9th Annual USB Bioassay Conference

24-26 March 2025
Tucson, AZ, USA

Welcome Back & Introduction

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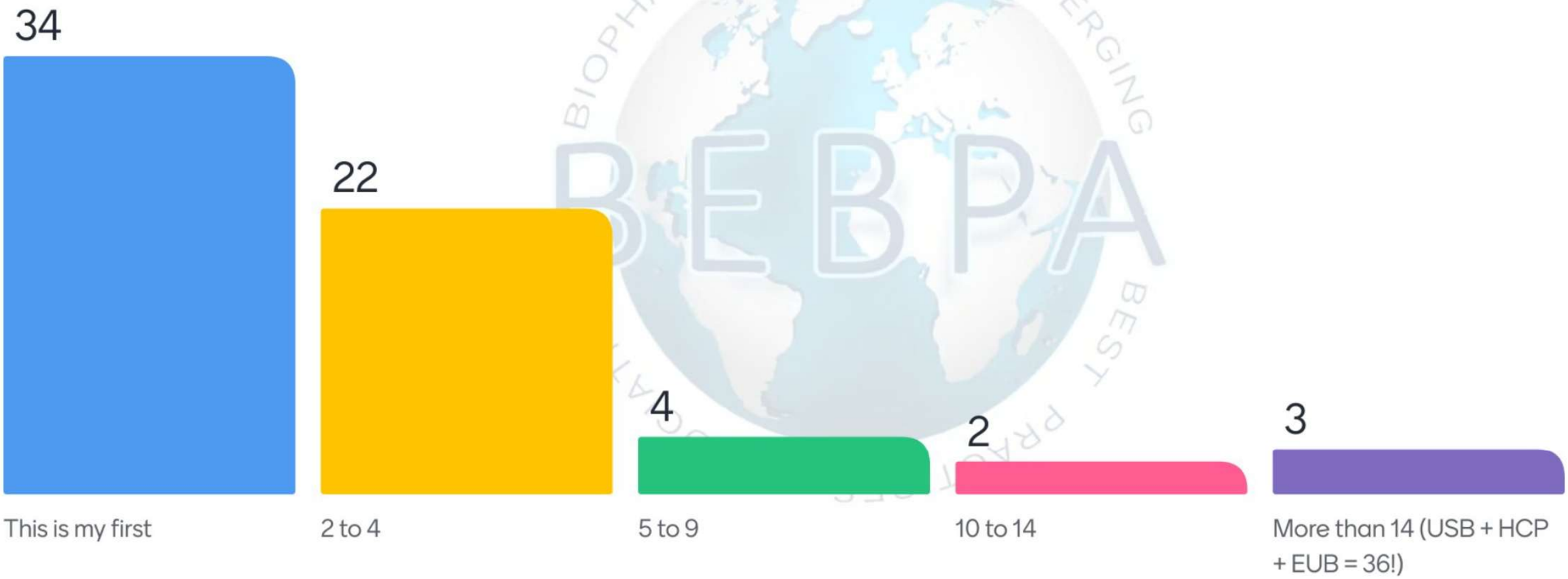
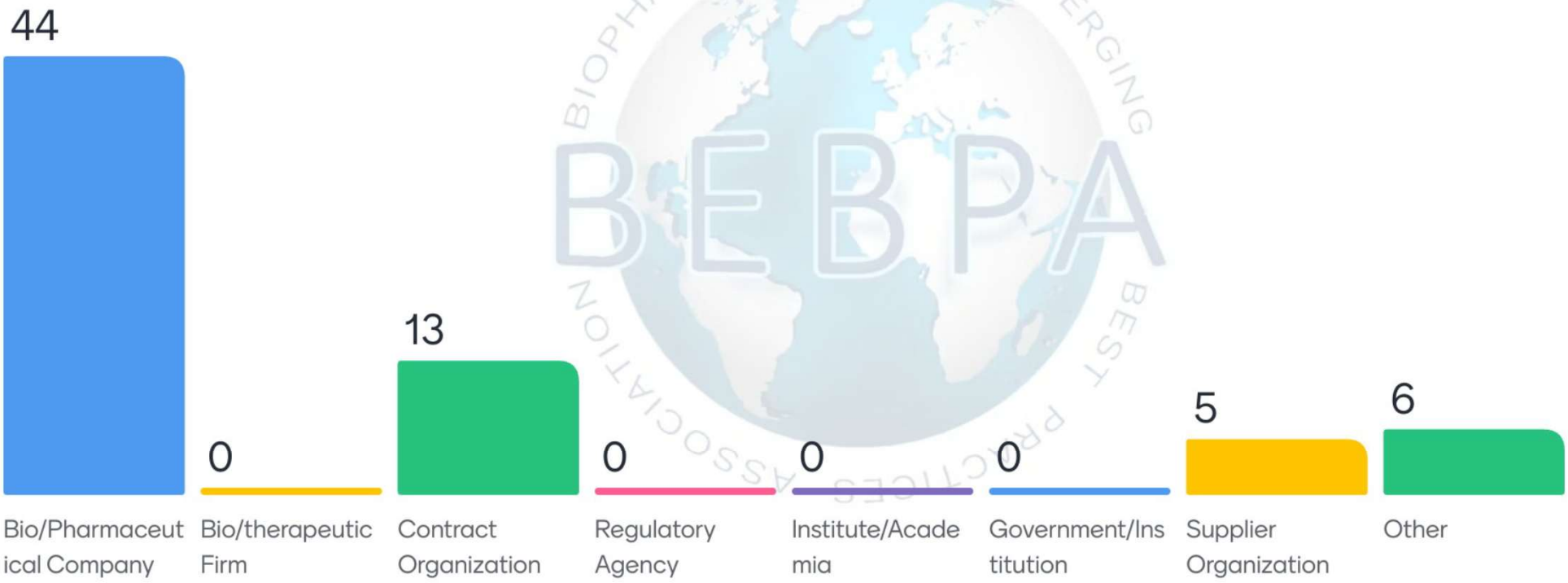
Principal Consultant
Quality Services
BEBPA President

