13th Annual HCP Conference

28-30 May 2025

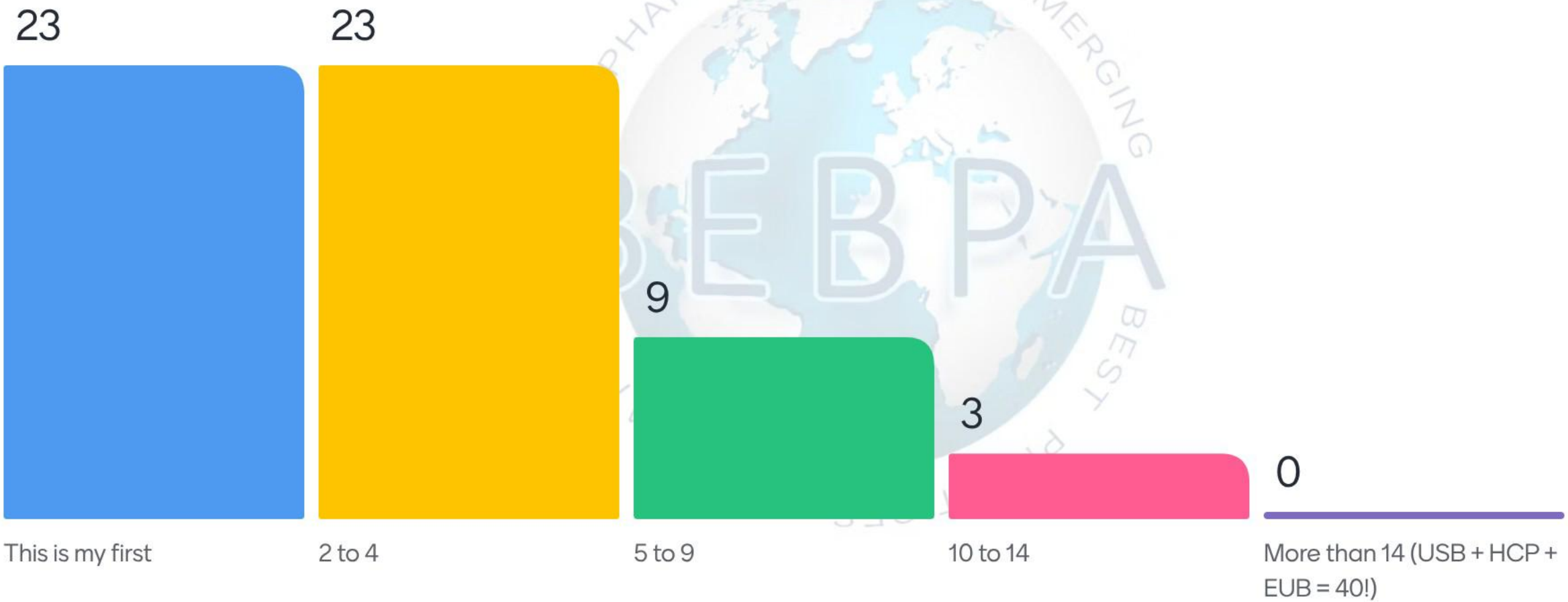
Bled, Slovenia

Welcome Back & Introduction

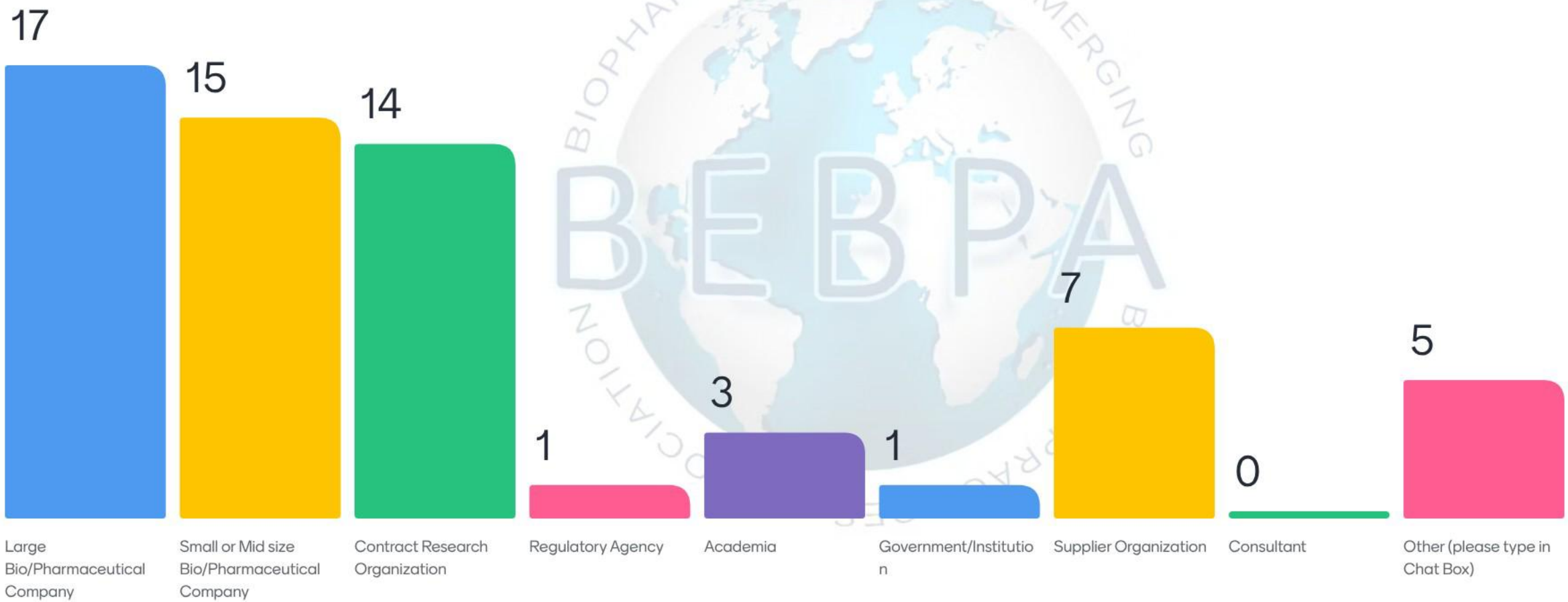
**Laureen Little
Principal Consultant
Quality Services
BEBPA President**

Audience Surveys

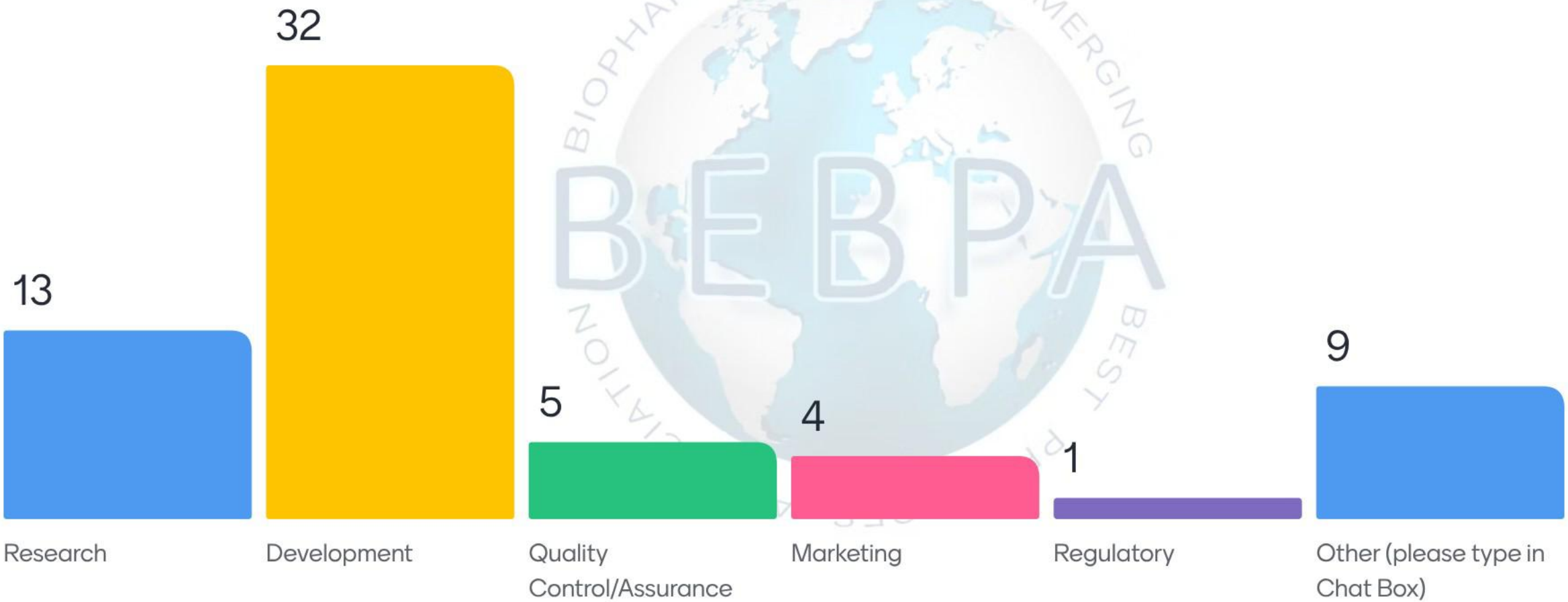
i.1 How many BEBPA Conferences have you attended?



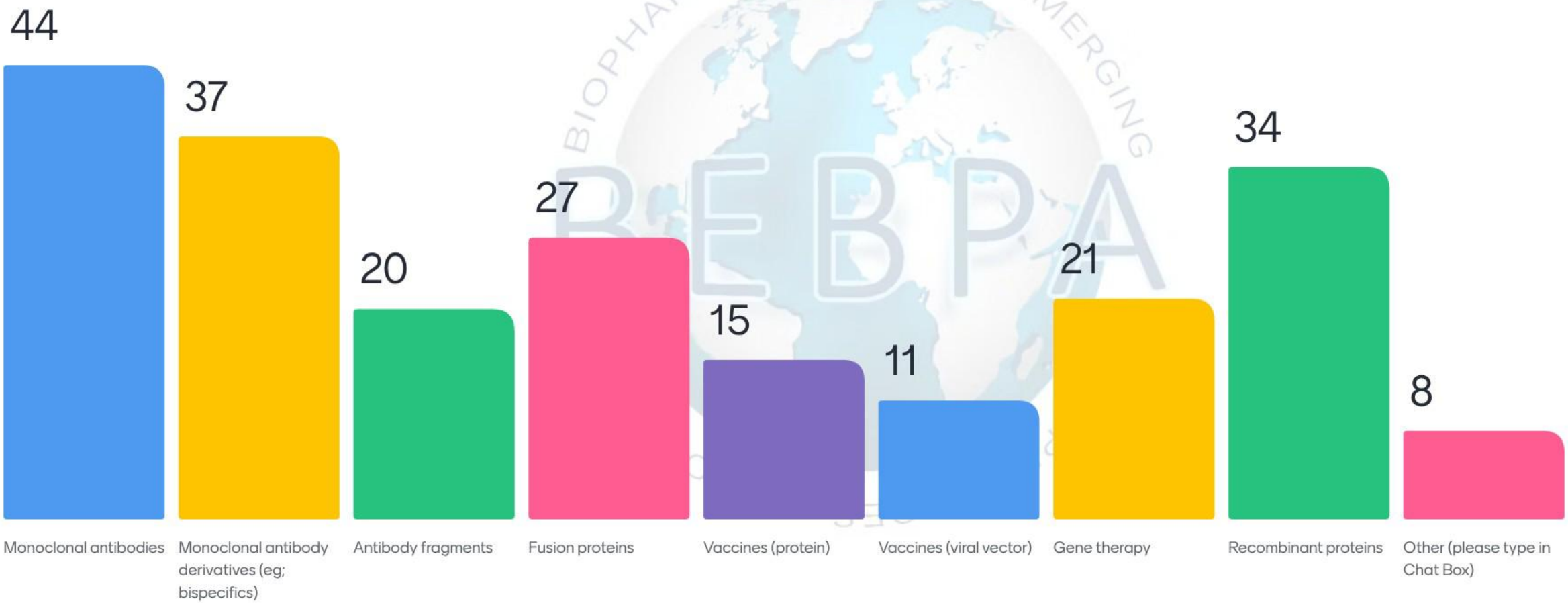
i.2 What type of organization do you work for?



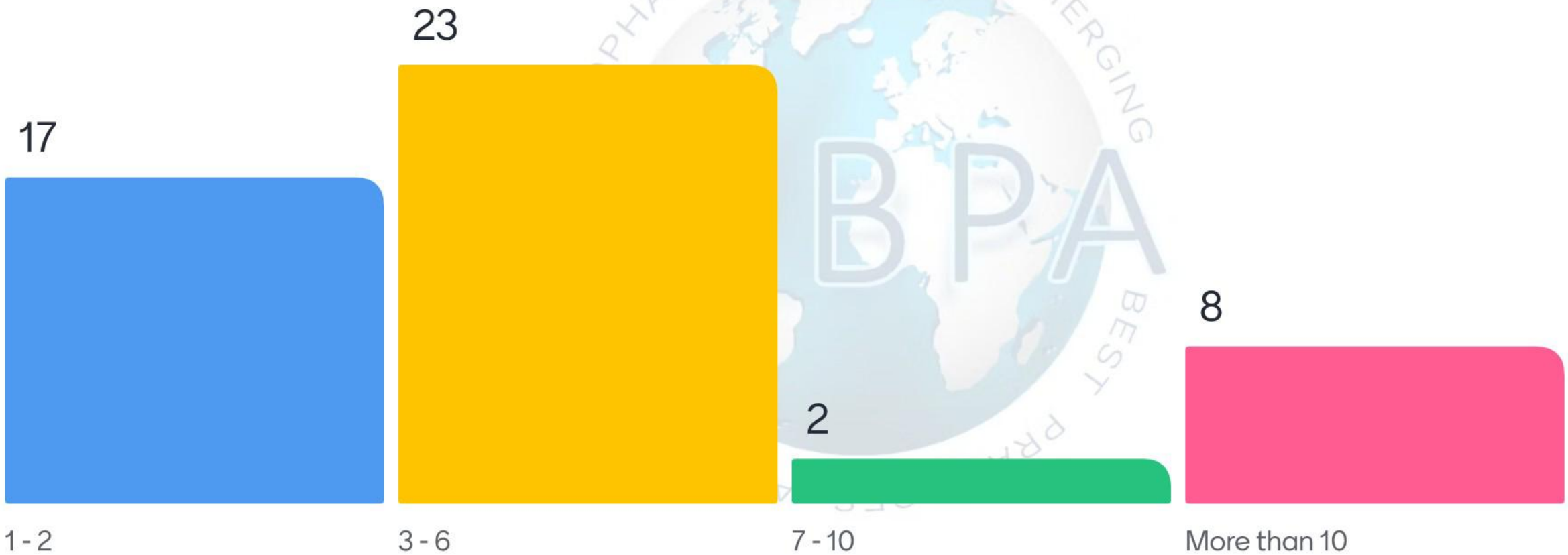
i.3 What part of the organization do your work for?



