BEBPA 2021 Host Cell Protein Symposium

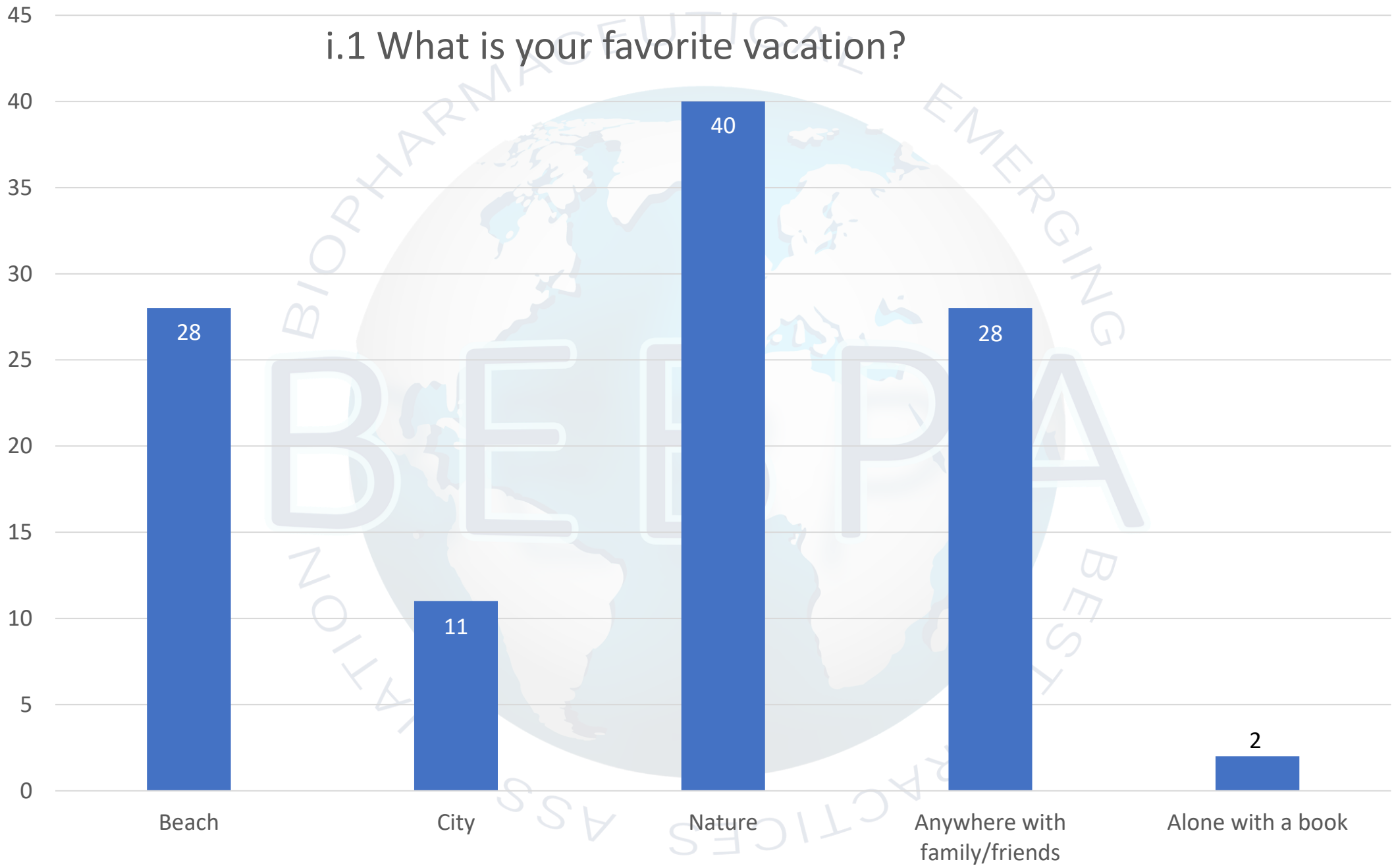
17-19 May 2021

*Our 5th **VIRTUAL** Conference!*

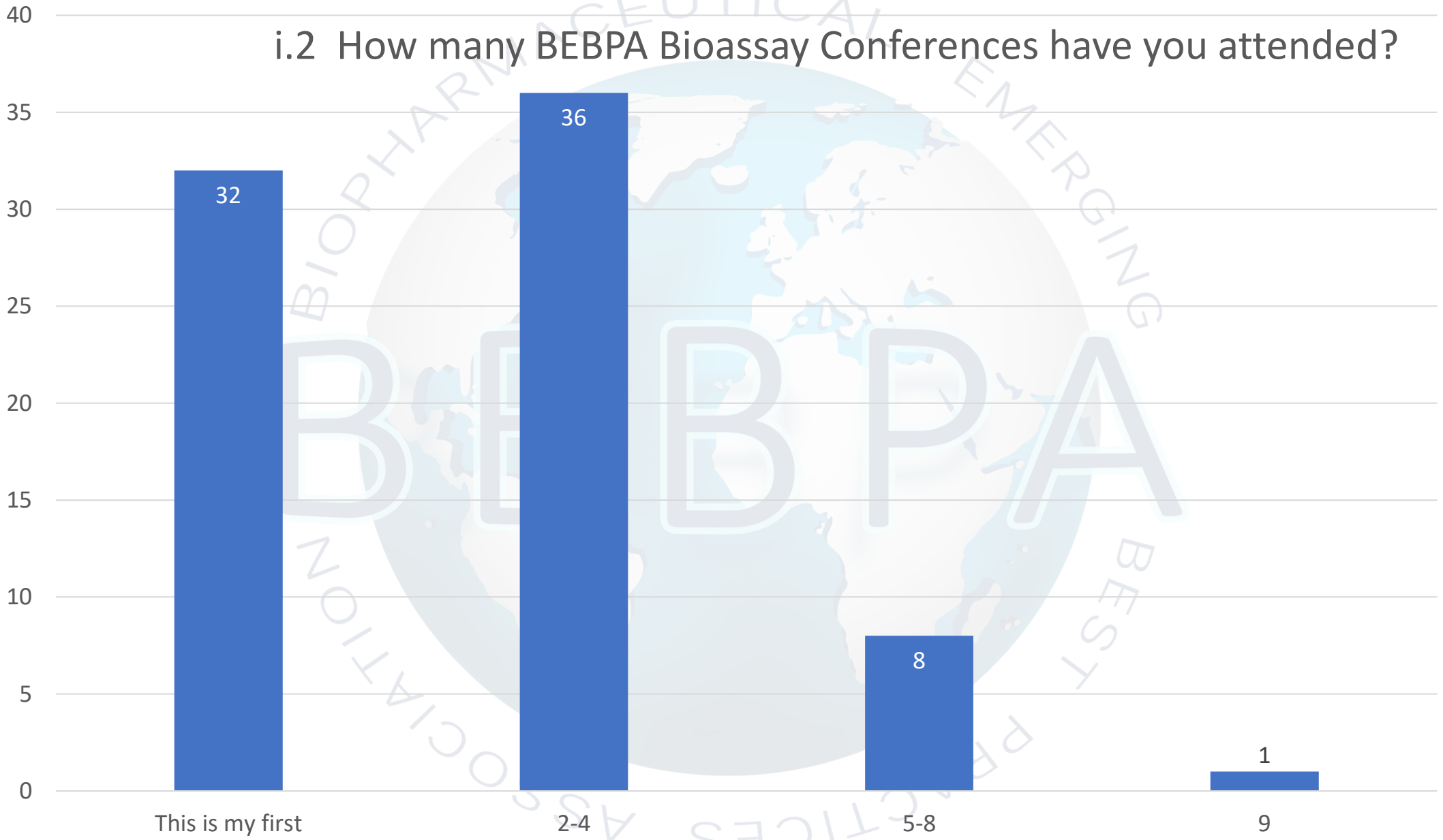
Audience Survey

Welcome & Introduction

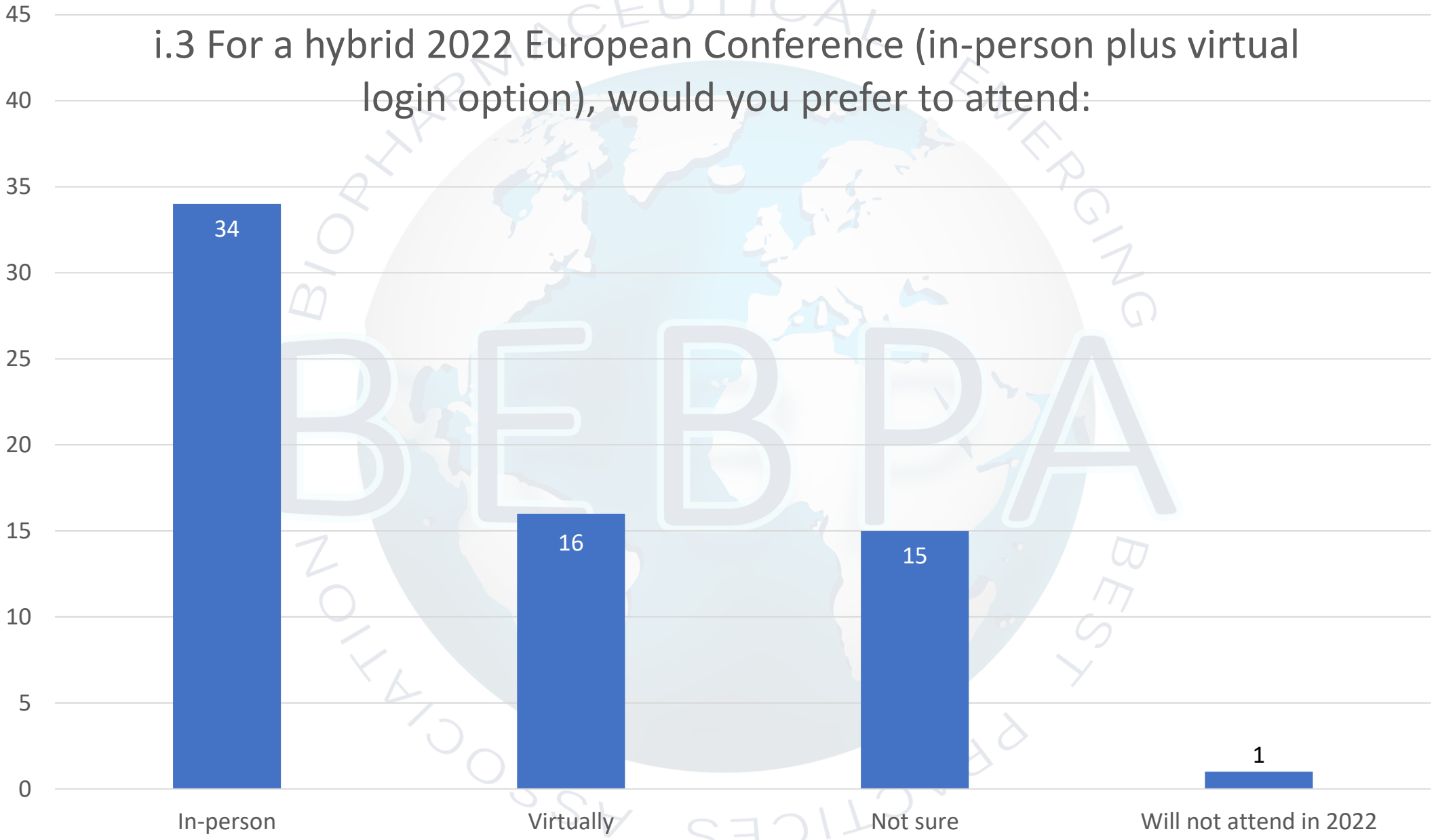
By: Denise Krawitz


i.1 What is your favorite vacation?
45
40
35
30
25
20
15
10
5
0
28
11
40
28
2
Beach
City
Nature
Anywhere with family/friends
Alone with a book

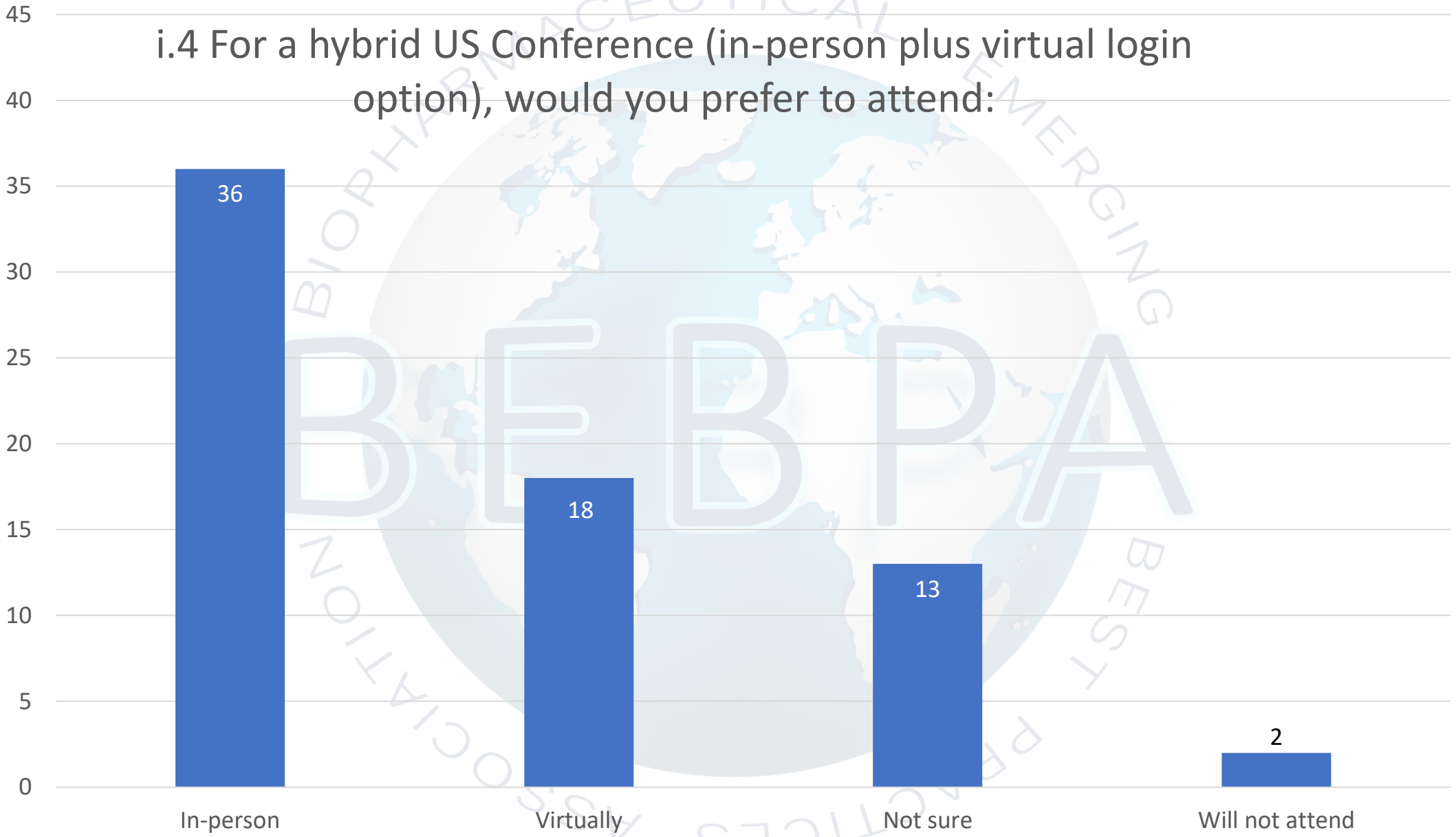
i.2 How many BEBPA Bioassay Conferences have you attended?



i.3 For a hybrid 2022 European Conference (in-person plus virtual login option), would you prefer to attend:



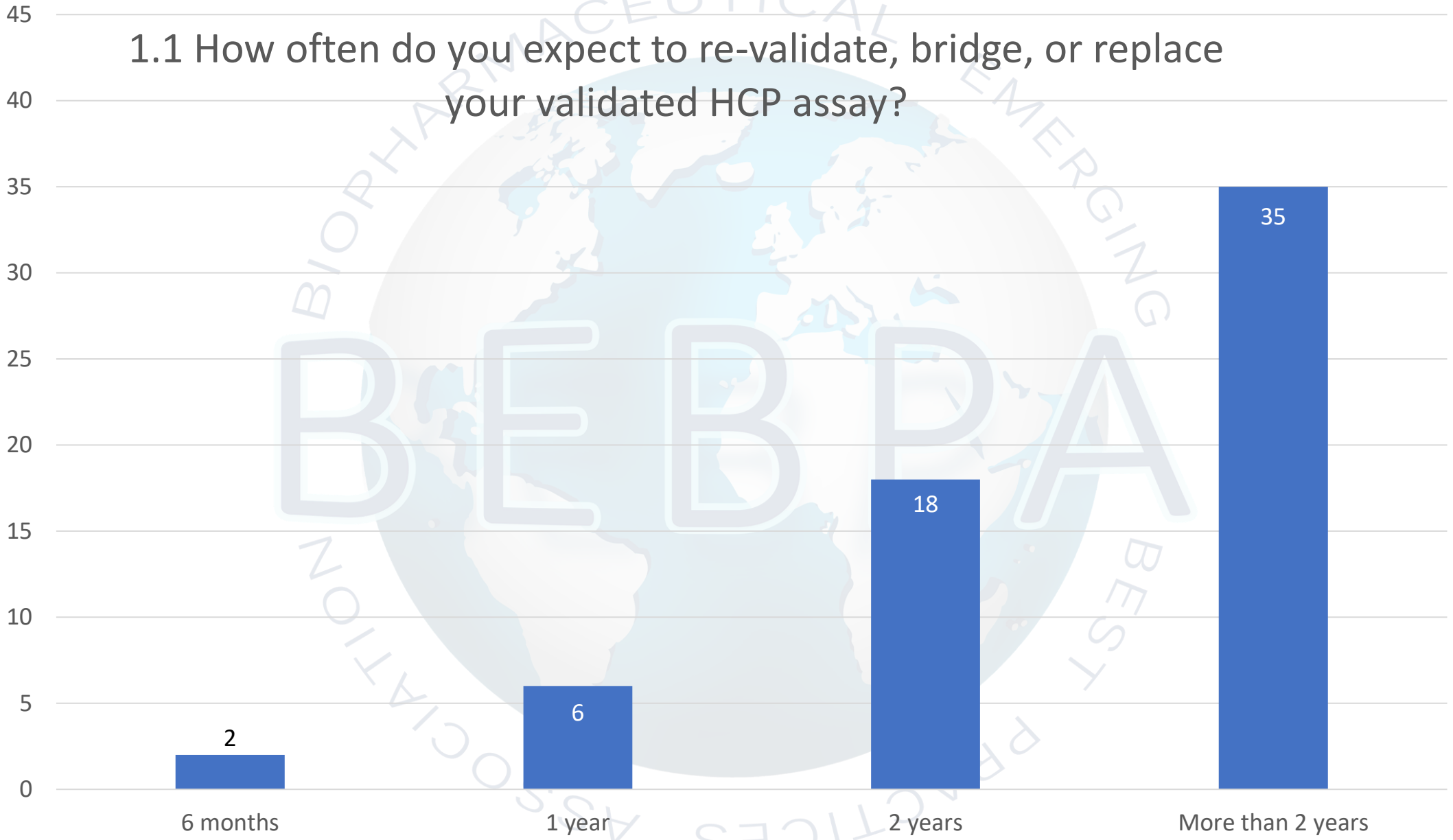
i.4 For a hybrid US Conference (in-person plus virtual login option), would you prefer to attend:



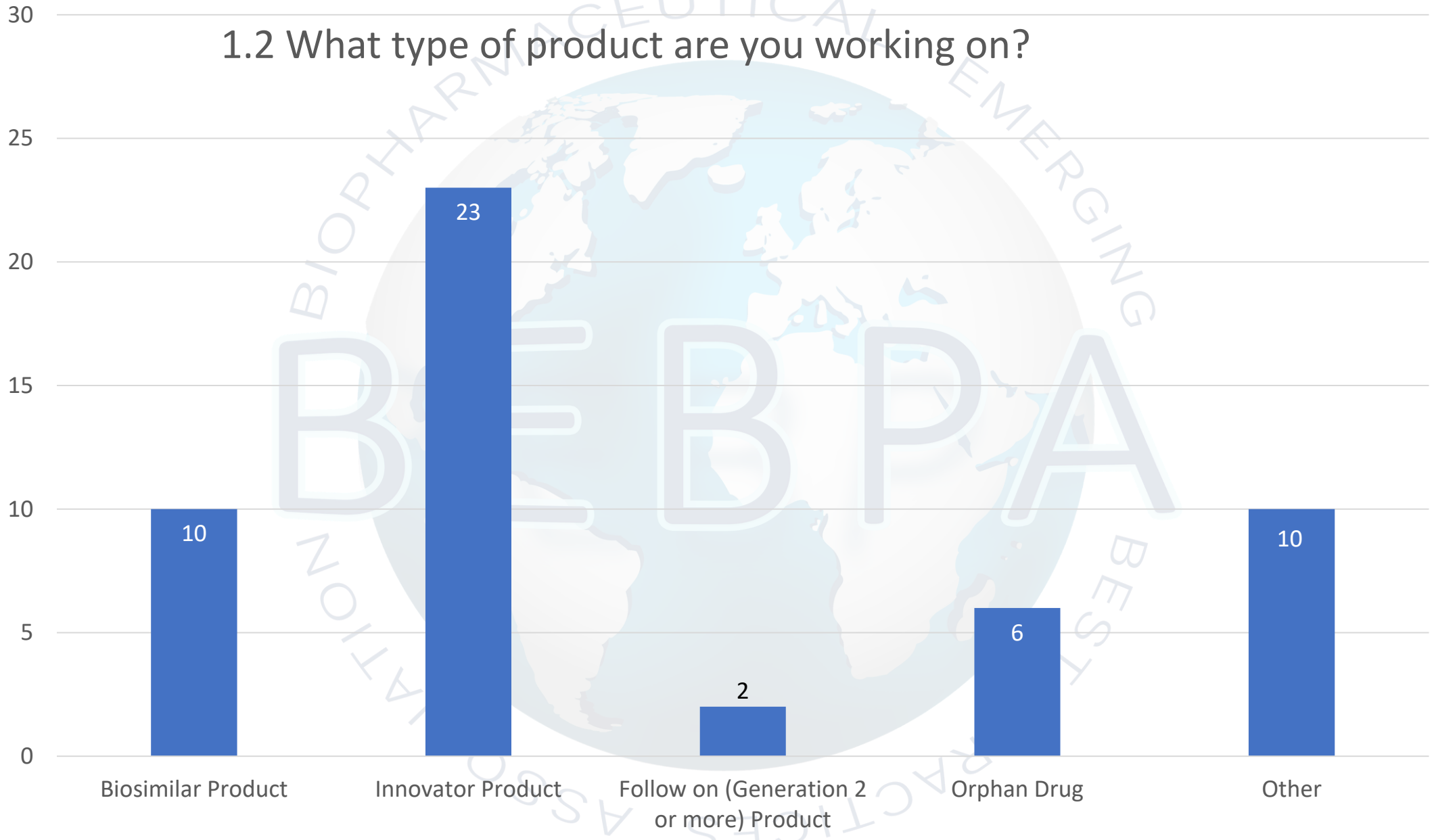
Session 1: 2021 Regulatory Trends for HCPs

Session Chair: Denise Krawitz

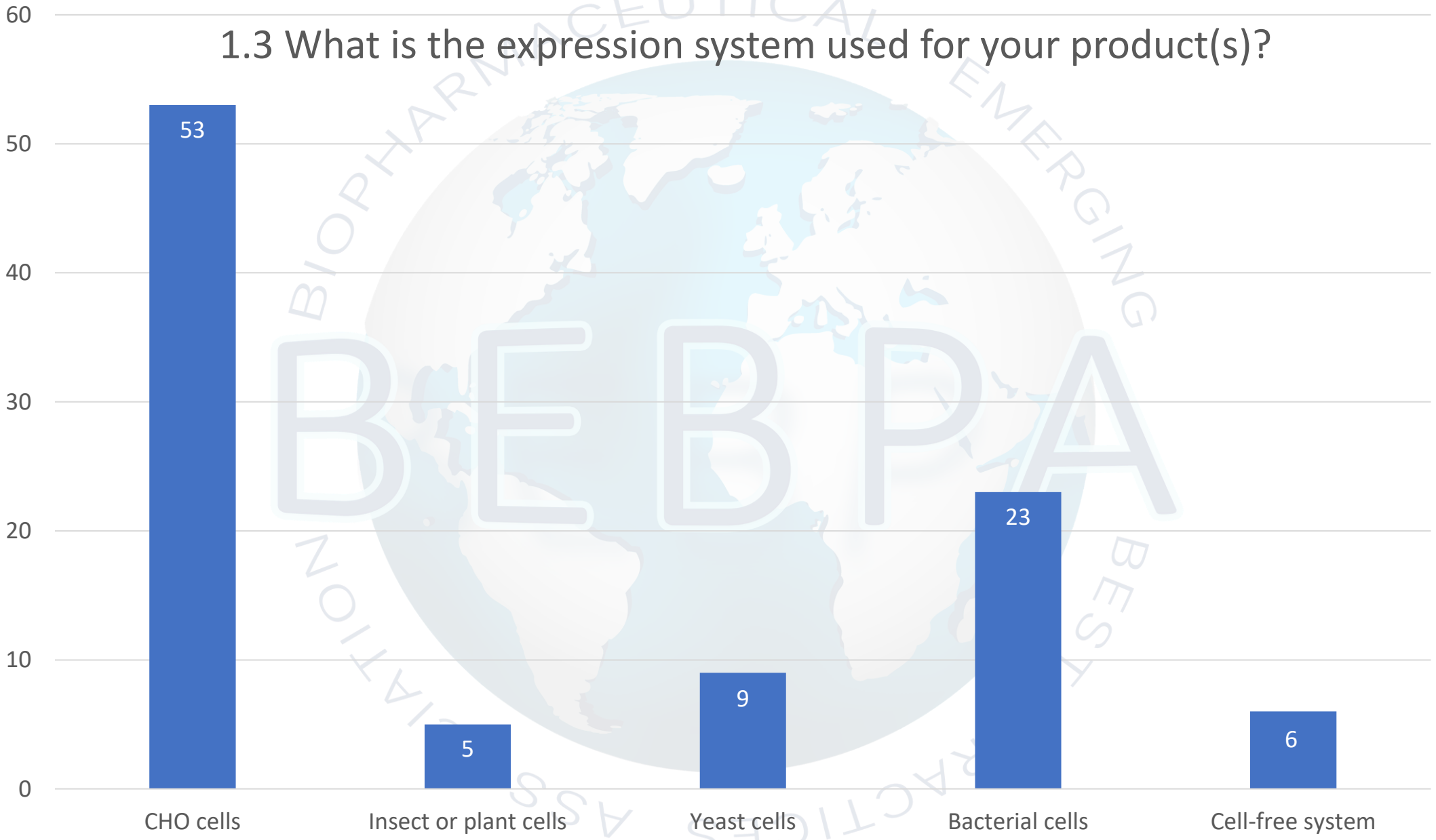
1.1 How often do you expect to re-validate, bridge, or replace your validated HCP assay?



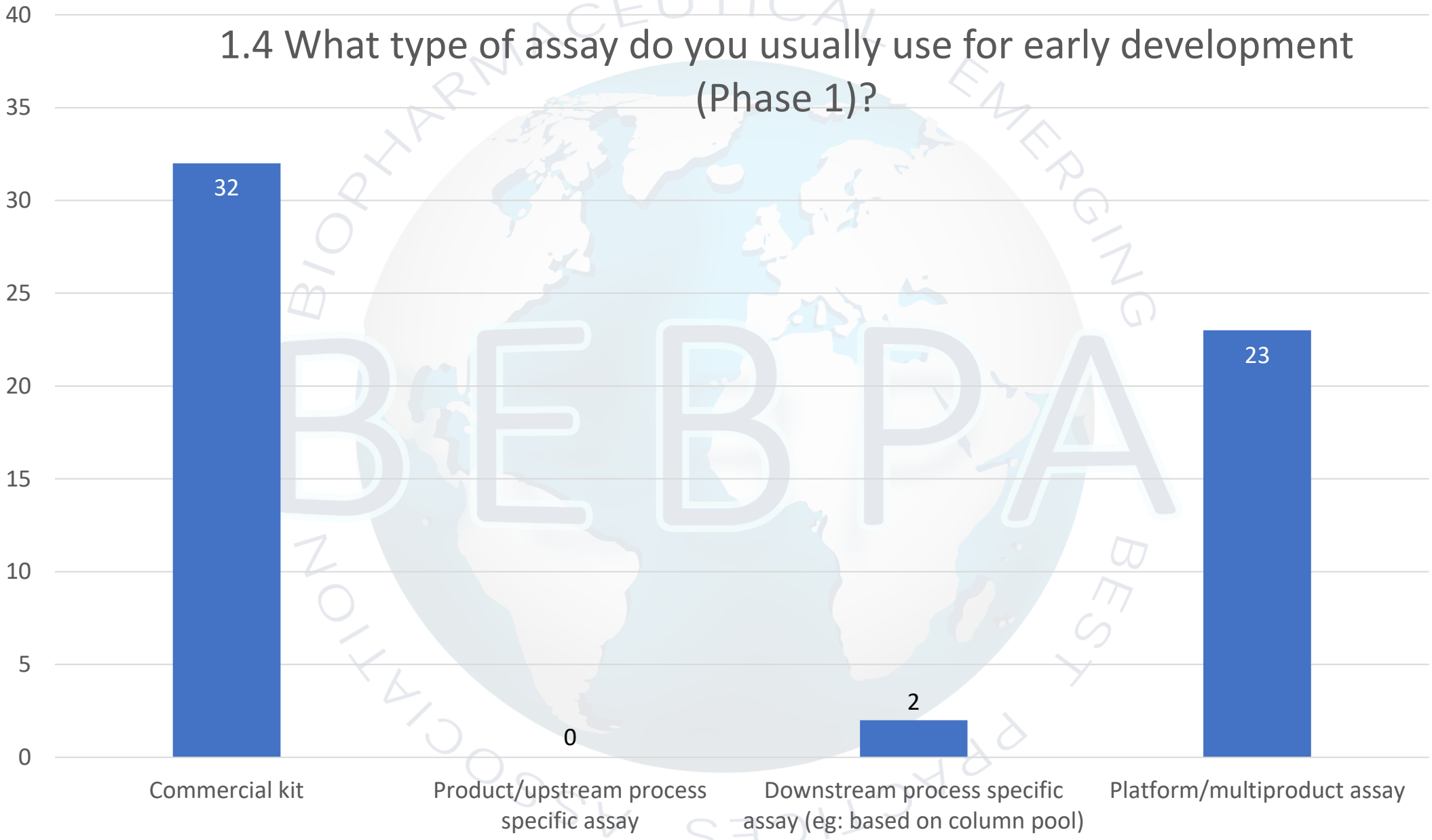
1.2 What type of product are you working on?



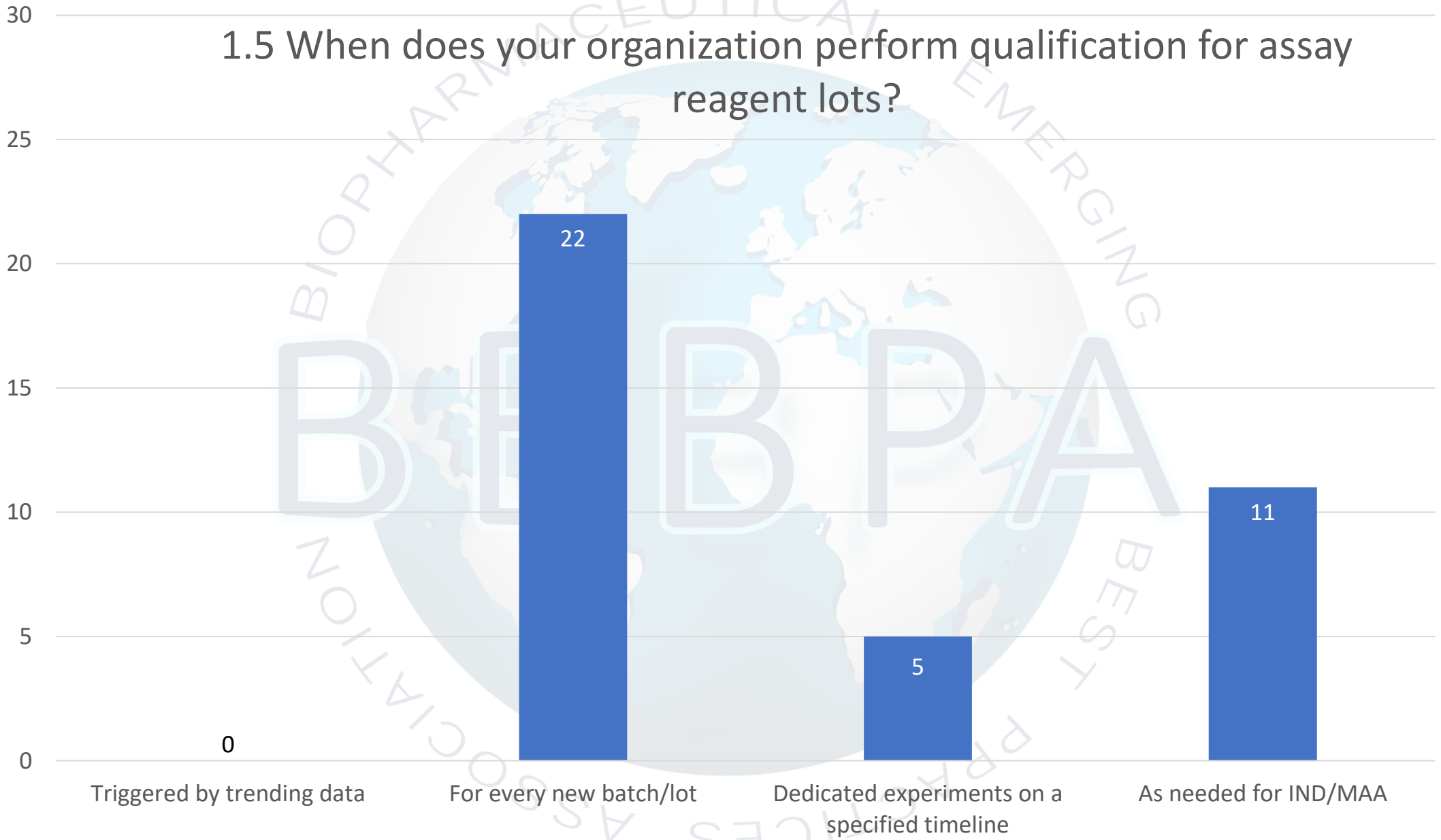
1.3 What is the expression system used for your product(s)?



