

# 11th Annual Host Cell Protein Conference

22-24 May 2023

Dubrovnik, Croatia

Audience Surveys



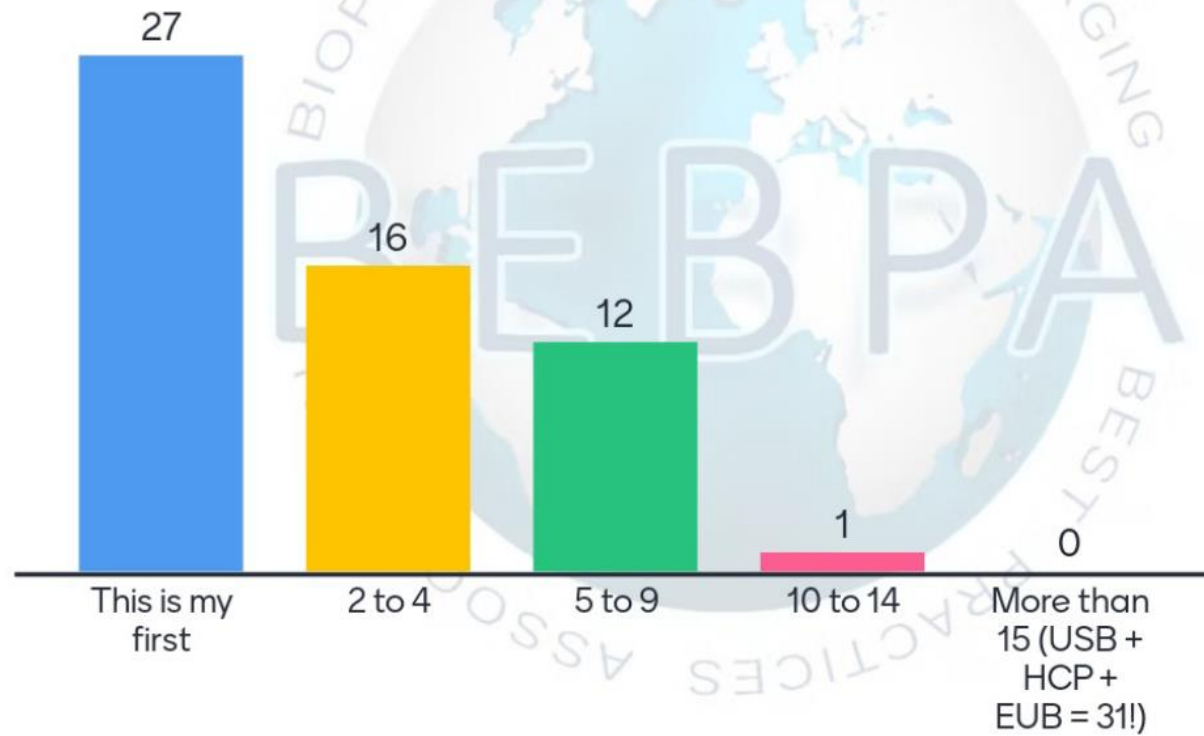
# Welcome Back & Introduction

Denise Krawitz, BEBPA Board & Scientific Committee

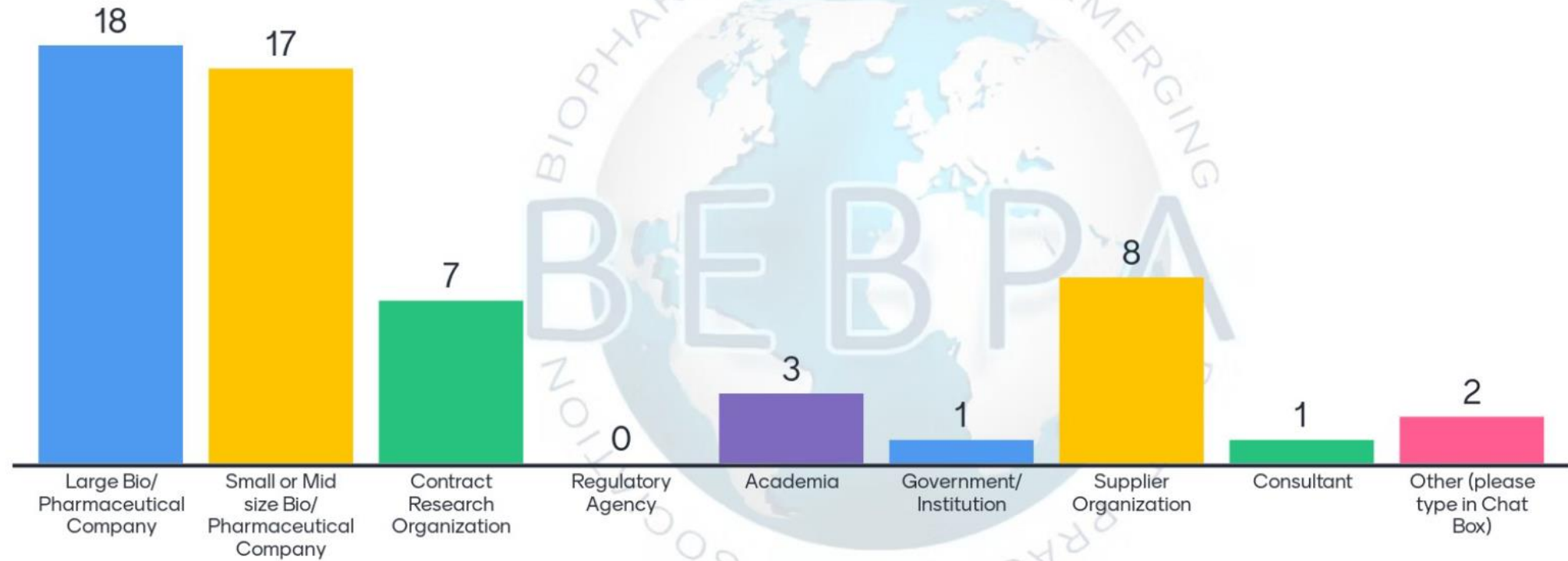
Introduction Audience Survey



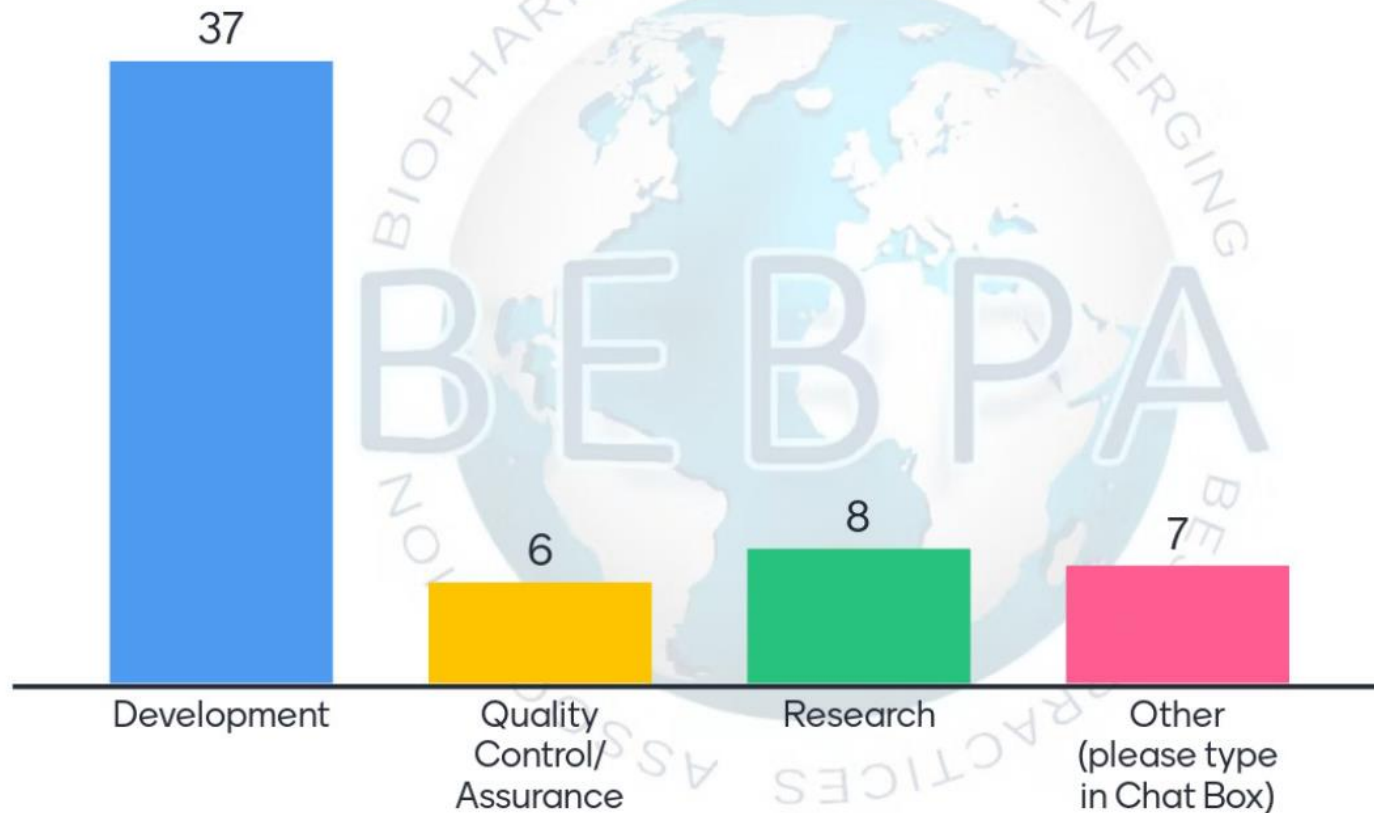
# i.1 How many BEBPA Conferences have you attended?



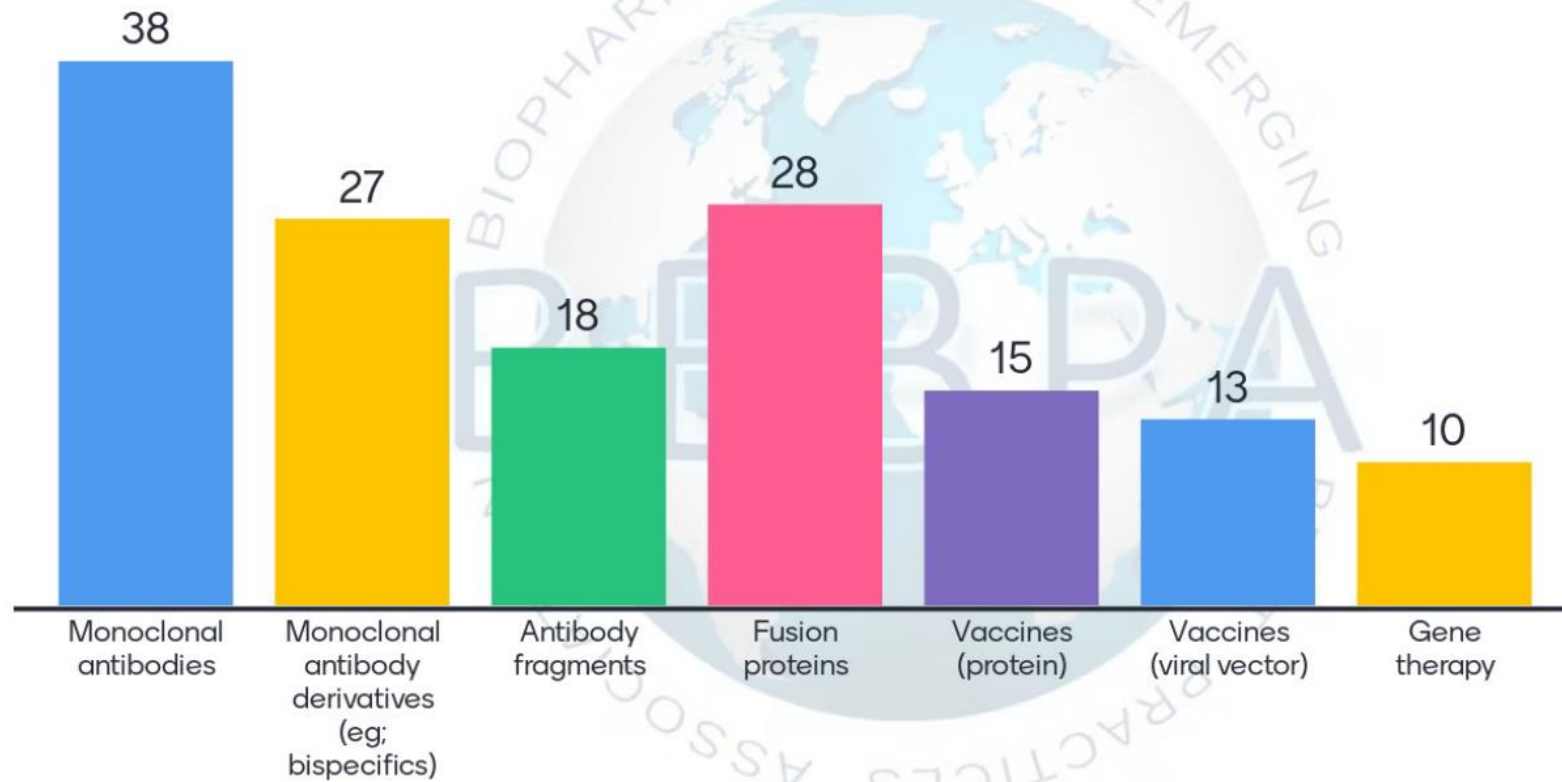
# i.2 What type of organization do you work for?



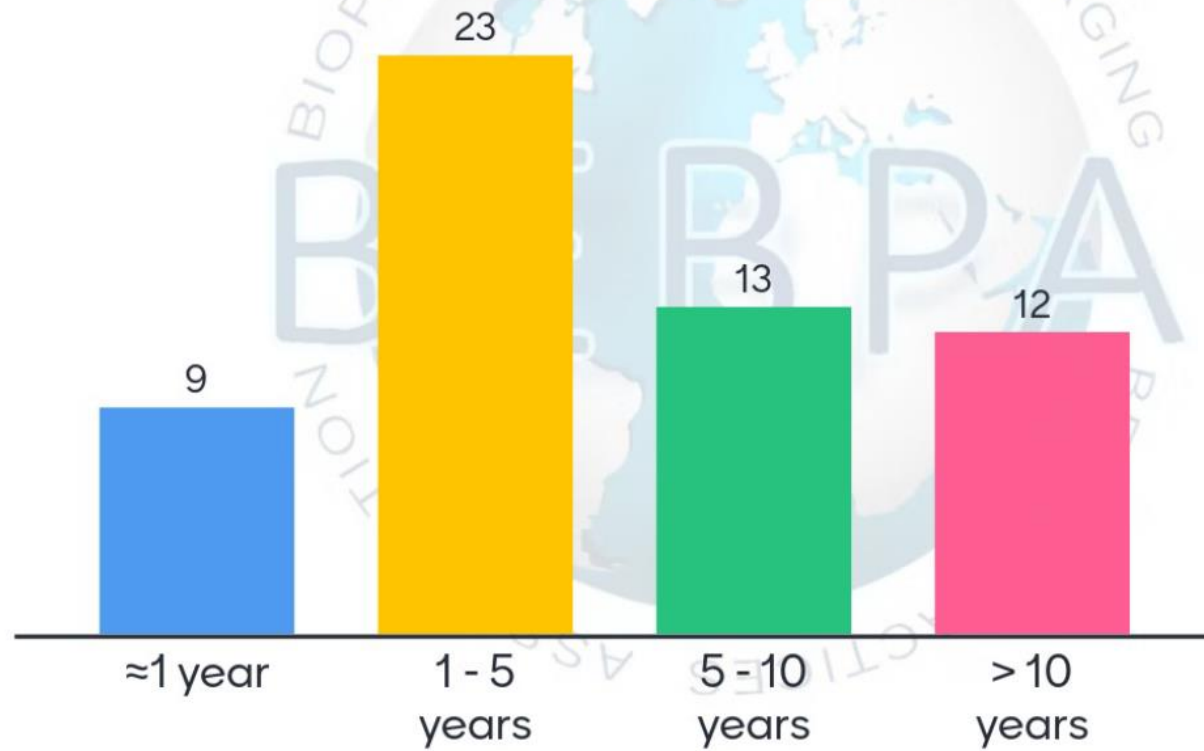
# i.3 What part of the organization do your work for?