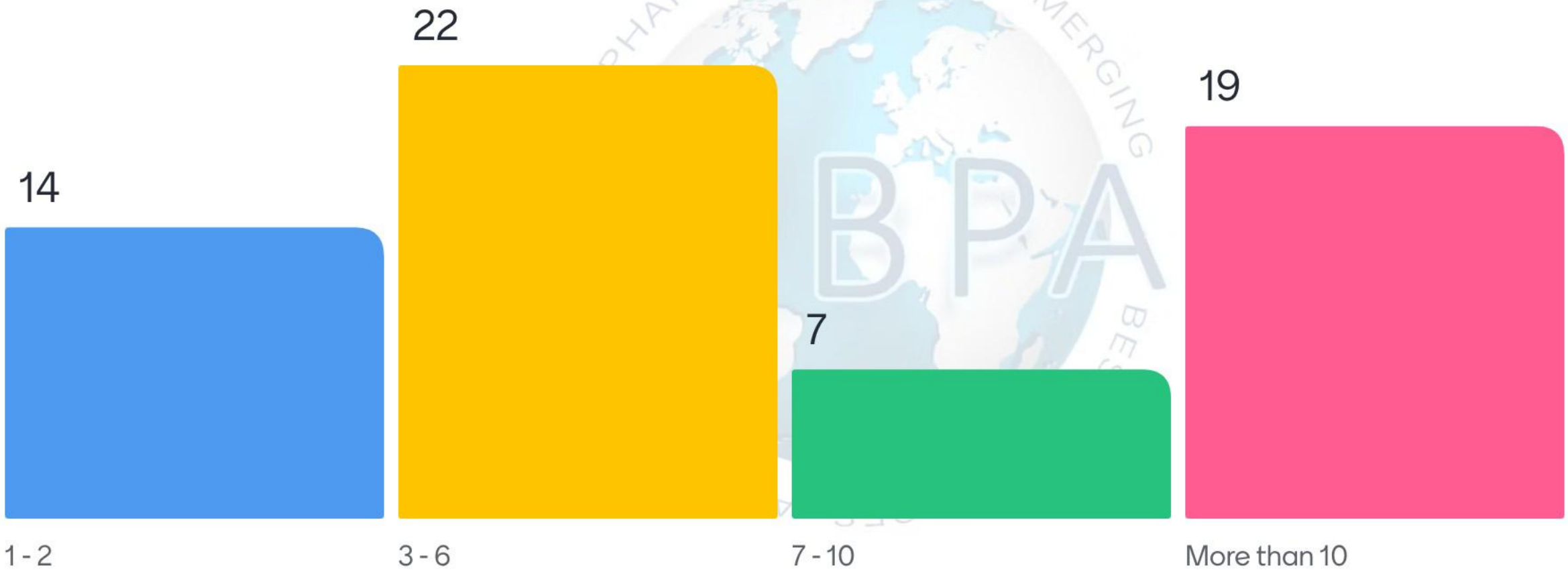
i.4 What product modalities do you work to develop?



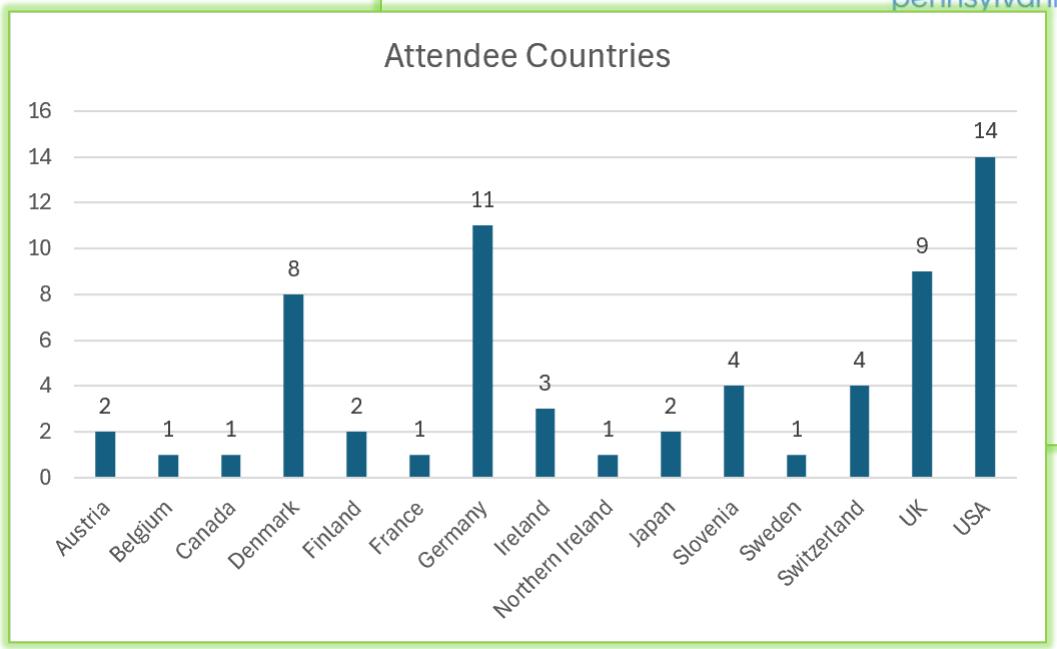
i.5 How many products that you have worked on are affected by HCP-related setbacks?



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



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



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DAY 1 Audience Surveys

Session 1

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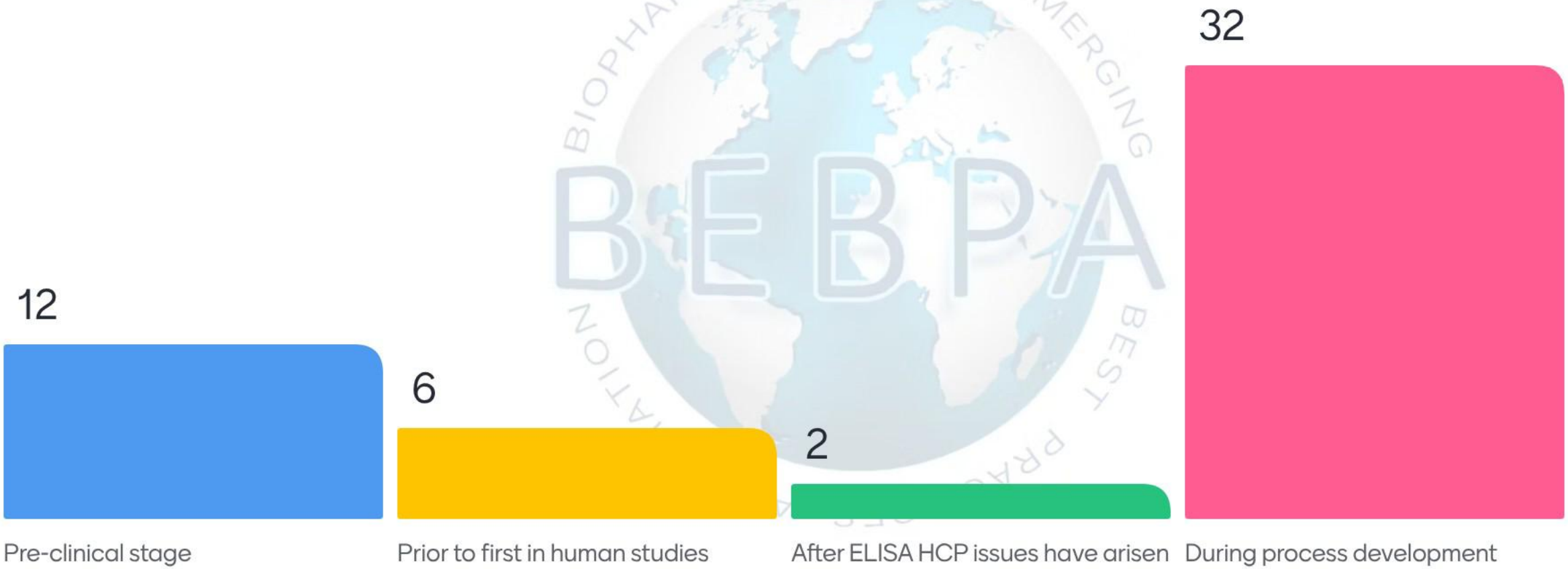
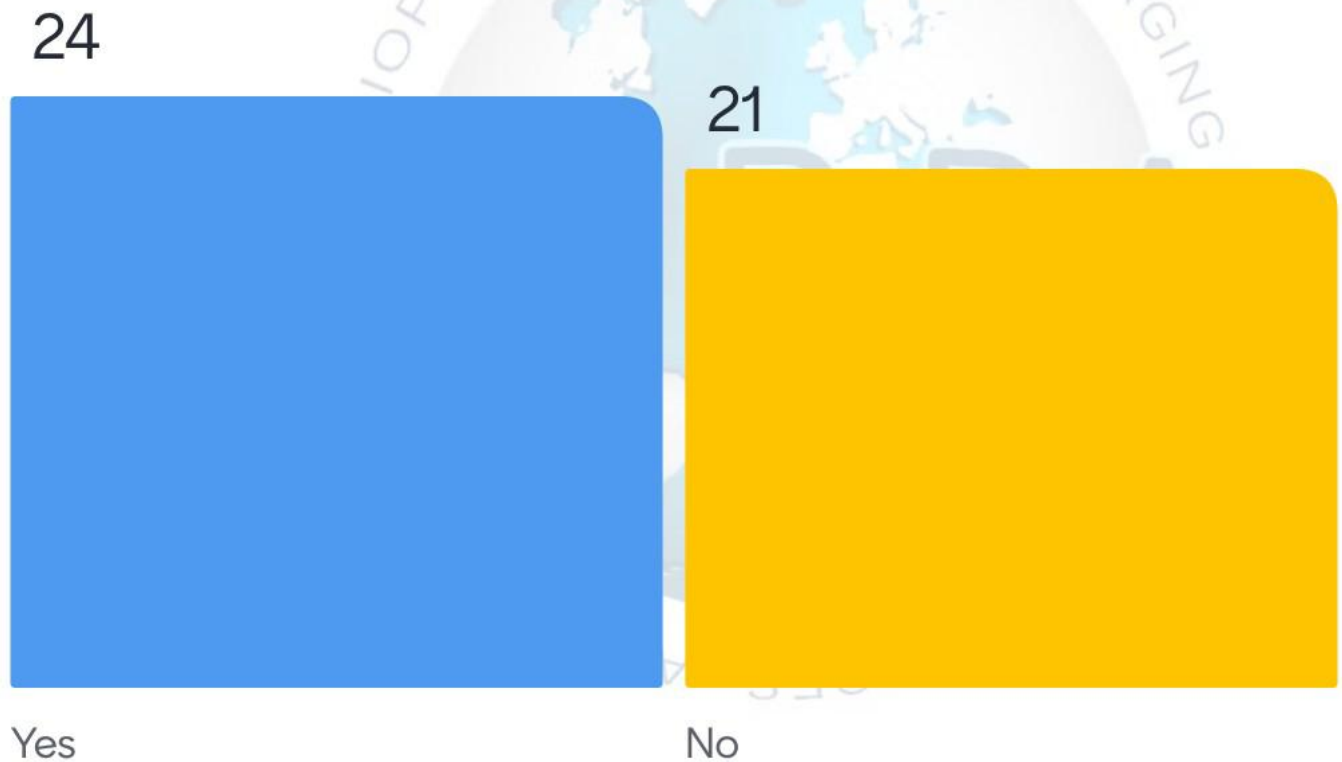
Session 2

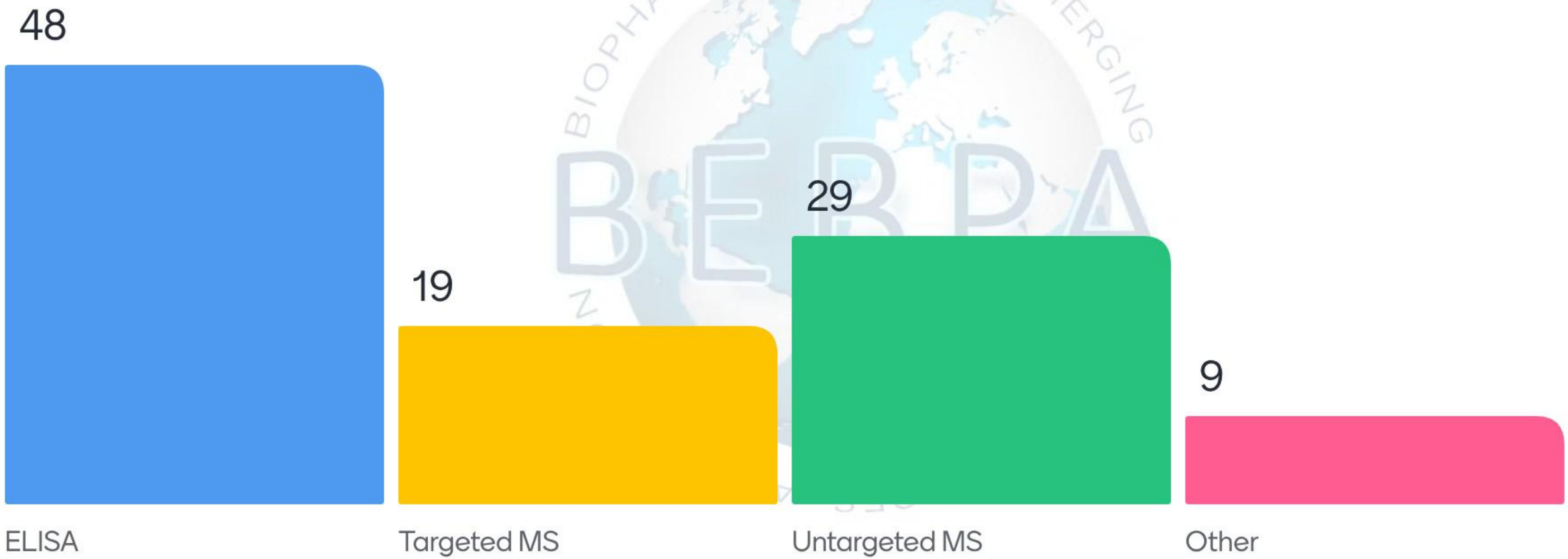
1.1 At what stage of development do you ID HCPs?