1.4 What type of assay do you usually use for early development (Phase 1)?



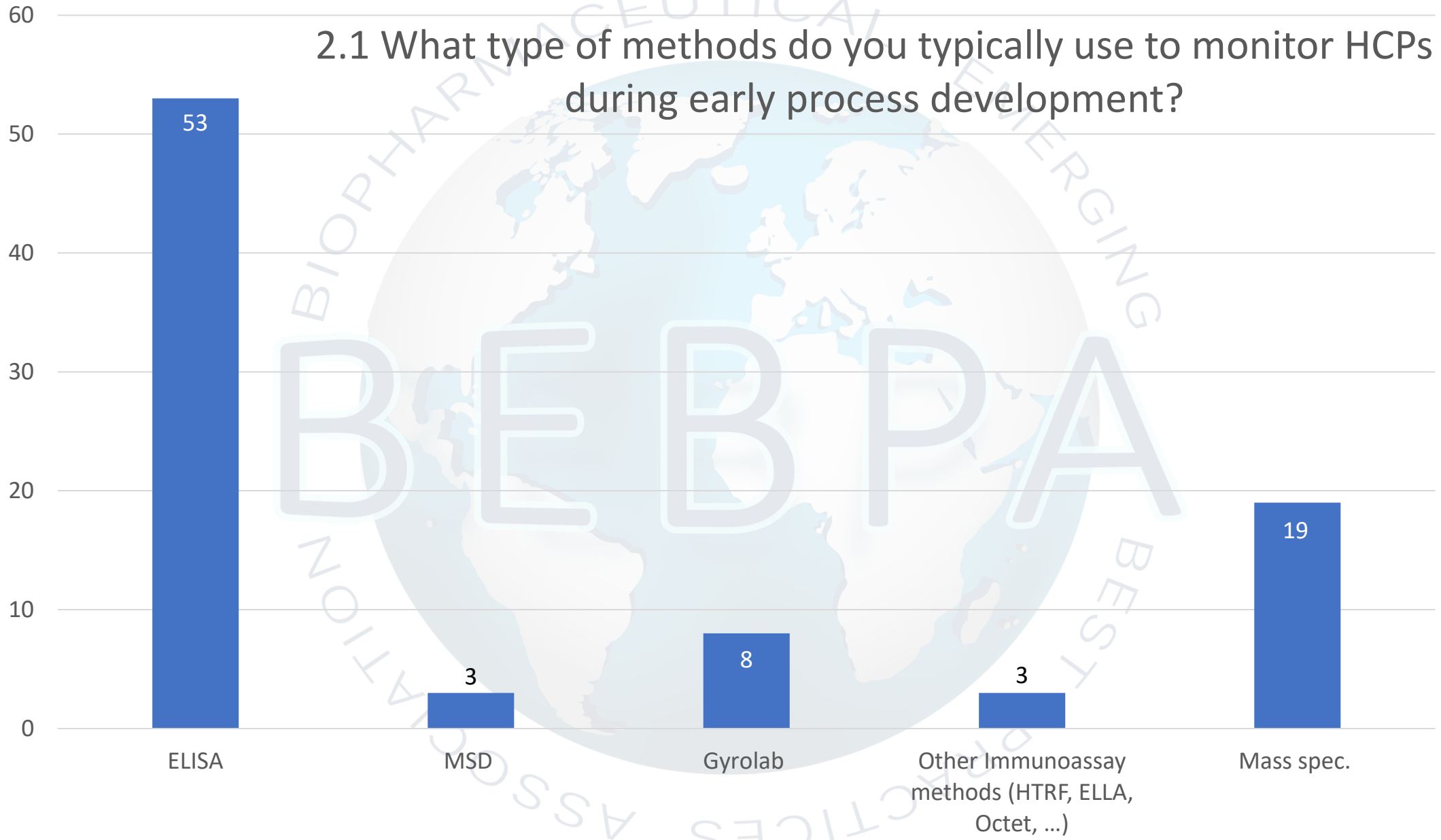
1.5 When does your organization perform qualification for assay reagent lots?



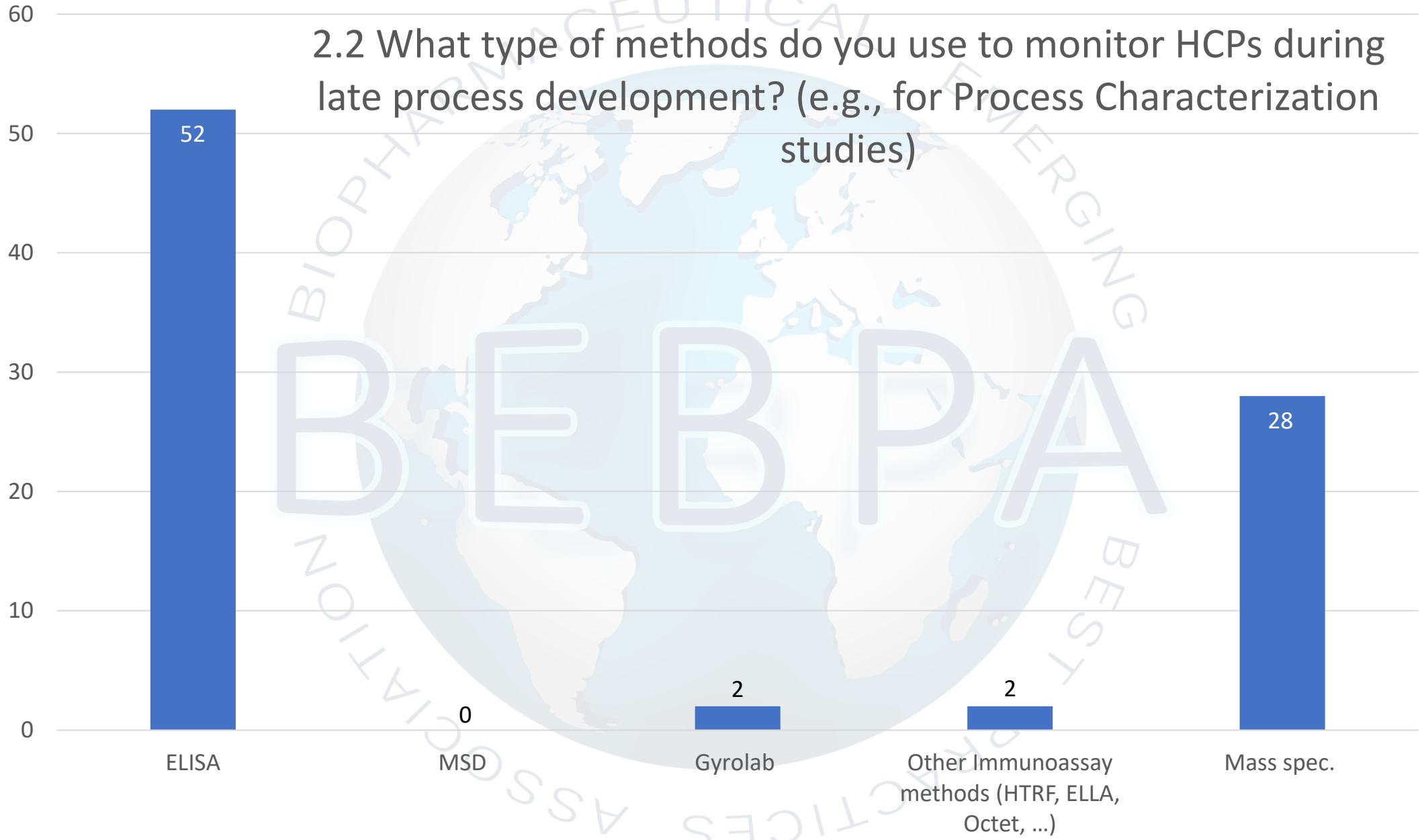
Session 2: High-Throughput HCP Analysis

Session Chair: Olaf Stamm

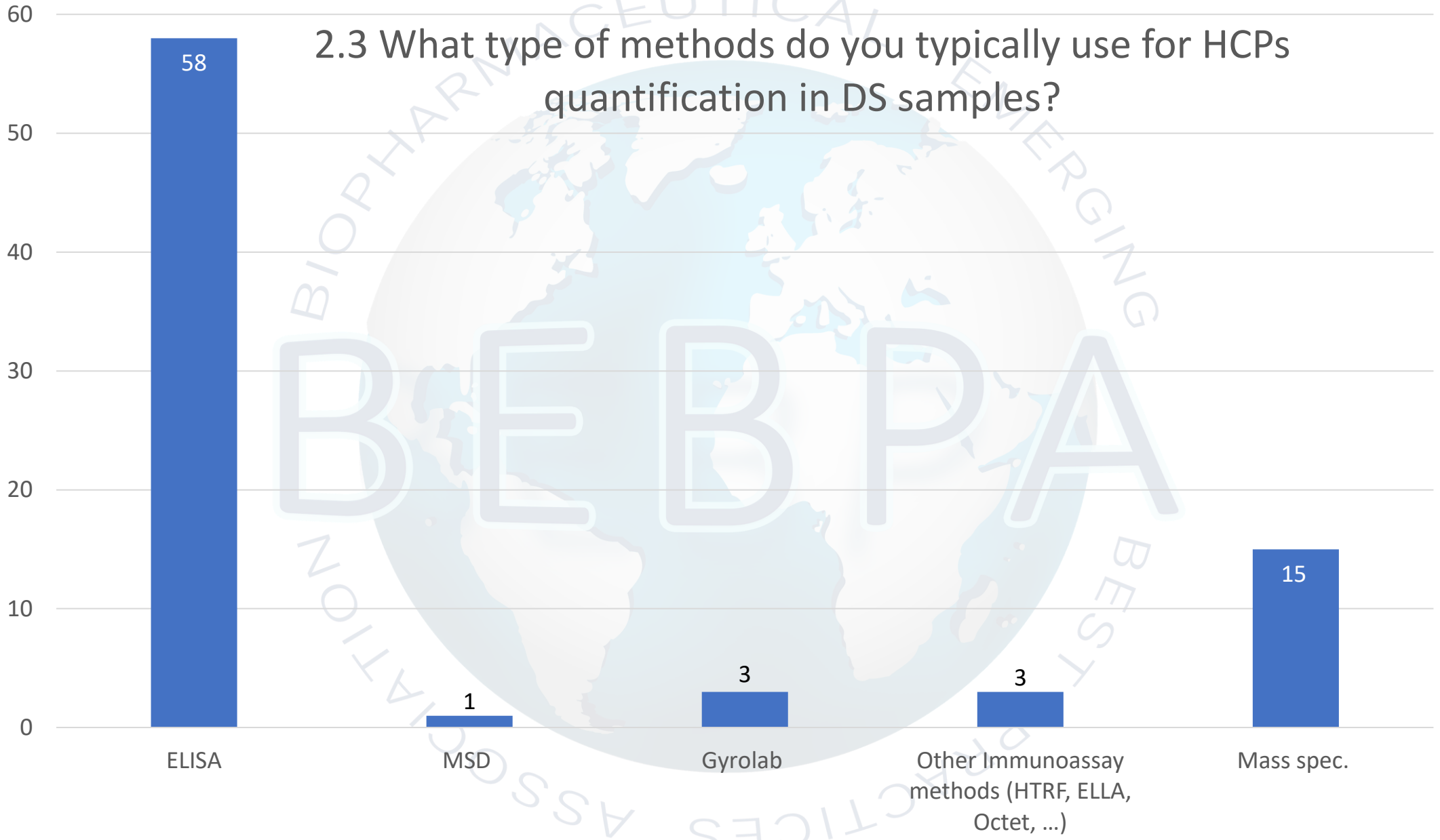
2.1 What type of methods do you typically use to monitor HCPs during early process development?



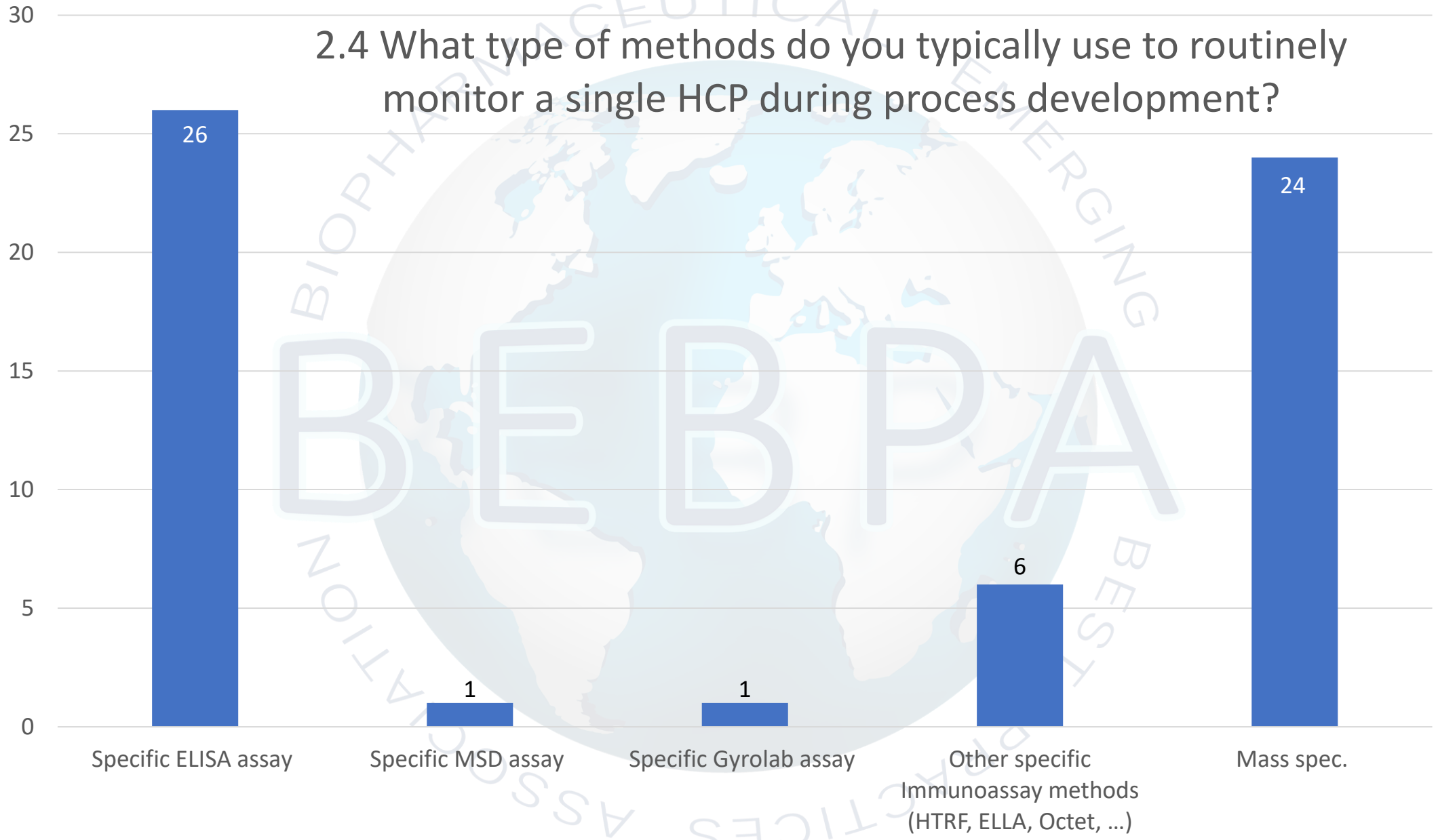
2.2 What type of methods do you use to monitor HCPs during late process development? (e.g., for Process Characterization studies)



