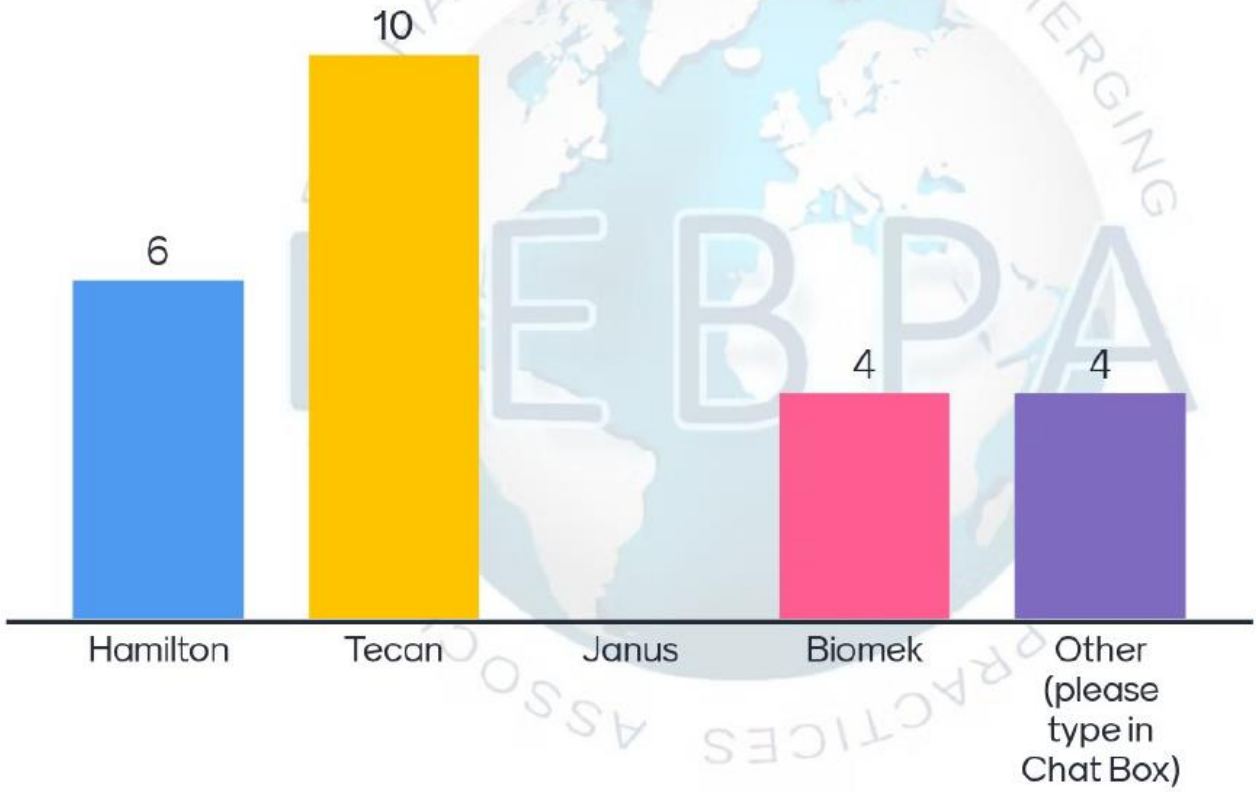
IG2.1 Do you currently use a fully automated end-to-end HCP ELISA system?