Day 1 Audience Surveys

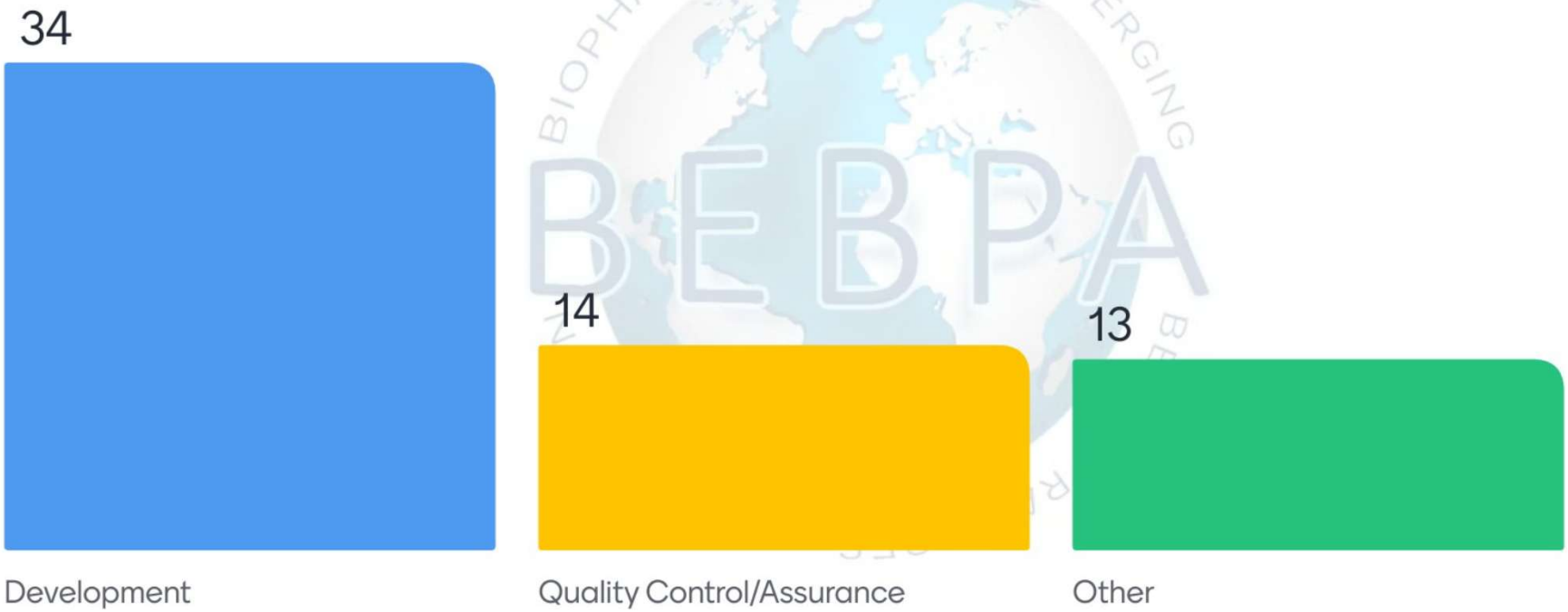
i.1 How many BEBPA Conferences have you attended?



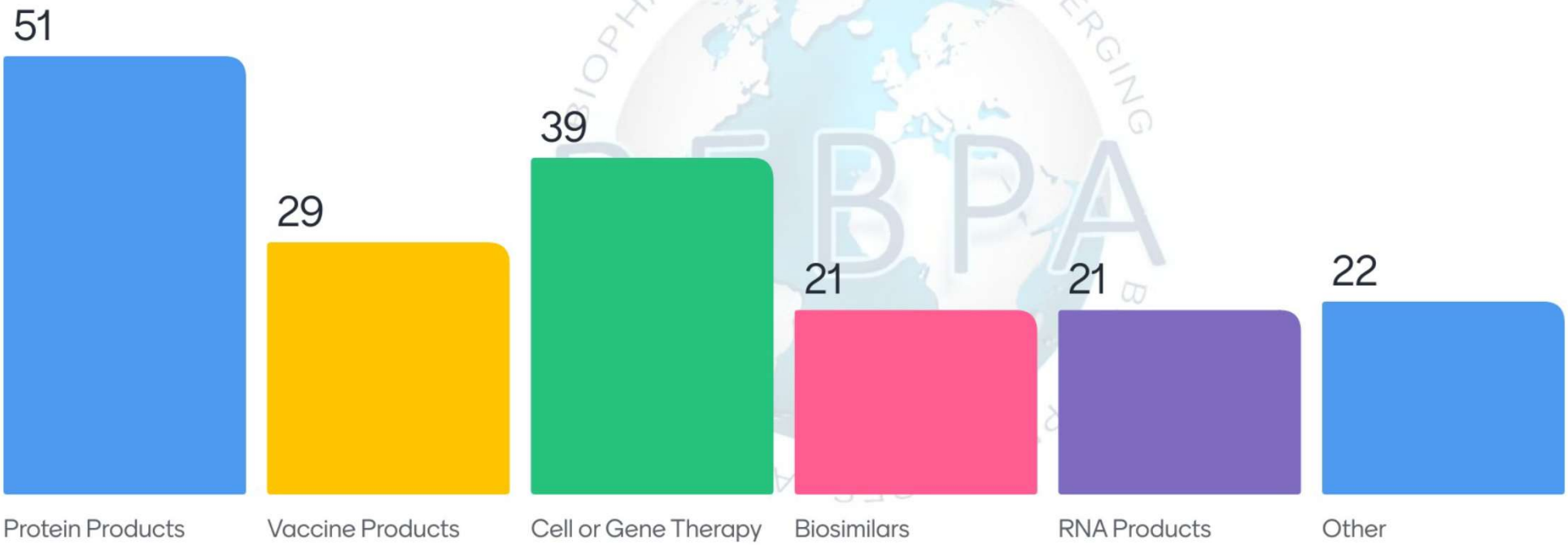
i.2 What type of organization do you work for?