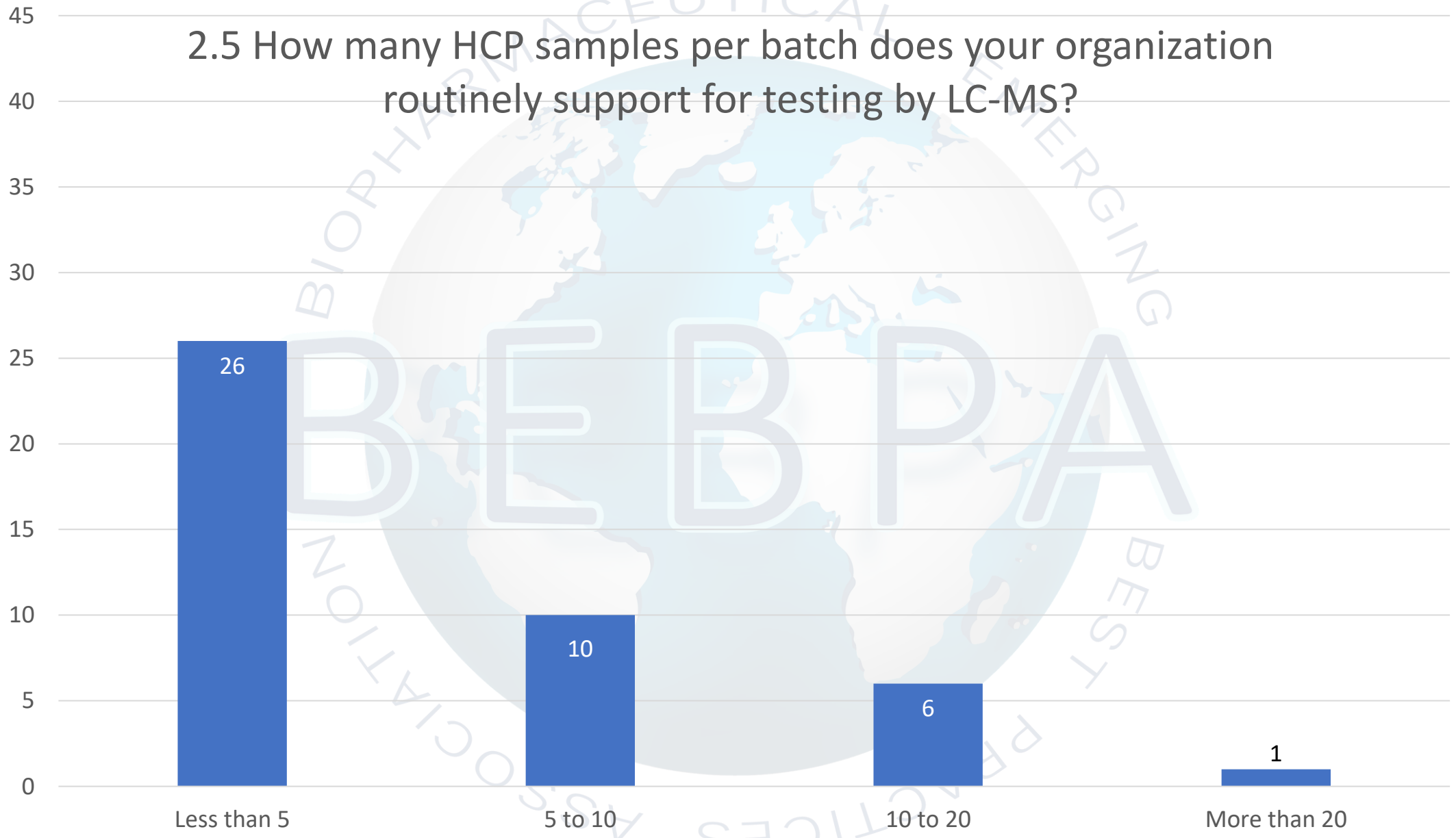
2.3 What type of methods do you typically use for HCPs quantification in DS samples?



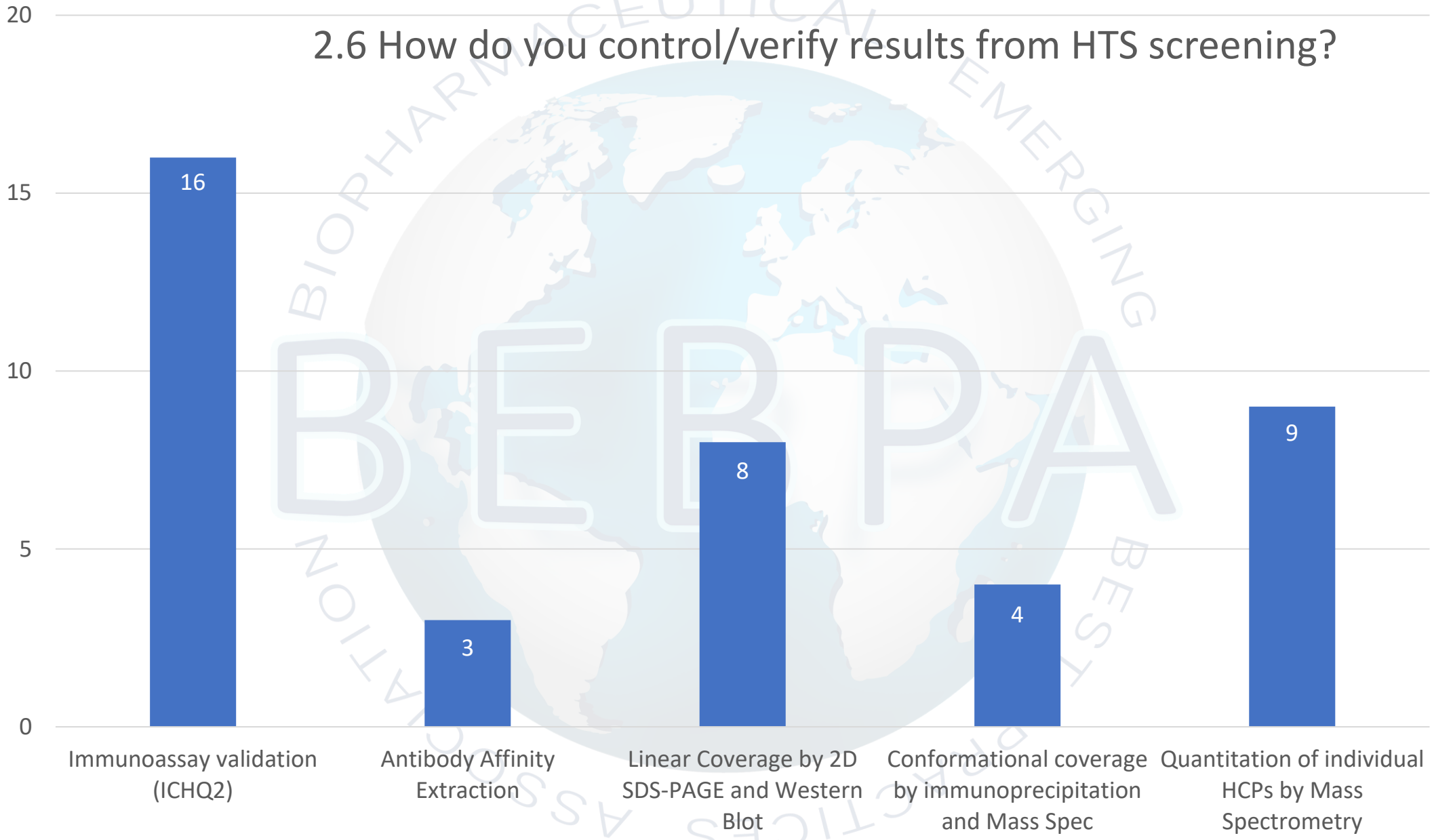
2.4 What type of methods do you typically use to routinely monitor a single HCP during process development?



2.5 How many HCP samples per batch does your organization routinely support for testing by LC-MS?



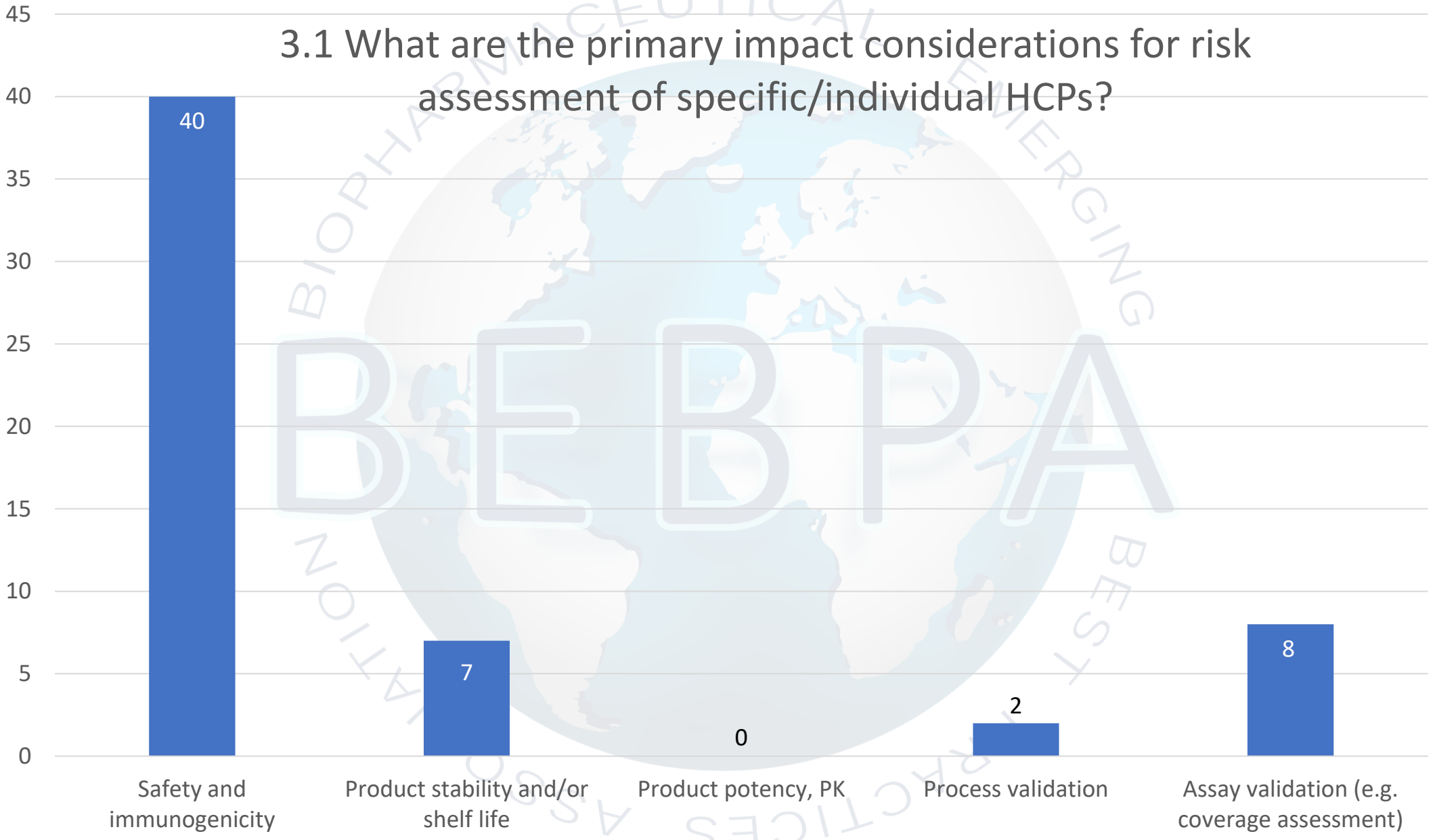
2.6 How do you control/verify results from HTS screening?



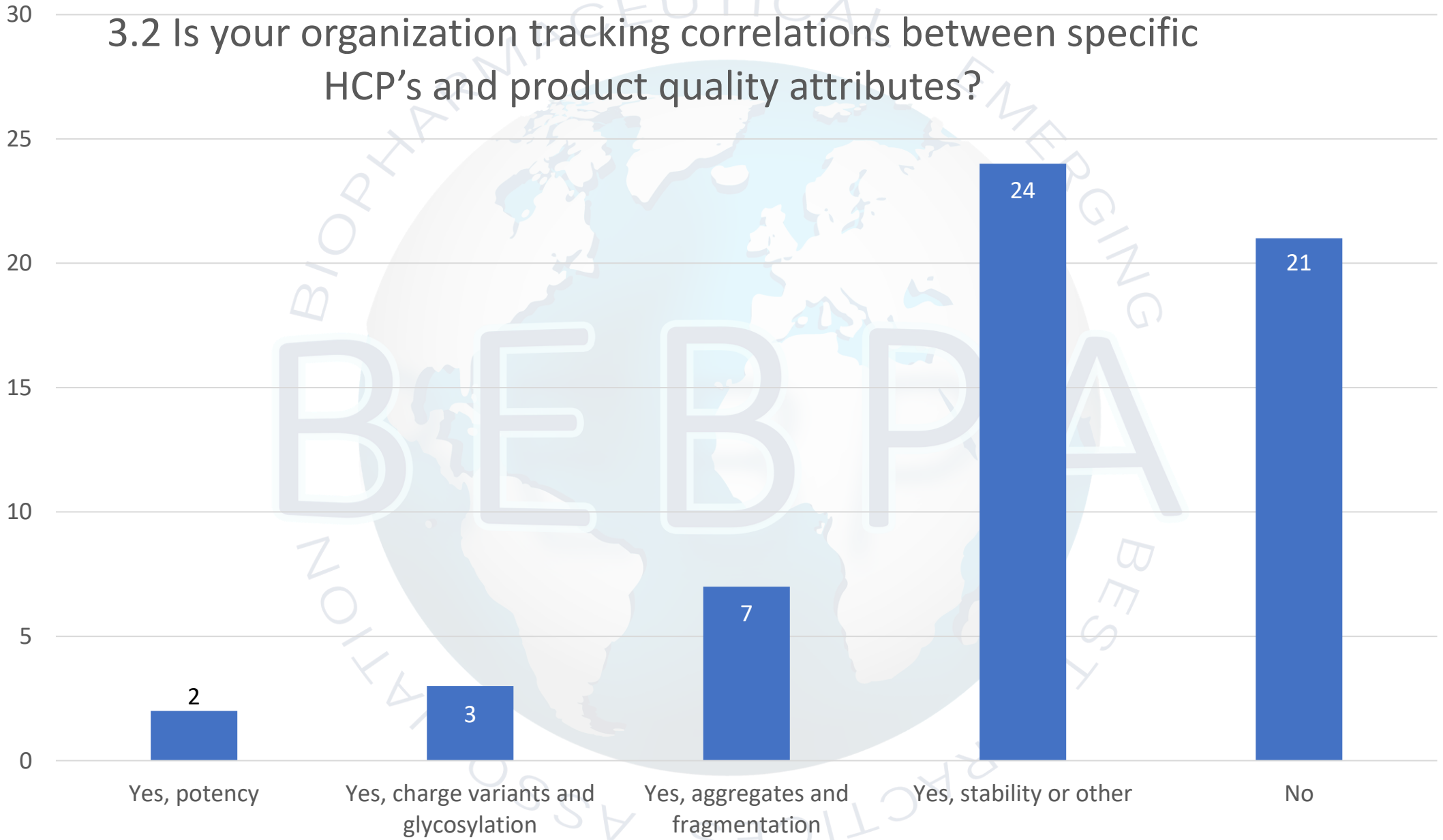
Session 3: Management of Individual HCP Impurities

Session Chair: Christina de Zafra

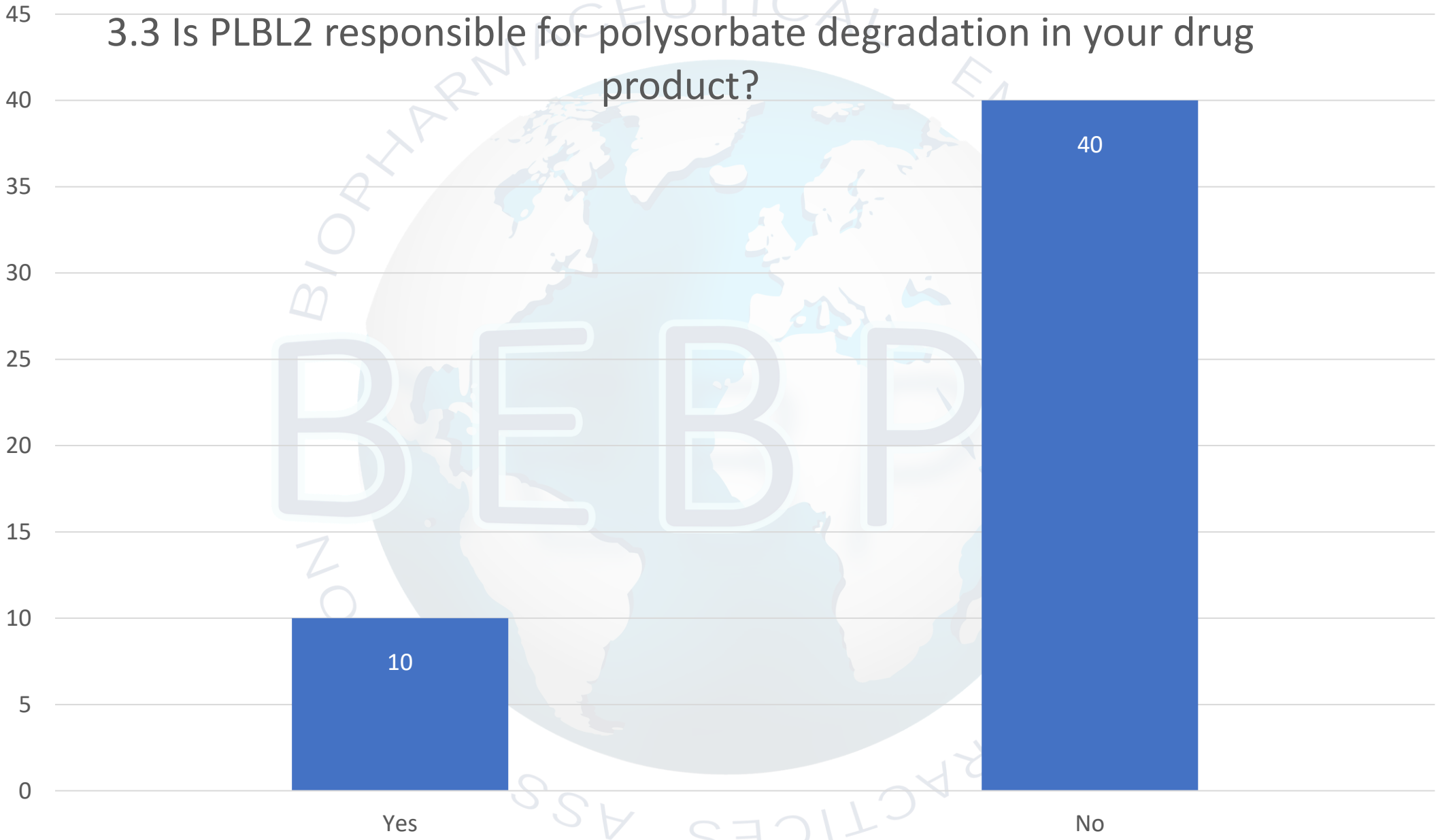
3.1 What are the primary impact considerations for risk assessment of specific/individual HCPs?