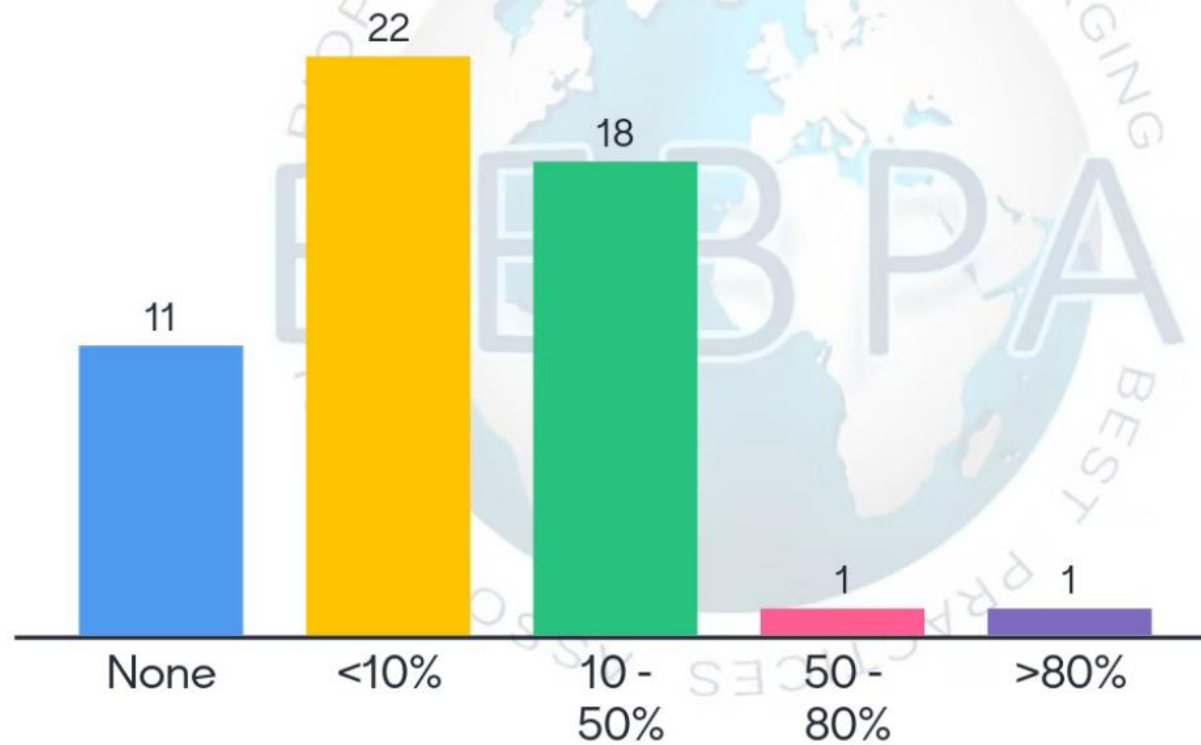
# i.4 What product modalities do you work to develop?



# i.5 How many years have you worked with HCP assays?

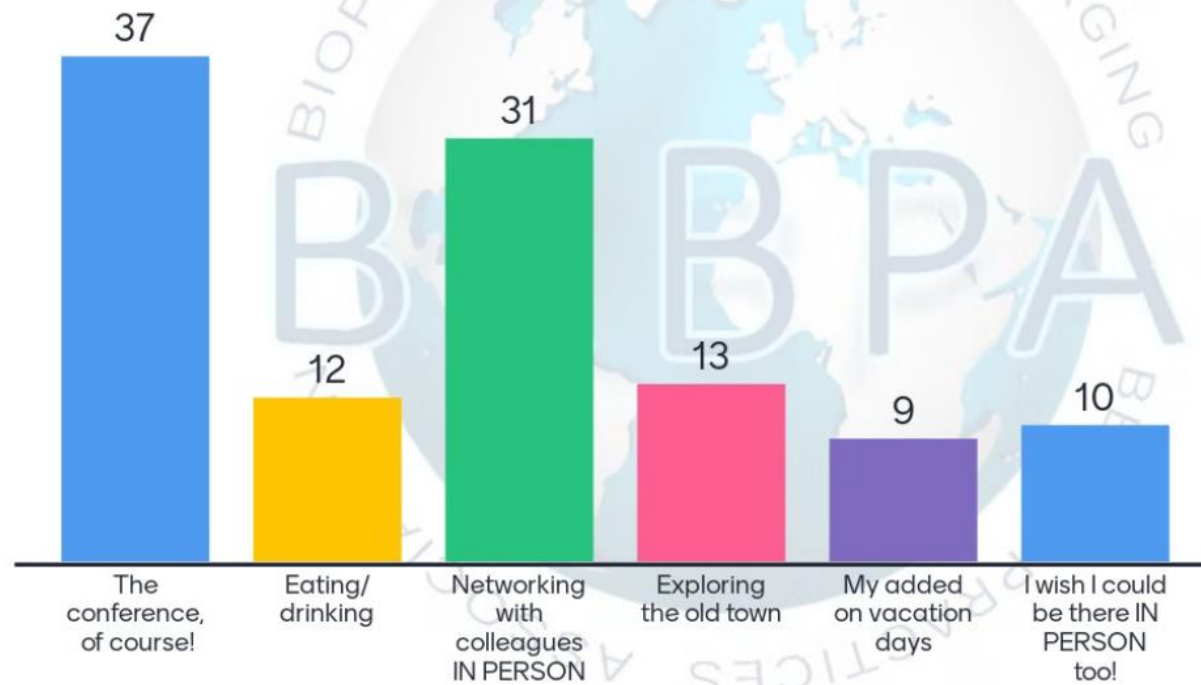


# i.6 How many products that you have worked on are affected by HCP-related setbacks?





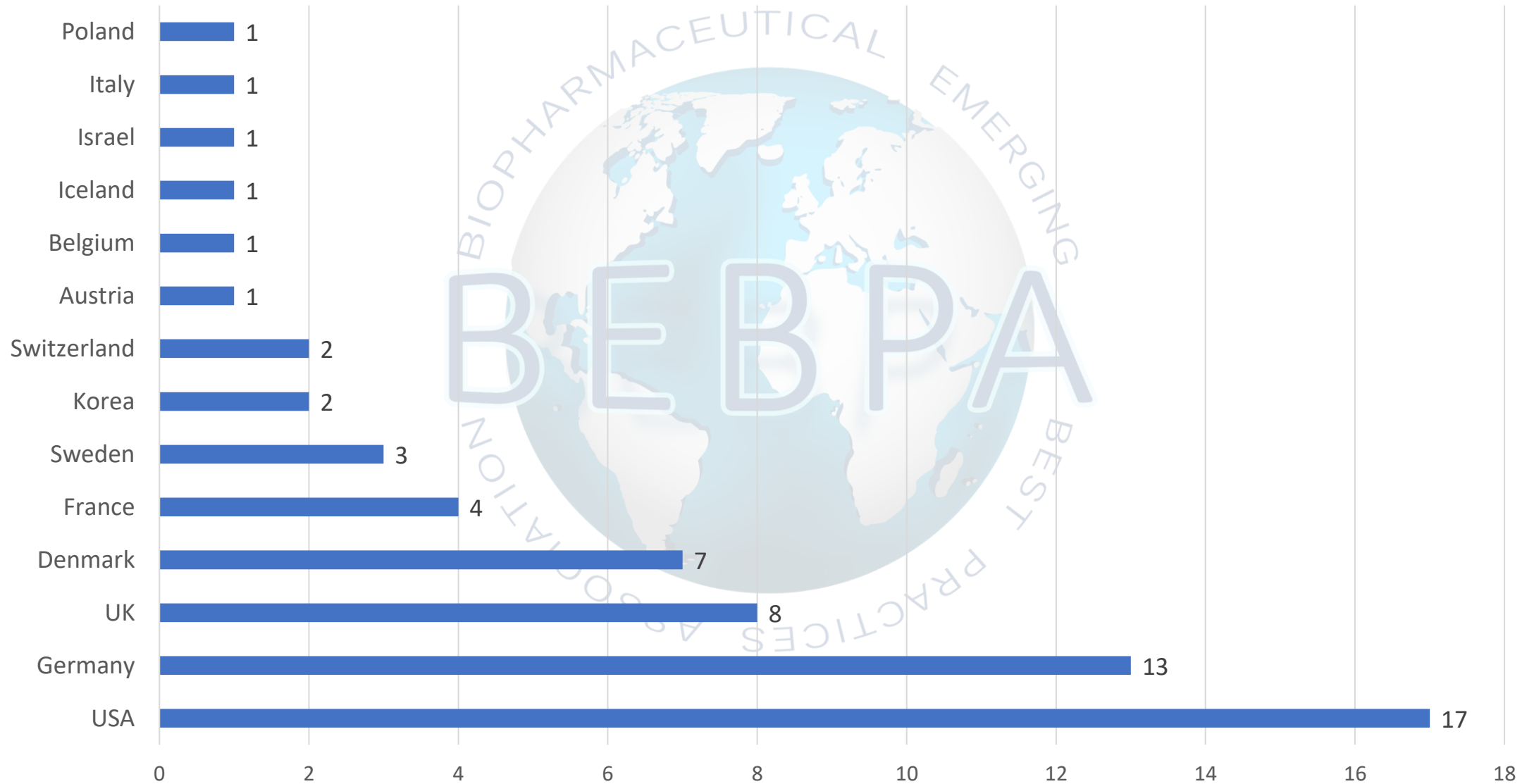
# i.7 What are you most looking forward to in Dubrovnik?





## i.8 Where are you from (what country)?

(62 respondents)

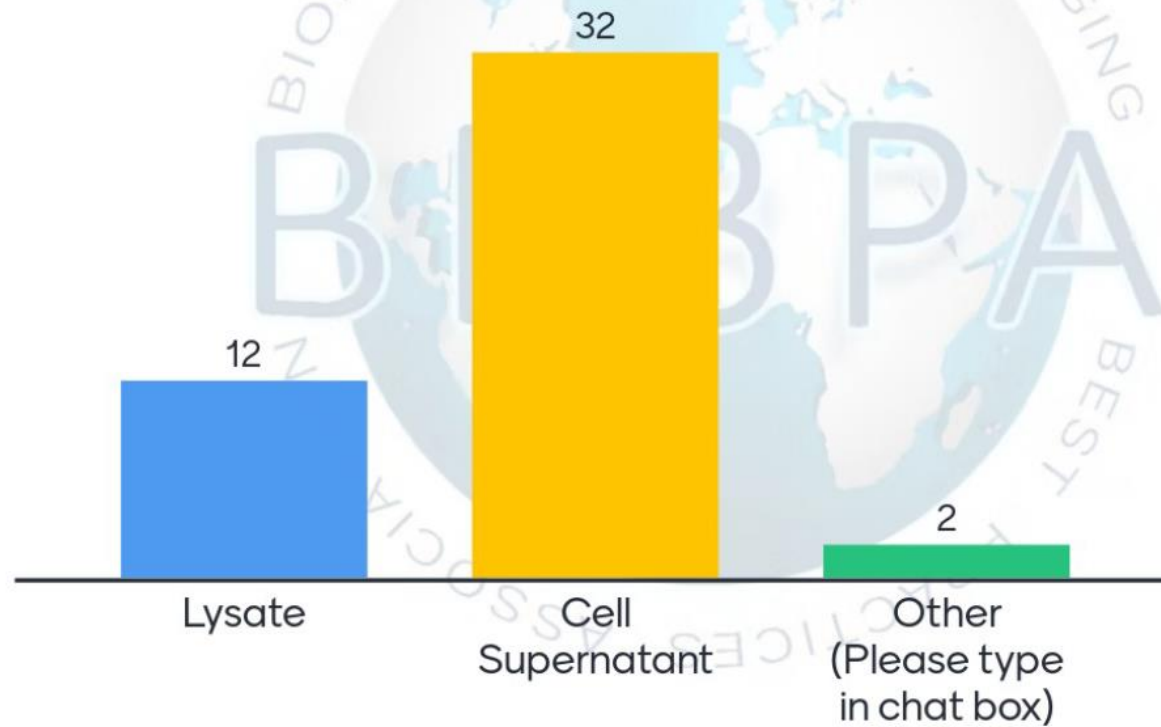


# Session 1: HCP Profiling During Process Development

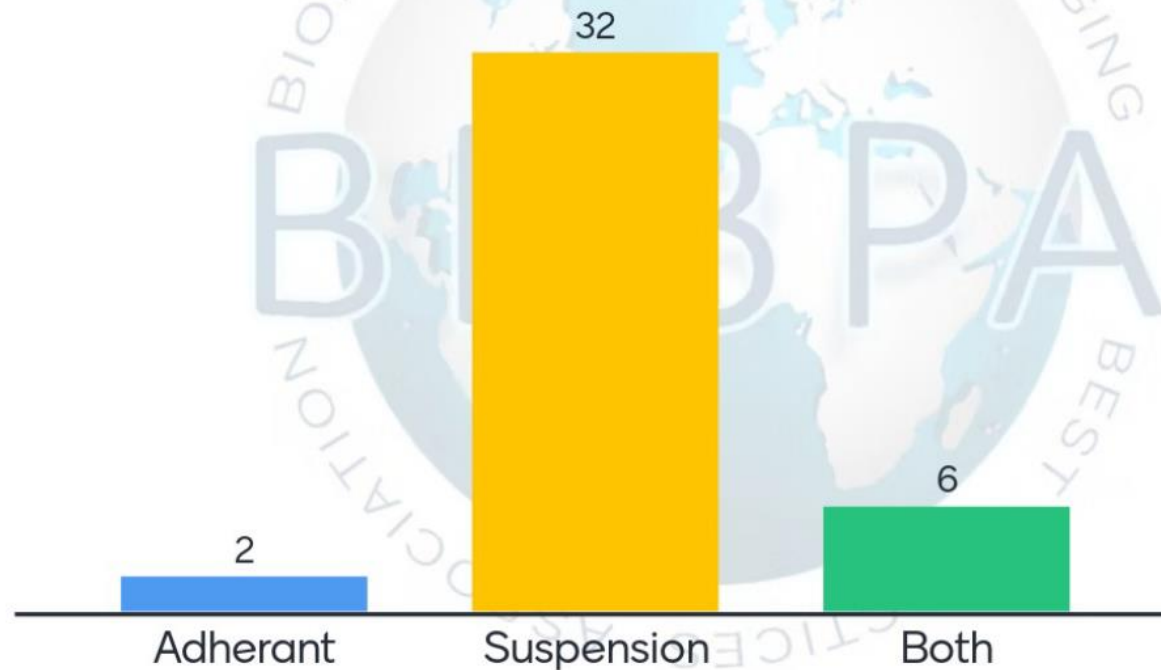
Session Chair: Denise Krawitz, Principal Consultant, CMC Paradigms LLC