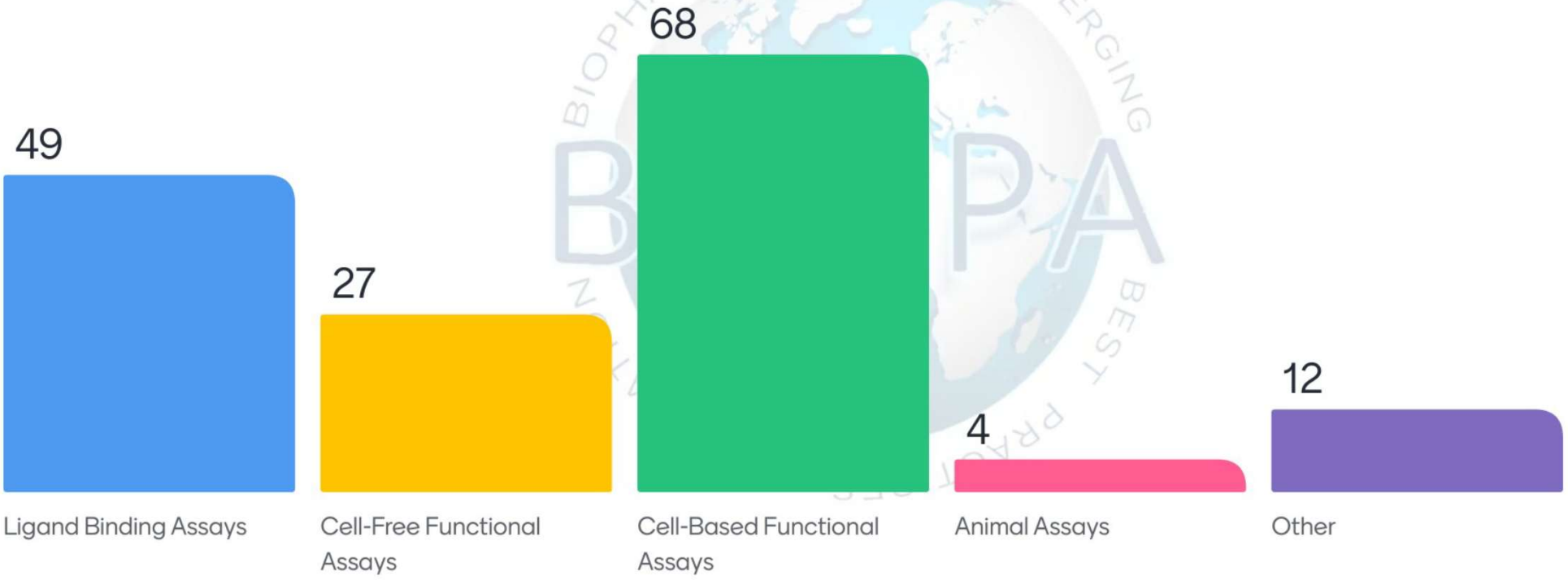
i.3 What part of the organization do your work for?



i.4 What type of products do you work with? (Check all that apply)



i.5 What type of assays do you develop? (Check all that apply)