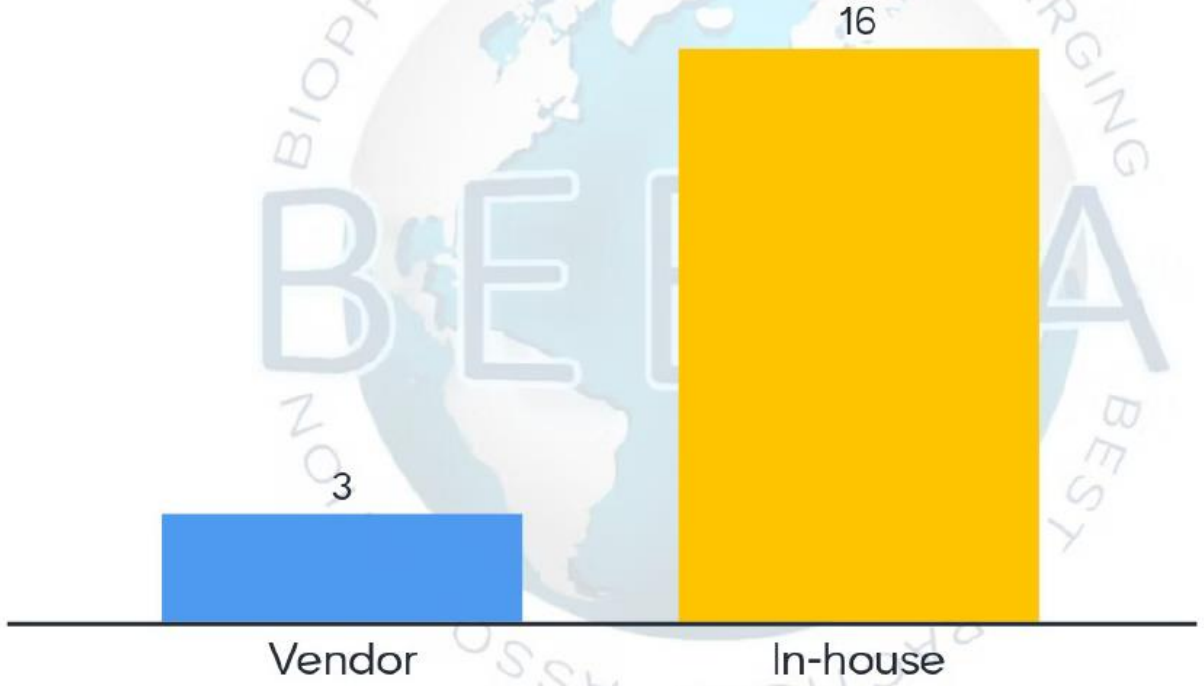
IG2.2 Are you happy with your current ELISA automation system?



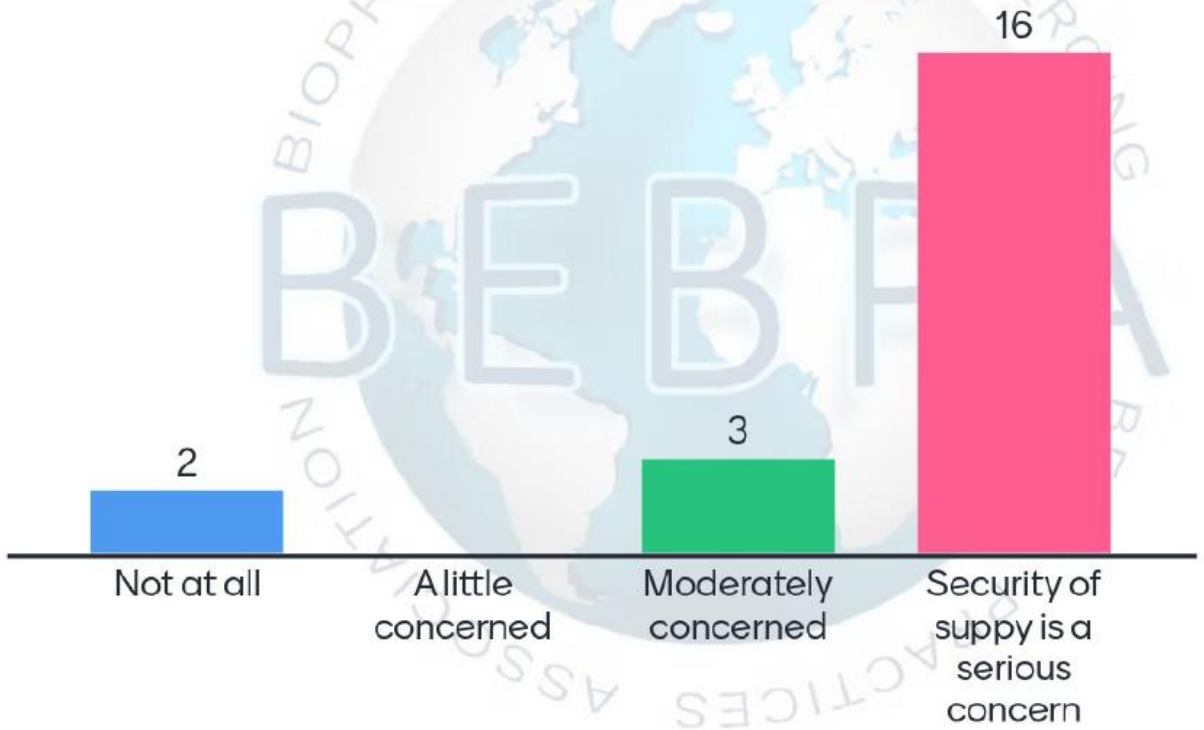
IG2.3 Which liquid handler(s) are you using?