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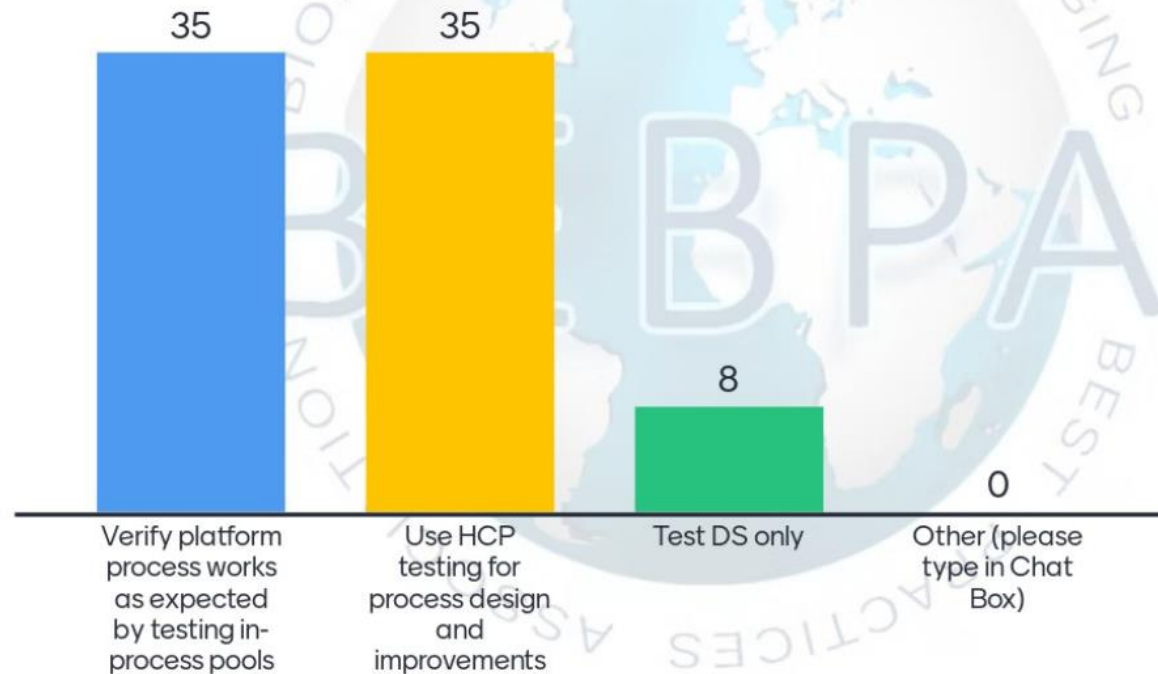
# 1.1 Does your bioprocess workflow utilize cell lysate or cell supernatant material?



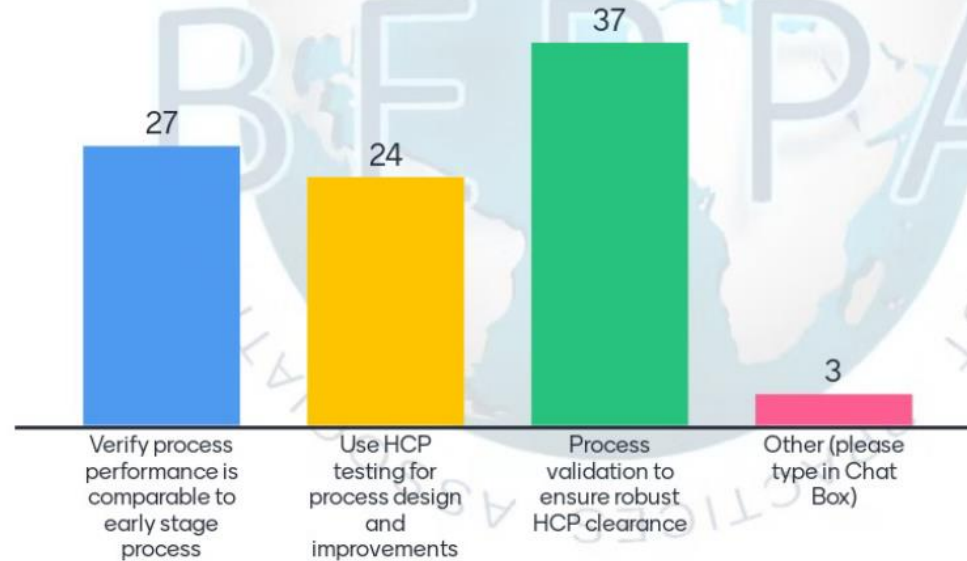
# 1.2 Do you utilize adherant or suspension mammalian cells as a host cell platform?



# 1.3 How do you use HCP testing in early-stage development (Phase 1/2)?

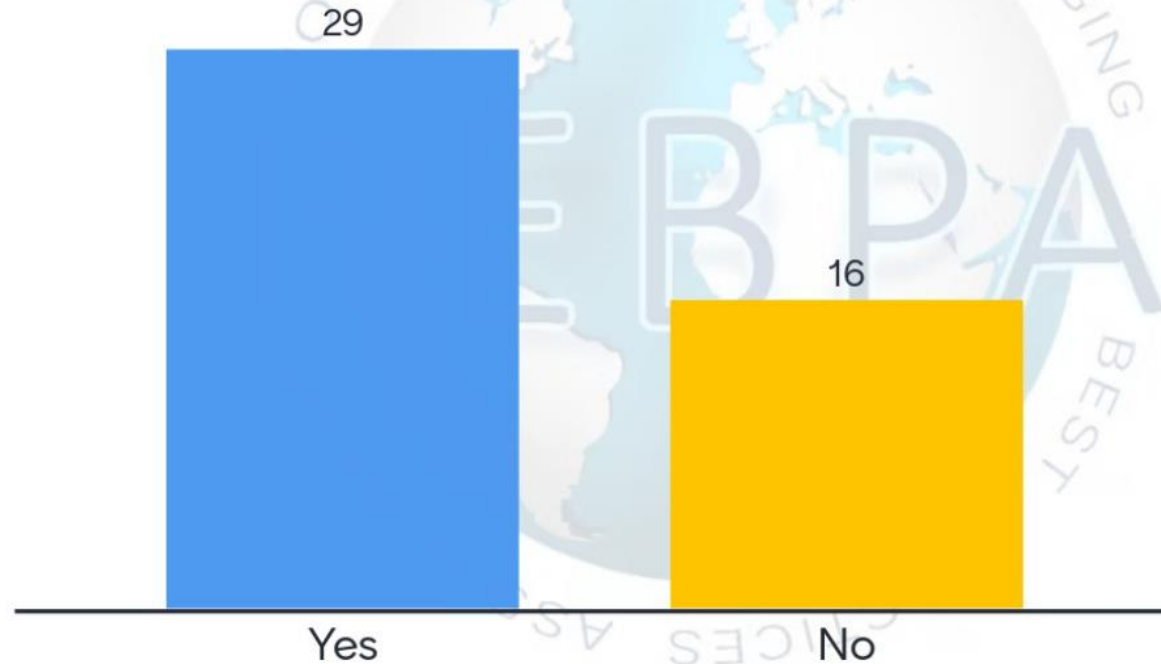


# 1.4 How do you use HCP testing in late stage development (Pivotal studies, commercialization)





# 1.5 Have you used HCP data to support upstream process decisions?



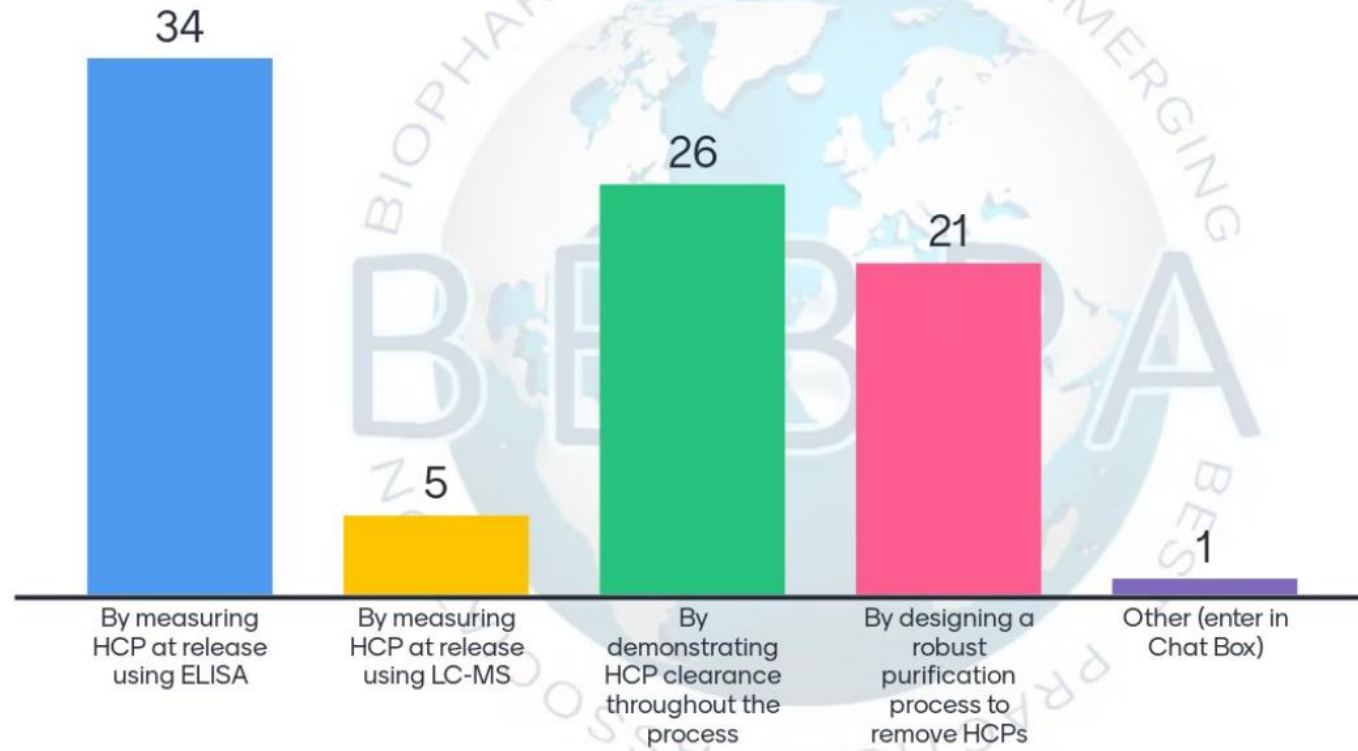
# Session 2: Implementation of HCP ELISAs: Commercial, Platform, and Process-Specific Assays

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

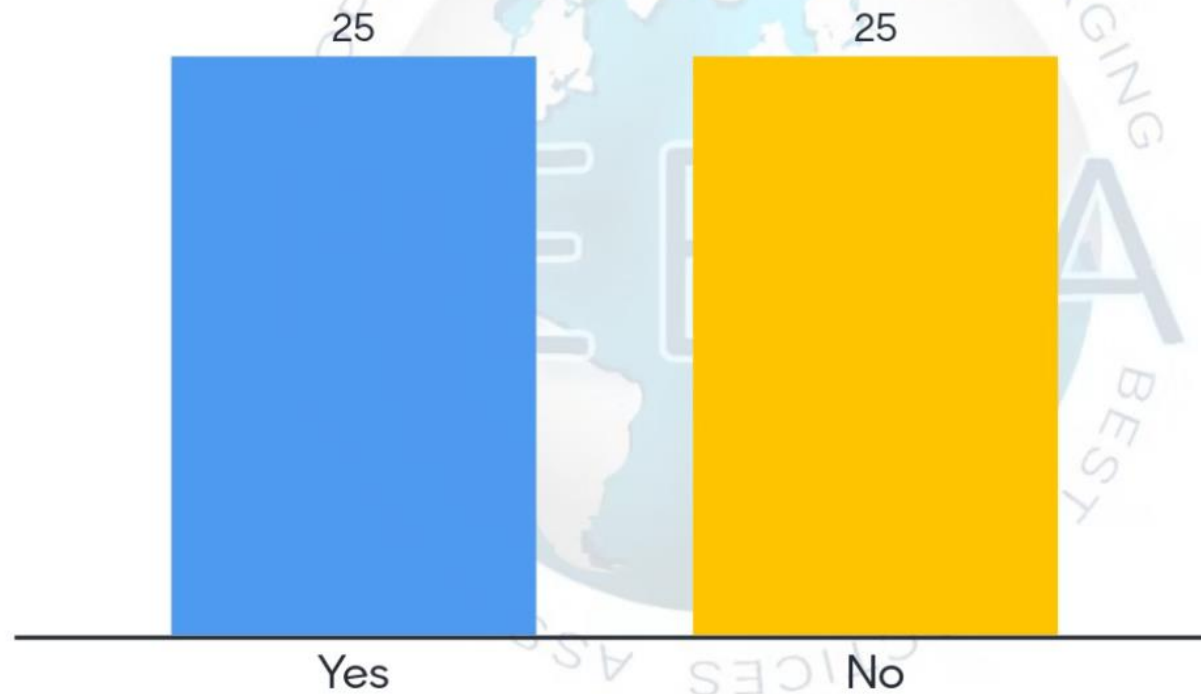
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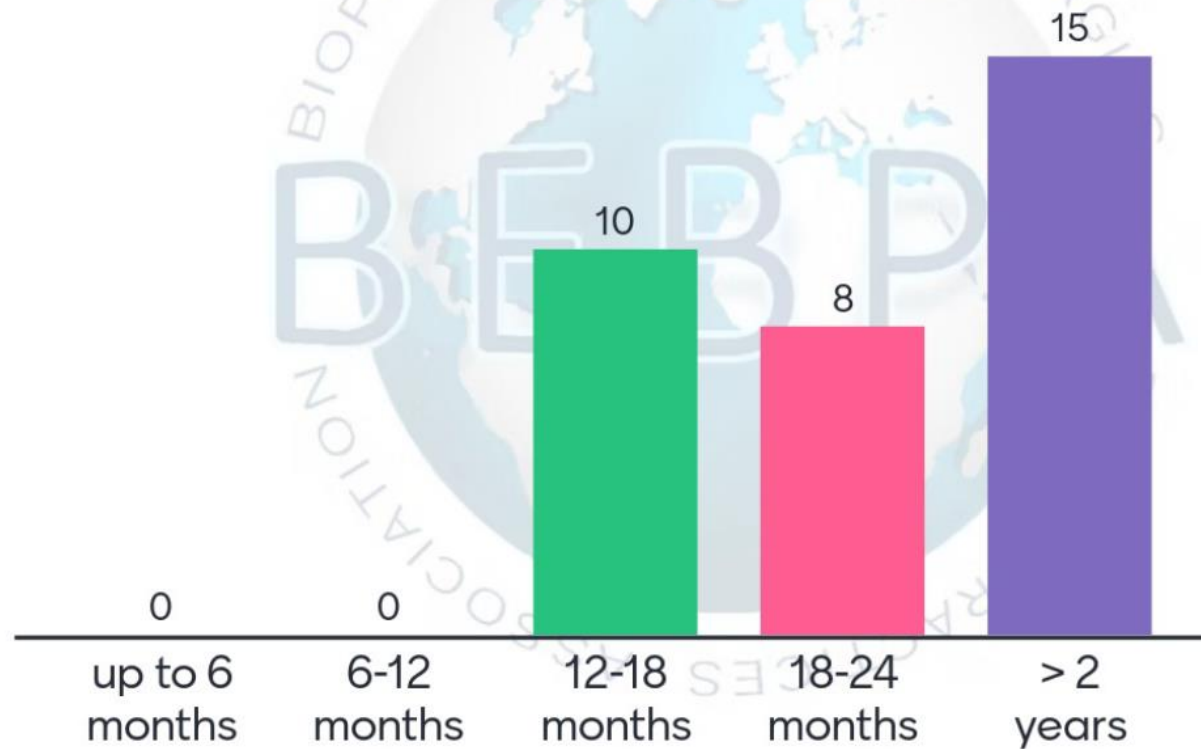
# 2.1 How do you control HCPs?