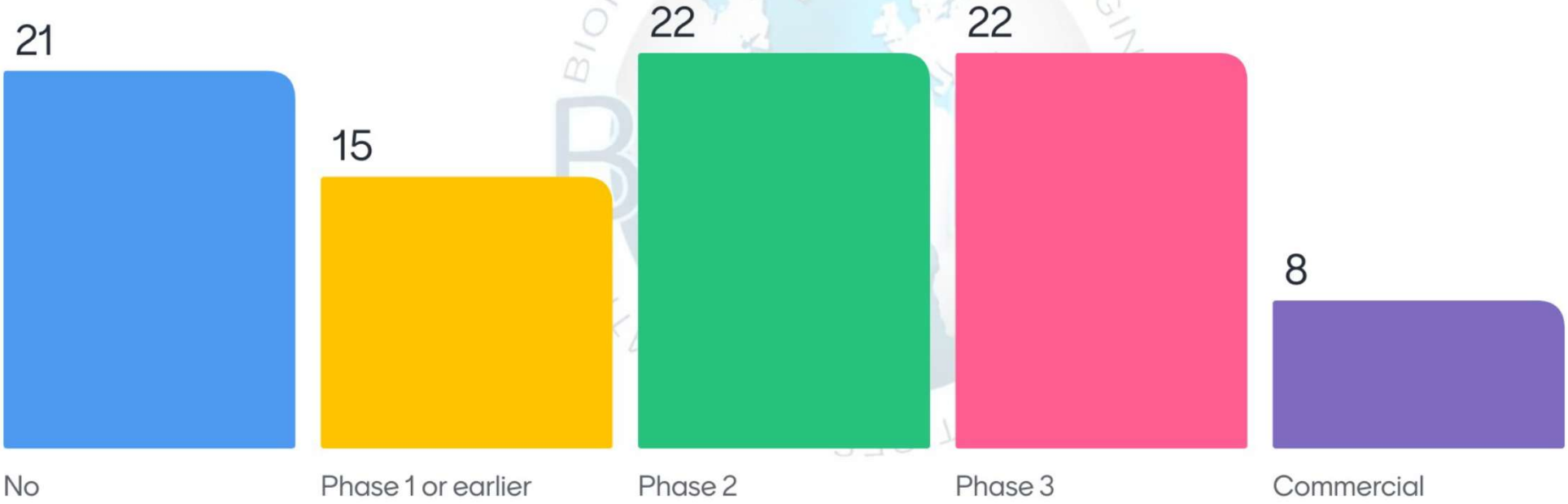
Day 1 Audience Surveys

Session 1: Current Trends

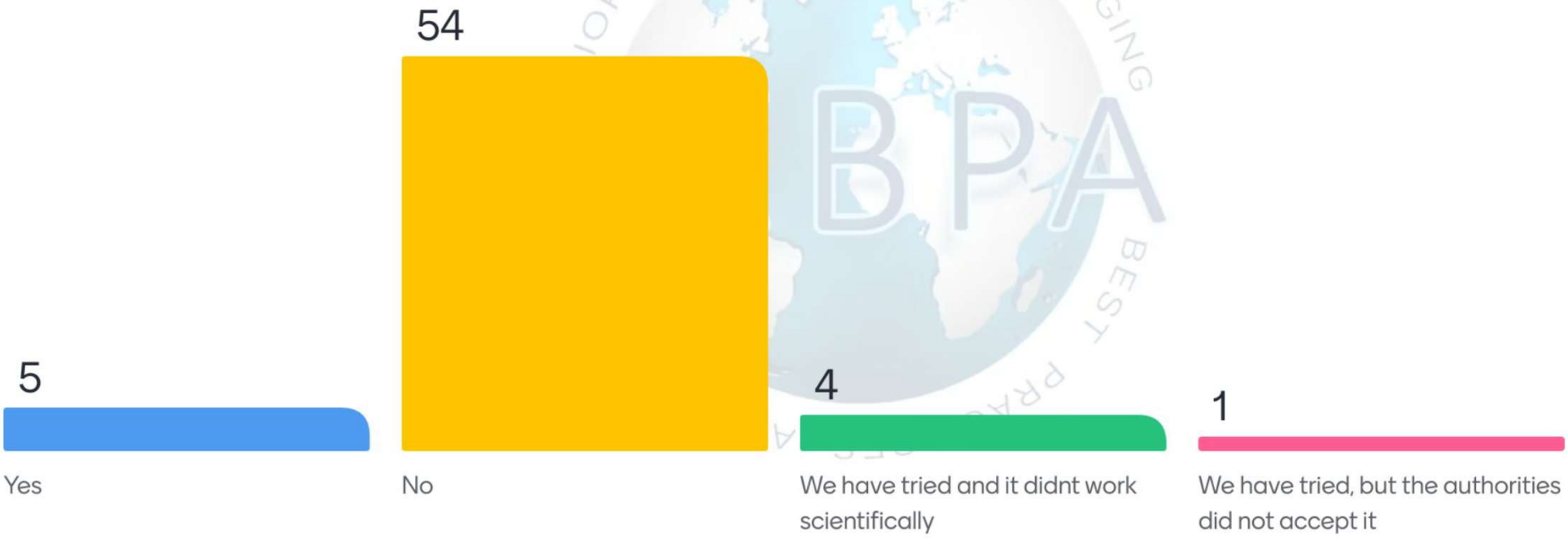
Session 2: Negotiating Complex Products

Session 3: Special TAE Introduction

1.1 Have you ever had to bridge two potency bioassays? If so, at what stage of development



1.2 Have you replaced a bioassay with an SPR (Surface Plasmon Resonance) binding activity assay?



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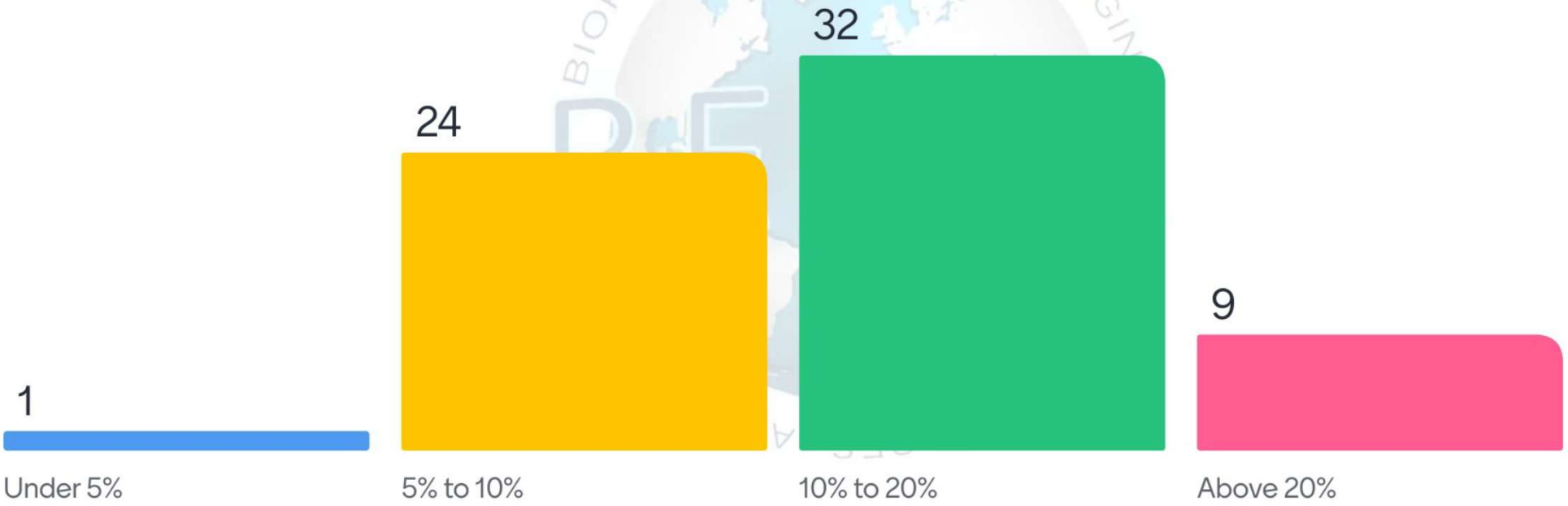
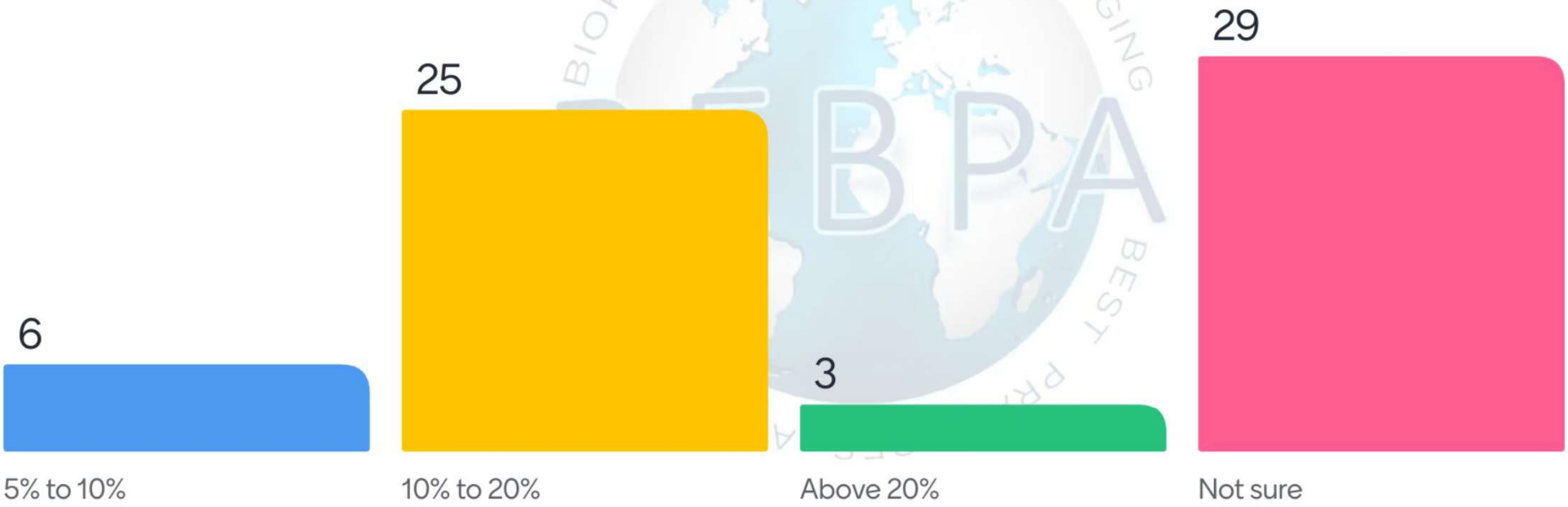
1.3 What is the IP (in terms of %CV) of a typical bioassay in your shop?