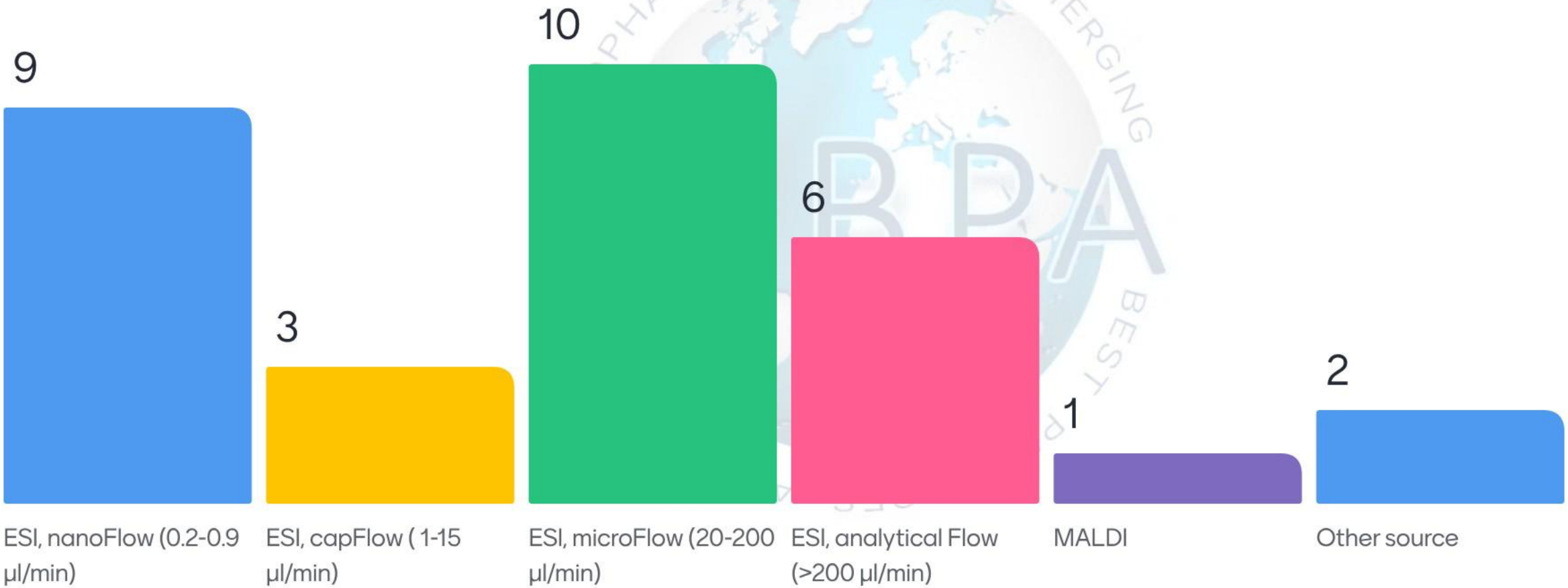
1.2 Do you have a formal risk assessment program for HCPs found in your products?



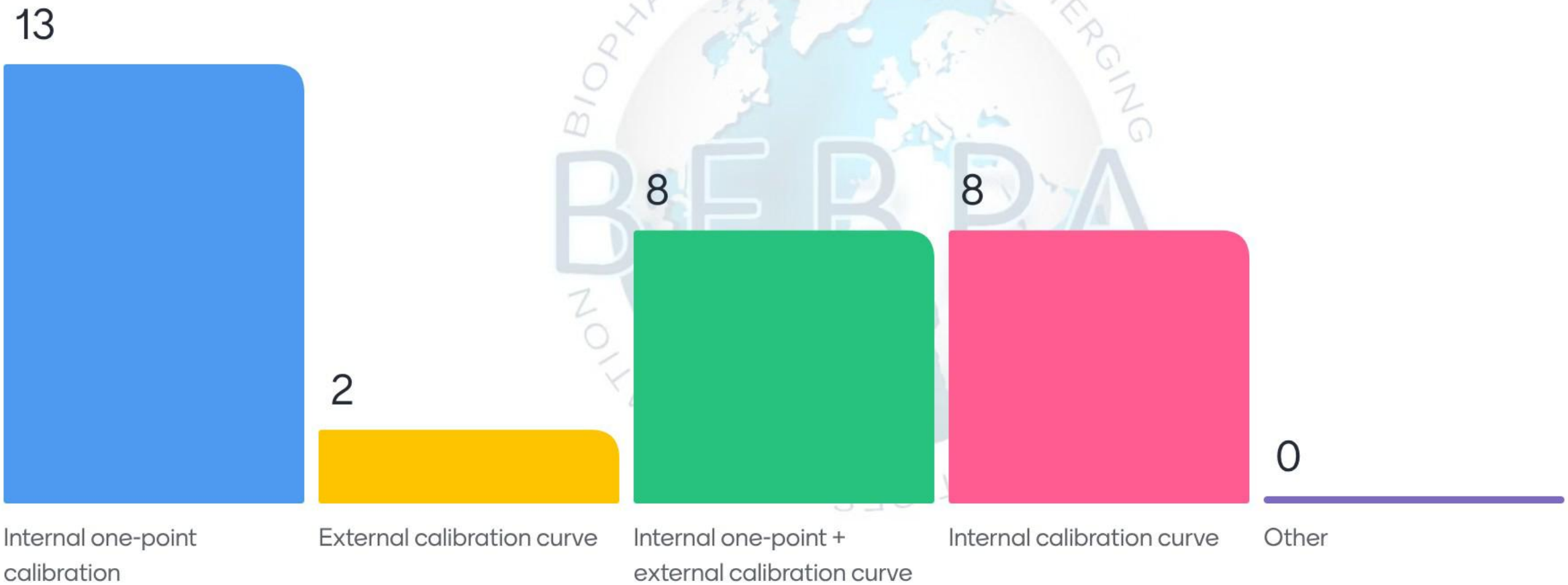
1.3 Which technique(s) are you using for HCP detection?



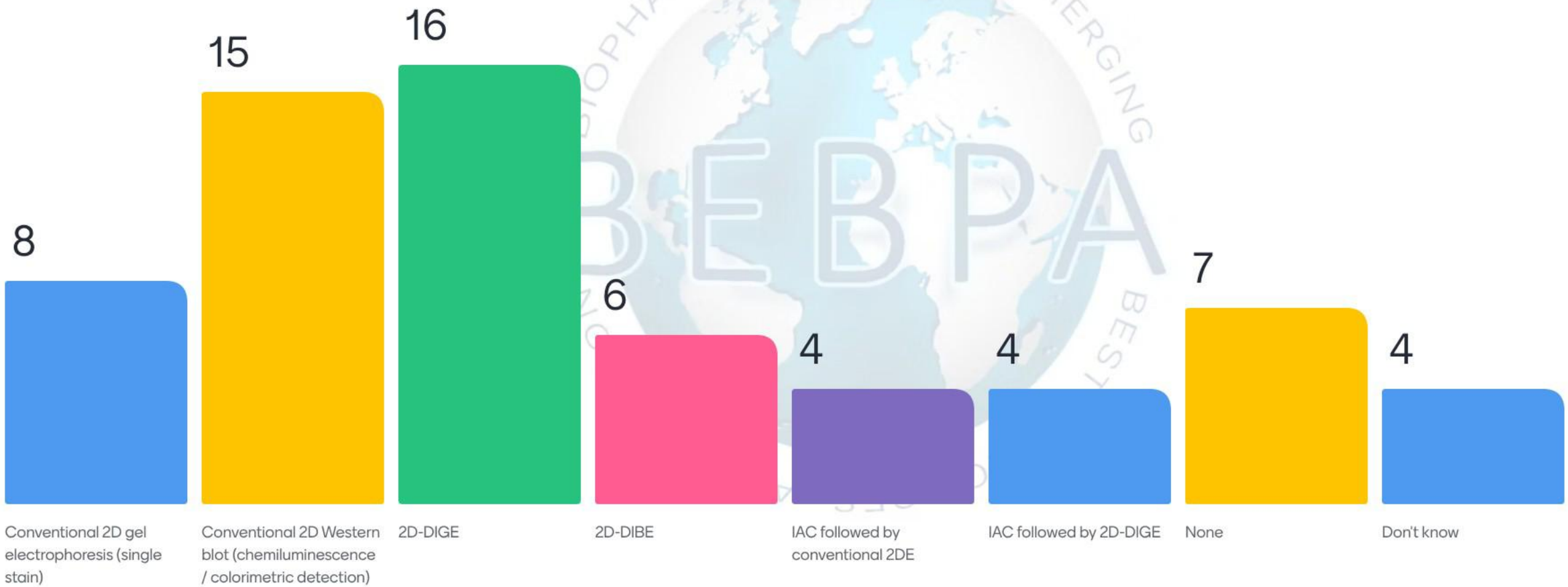
1.4 For MS users: Which source are you using for HCP quantification?



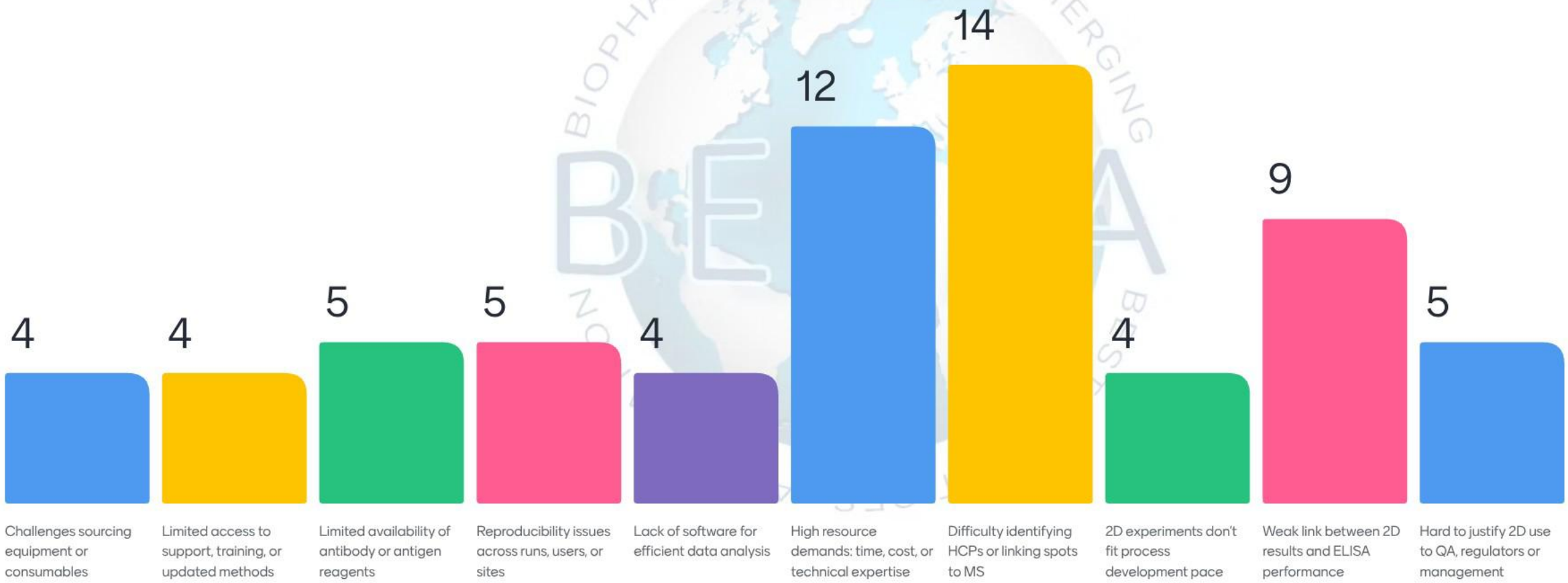
1.5 For MS users: Which type of calibration do you use?