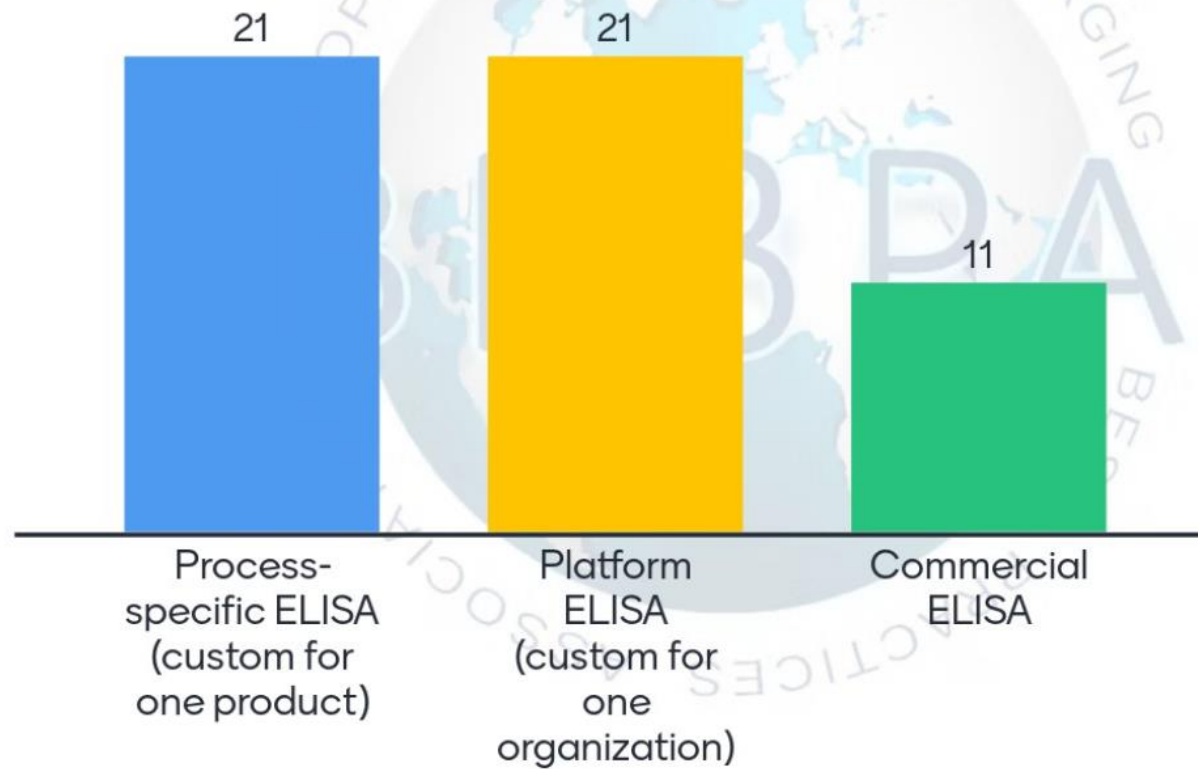
## 2.2 Have you ever participated in development of an HCP ELISA from scratch



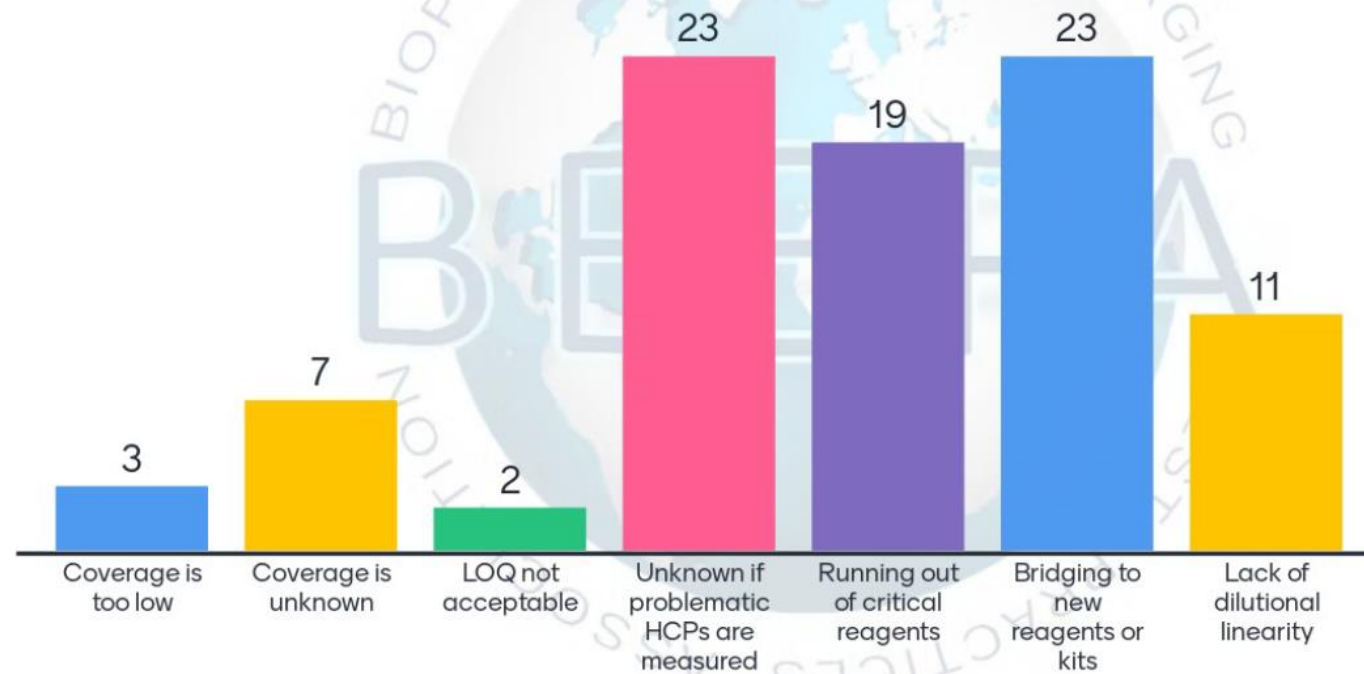
## 2.3 How long did development of an HCP assay take? Immunogen generation through validation



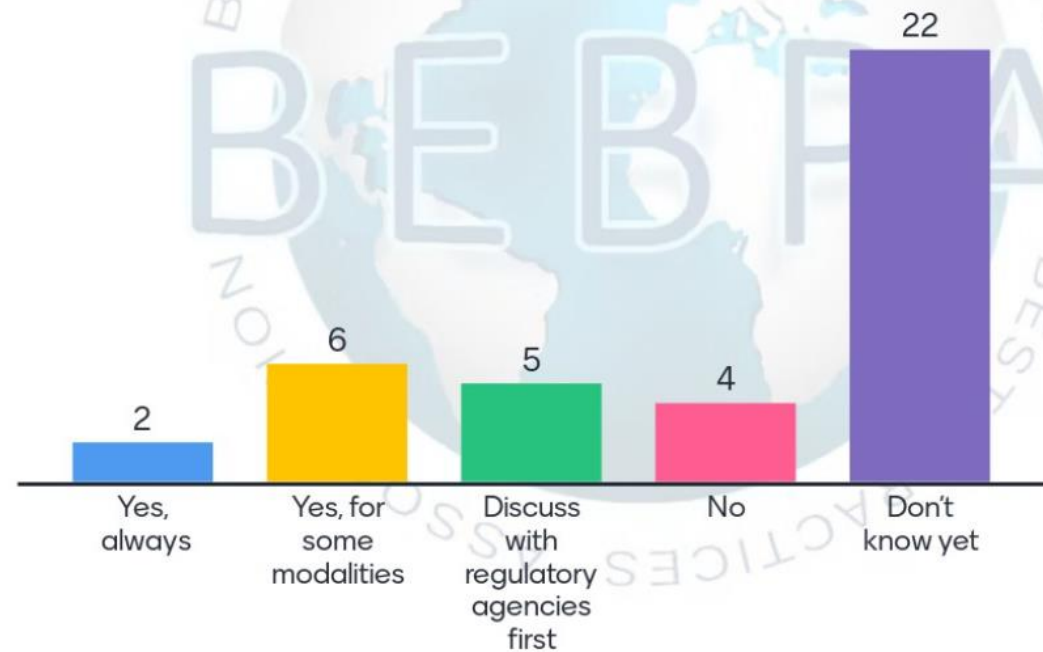
## 2.4 Which ELISA do you use for late stage development and commercial phase?



## 2.5 What are the main shortfalls the HCP ELISA you are currently using?

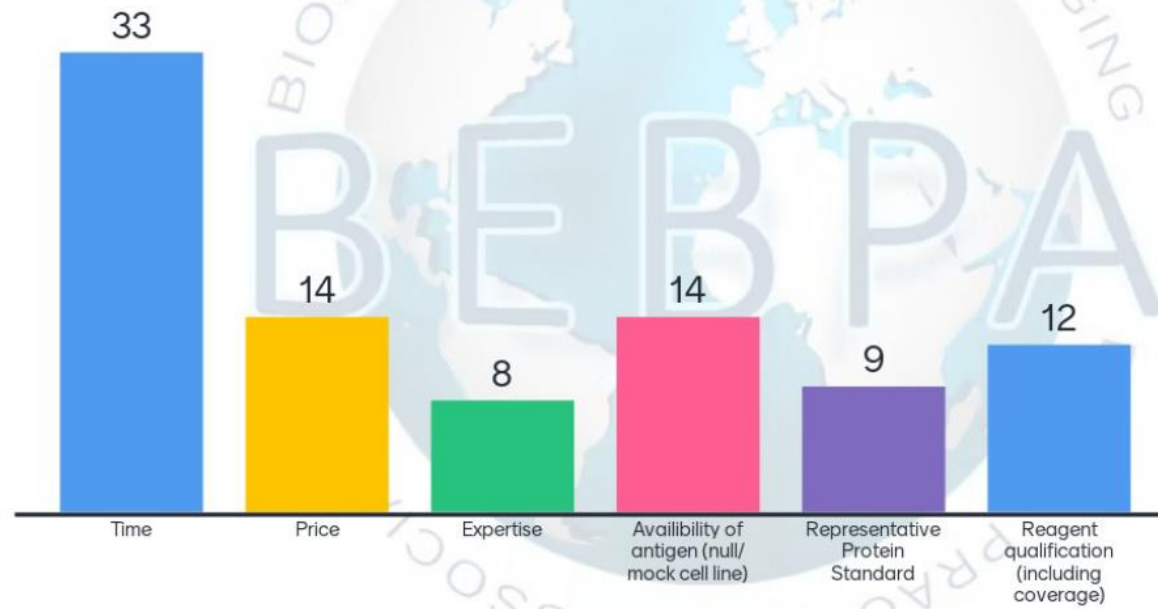


## 2.6 Do you apply USP <1132> for other modalities other than recombinant proteins, such as DNA/RNAs, viral vectors and vaccines





# 2.7 What are your challenges to develop process specific assay?



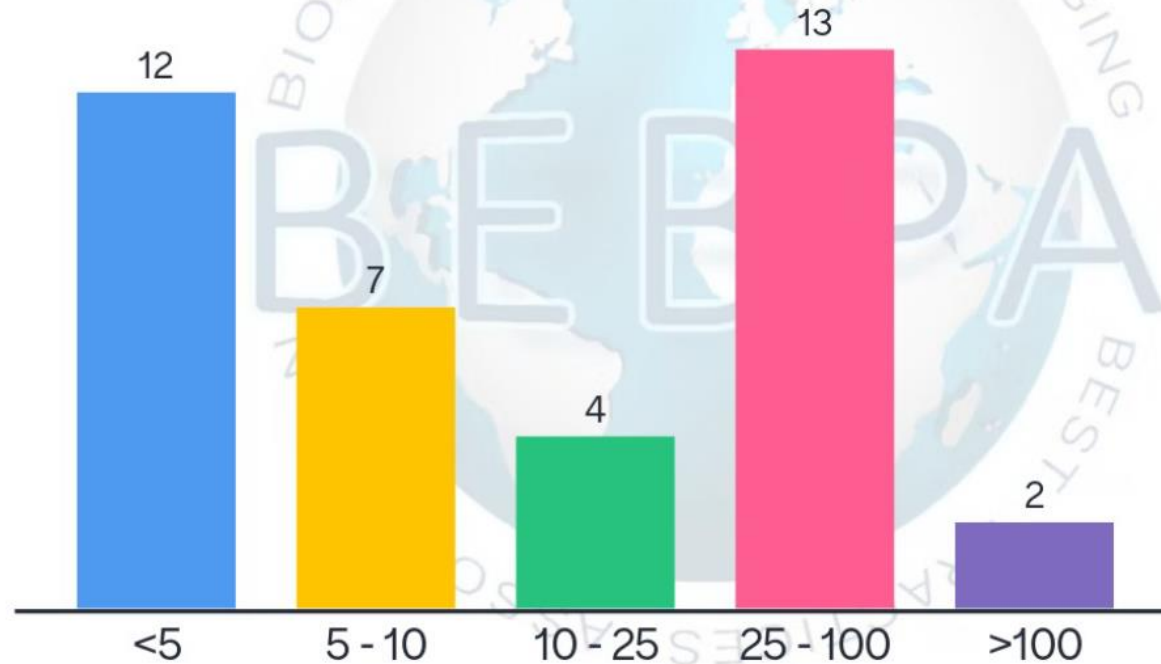
# Session 3: Alternatives to ELISA for HTP and Routine HCP Testing