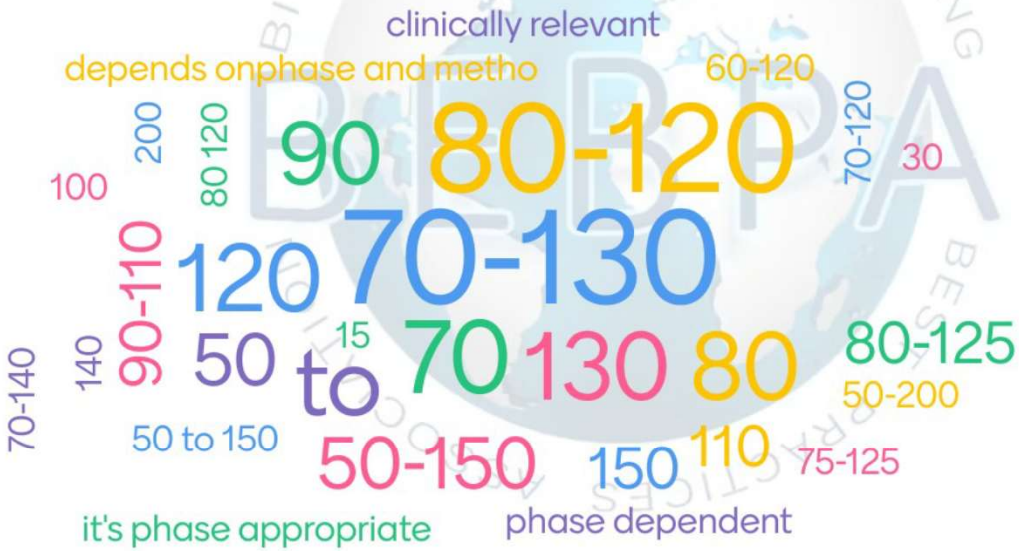


1.4 What is the process capability (in terms of the %CV about target) batch potency of a typical product submitted for release testing in your shop?

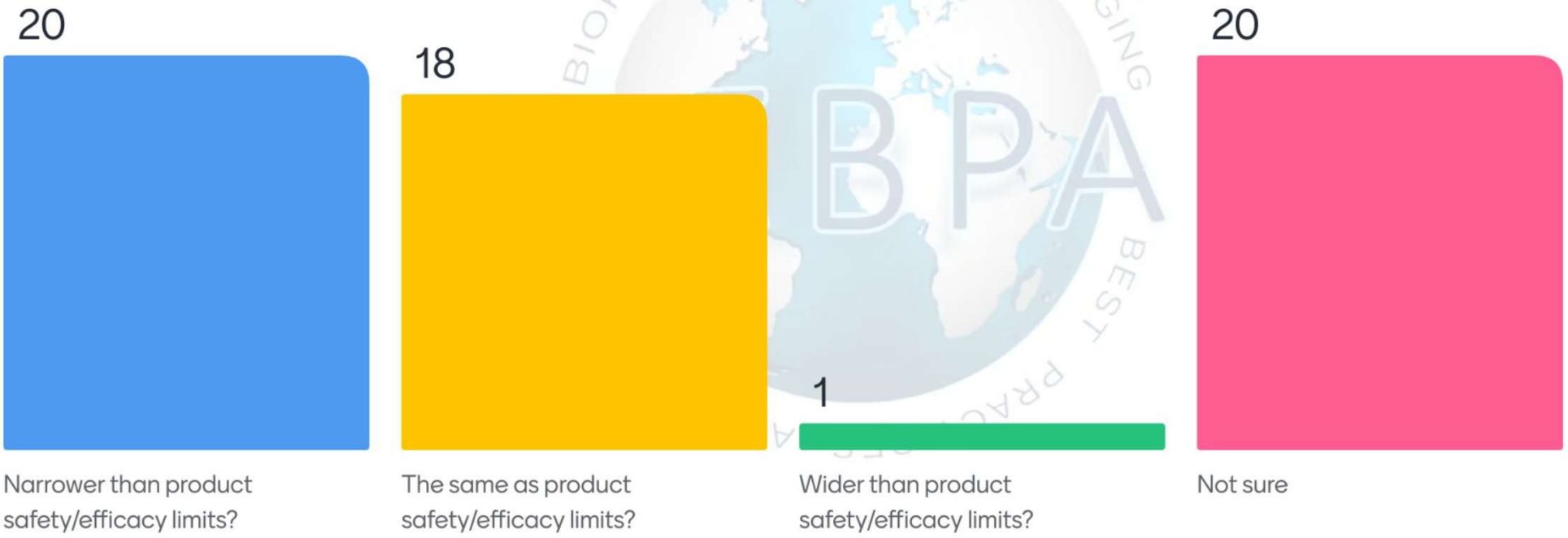


1.5 What range of potency defines an acceptable batch of a product (in terms of safety & efficacy) produced in your shop? (e.g., 90-110%? 80-120%?)