1.6 What 2D methods do you use in your HCP-related work?



1.7 What challenges do you face when using 2D methods in your HCP-related work?



DAY 2 Audience Surveys

Session 3

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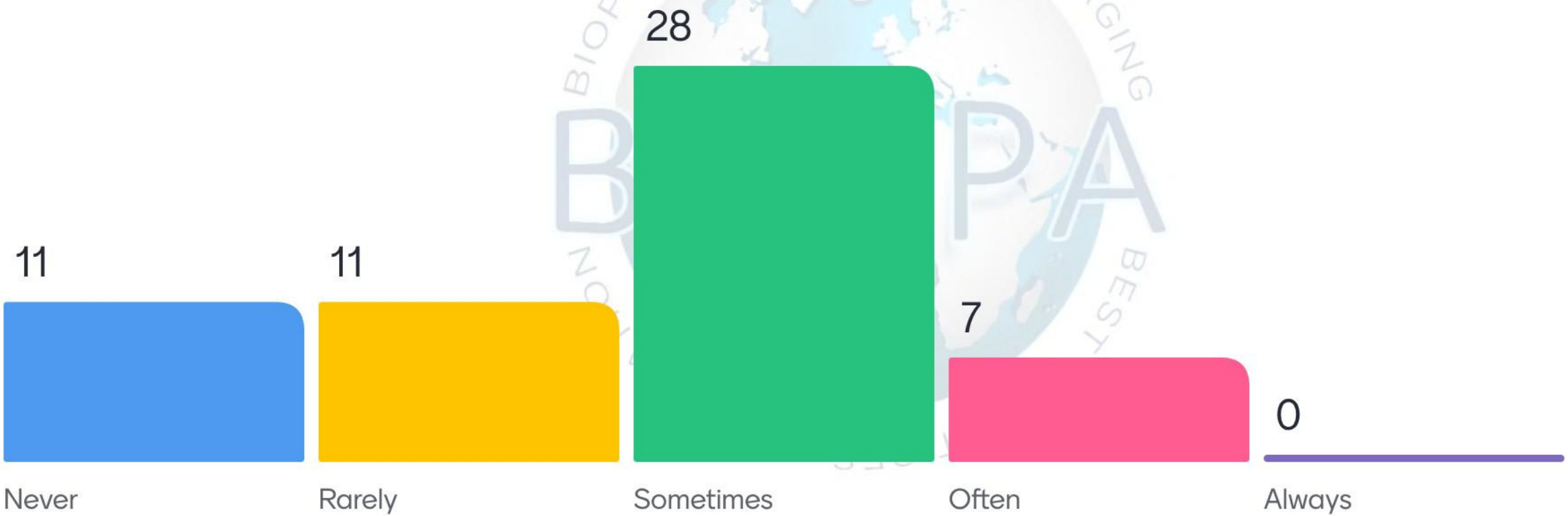
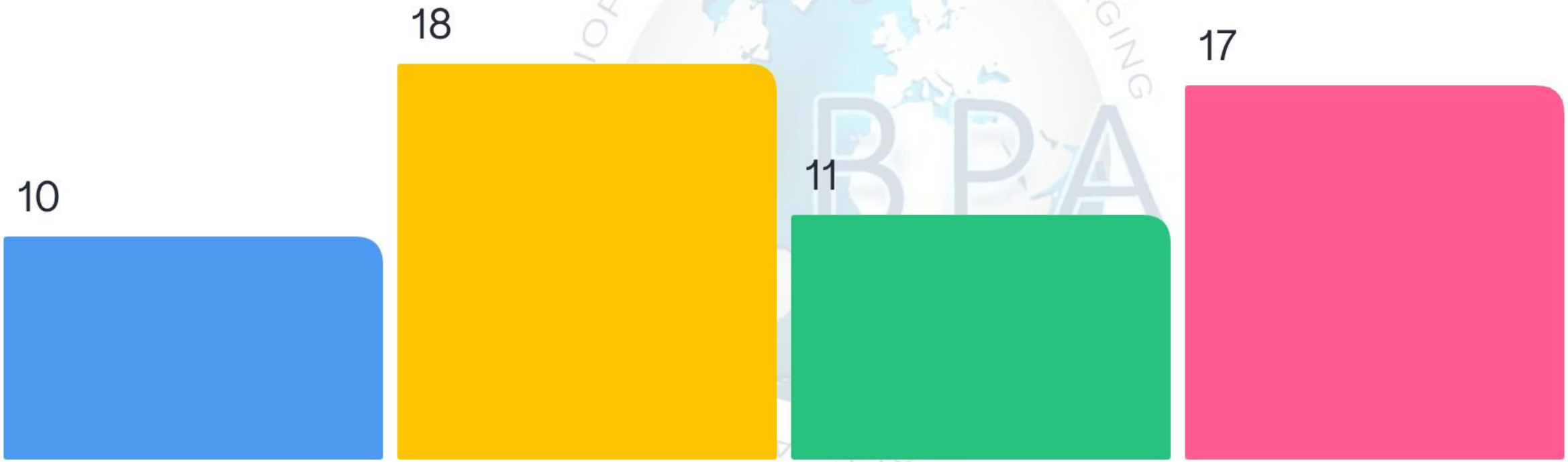
Session 4

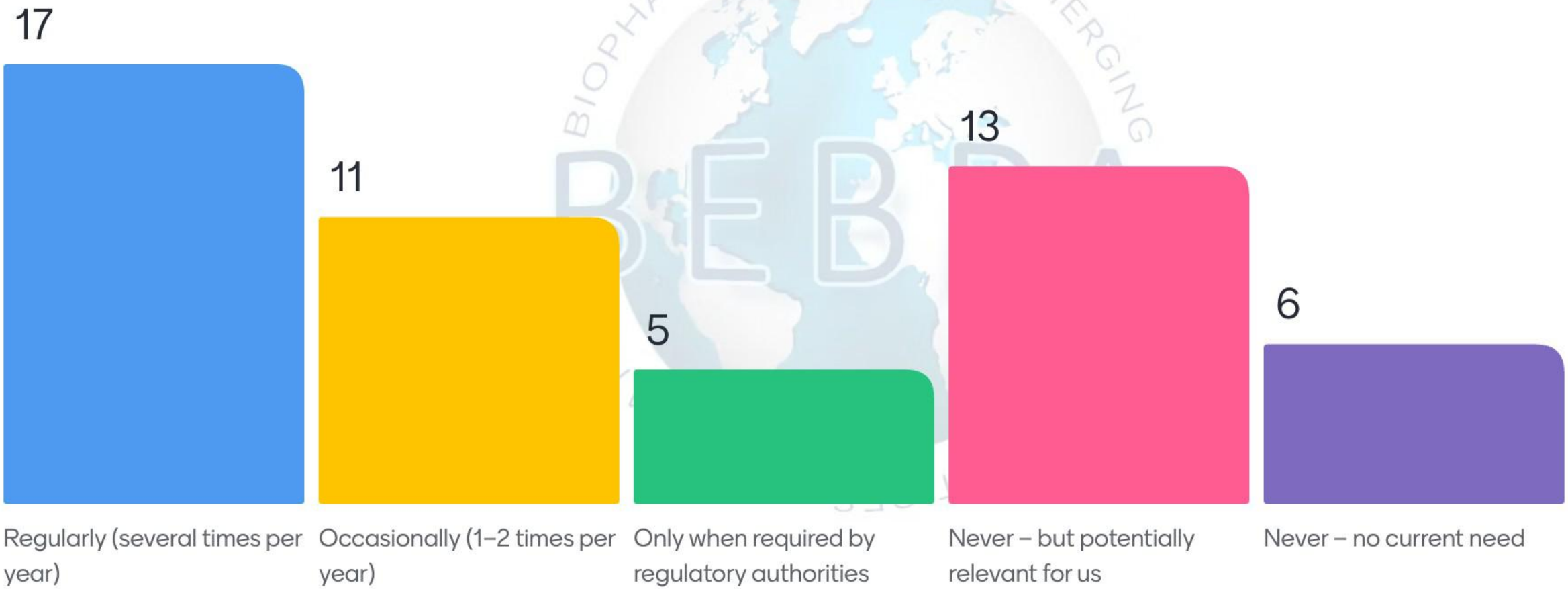
2.1 How frequently do you encounter issues related to Polysorbate degradation in your projects?



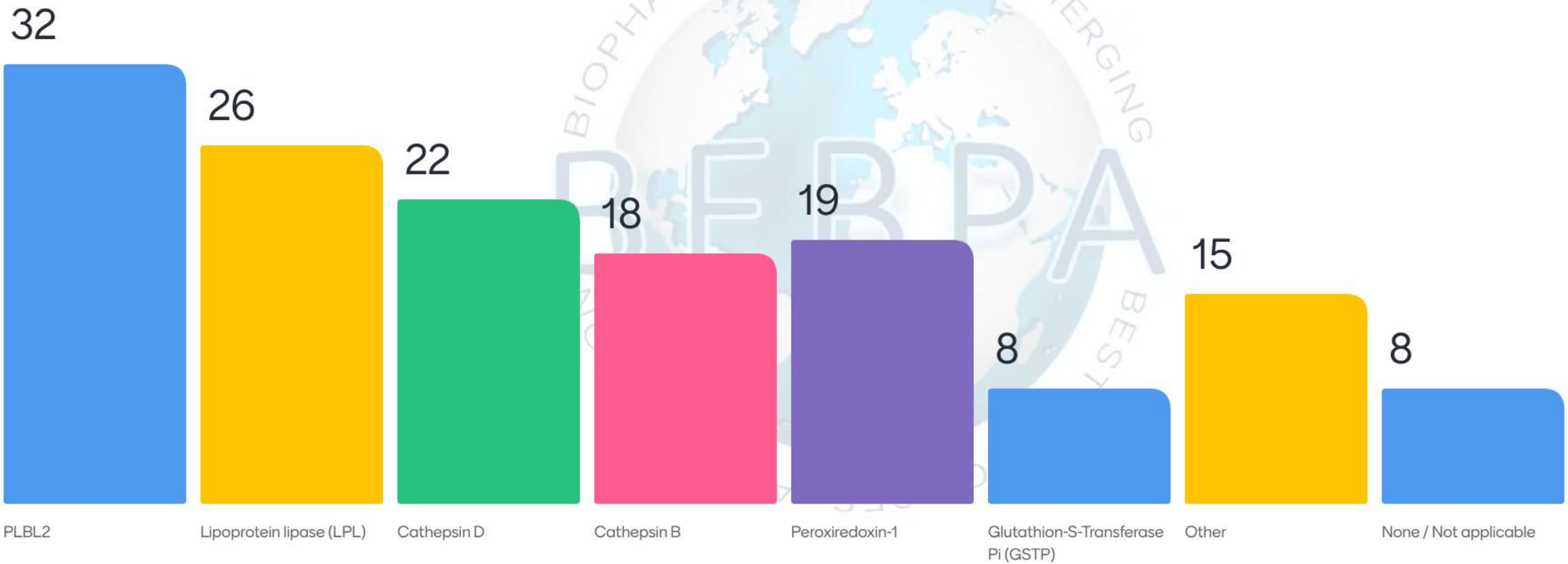
2.2 Do you have specific methods in place to identify enzymatically active host cell proteins in your projects? If yes, what are they?



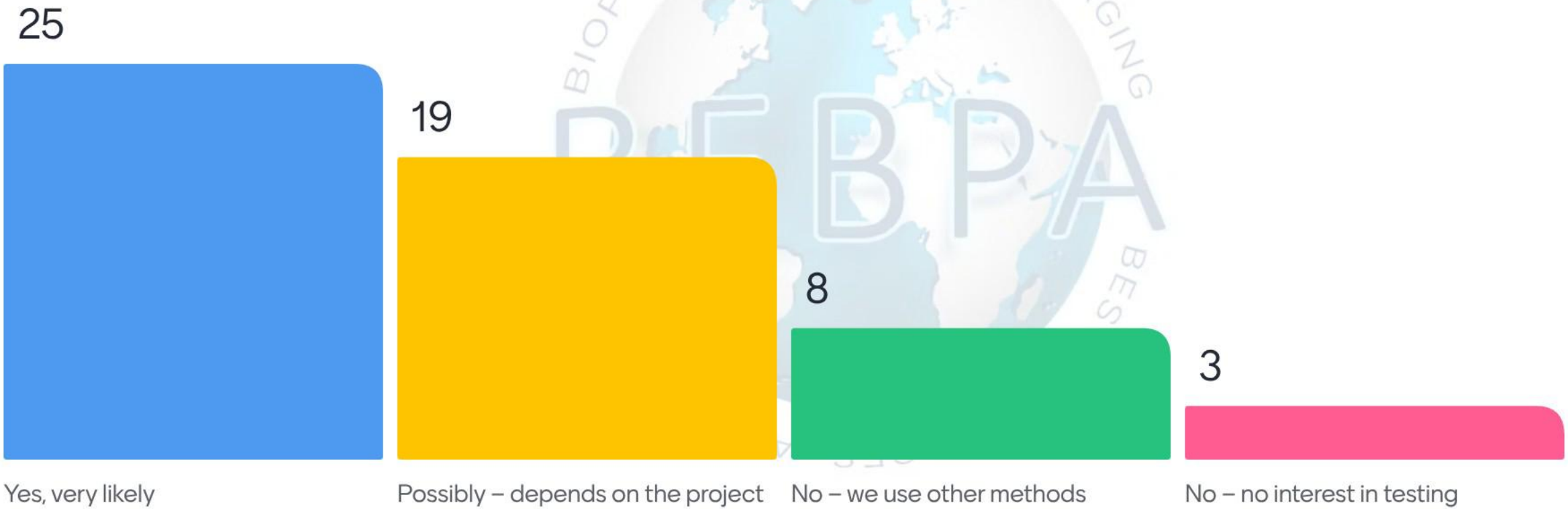
2.3 How frequently do you test for specific HCPs (e.g., for PLBL2 or Cathepsin B) in your current projects?



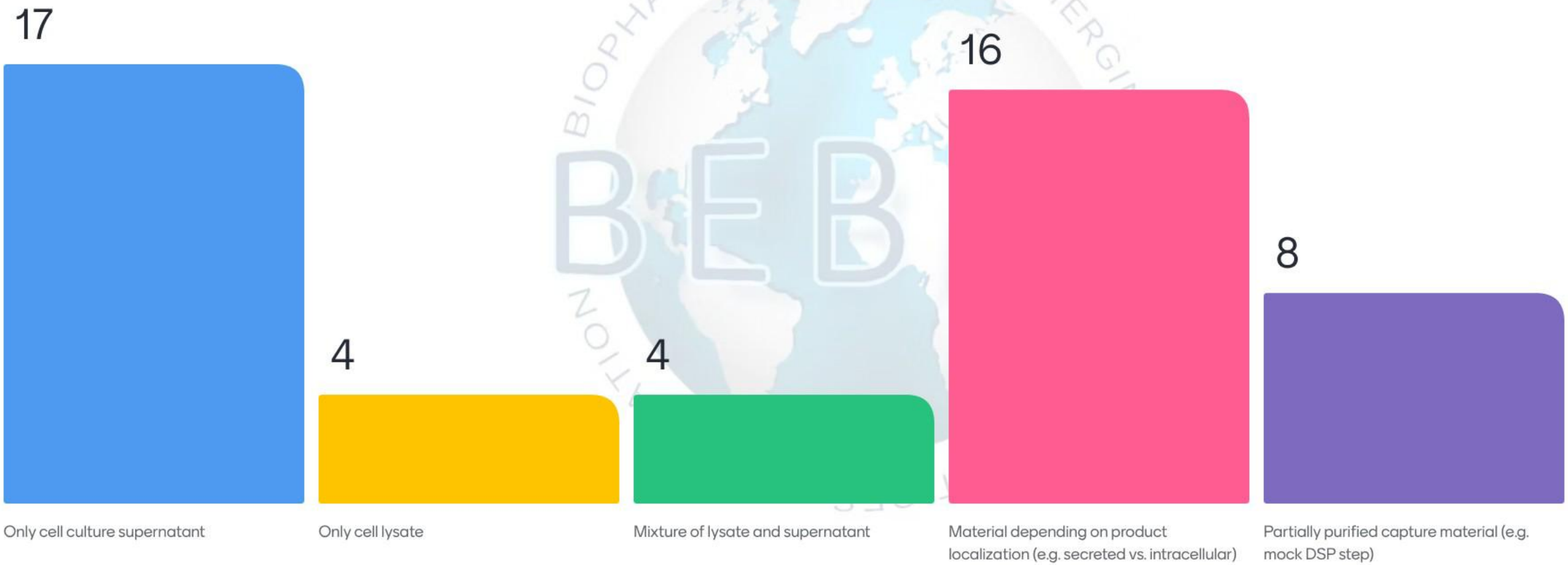
2.4 Which high-risk HCPs are relevant in your development programs?