Session Chair: Thomas Wärner, Senior Principal Scientist, Boehringer Ingelheim

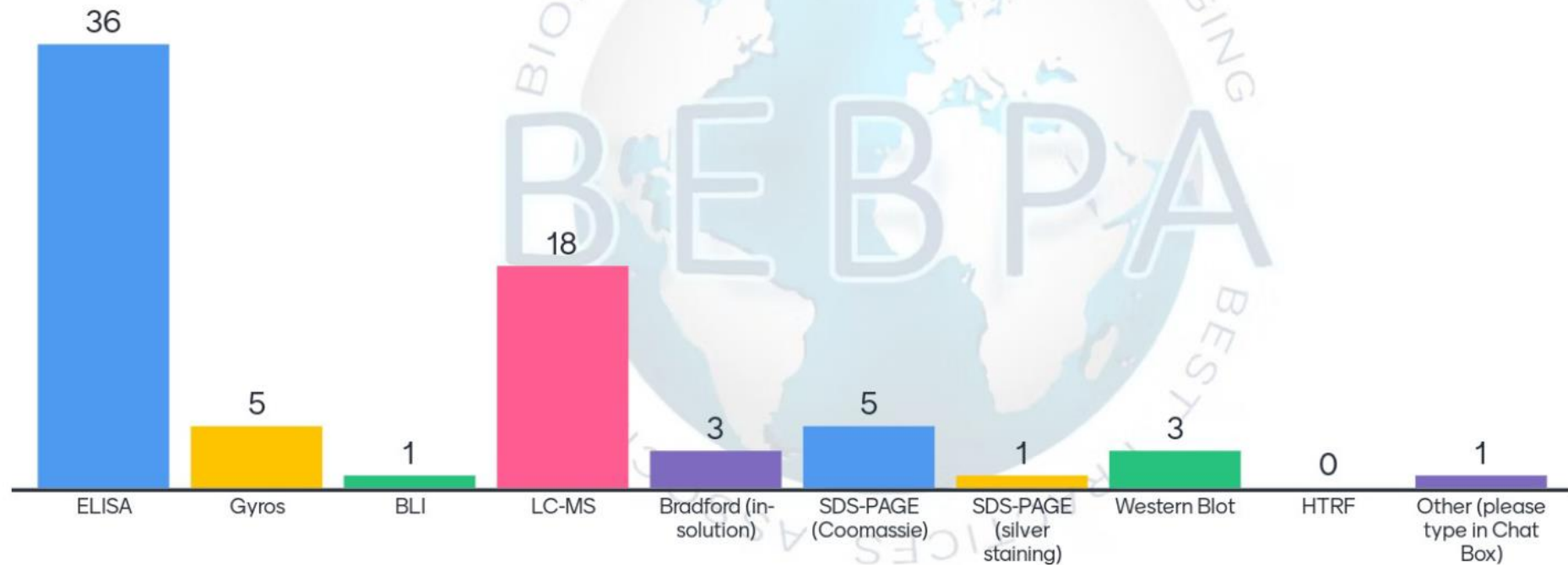
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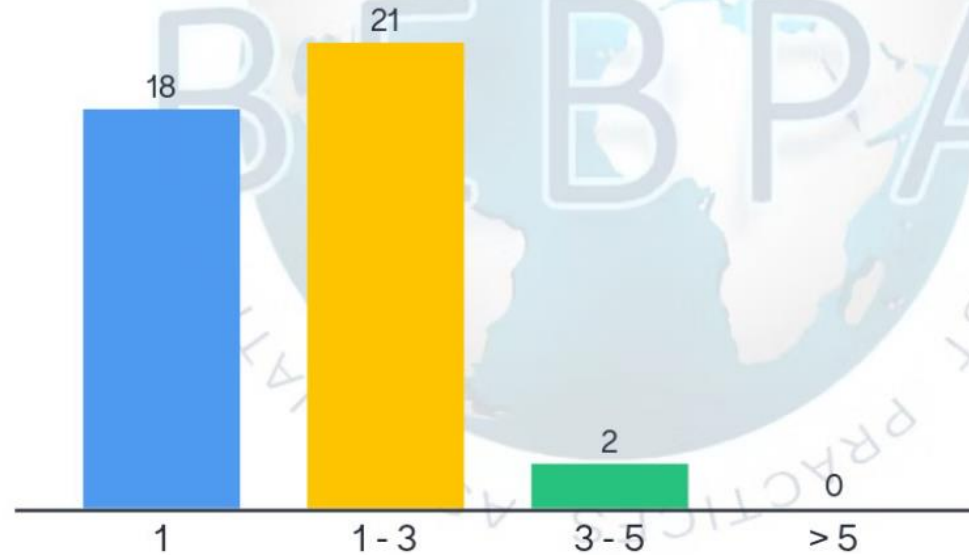
# 3.1 How many HCP samples are processed per week in your lab?



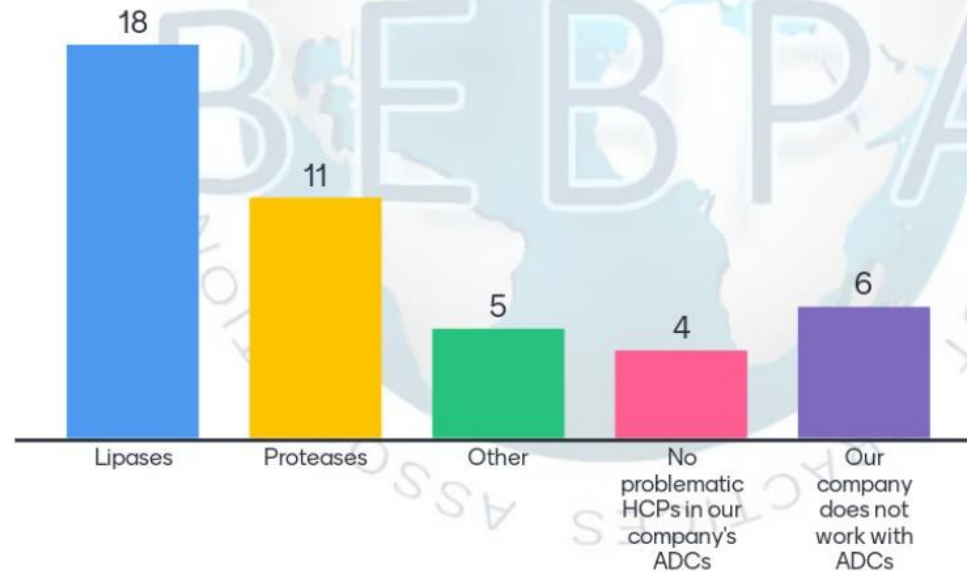
## 3.2 What types of assays do you use for total or individual HCP quantification?



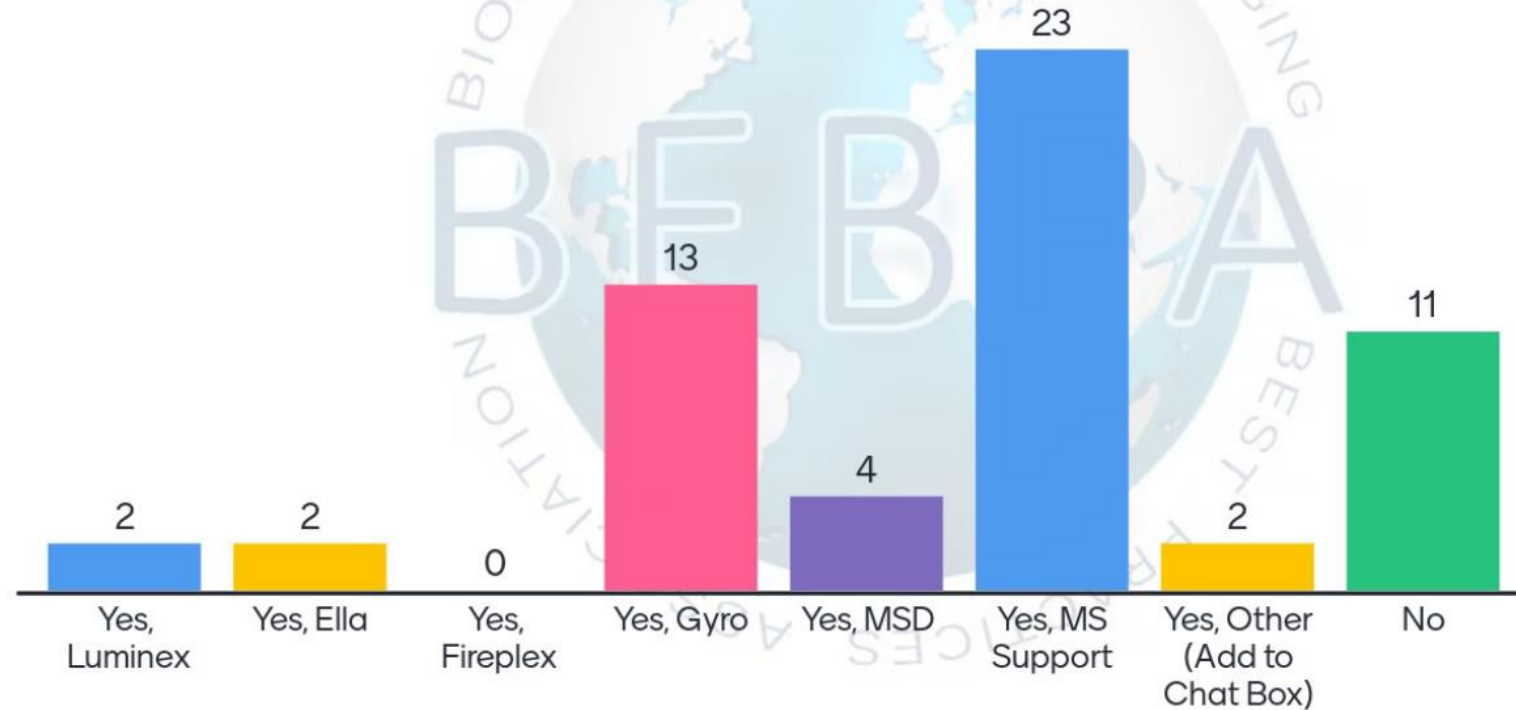
### 3.3 How many HCP assays do you routinely use for a given product? EG; total HCP and specific HCPs



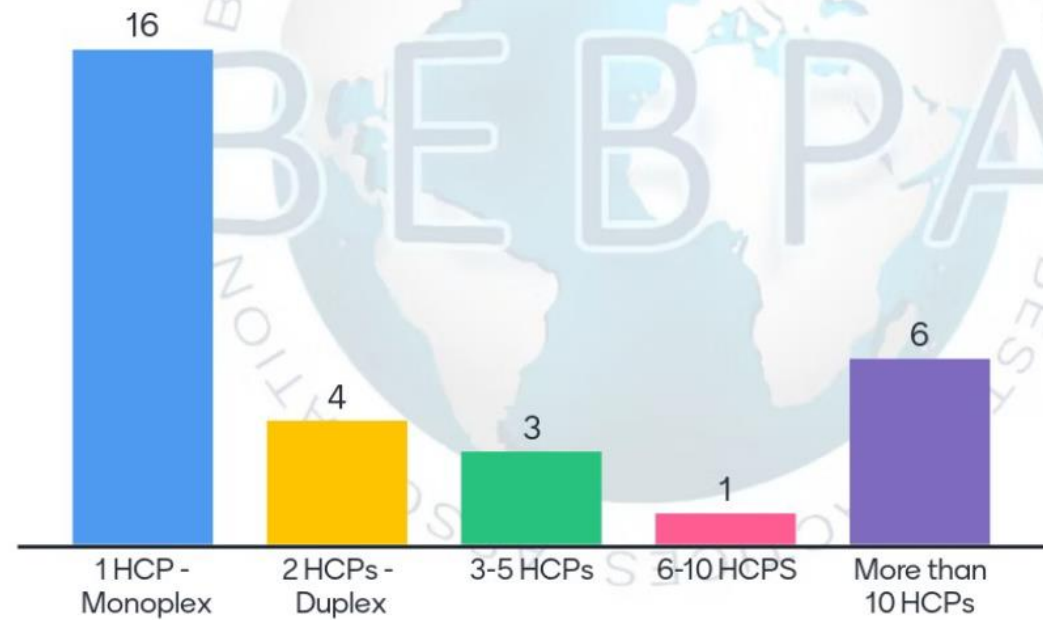
# 3.4 Which HCPs are most problematic for your company's antibody drug conjugates or bioconjugates?



# 3.5 Is your company currently pursuing alternatives to ELISA for HCP analysis?



### 3.6 What is the highest level of HCP multiplexing actively being utilized at your company for individual HCP quantification?