86 responses



1.6 For a typical product produced in your shop, Are the batch release limits.....

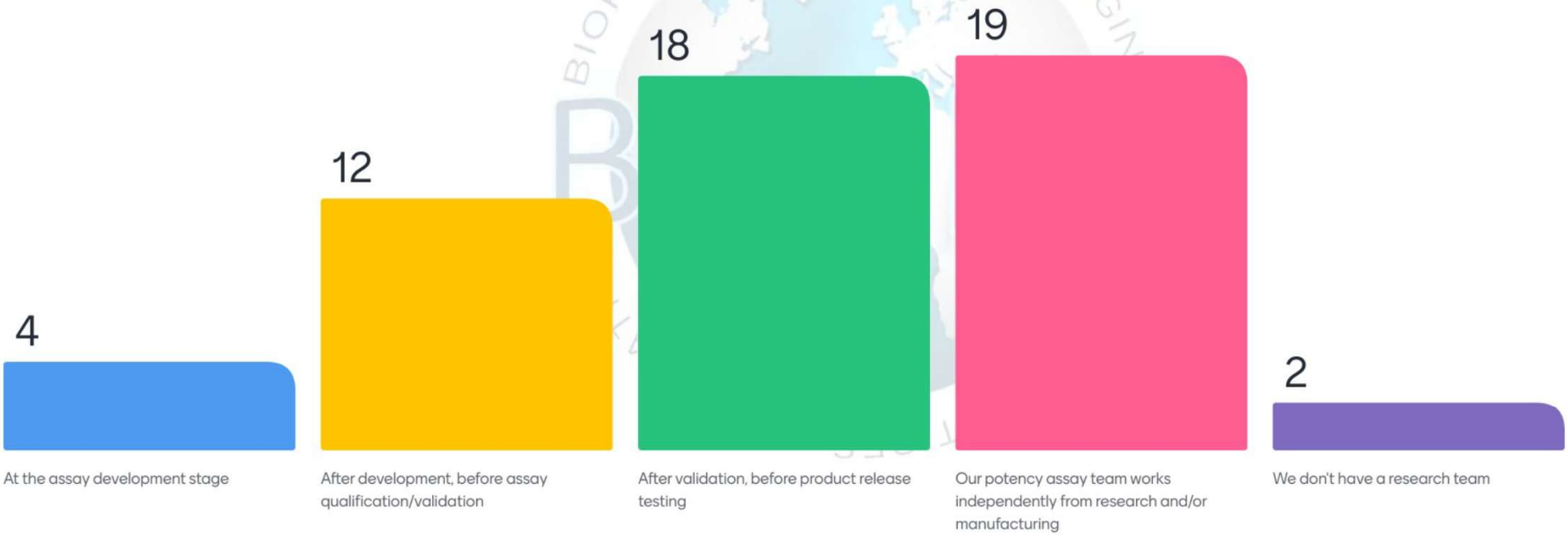


Day 2 Audience Surveys

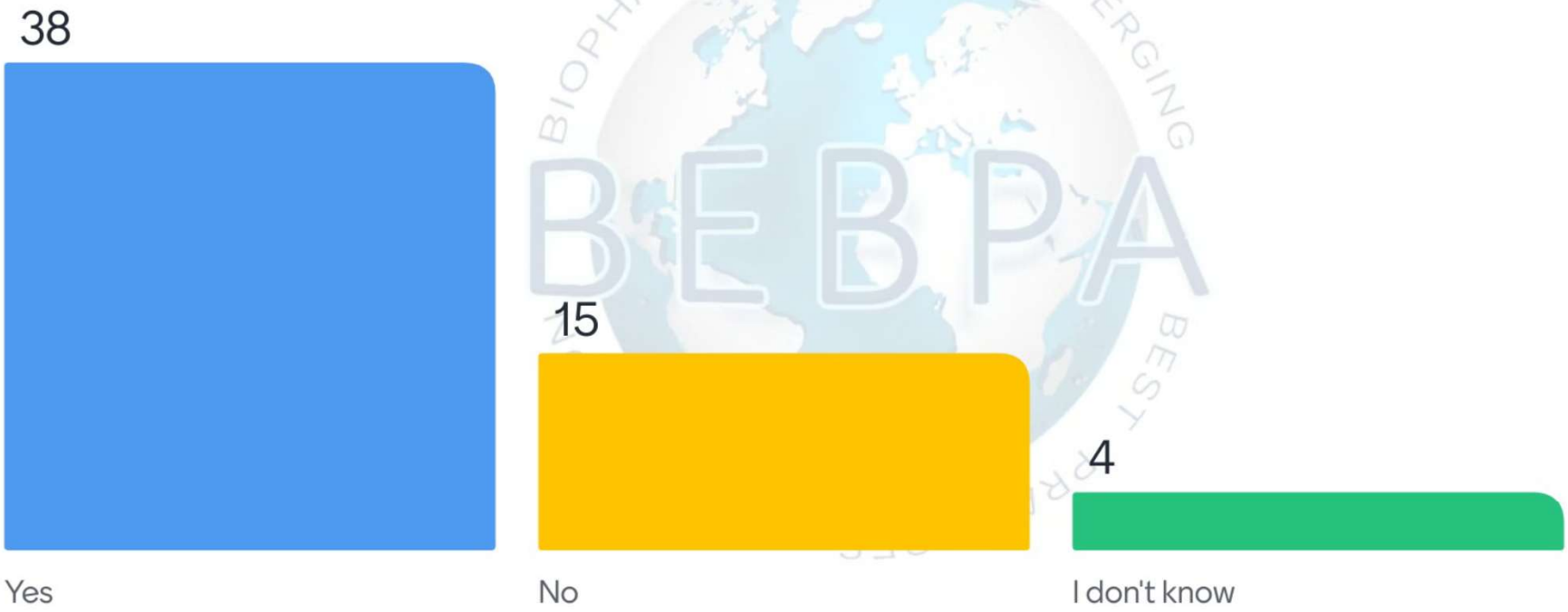
Session 4: Bioassay Development for Well-Characterized Biotech Products