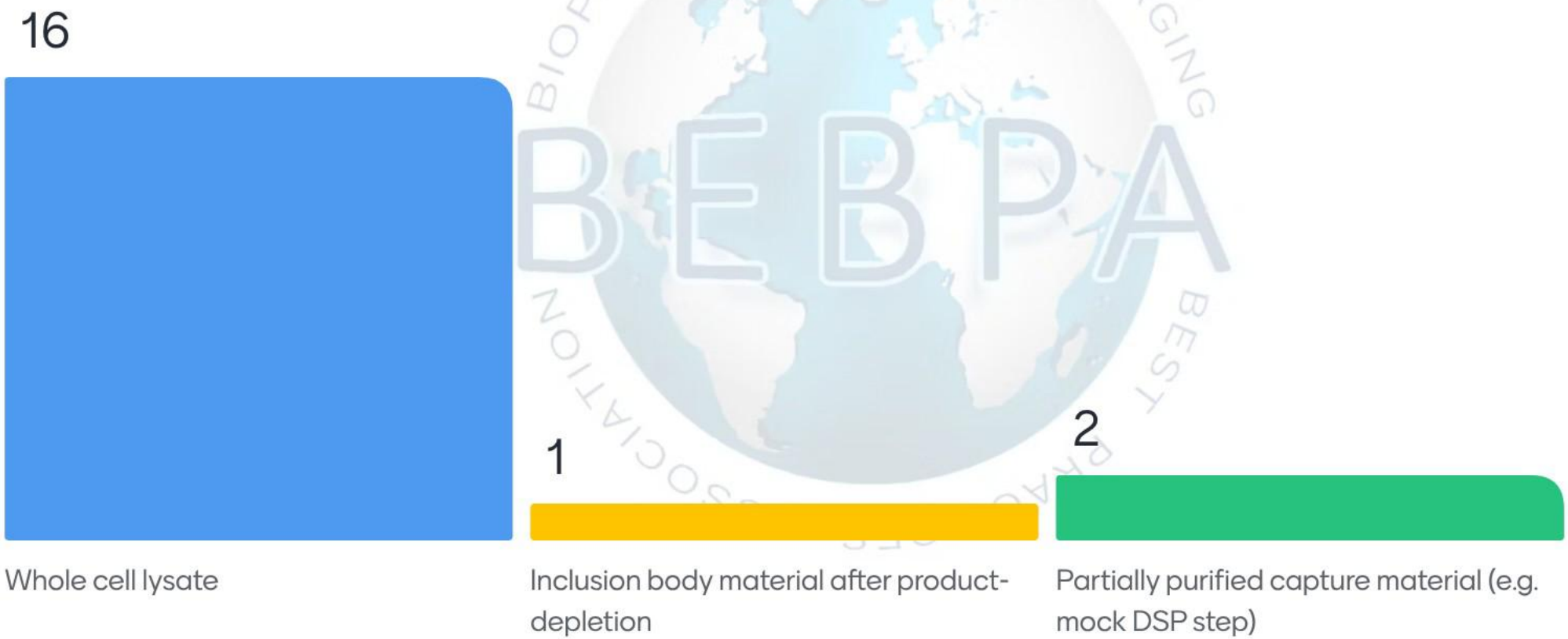
2.5 Would you be interested in qualified ready-to-use ELISA kits for quantification of high risk HCPs?



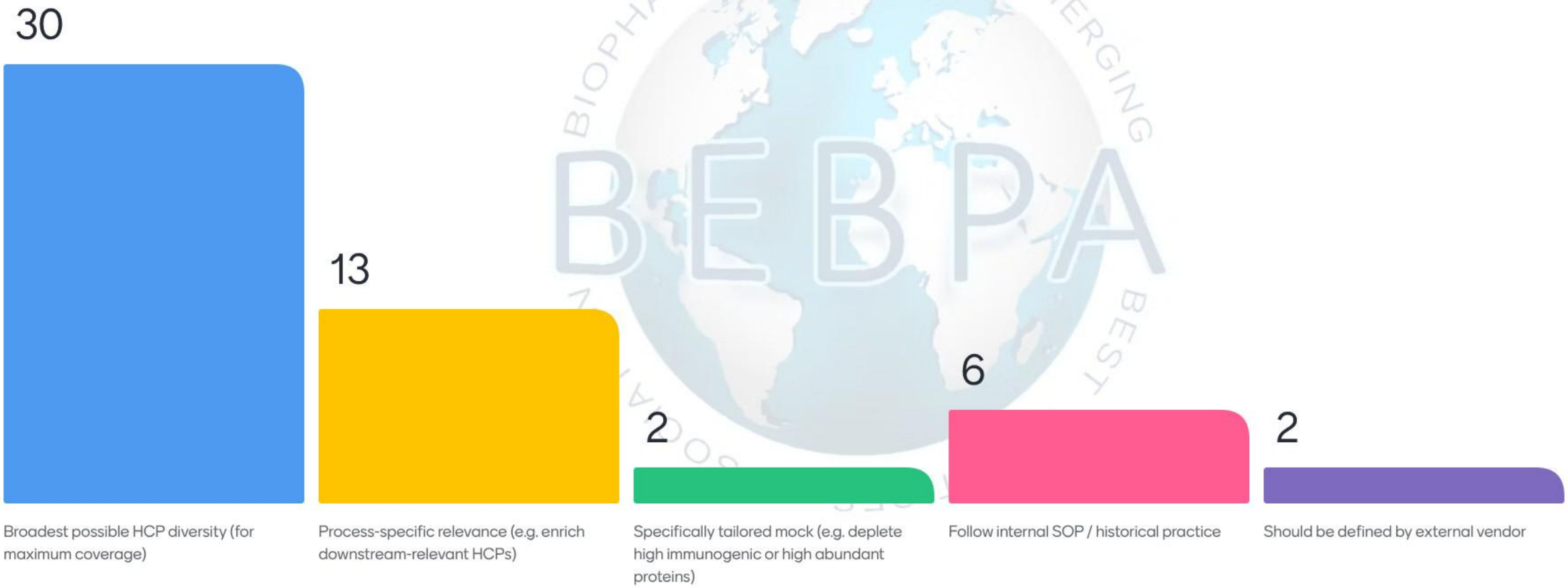
2.6 What type of mock material do you typically use for HCP antibody generation?



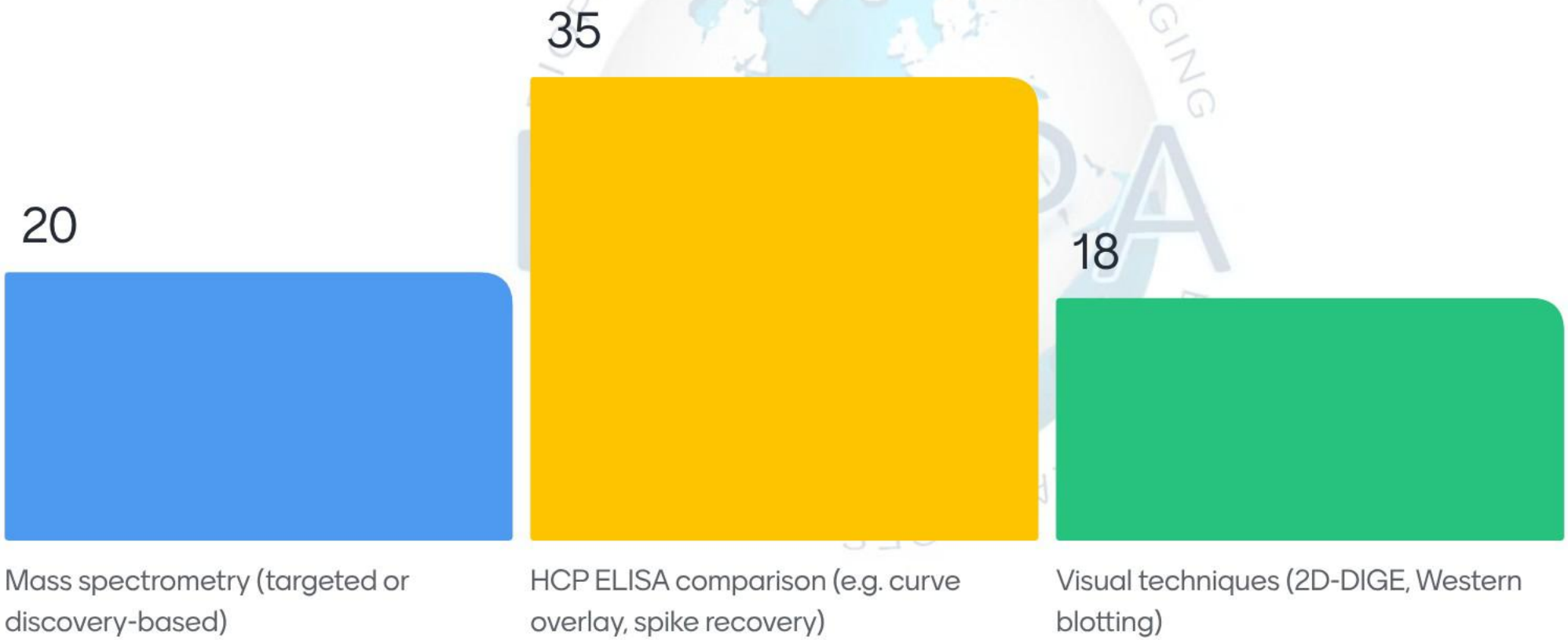
2.7 In case of product expression in inclusion bodies, which strategy do you use for mock material preparation?



2.8 When selecting a mock strategy, which aspects do you consider?

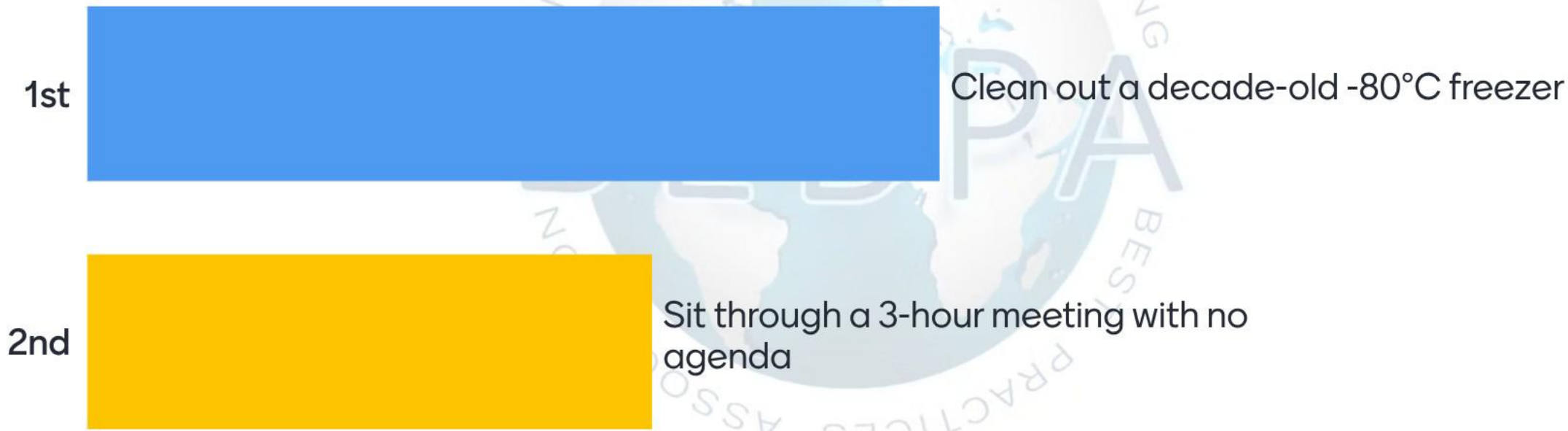


2.9 Which methods do you routinely apply for bridging studies (e.g. for reagent changes or process modifications)?

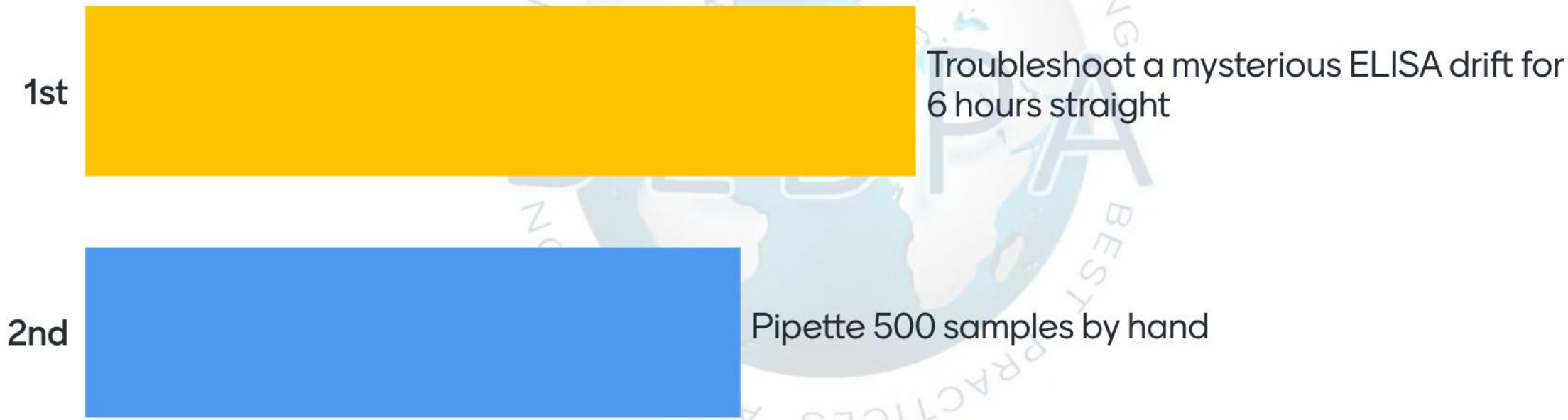



Glitter Break!
Would you rather.....