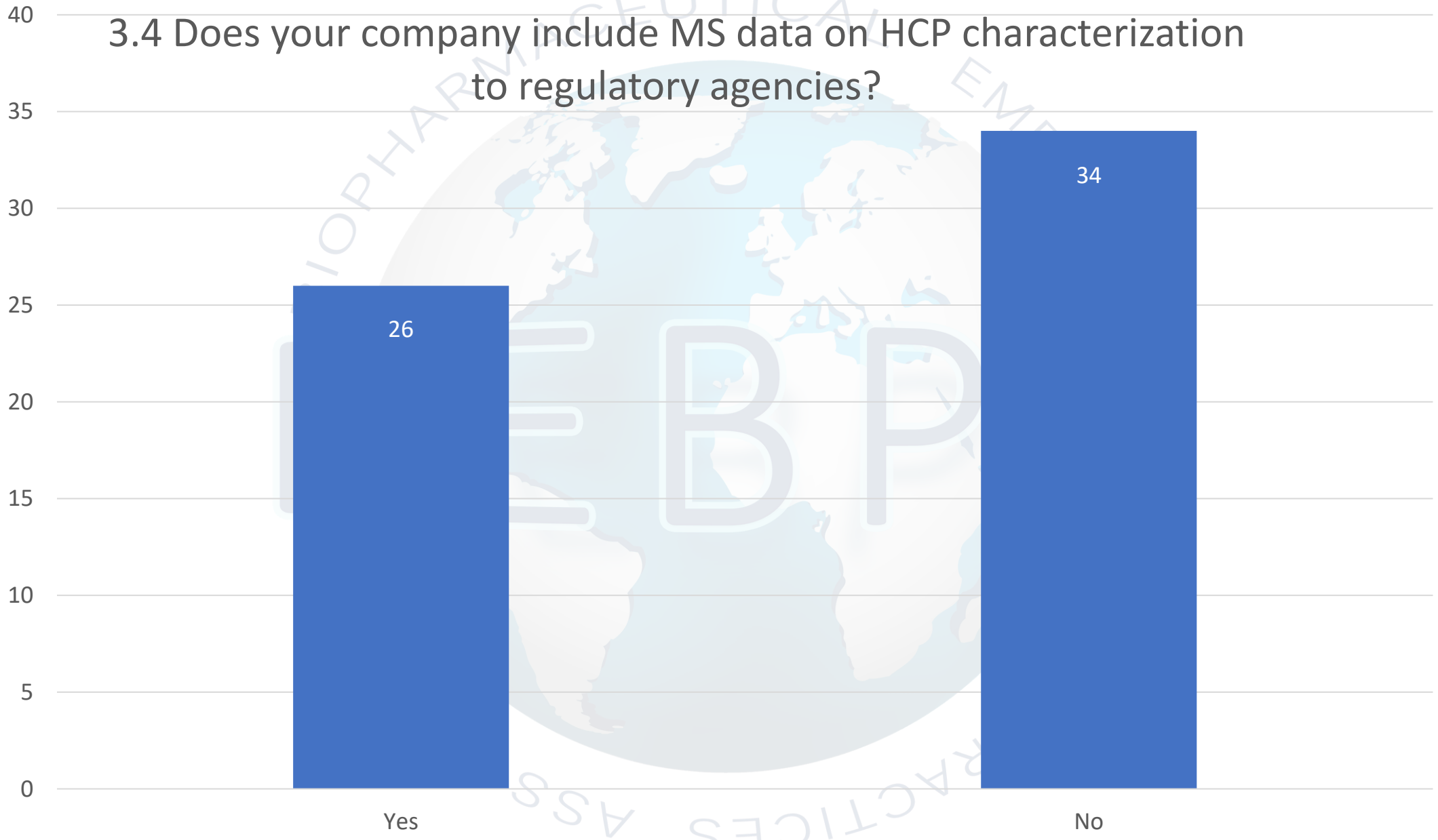


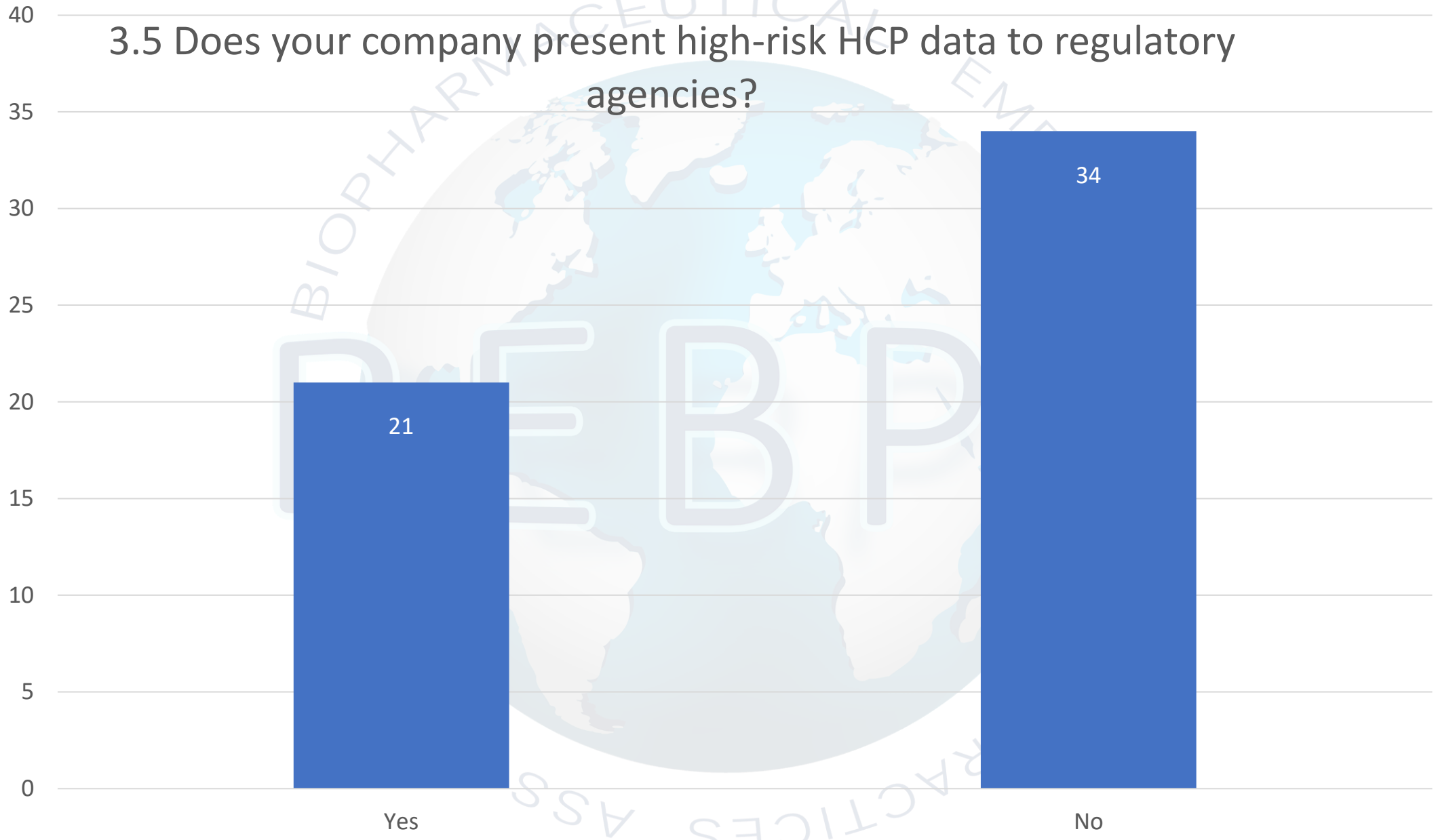
3.2 Is your organization tracking correlations between specific HCP's and product quality attributes?

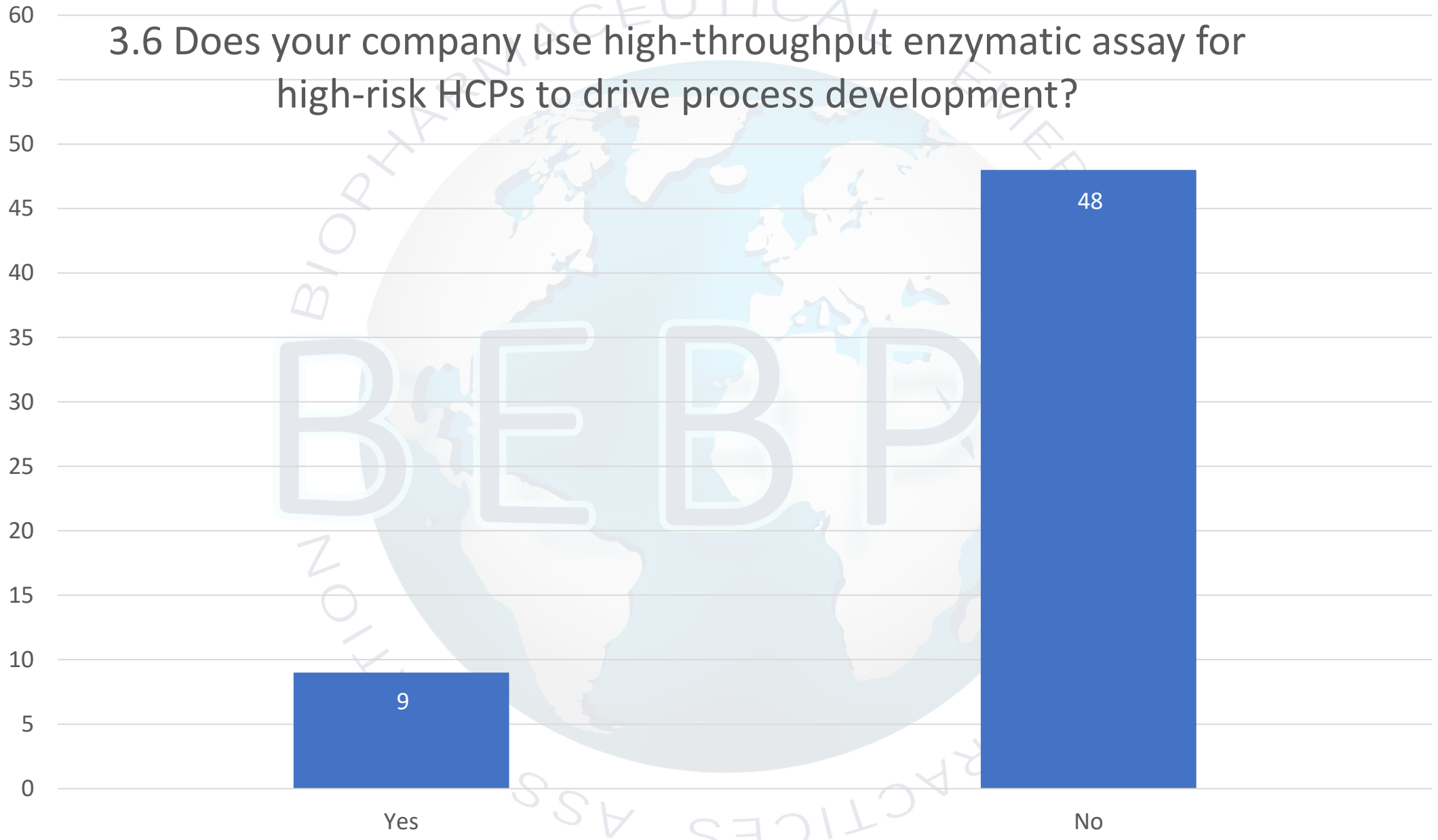


3.3 Is PLBL2 responsible for polysorbate degradation in your drug product?




3.4 Does your company include MS data on HCP characterization to regulatory agencies?
40
35
30
25
20
15
10
5
0
26
34
Yes
No

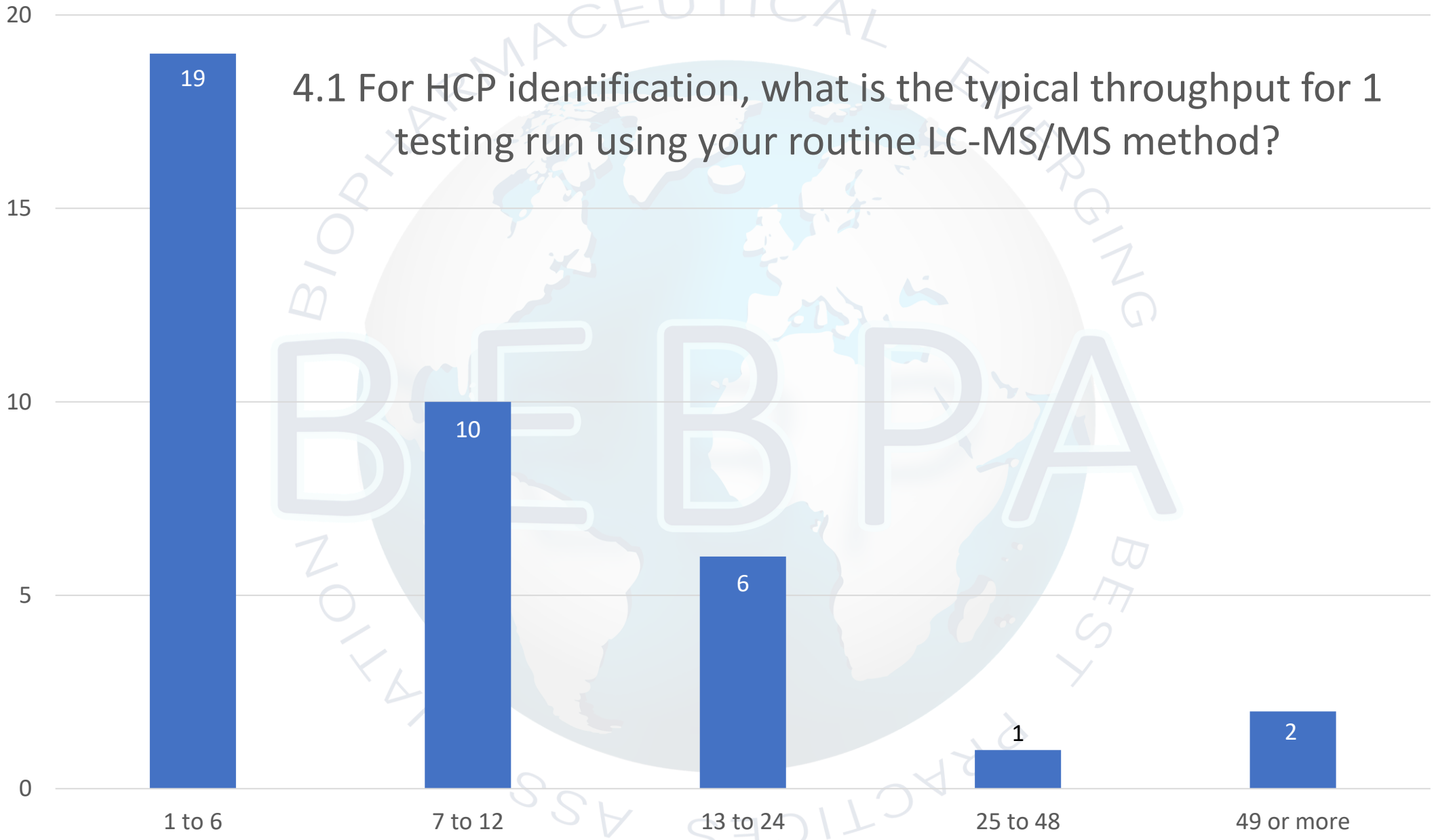

3.5 Does your company present high-risk HCP data to regulatory agencies?
40
35
30
25
20
15
10
5
0
21
34
Yes
No


3.6 Does your company use high-throughput enzymatic assay for high-risk HCPs to drive process development?
60
55
50
45
40
35
30
25
20
15
10
5
0
9
48
Yes
No