Session 5: AI and Automation for Bioassays

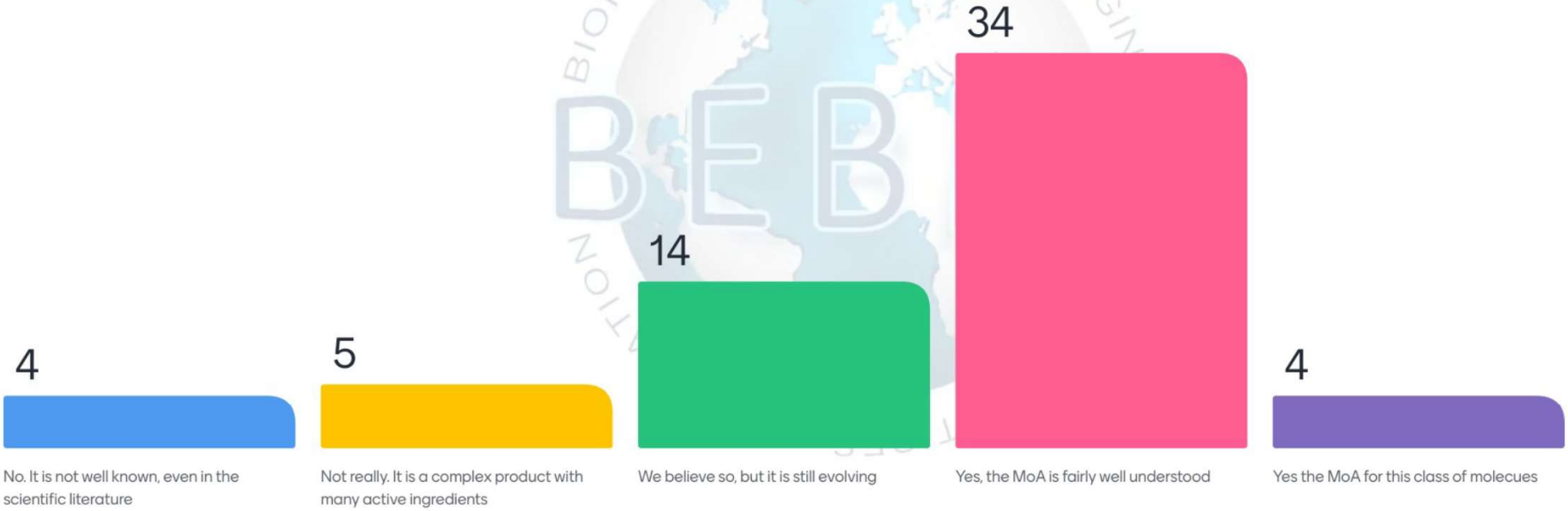
2.1 When does your research team hand off the potency assay to the manufacturing team?



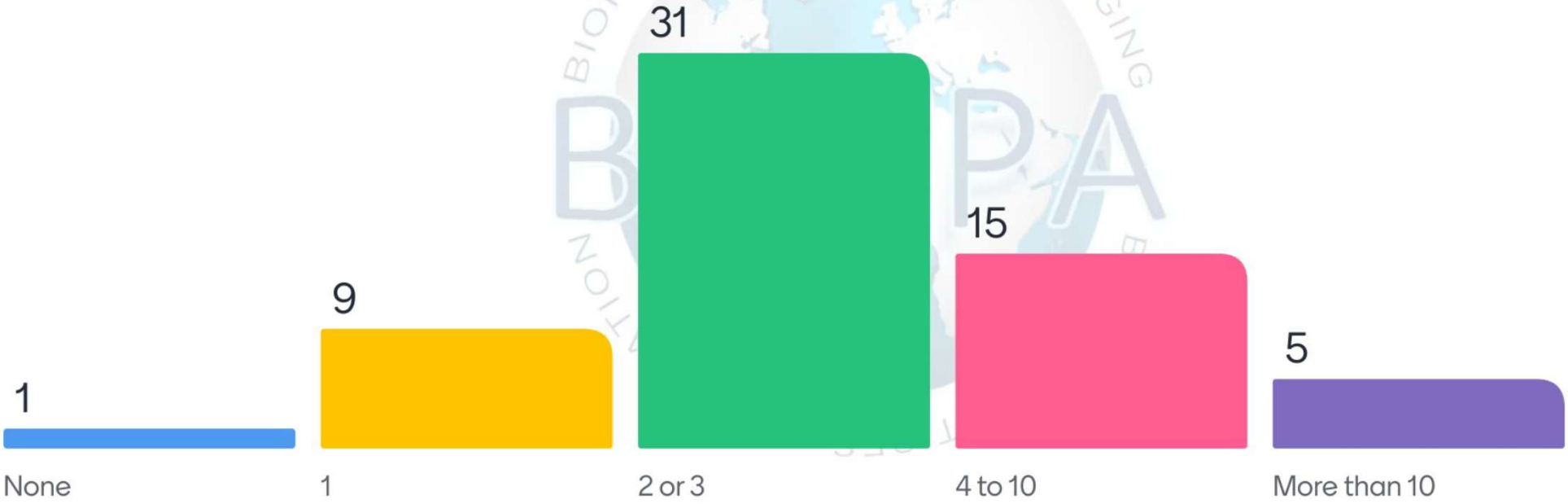
2.2 Is your company developing flow cytometry methods?



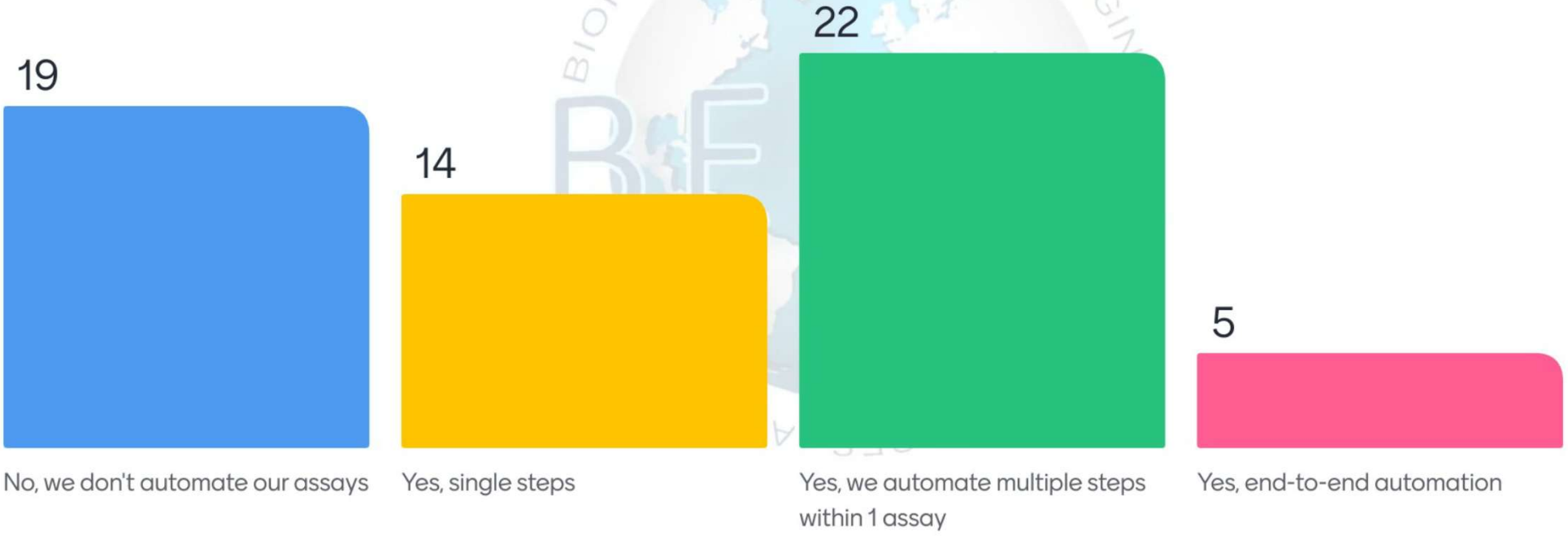
2.3 Do you understand the Mechanism of Action (MoA) of your product?