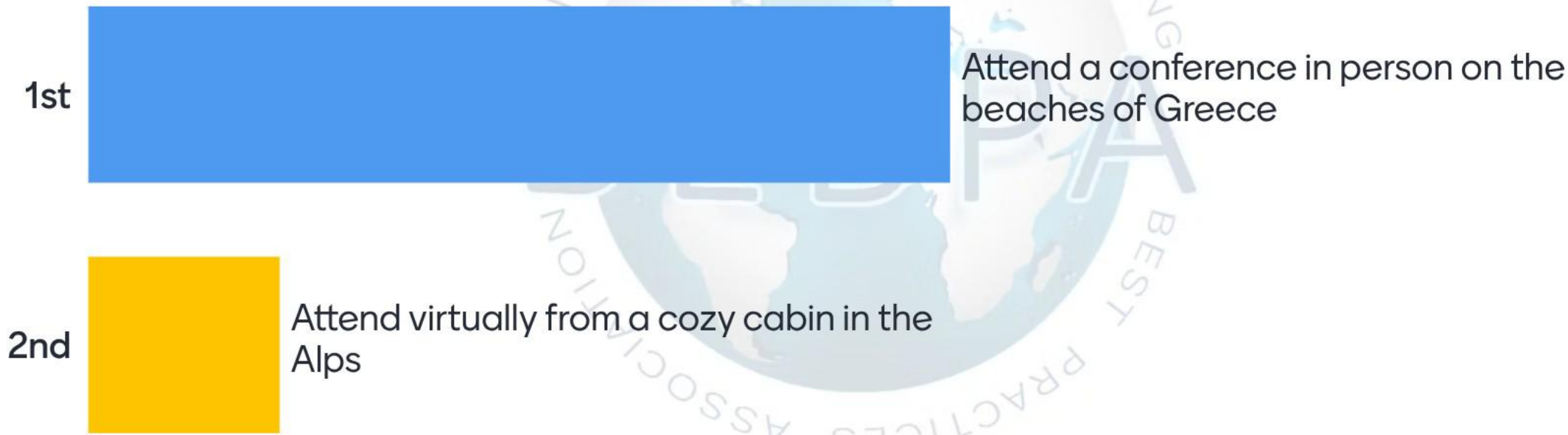
1. Would you rather.....



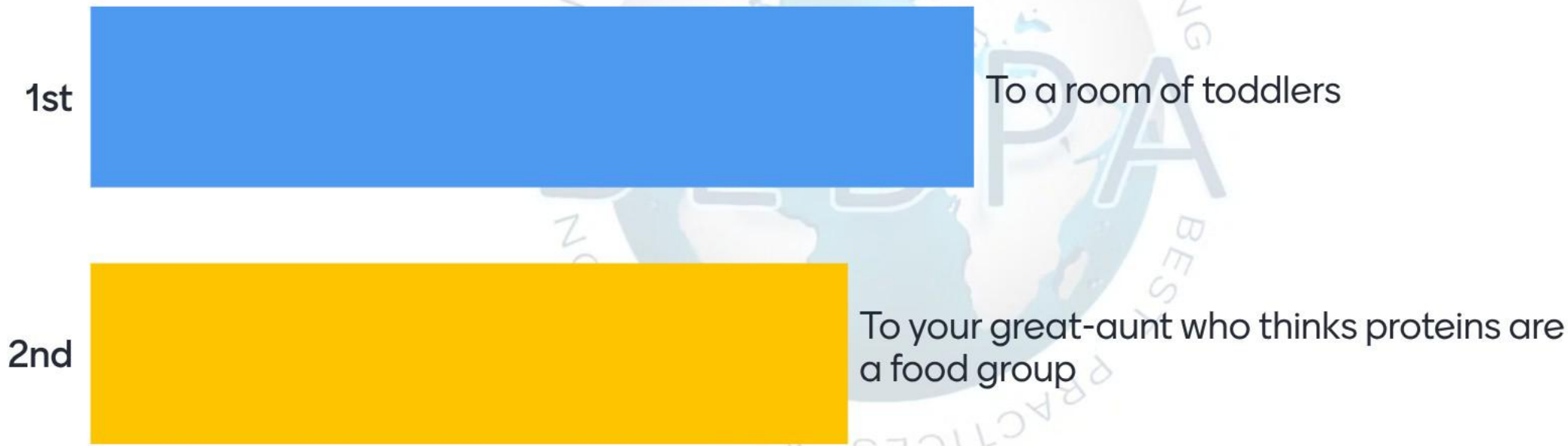
2. Would you rather.....



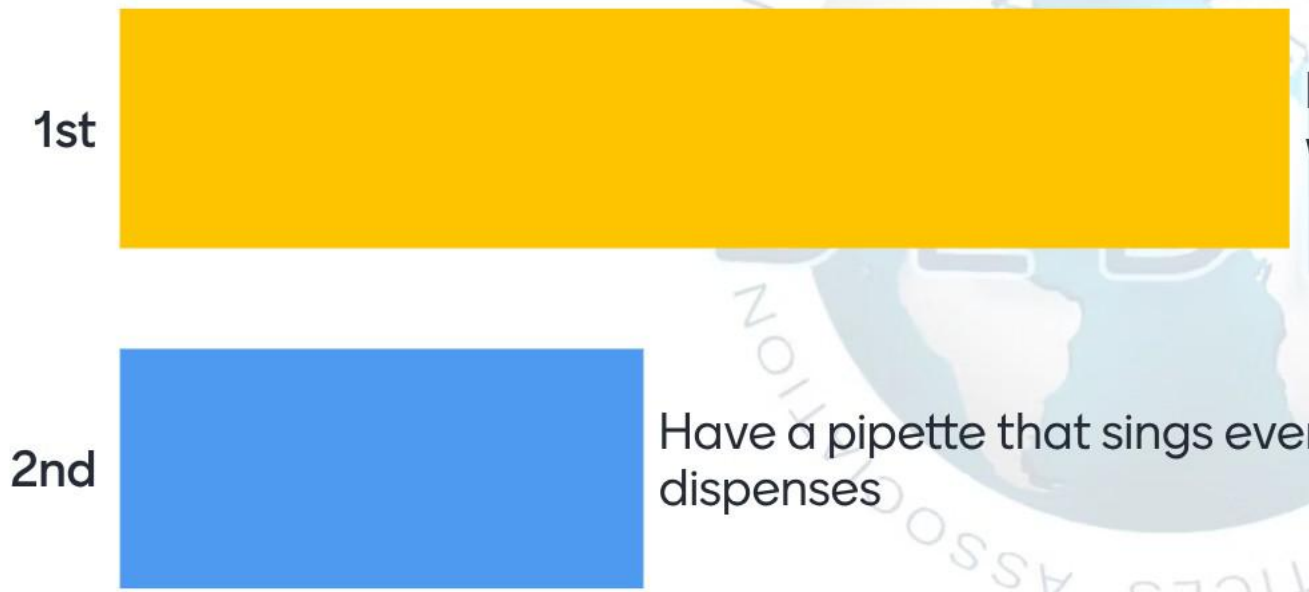
3. Would you rather.....



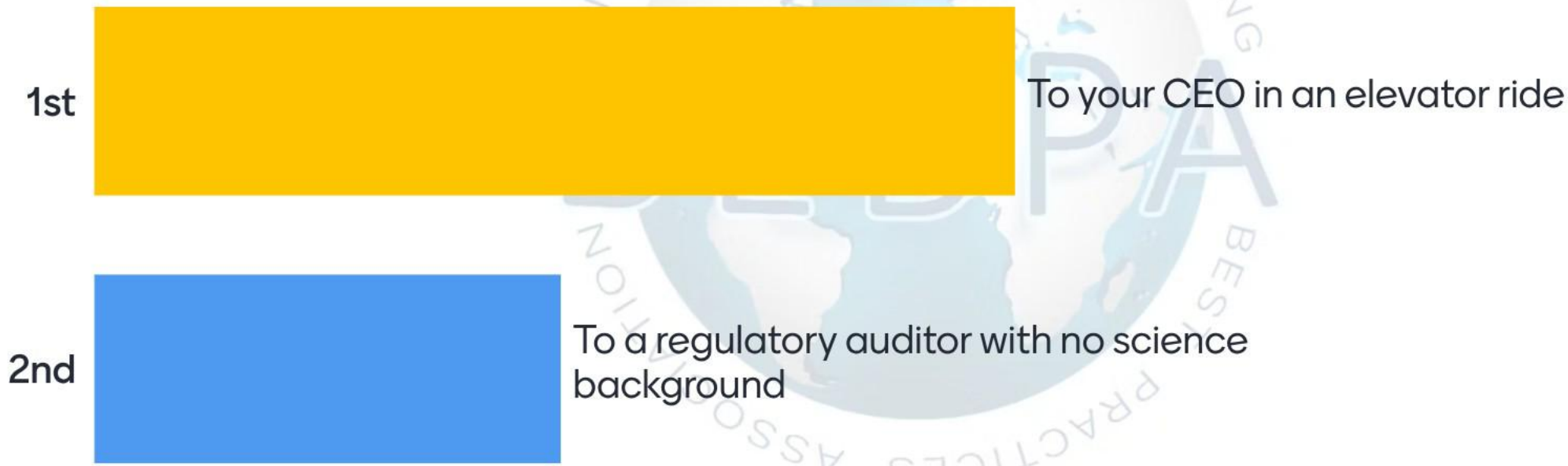
4. Would you rather explain your research.....



5. Would you rather.....



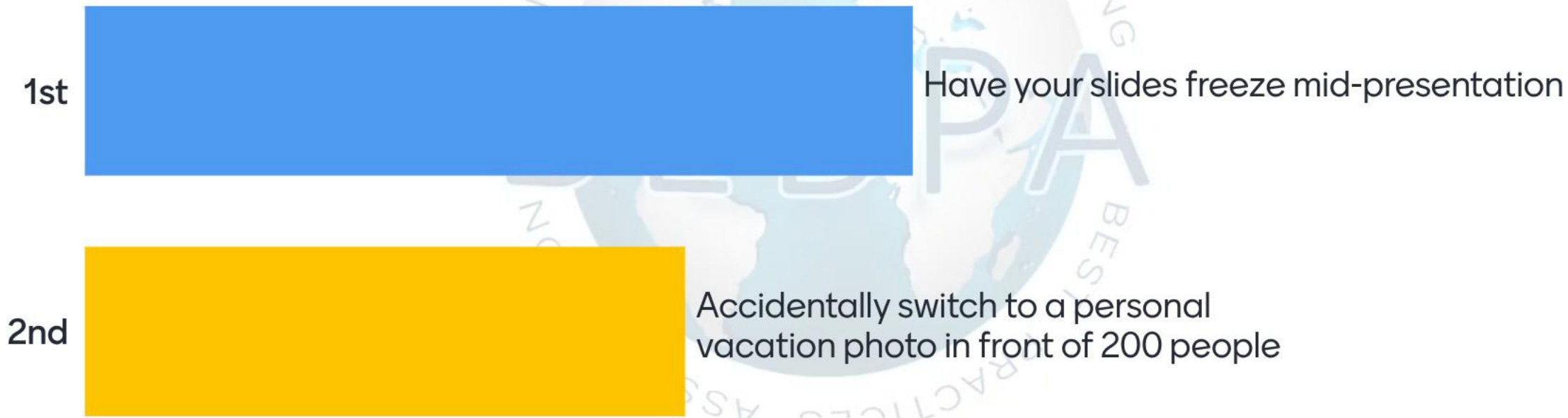
6. Would you rather explain HCP clearance.....



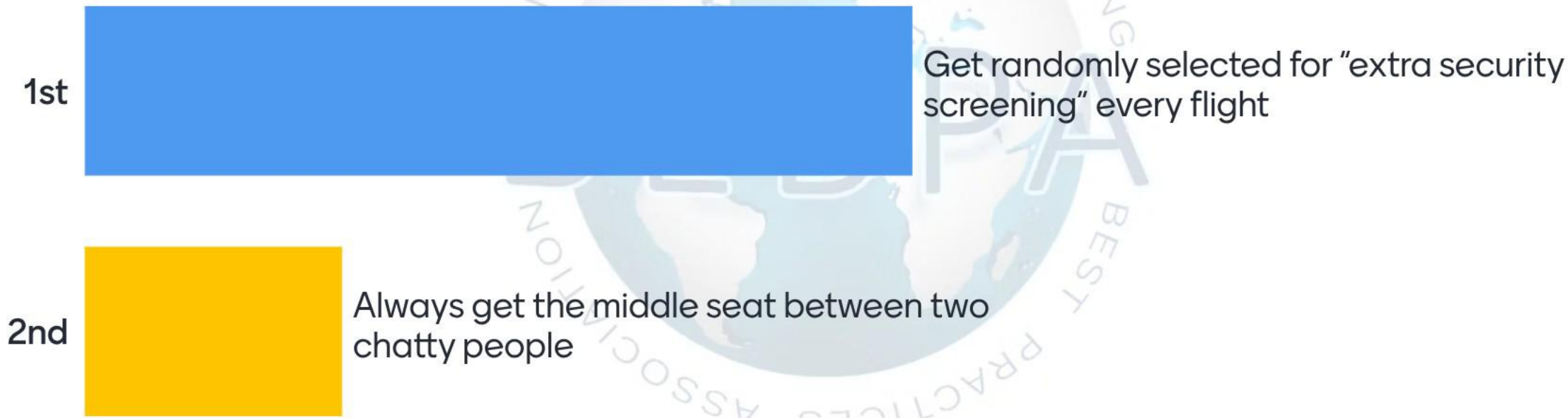
7. Would you rather.....