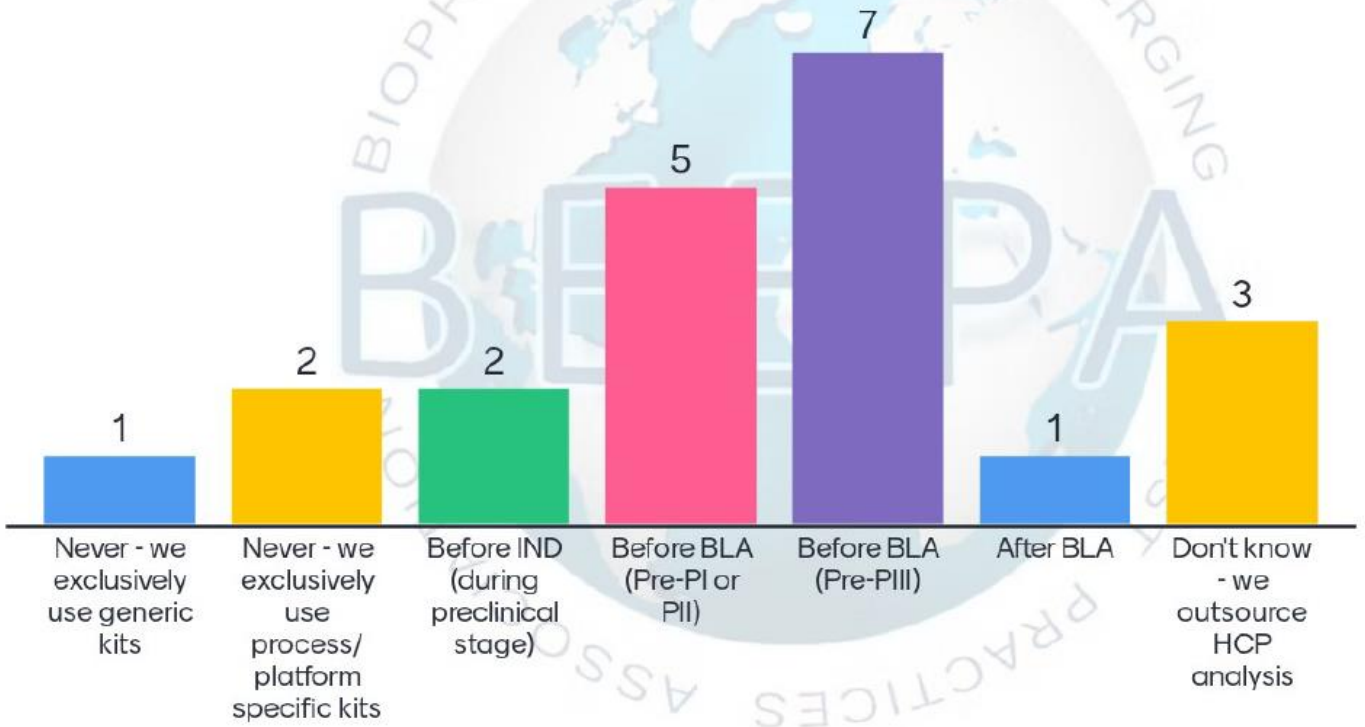
IG2.4 Does your vendor provide the scripts for you, or do you create your own scripts and workflows?