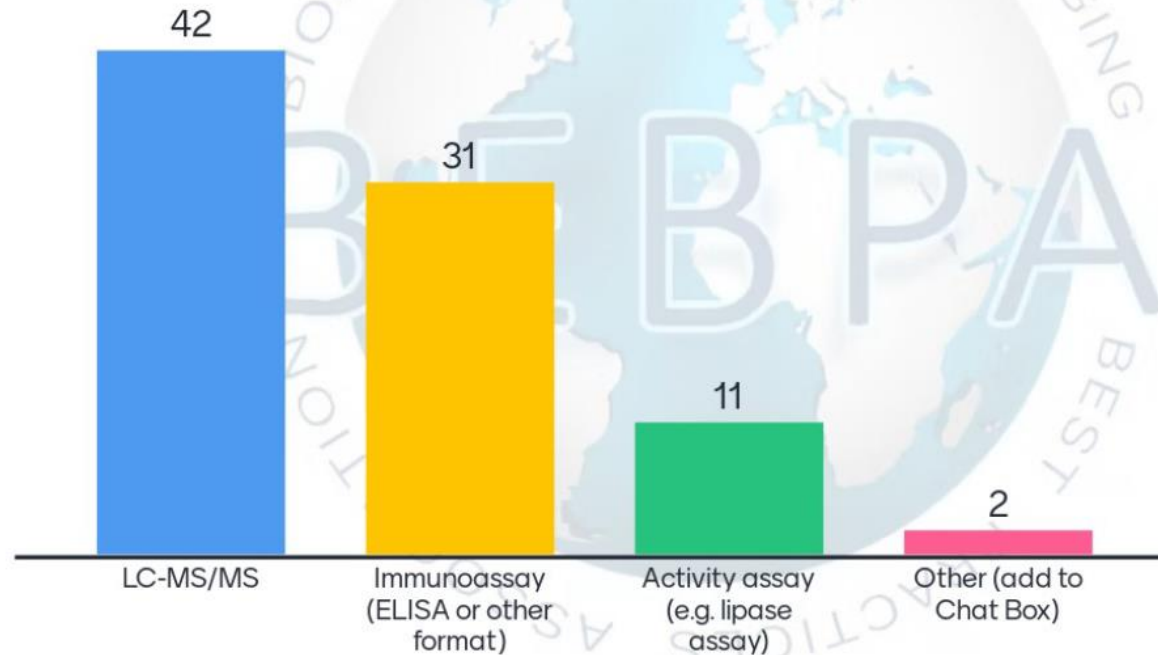


# Session 4: Methods for Detection of Low Abundance HCP's

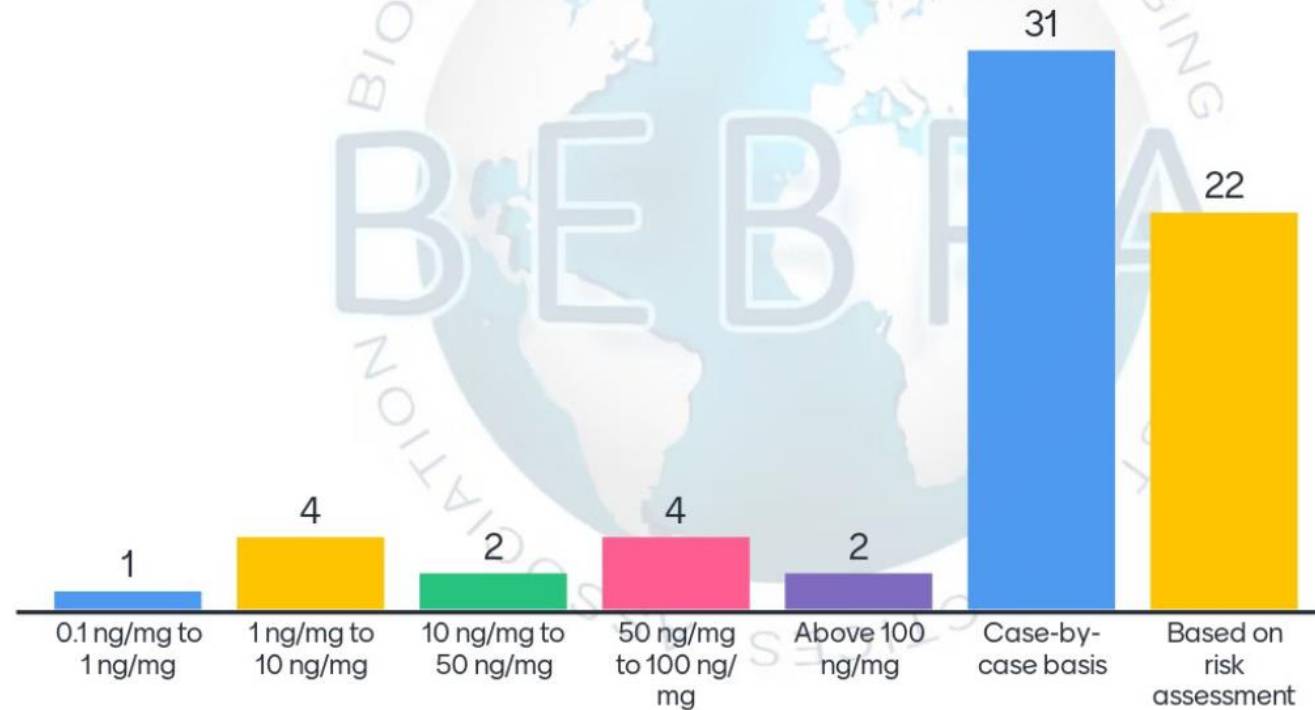
Session Chair: Stefanie Wohlrab, Senior Scientist, Roche Diagnostics GmbH

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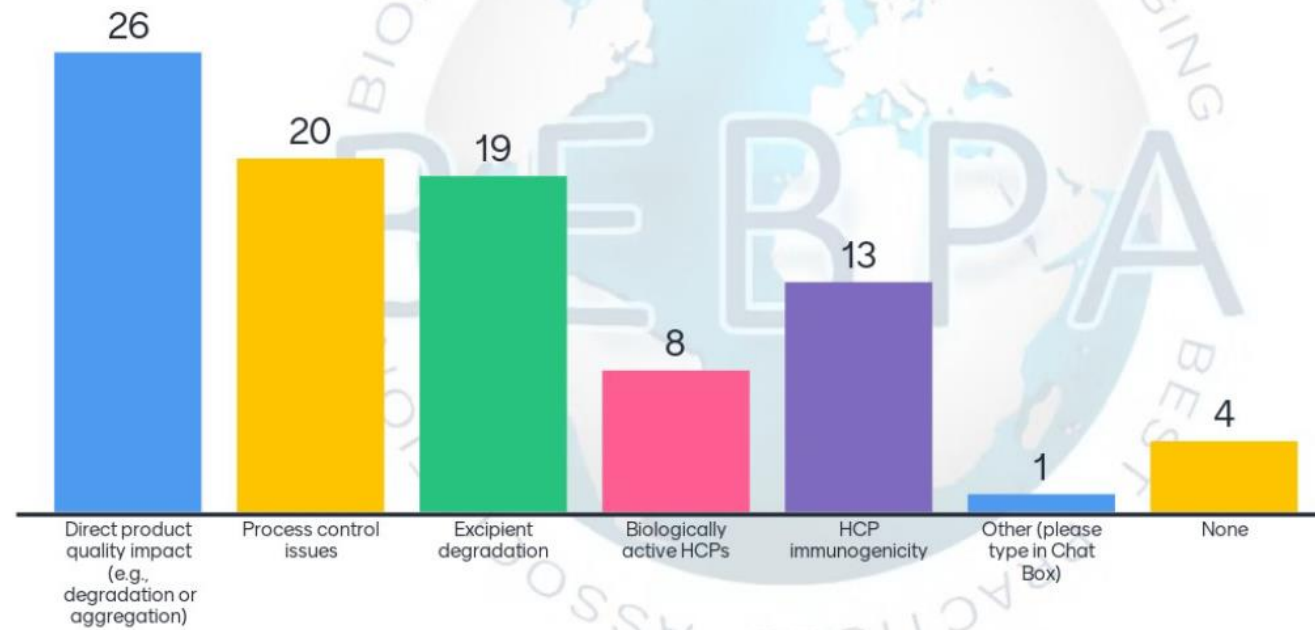
# 4.1 What methods are used at your company for low abundance HCP detection?



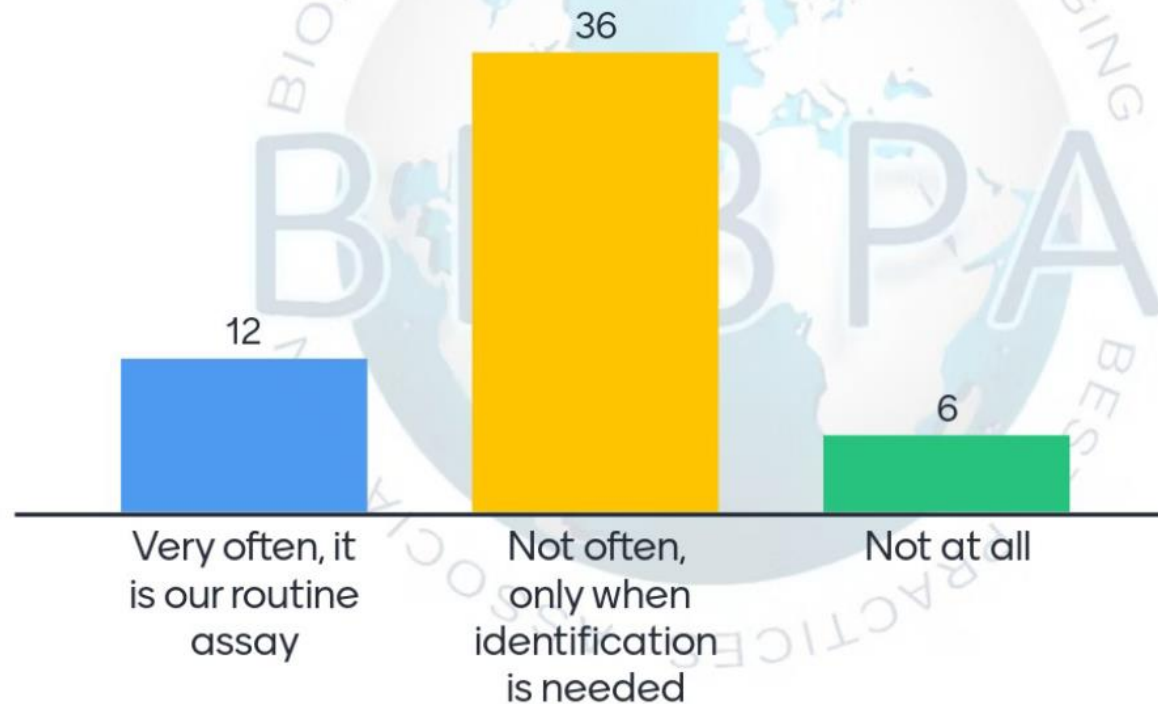
# 4.2 For individual HCPs, at what level do you present to regulatory agencies?



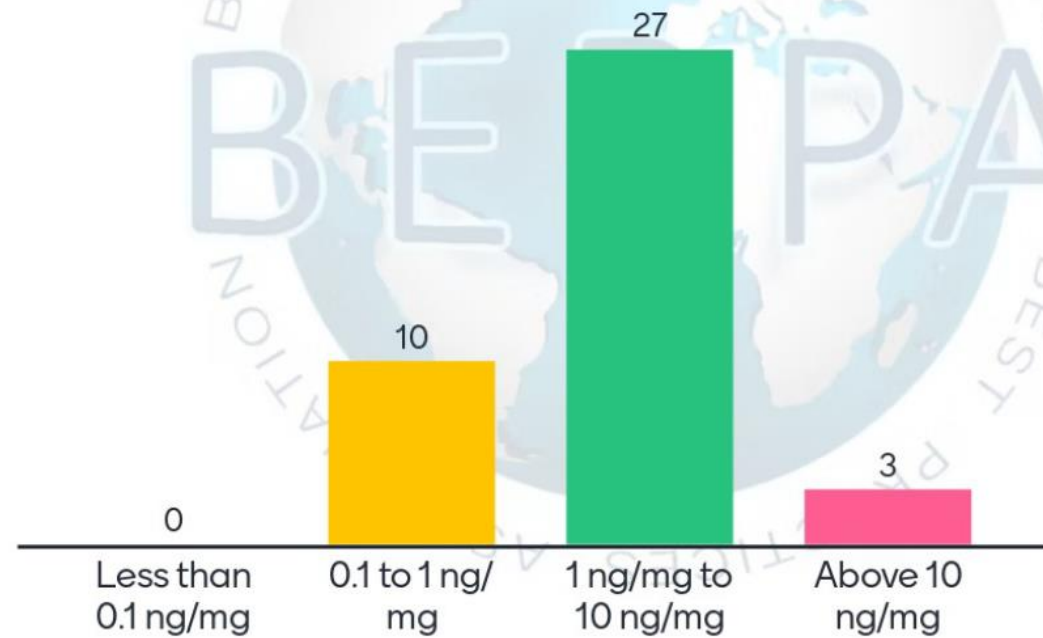
# 4.3 Which HCP-related issues have you encountered?



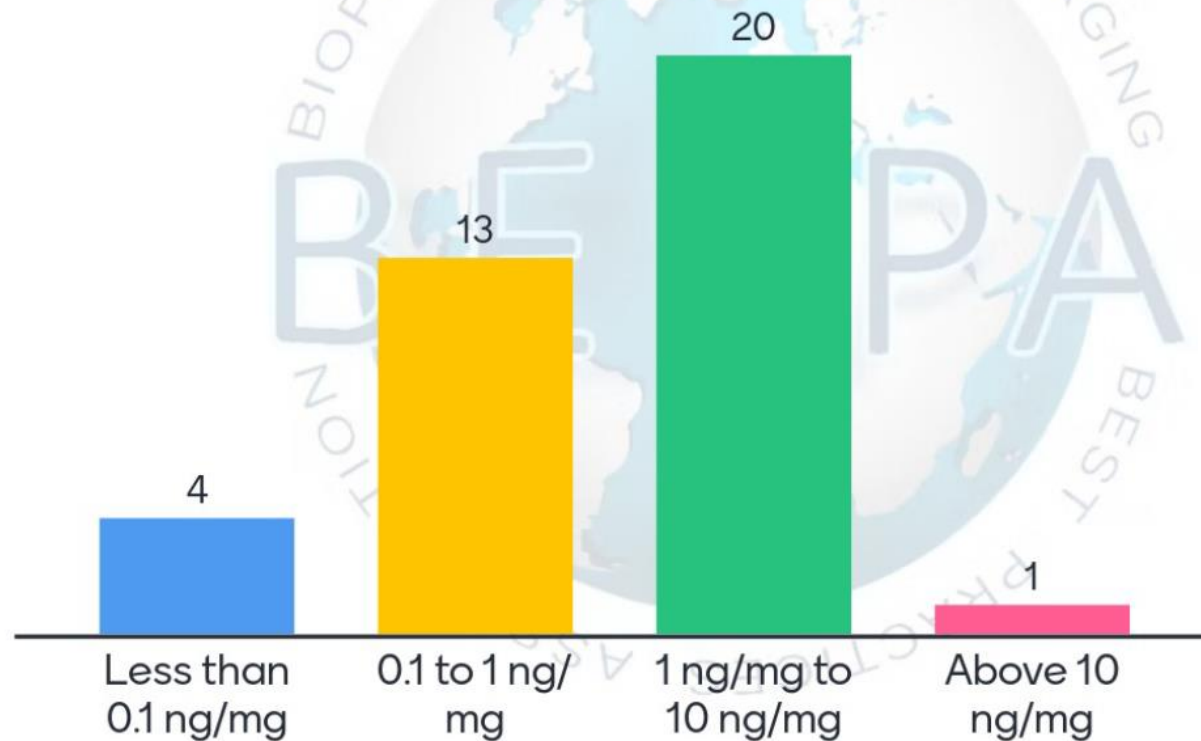
# 4.4 How often do you use LCMS for low abundance HCP analysis?