8. Would you rather.....

9. Would you rather.....



10. Would you rather.....



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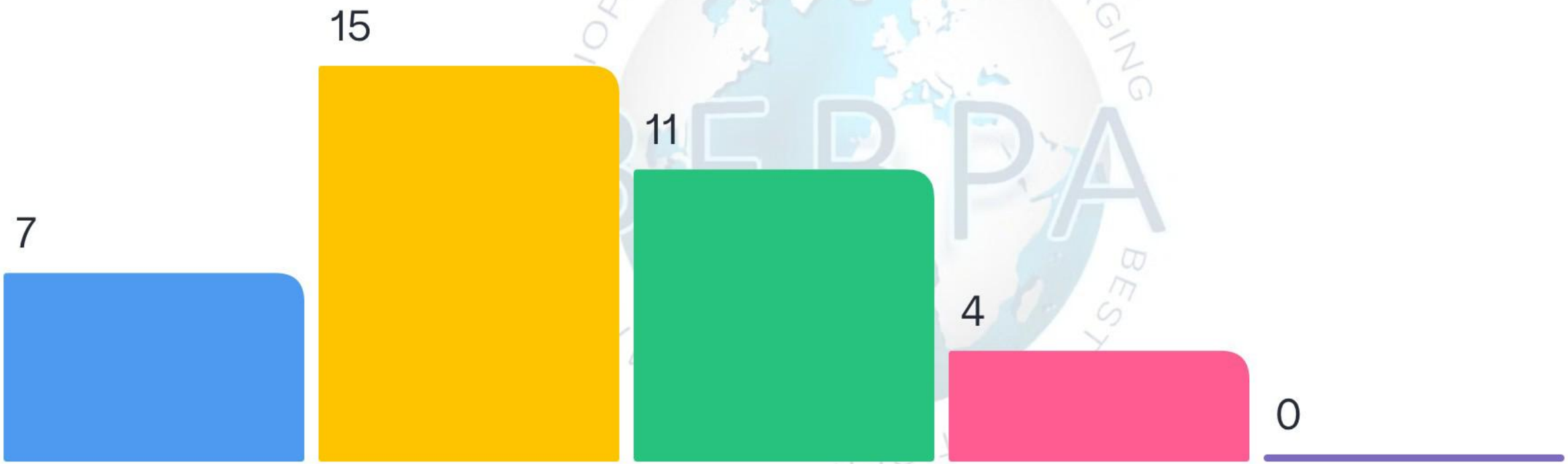
DAY 3 Audience Surveys

Workshop 1: Navigating HCP Analytics: Debunking Common Myths and Applying a Strategic and Systematic Approach for Success

Audience Surveys

Friday, 30 May 2025

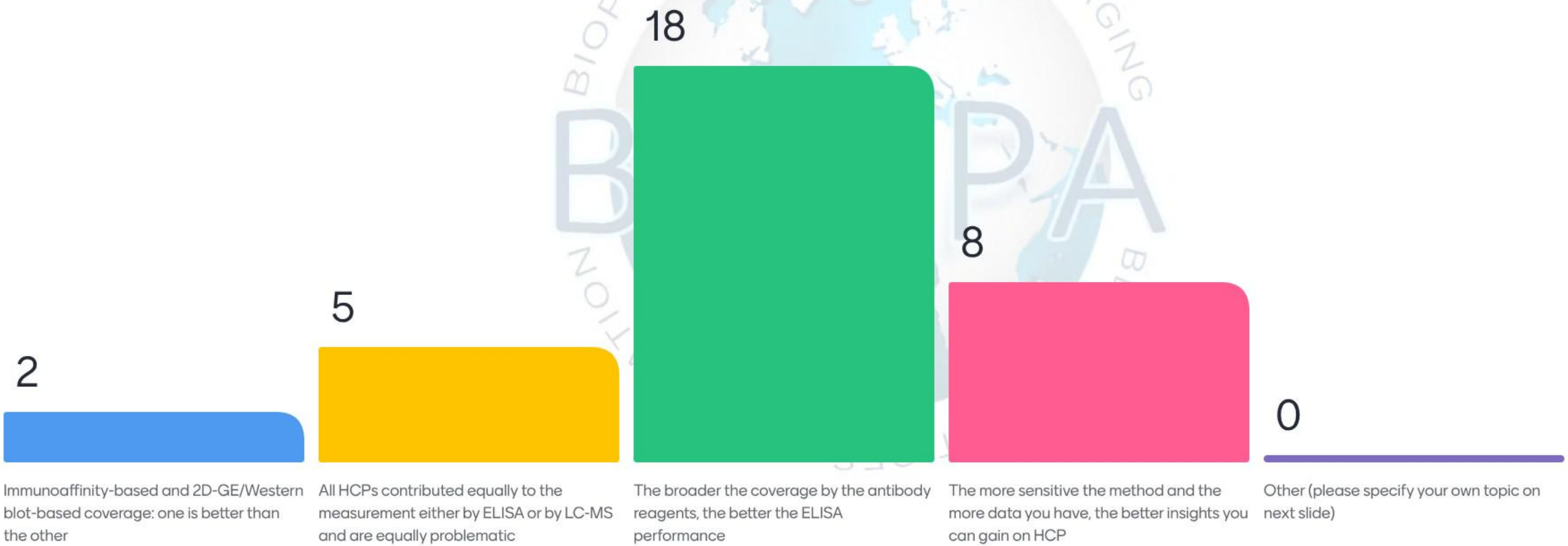
WS1.1 Which of the following topics would you like to learn the most about at our workshop?



WS1.1a OTHER: What other topics would you like to learn the most about at our workshop? (type in answer)

ELISA	LCMS	How to better understand my process	Feedback for Bioprocess
Troubleshooting ELISA issues	Ways to standardize practices across the industry	Dilution linearity for at QL ELISA	2D coverage
How to set spec limits	How we can standardize the HCP-MS workflow.	How to look at mass spec data at each step of our process and see what is a good rate of clearance- also if there are hcps of concern, at what point must they be cleared	Compare LC ms with elisa wuant
Immunisation	ELISA validation	MS process dev support	How to balance ELISA and MS to support processing dev?

WS1.2 Which of the following common myths would you like to learn the most about at our workshop?



WS1.2a OTHER: What common myths would you like to learn the most about at our workshop? (type in answer)

Process specific assay is always better than platform or generic	Either MS or ELISA is better	MS coverage is a good bridging strategy	LC-MS HCP GMP release
Quantitative answers	Biophysics of linearity issues in ELISA	Need for process specific assay	DSP can solve all HCP problem
An HCP ELISA is actually quantitative...	Sensitivity of assay	Quantitation's possible	Process specific Vs platform ELISA
MS can solve all HCP issues.	LC-MS HCP GMP release		

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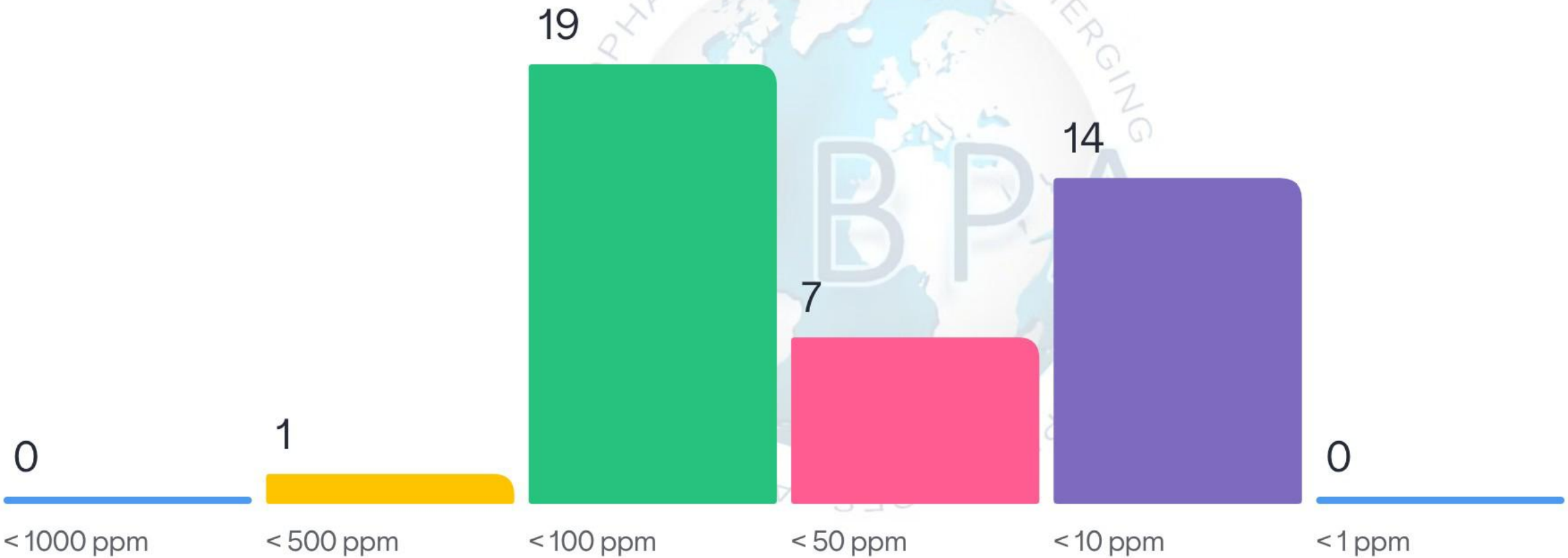
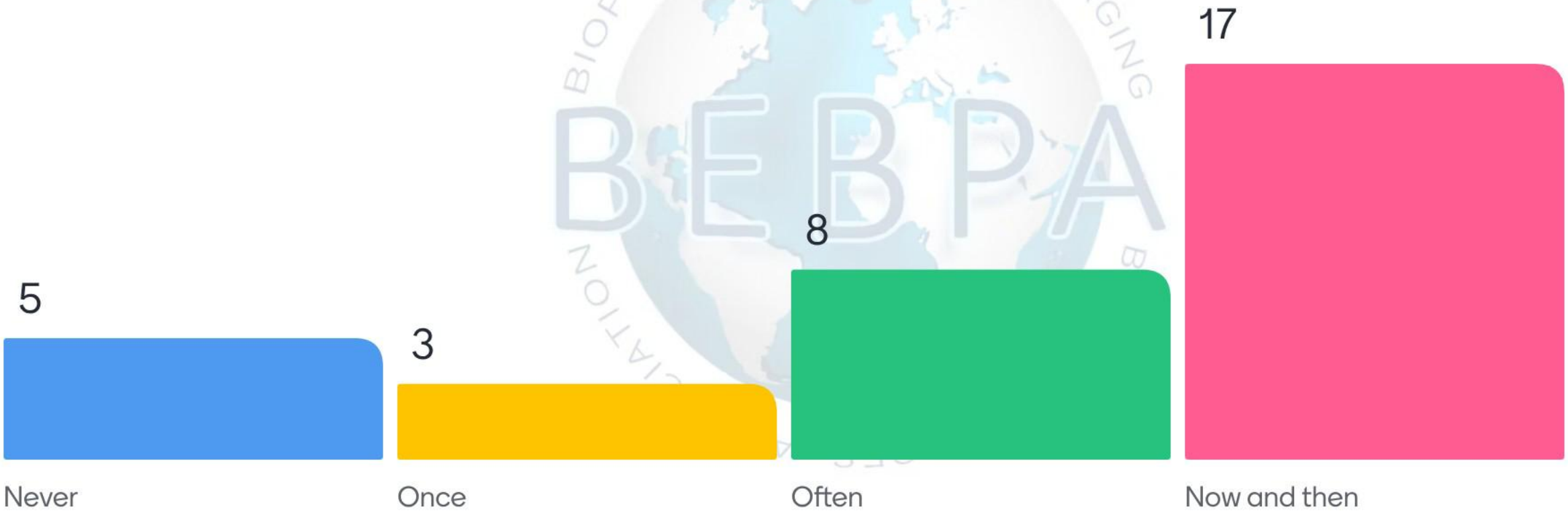
DAY 3 Audience Surveys

Session 5

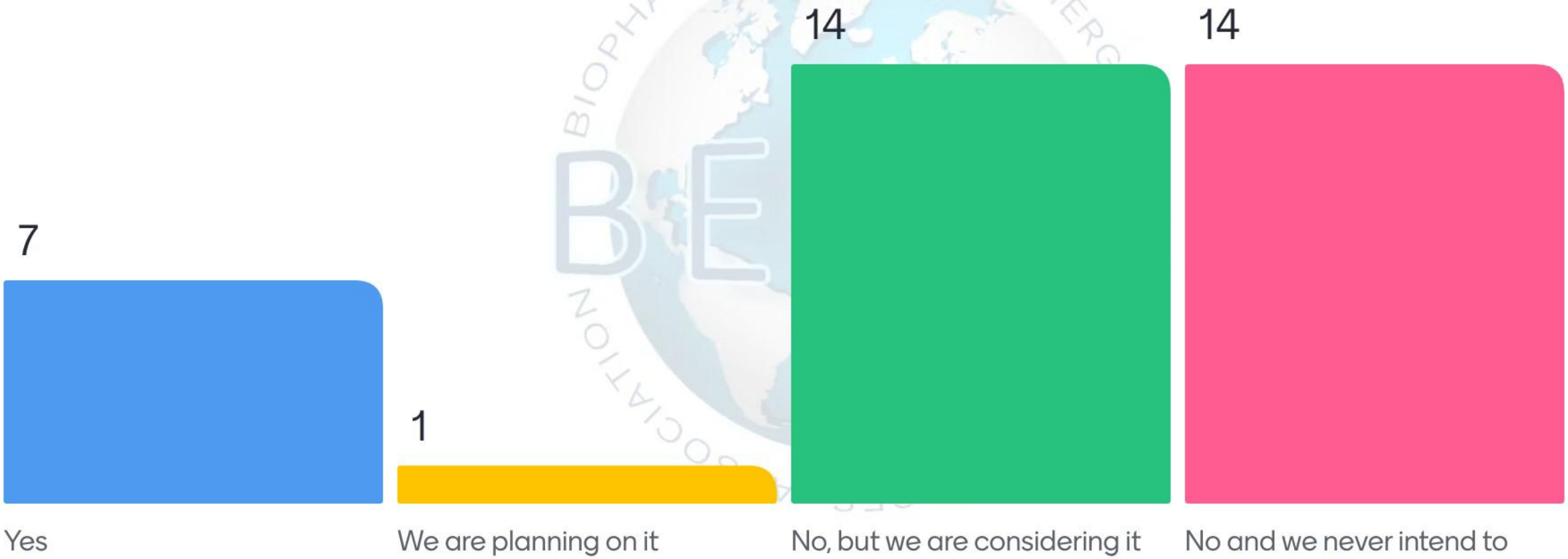
3.1 What HCP levels do you consider to be safe?