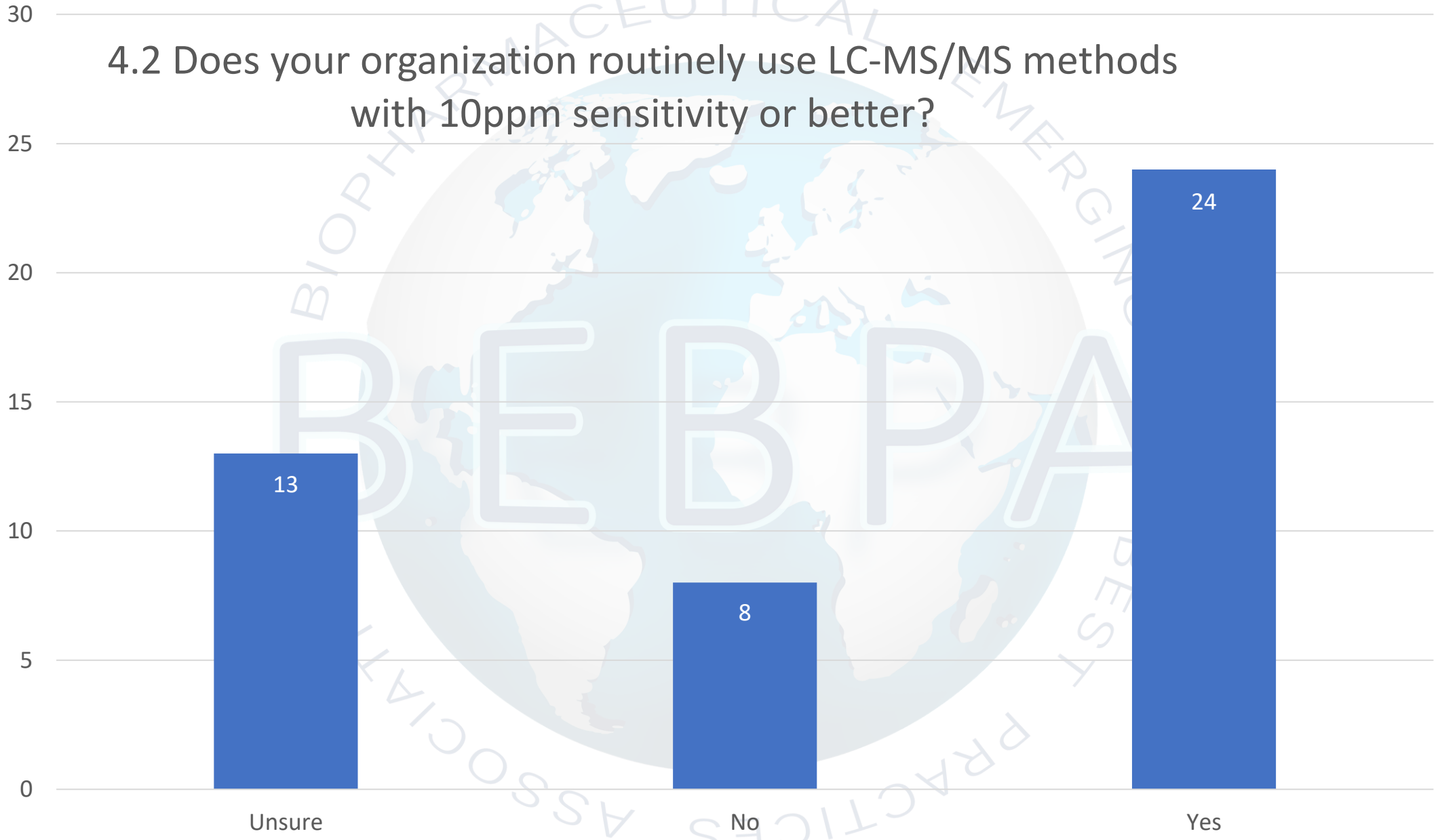
Session 4:
MS Improvements That Lead to Reliable HCP Profiling

Session Chair: Ned Mozier

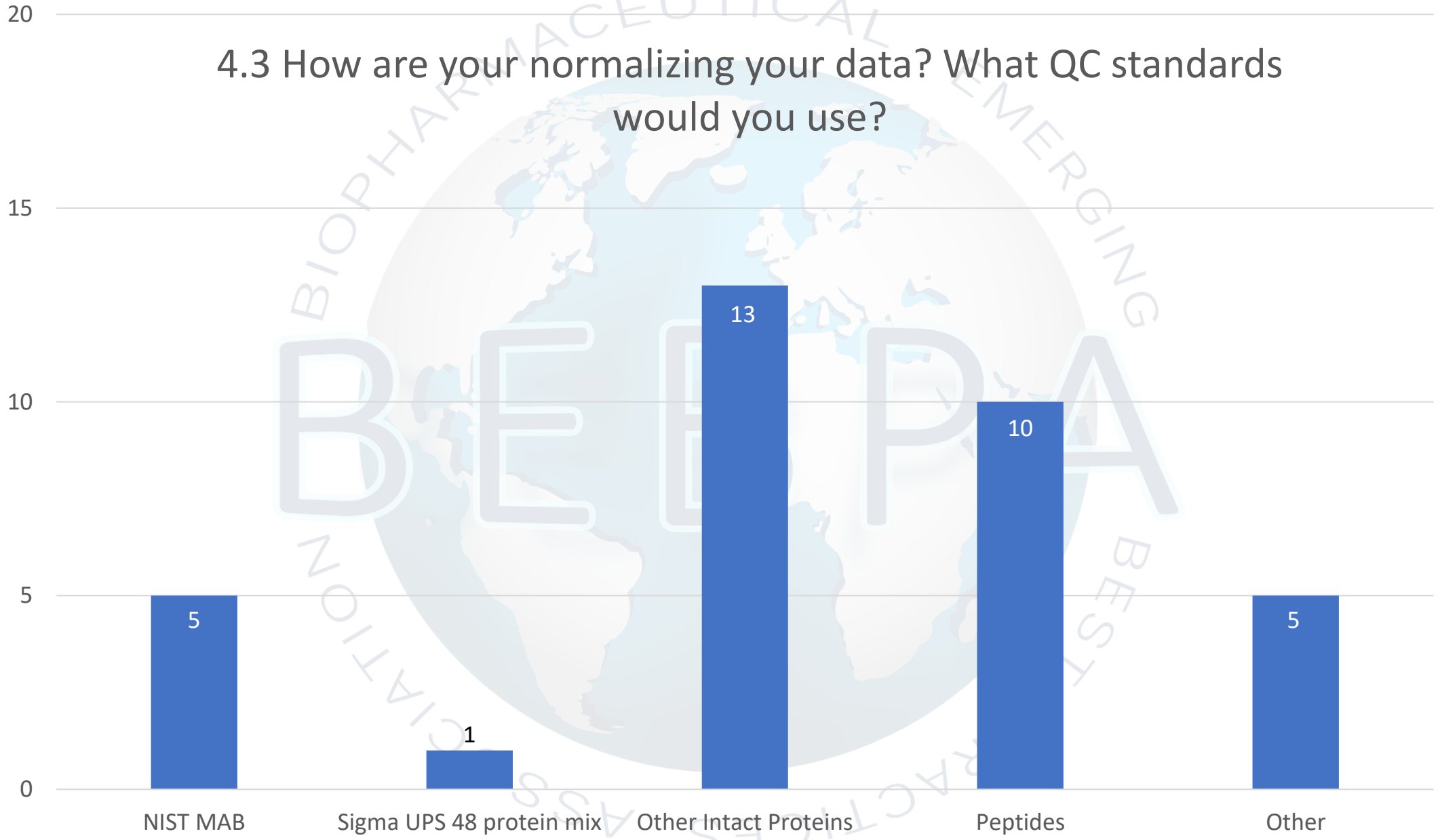
4.1 For HCP identification, what is the typical throughput for 1 testing run using your routine LC-MS/MS method?