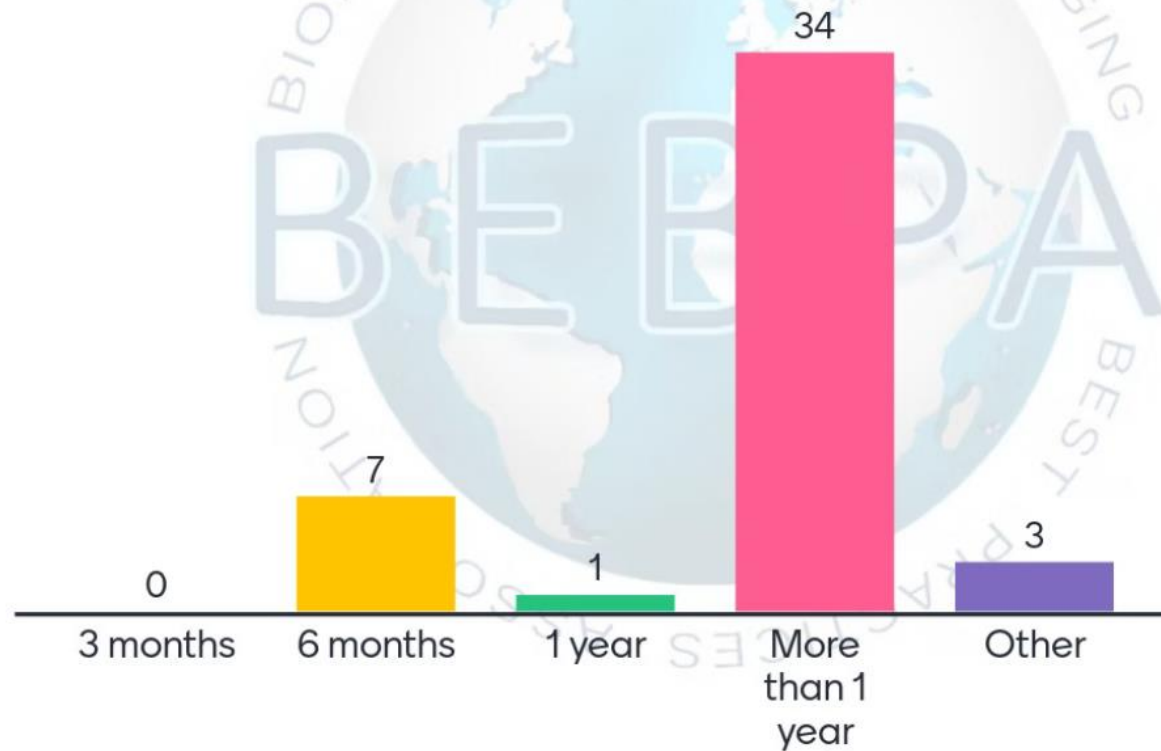
# 4.5 What is the sensitivity of your generic LC-MS/MS method for HCP identification and quantification? (Target HCPs unknown)



## 4.6 What is the sensitivity of your LC-MS/MS method for a known HCP identification and quantification?

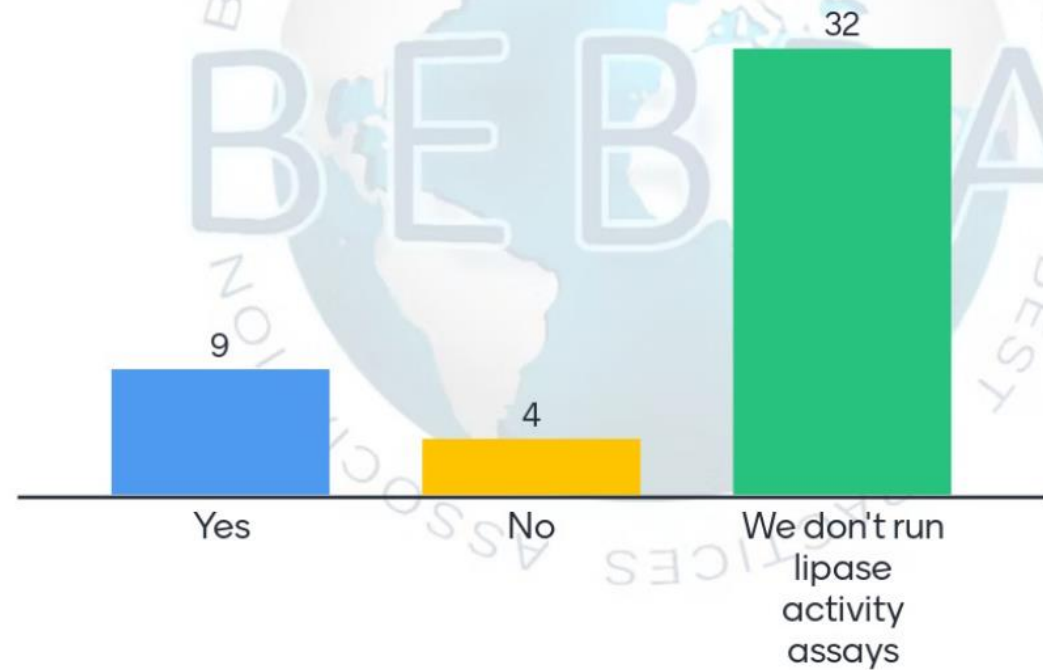


# 4.7 How long does it take for development of an individual HCP ELISA at your company?





# 4.8 Is there a strong correlation between your companies lipase-based HCPs and lipase activity assays?



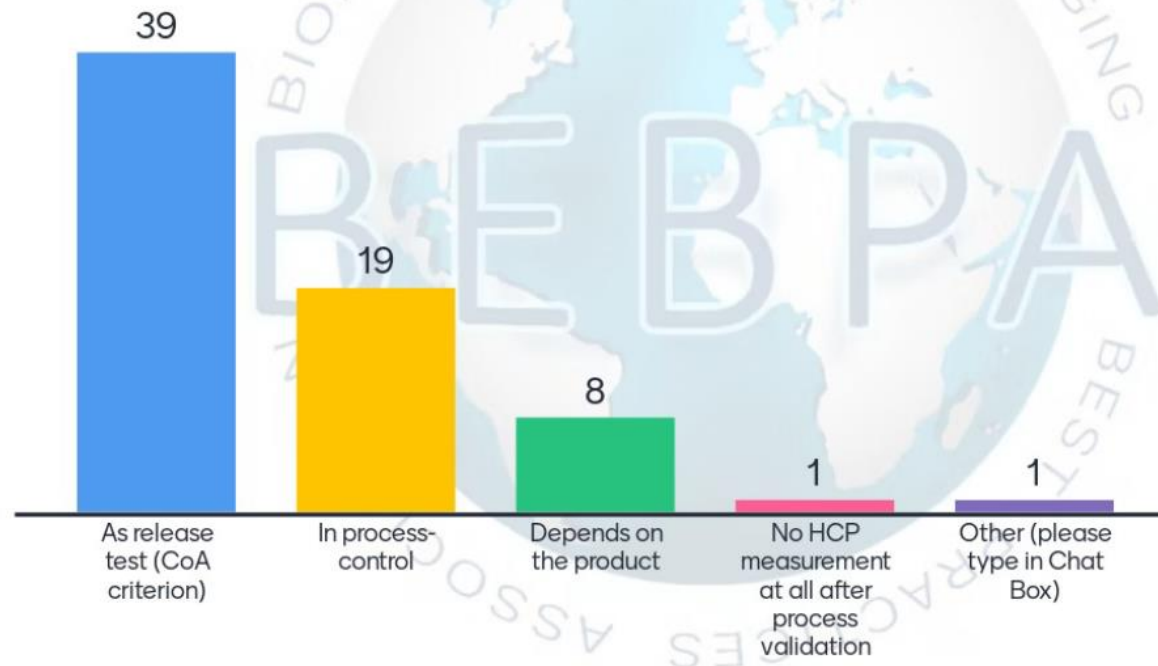
# Session 5: Guidance

Session Chair: Fengqiang Wang, Principal Scientist, Merck

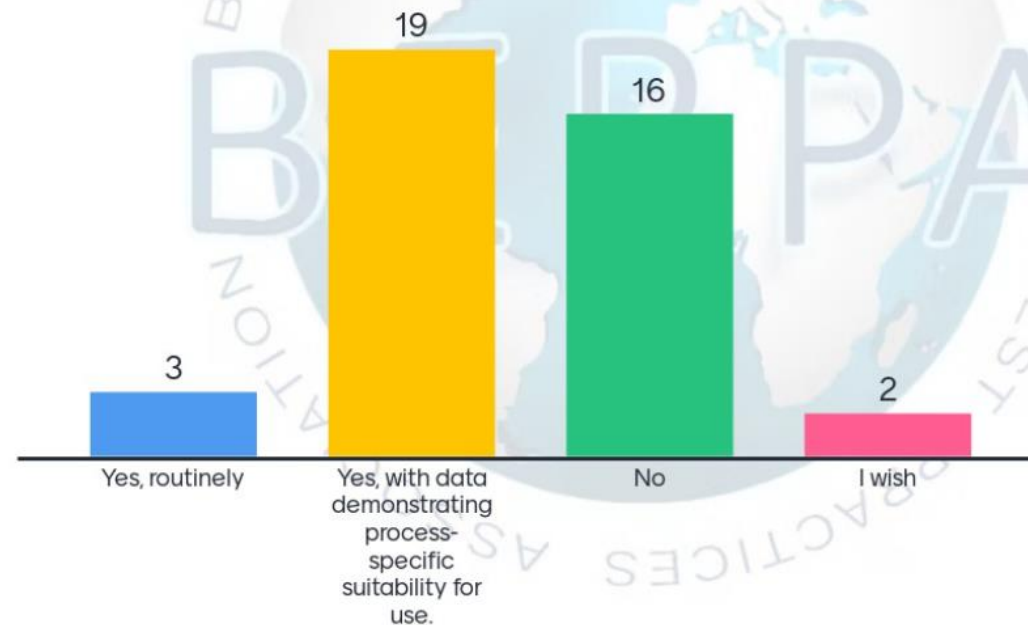
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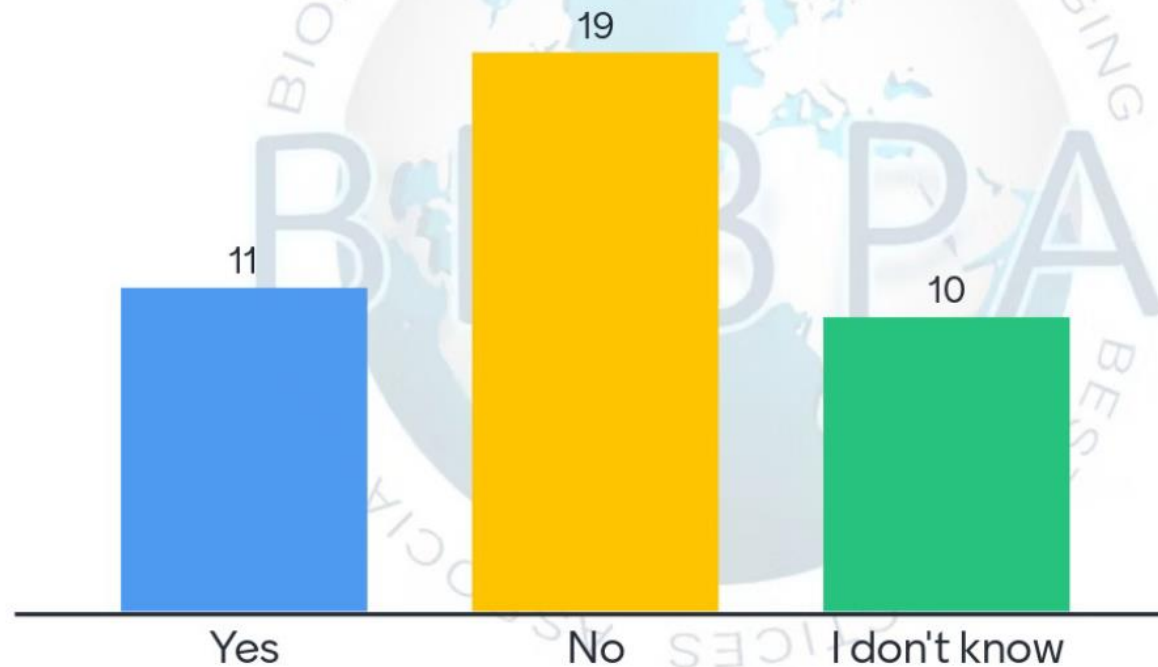
# 5.1 How is HCP measurement performed during commercial phases?



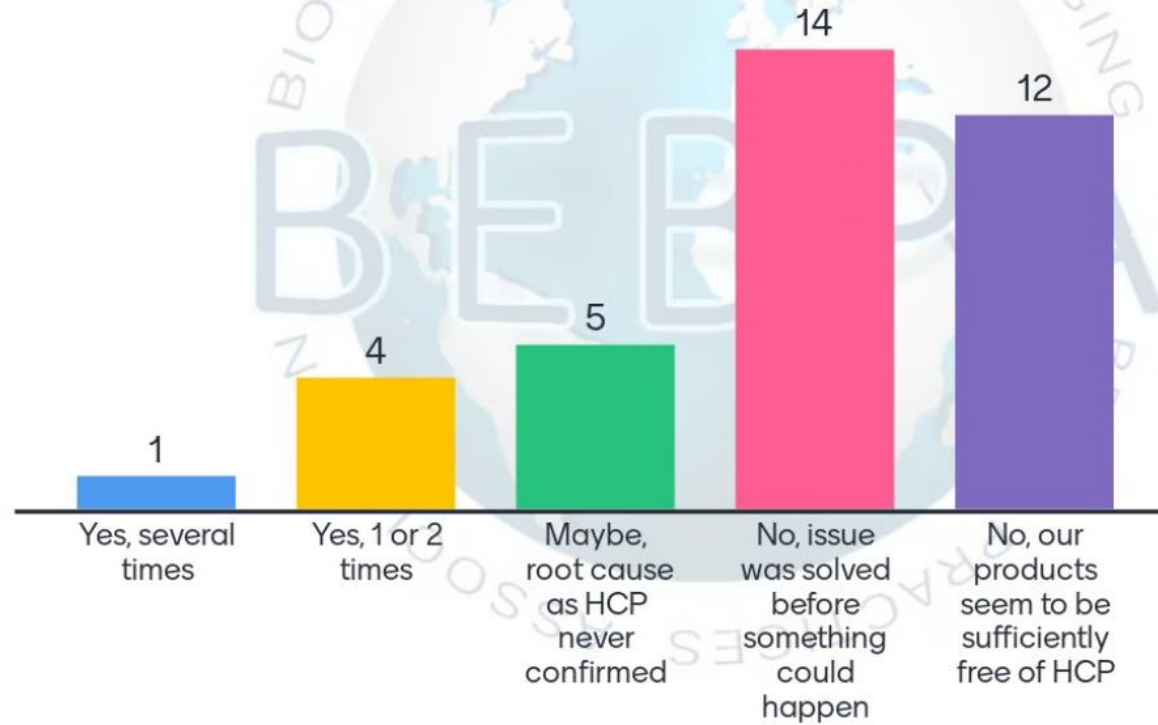
## 5.2 Has your company ever used a commercial HCP assay to support a marketing authorization application (MAA or BLA)?