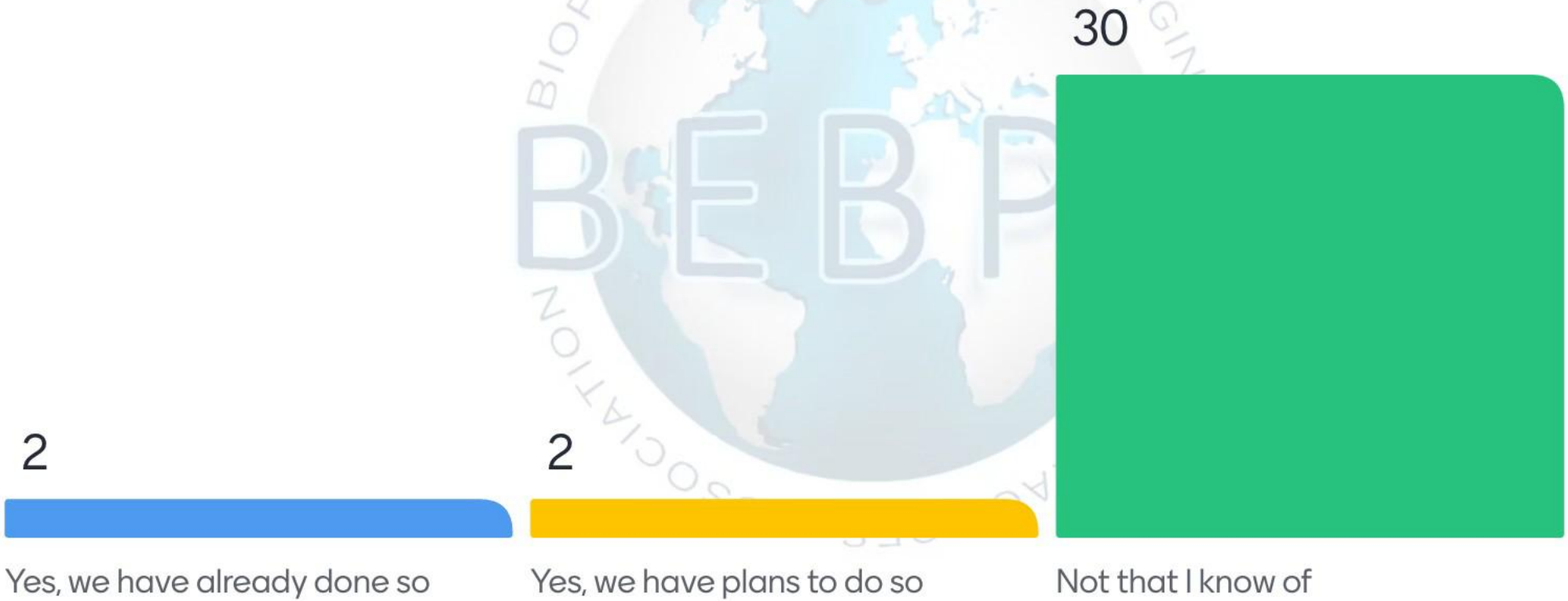
3.2 Have you identified HCPs present in your product but not detected by ELISA?



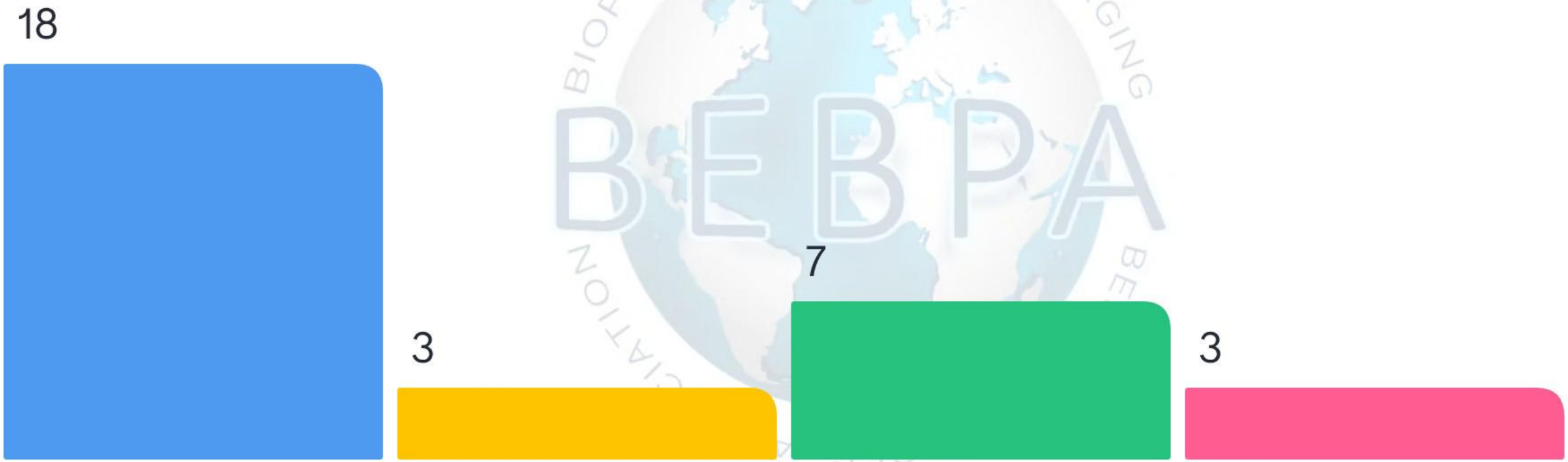
3.3 Have you put an MS method into the QC lab?



3.4 Has your company considered expressing your rDNA products in cell substrates derived from knock-out animals?



3.5 What kind of results have you seen when bridging a generic HCP kit with an upstream platform or process-specific assay?



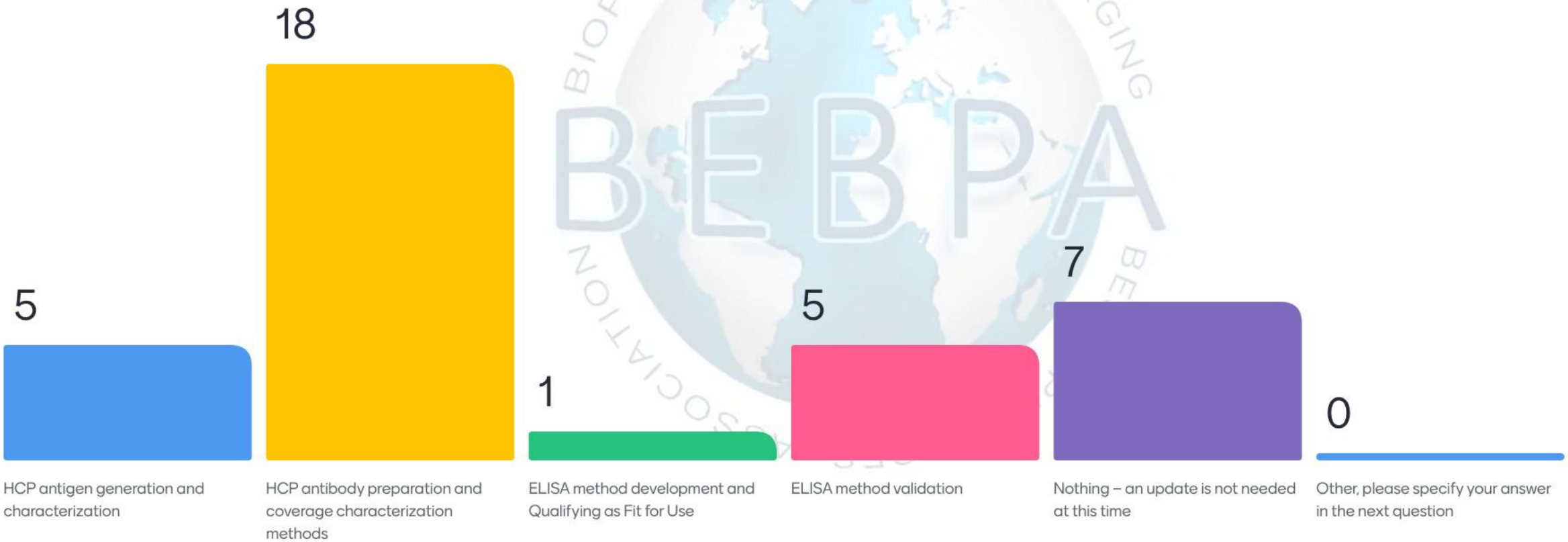
Upstream platform or process-specific assay detects more HCPs than generic kit in all process intermediates and DS.

Upstream platform or process-specific assay detects more HCPs in unpurified cell culture harvest and drug substance

Upstream platform or process-specific assay detects more HCPs than generic kit in certain process intermediates

Upstream platform or process-specific assay detects less HCPs than generic kit

3.6 There are suggestions that USP <1132> (HCP ELISAs) should be updated. If it were to be updated, what subjects do you think need updating?



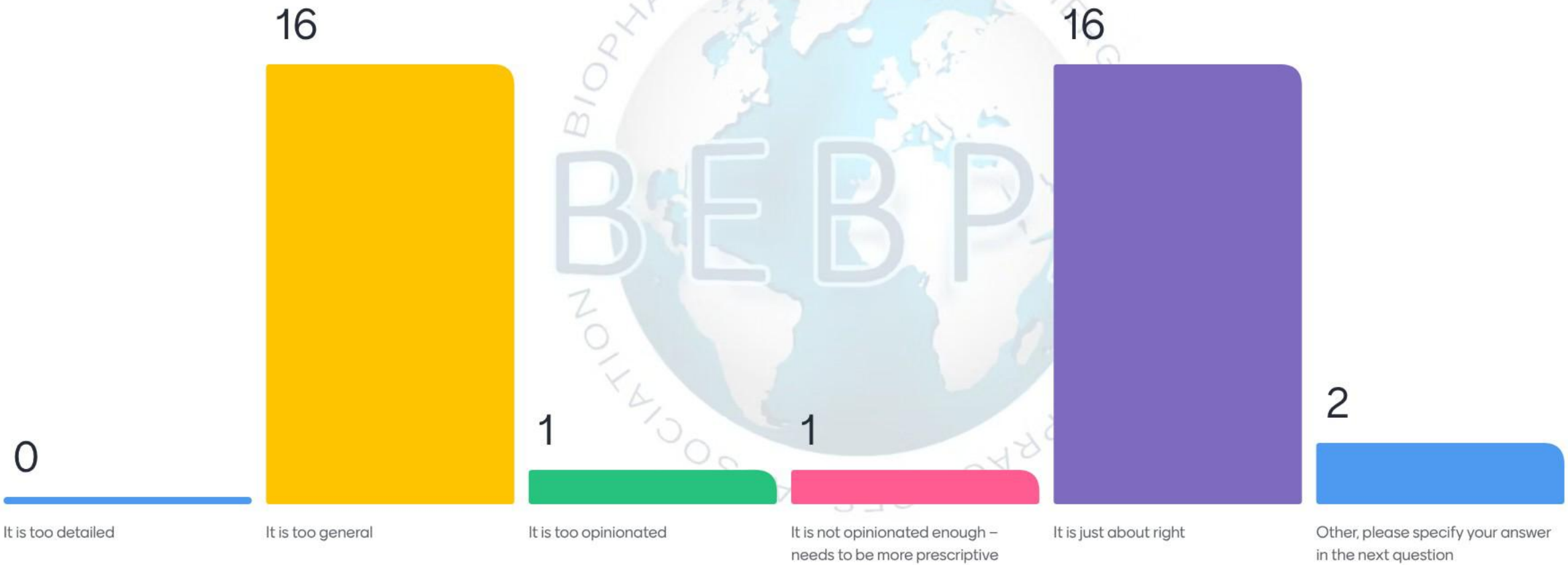
3.6a If USP <1132> were to be updated, what OTHER subjects do you think need updating? *(type in answer)*

CI Evaluation for accuracy validation

LC-MS-Coverage

Specification limit

3.7 If you have read USP <1132.1>, how would you characterize it?



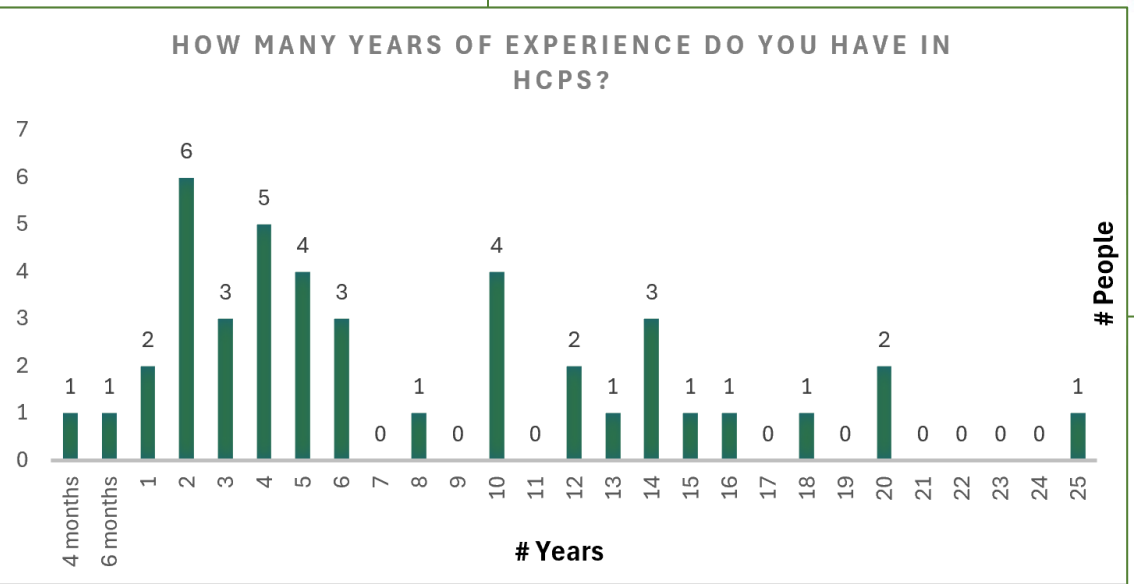
3.7a If you have read USP <1132.1>, how would you OTHERWISE characterize it? *(type in answer)*

NA

It Accounts for the Challenger with mass spec

Best practices for quantitation

3.8 How many years of experience do you have in HCPs? *(type in number)*



From 42 HCP Attendees in 2025:

Total # Years = 322 years, 10 months!

(~avg. = 7.6 years)


BIOPHARMACEUTICAL EMERGING BEST PRACTICES ASSOCIATION
BEBPA

Thank you!!