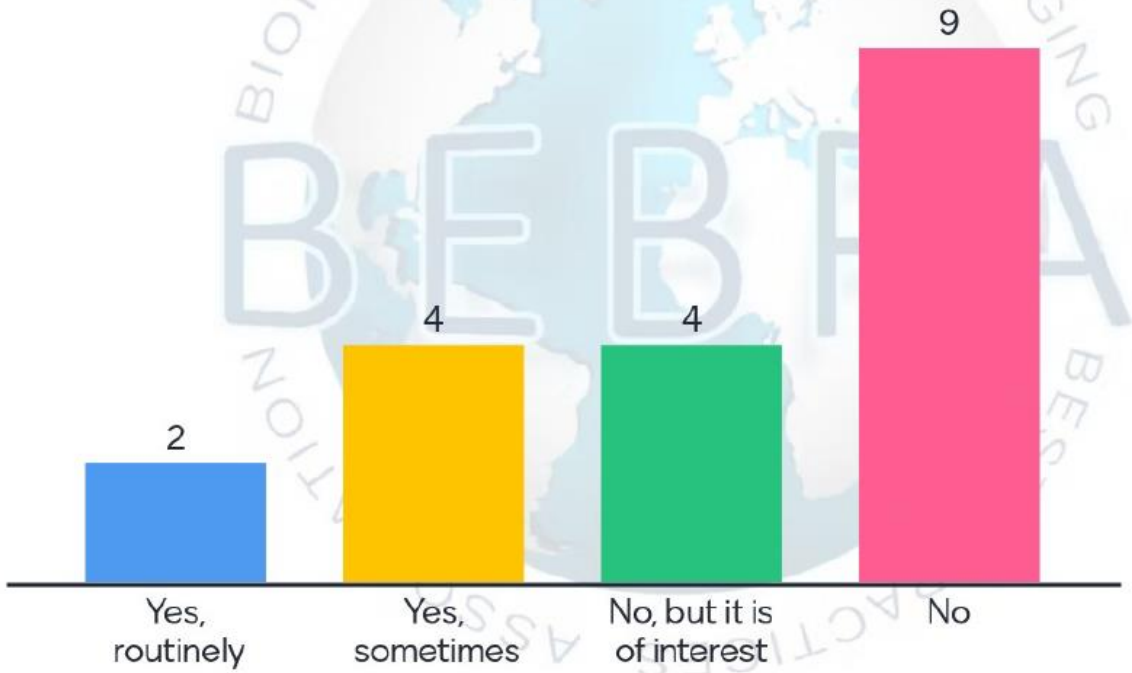
IG2.5 How concerned is your organization about the long-term (10+ years) security of supply of commercial ELISA critical reagents (Ab & prtn stnd)



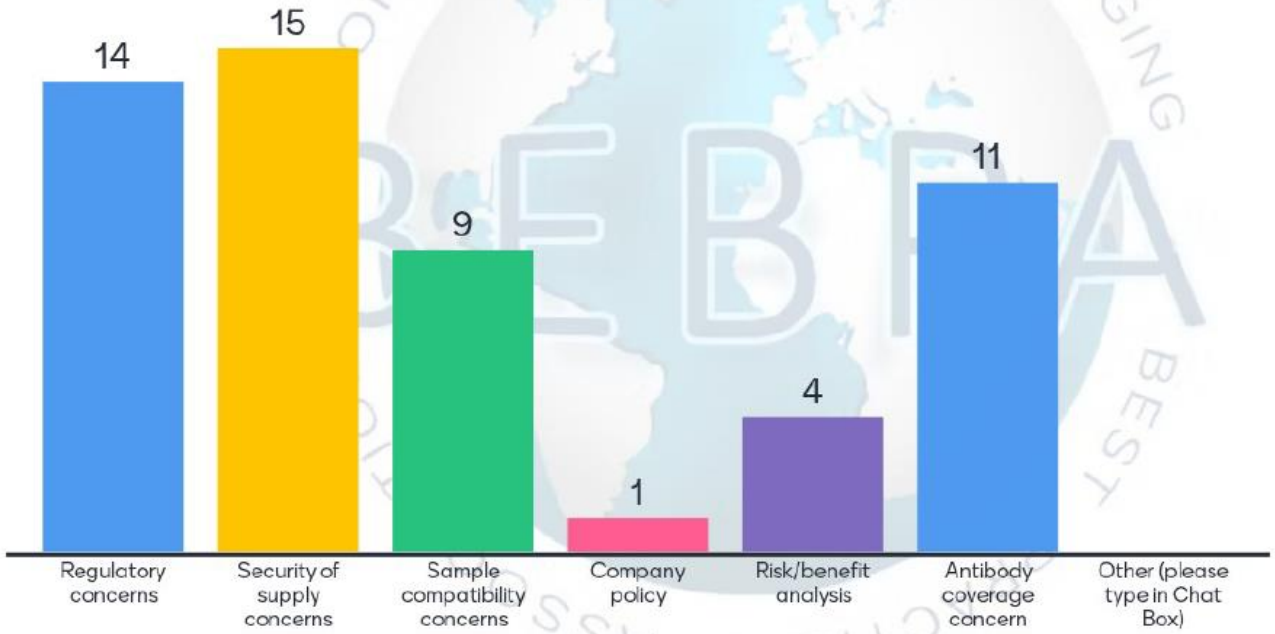
IG2.6 At what stage in process development does your organization typically transition to a process/platform specific assay.



IG2.7 Do you currently supplement your commercial HCP ELISA with a process-matched calibrator



IG2.8 What is preventing you from using a commercial HCP ELISA for production?

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Thank you!!