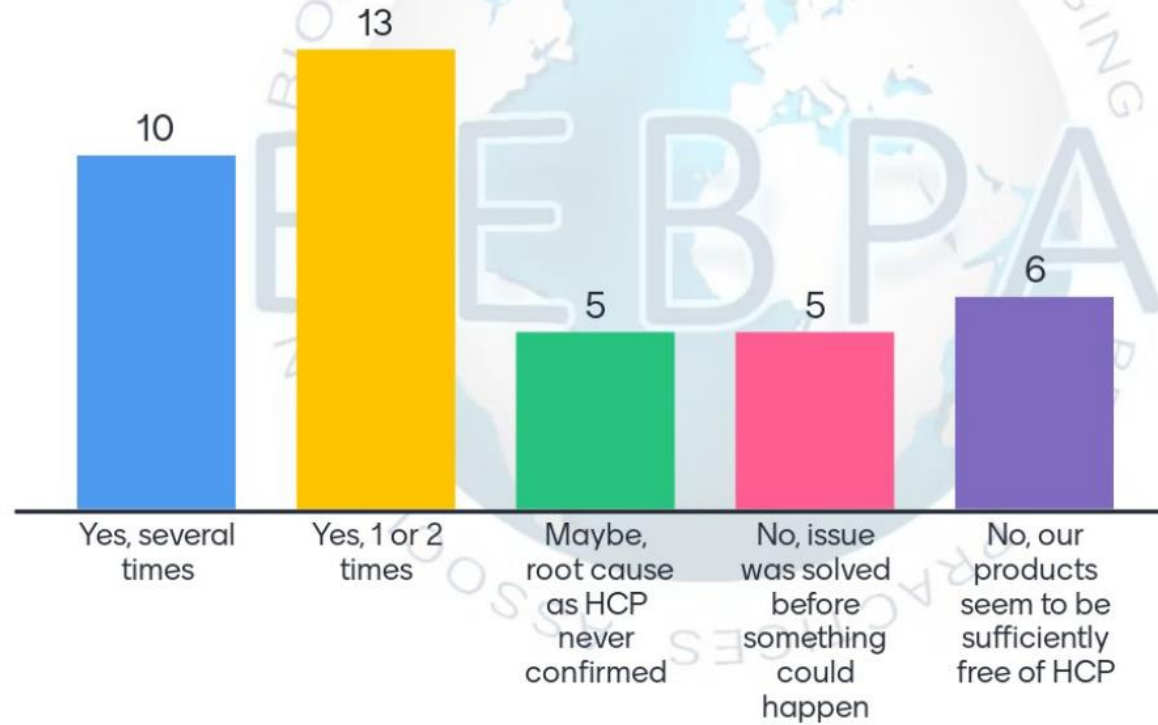
# 5.3 Do you have a formal risk assessment procedure in place for HCPs



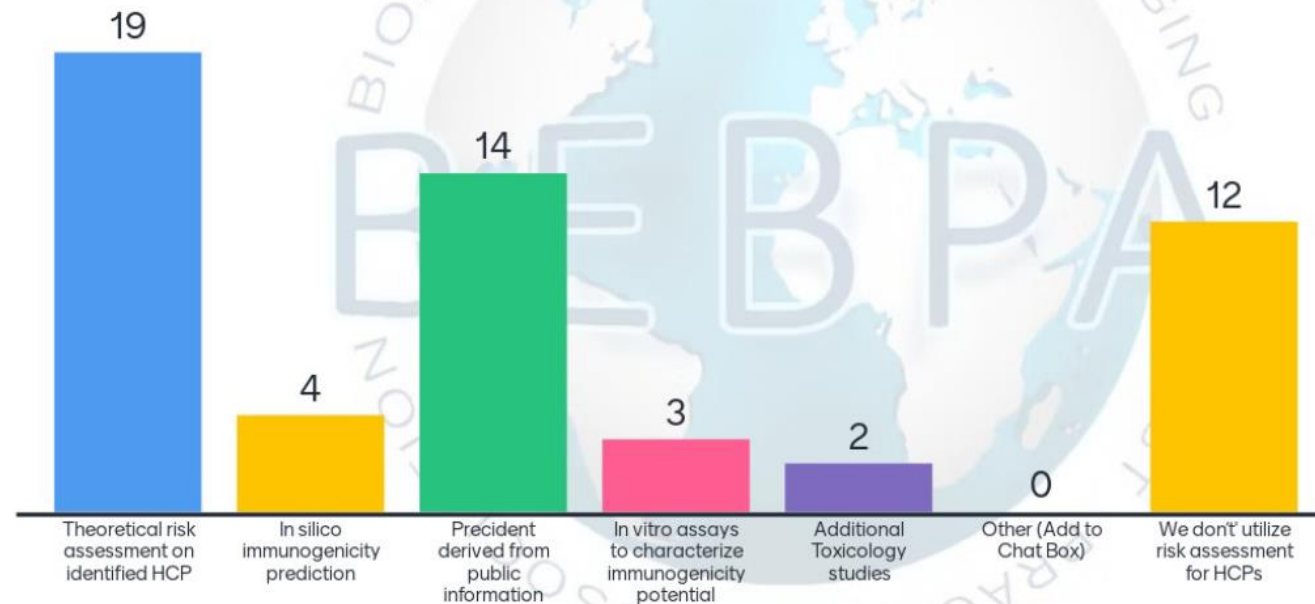
# 5.4 Has your company ever seen evidence of patient safety issues related to HCPs?



# 5.5 Has your company ever seen evidence of product quality issues related to HCPs?



# 5.6 What tools do you use to assess risk of HCPs?





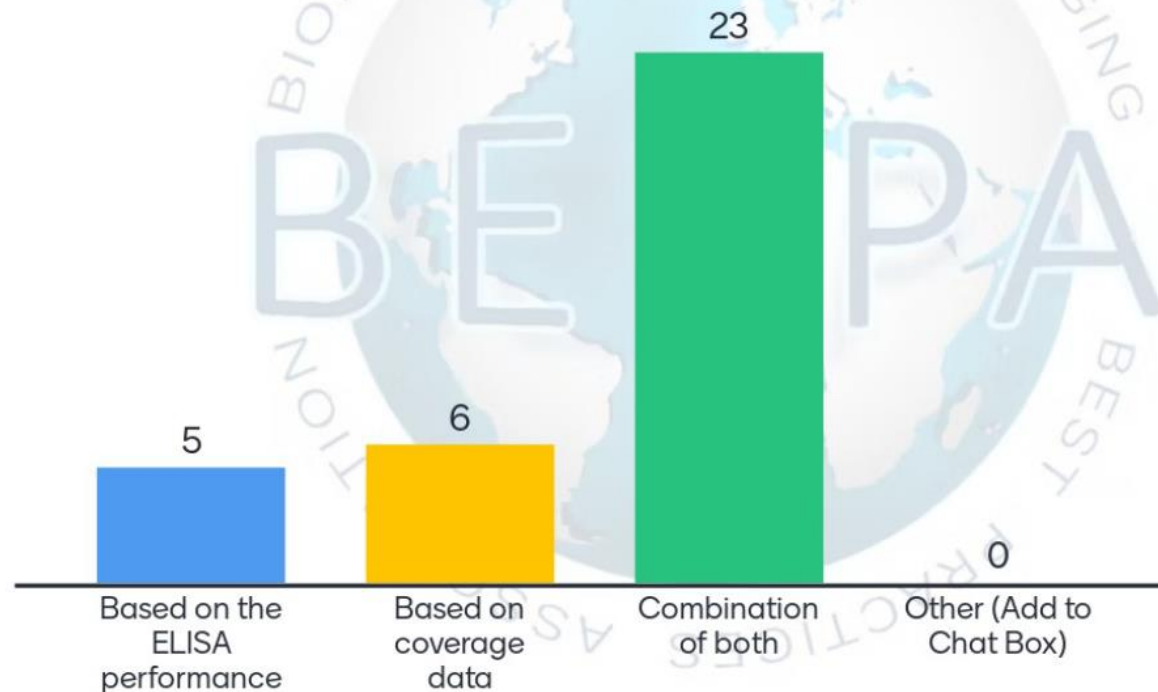
# Session 6: HCP Critical Reagent Characterization Methods

Session Chair: Frieder Kröner, Group Head - Impurities, Novartis Pharma AG

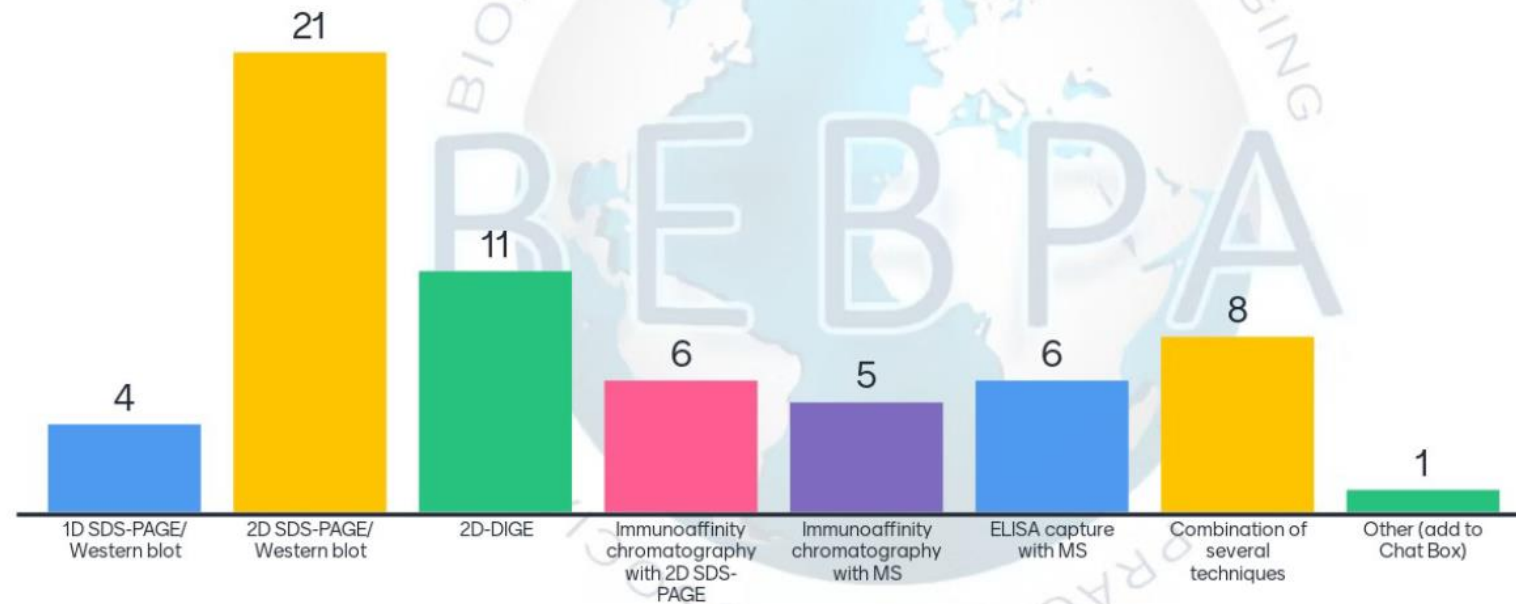
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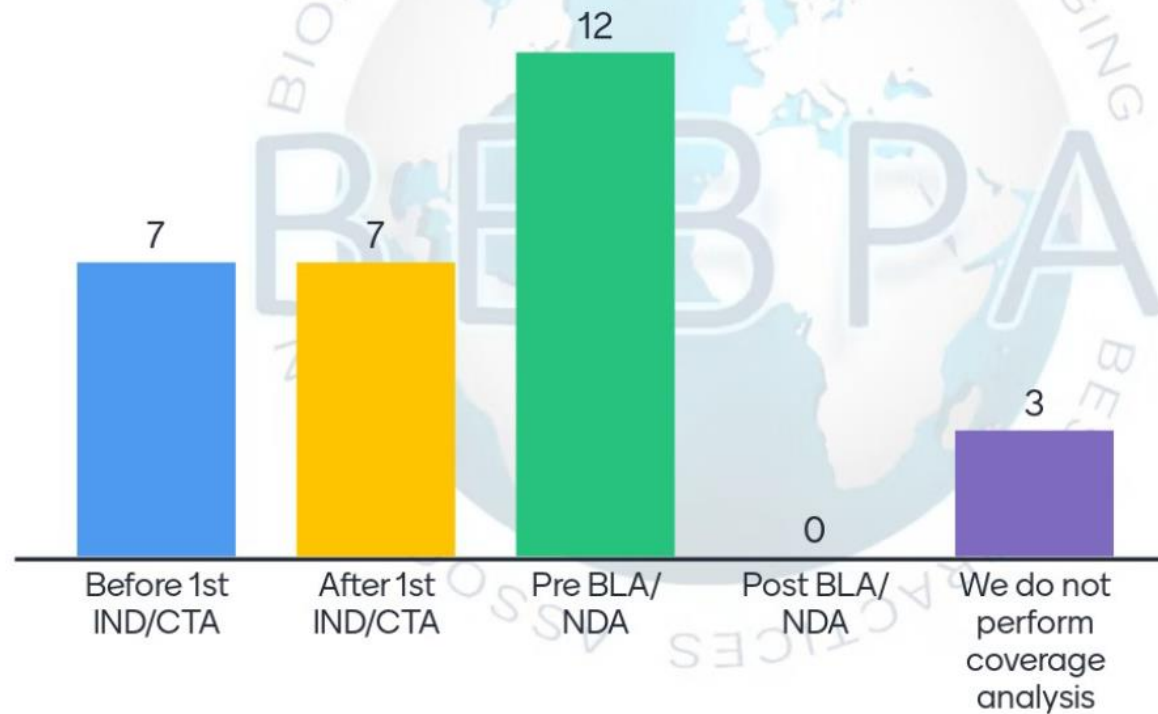
# 6.1 How do you evaluate whether a given HCP antibody is "fit-for-purpose"?



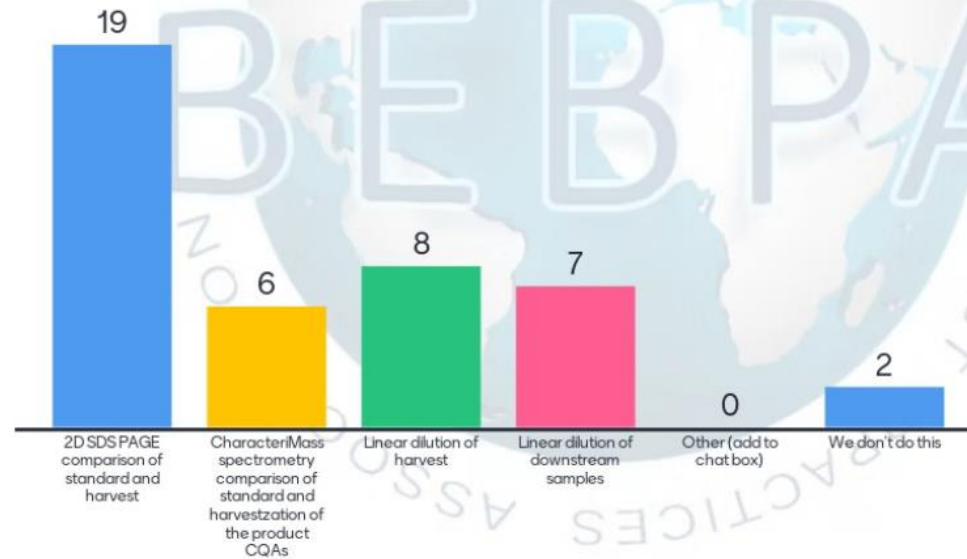
# 6.2 What method do you use for coverage analysis?



# 6.3 When do you perform antibody coverage analysis?



# 6.4 How do you demonstrate your HCP ELISA standard is representative of the HCPs in your harvest?





**Thank You!!**