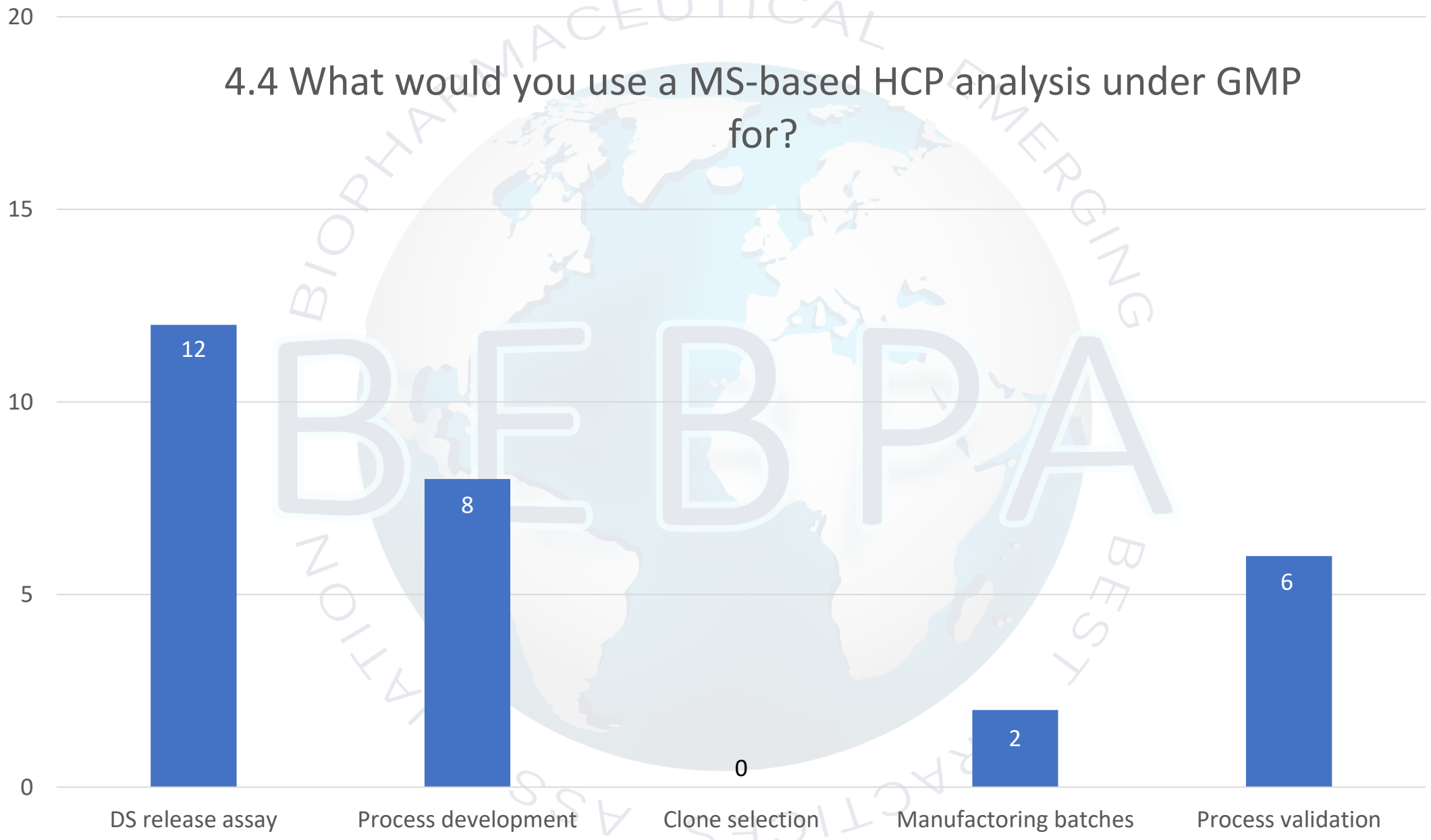


4.2 Does your organization routinely use LC-MS/MS methods with 10ppm sensitivity or better?

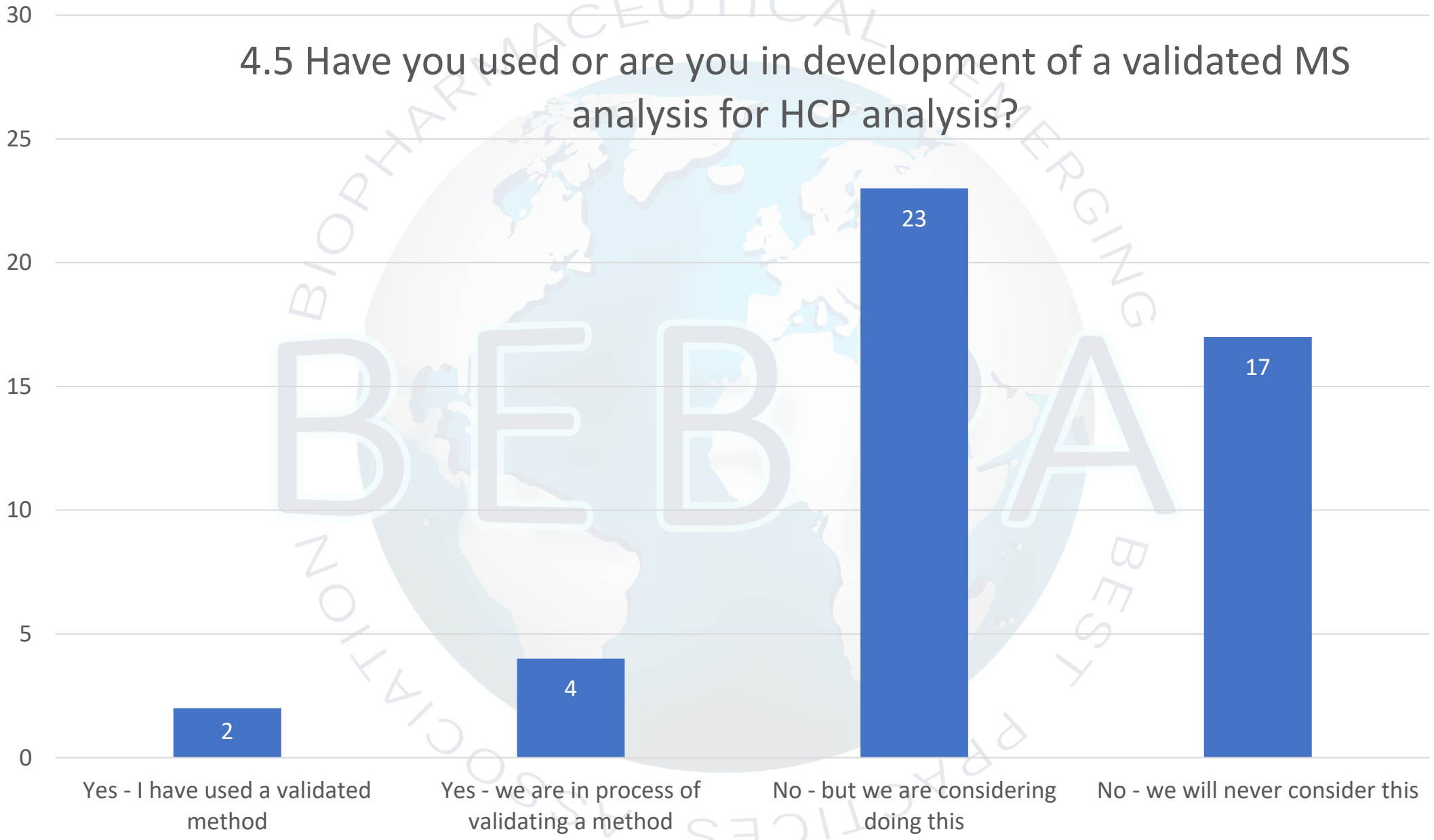


4.3 How are your normalizing your data? What QC standards would you use?

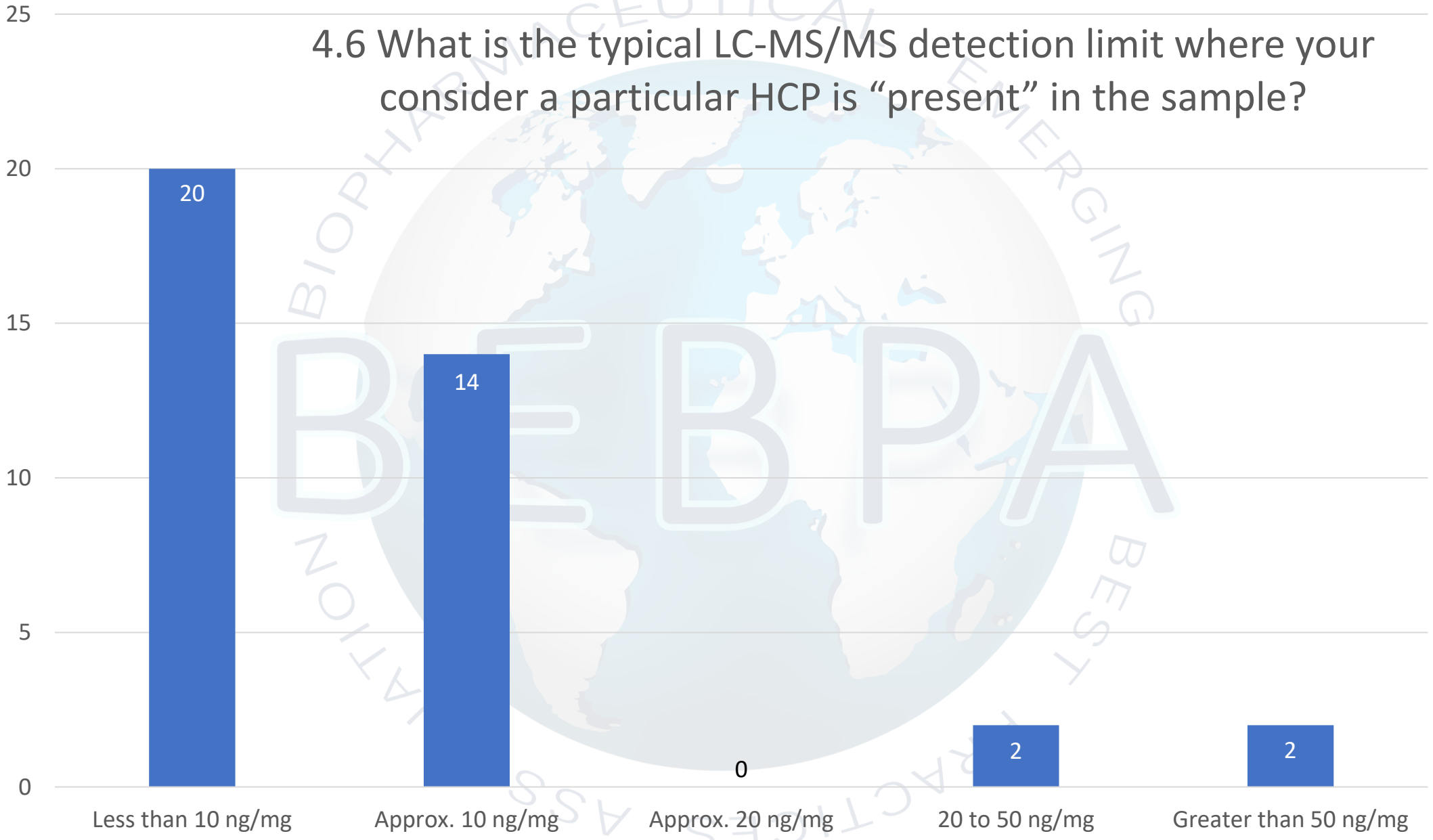



4.4 What would you use a MS-based HCP analysis under GMP for?
20
15
10
5
0
12
8
0
2
6
DS release assay
Process development
Clone selection
Manufactoring batches
Process validation

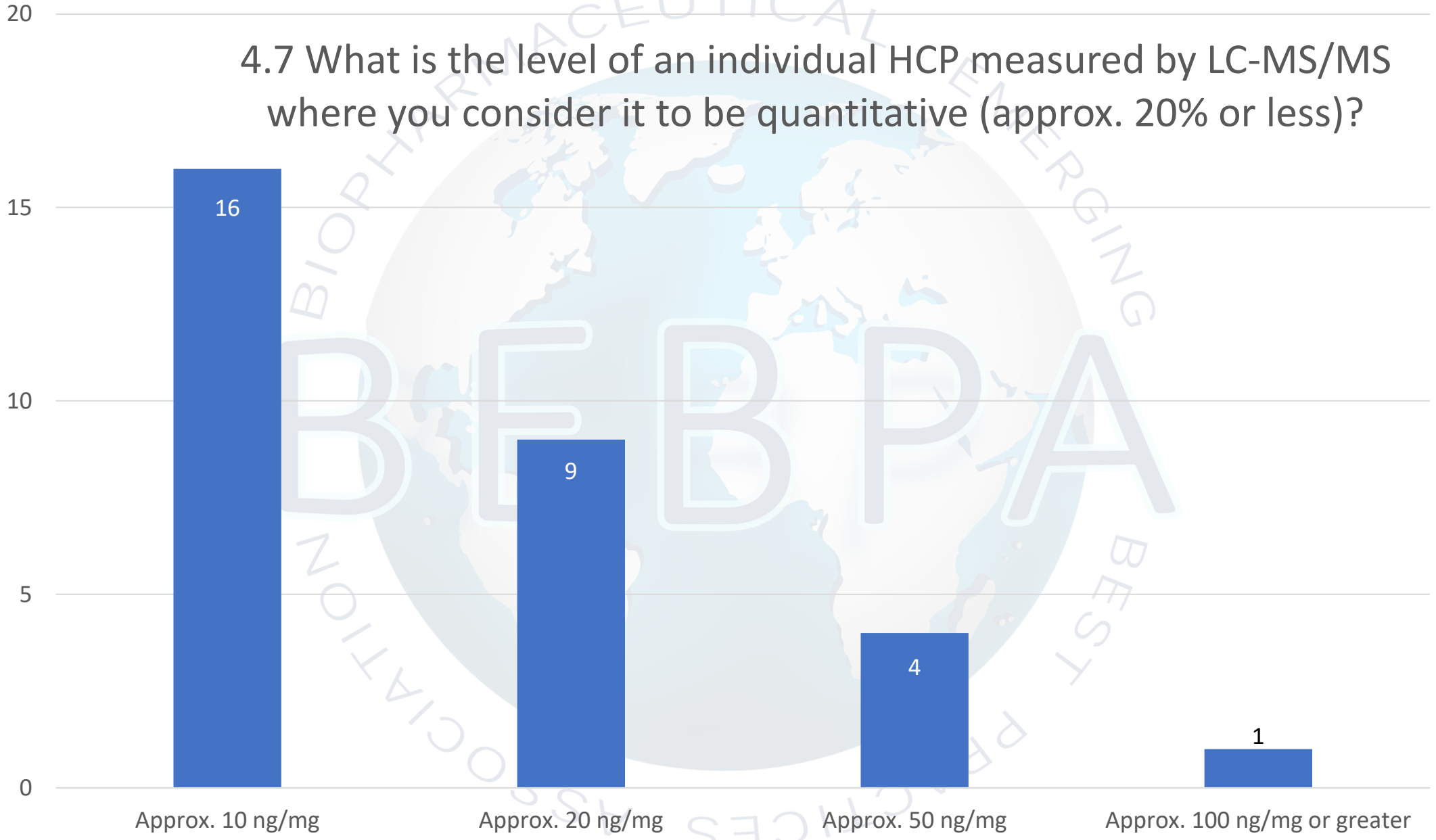
4.5 Have you used or are you in development of a validated MS analysis for HCP analysis?



4.6 What is the typical LC-MS/MS detection limit where your consider a particular HCP is “present” in the sample?



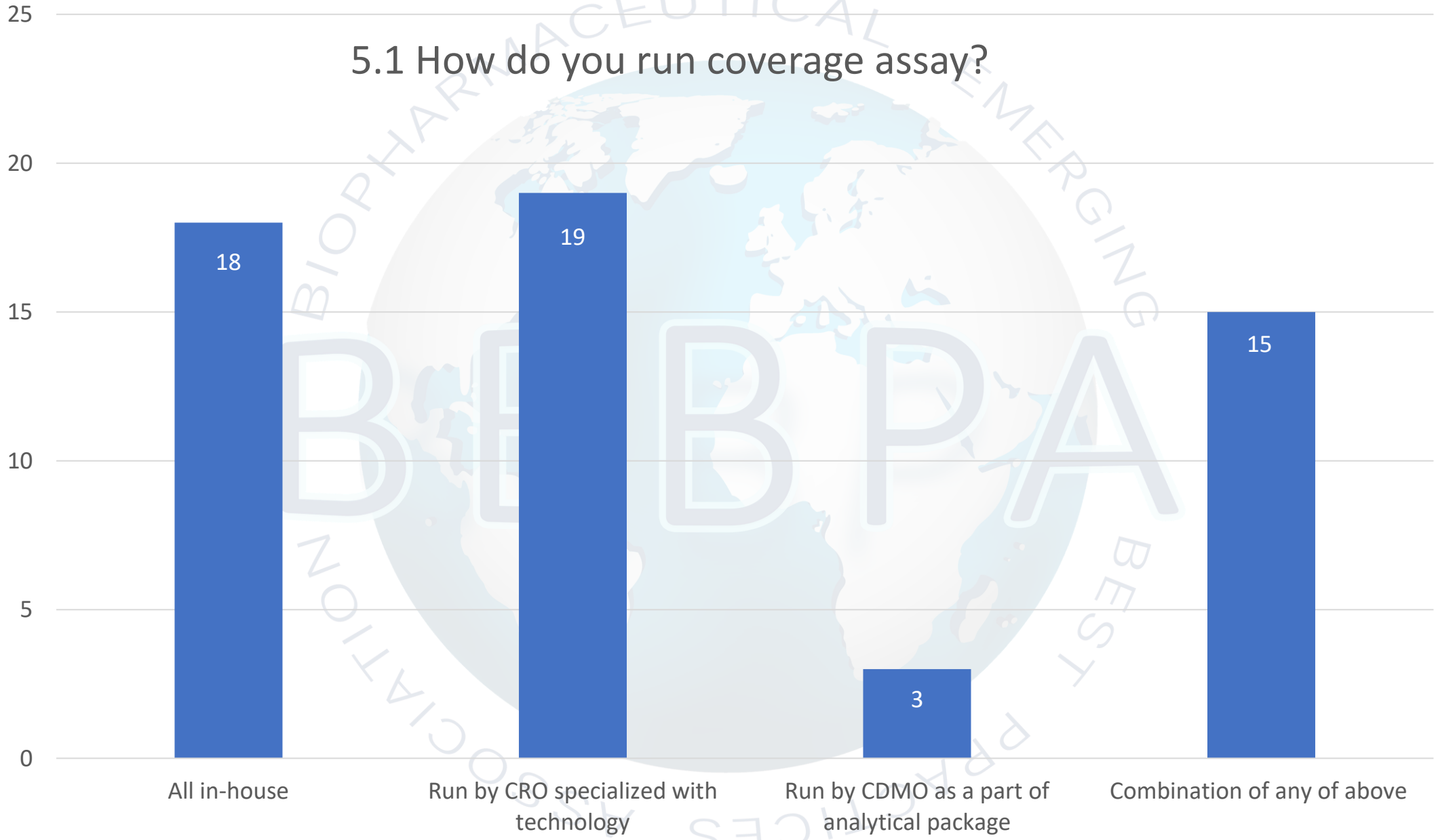
4.7 What is the level of an individual HCP measured by LC-MS/MS where you consider it to be quantitative (approx. 20% or less)?

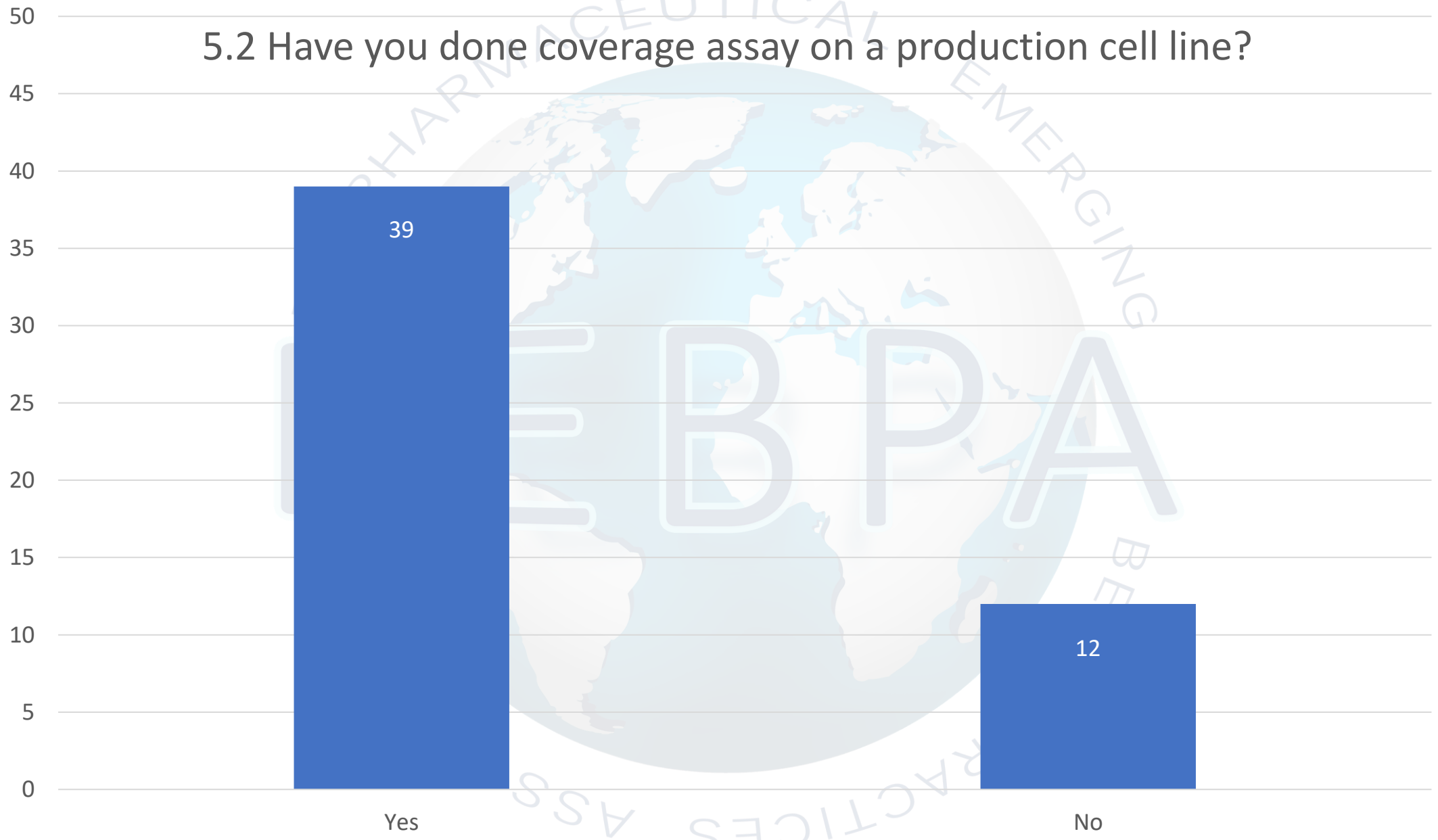


Session 4: HCP ELISA Development and Lifecycle Management

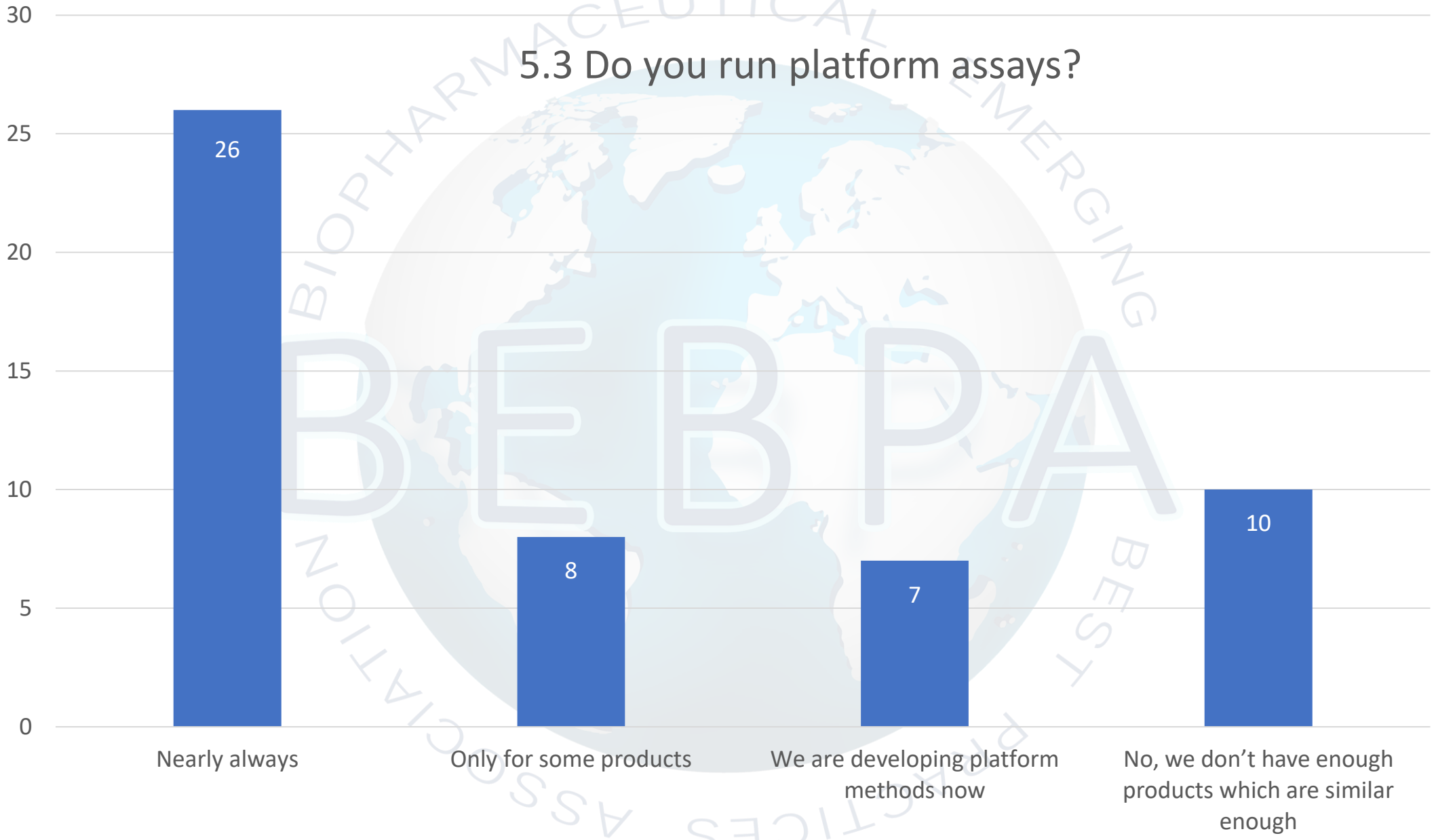
Session Chair: Heather Boux

5.1 How do you run coverage assay?

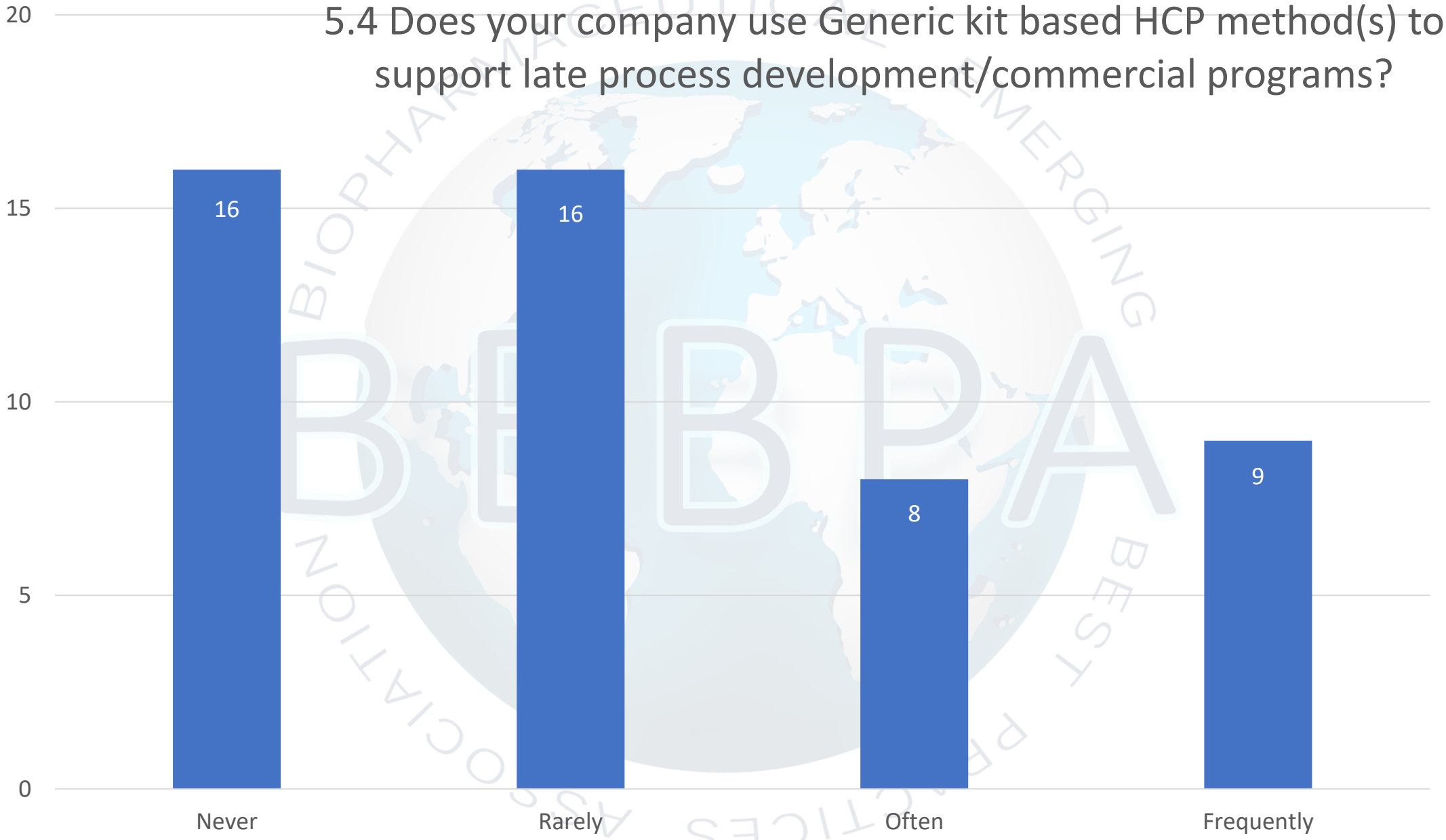



5.2 Have you done coverage assay on a production cell line?
50
45
40
35
30
25
20
15
10
5
0
39
12
Yes
No

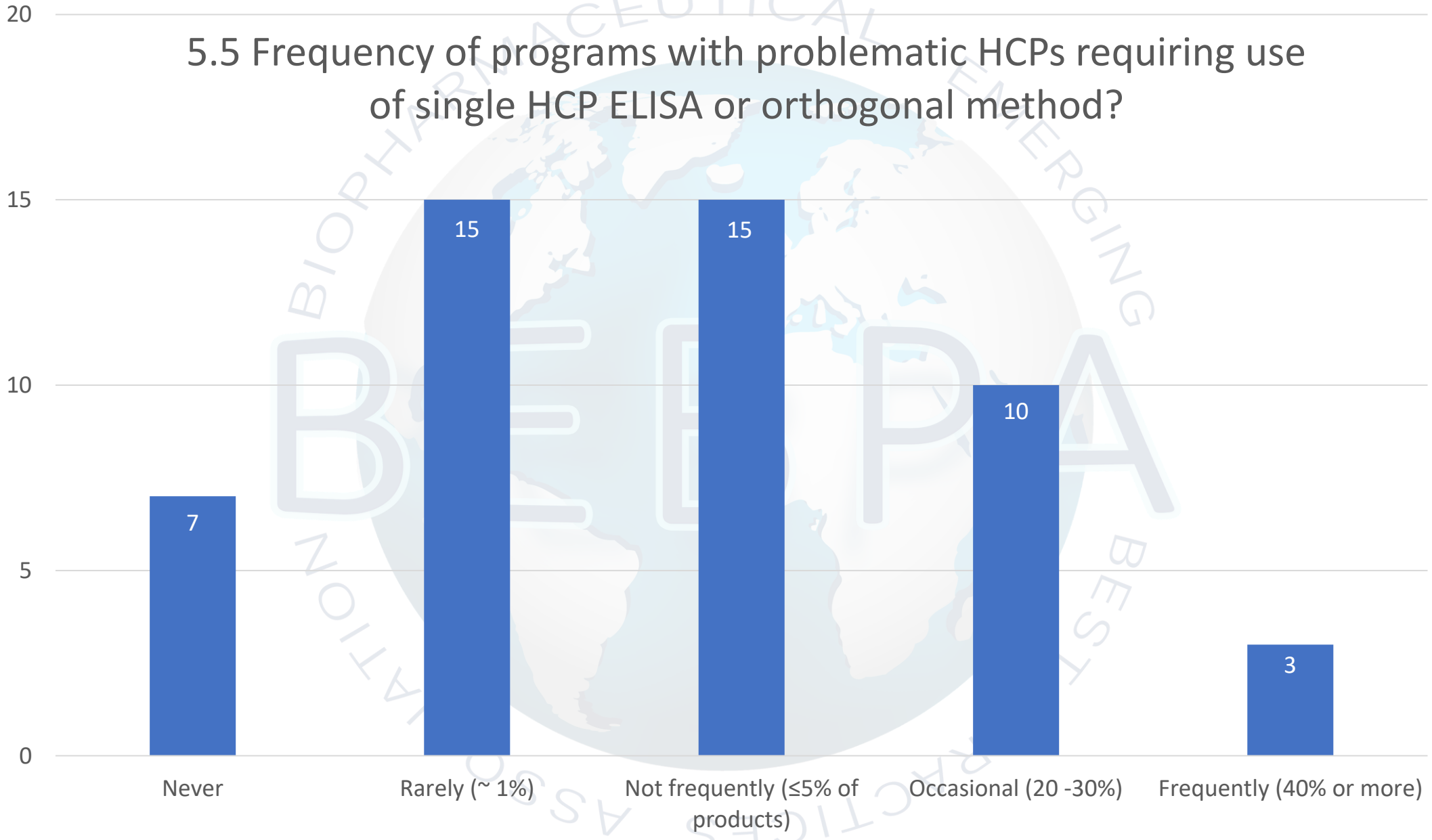
5.3 Do you run platform assays?



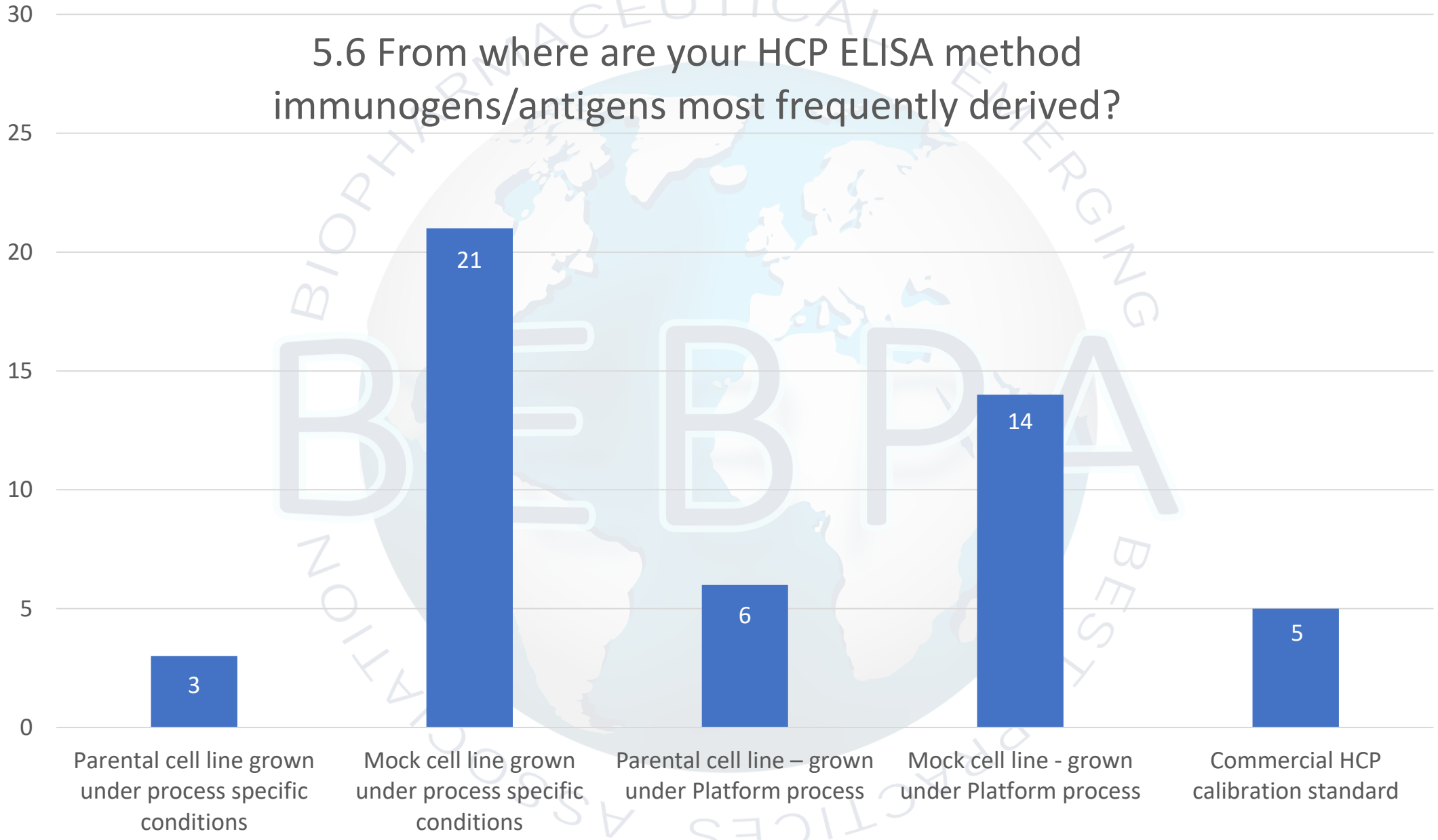
5.4 Does your company use Generic kit based HCP method(s) to support late process development/commercial programs?



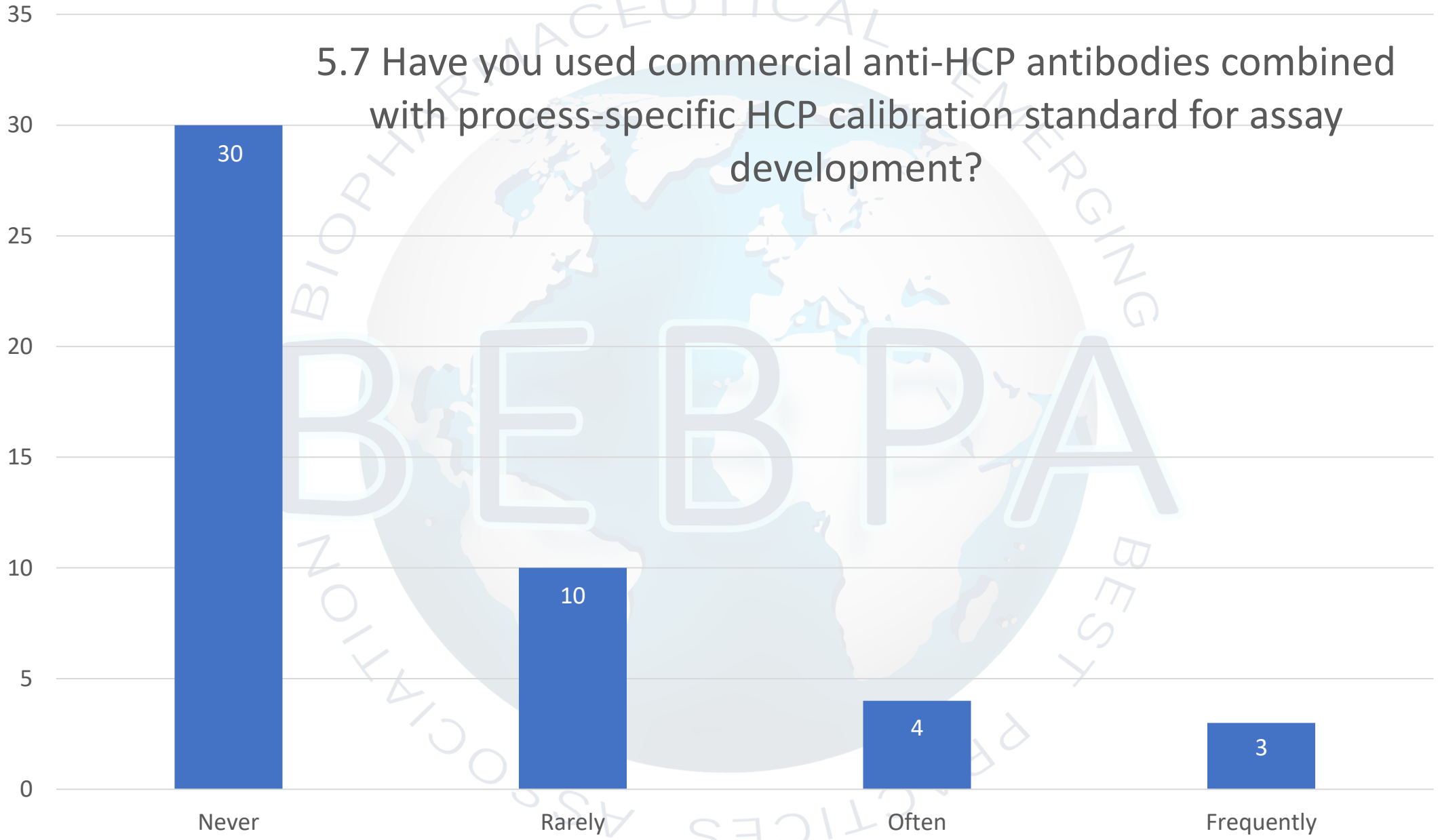
5.5 Frequency of programs with problematic HCPs requiring use of single HCP ELISA or orthogonal method?



5.6 From where are your HCP ELISA method immunogens/antigens most frequently derived?



5.7 Have you used commercial anti-HCP antibodies combined with process-specific HCP calibration standard for assay development?



THANK YOU

for attending BEBPA's 2021 Host Cell Protein Symposium

We could not have done this without YOU!