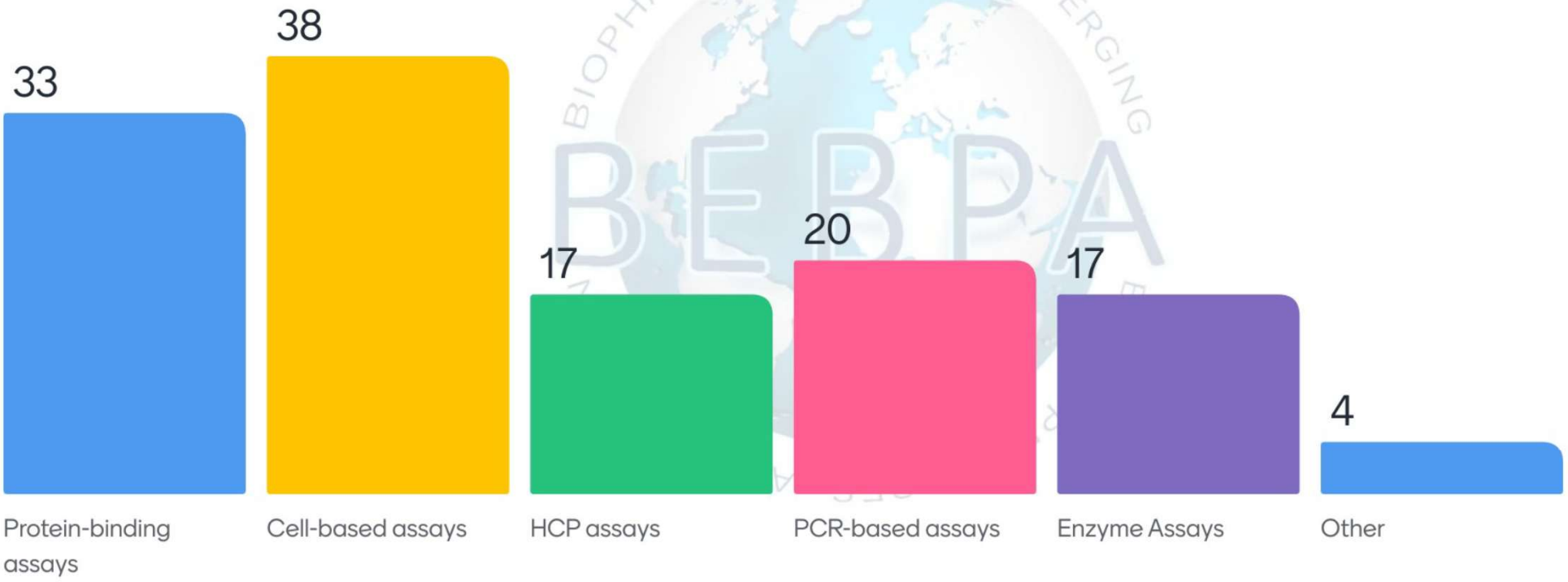
2.4 How many current and/or historical in-vitro assays have you used to monitor your product (check all that apply)



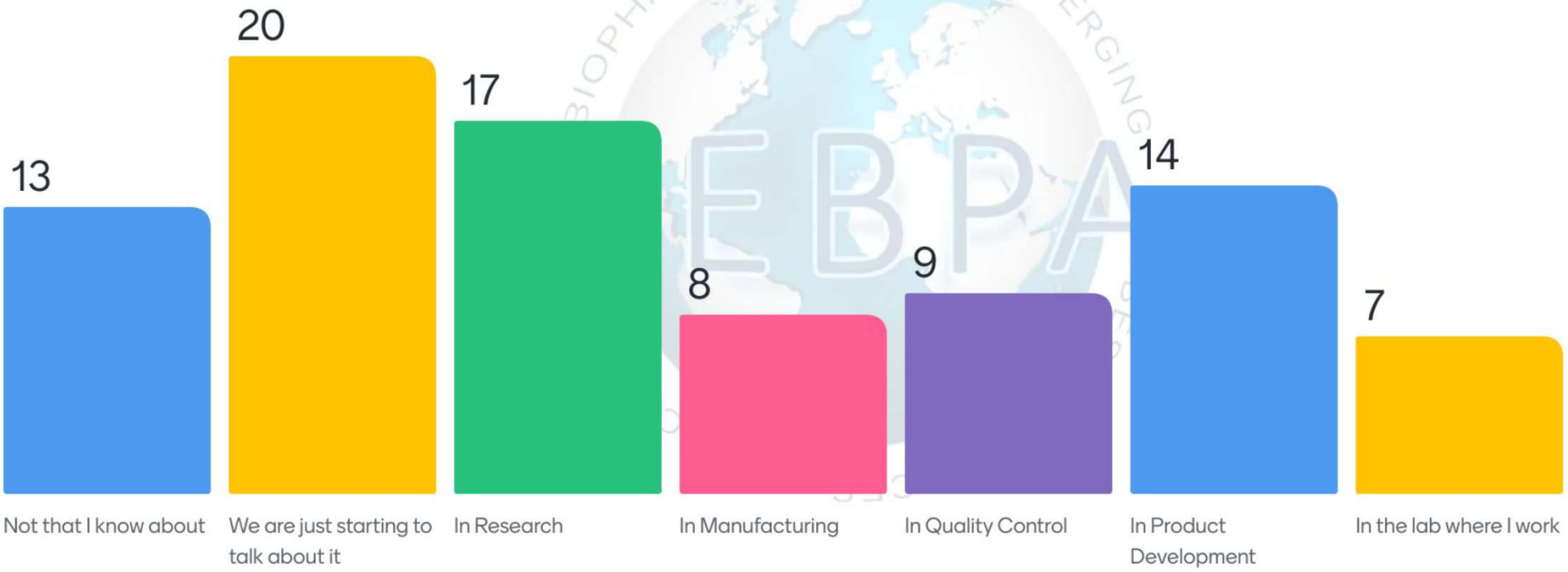
2.5 Do you automate your assays? If so what level of automation do you have?



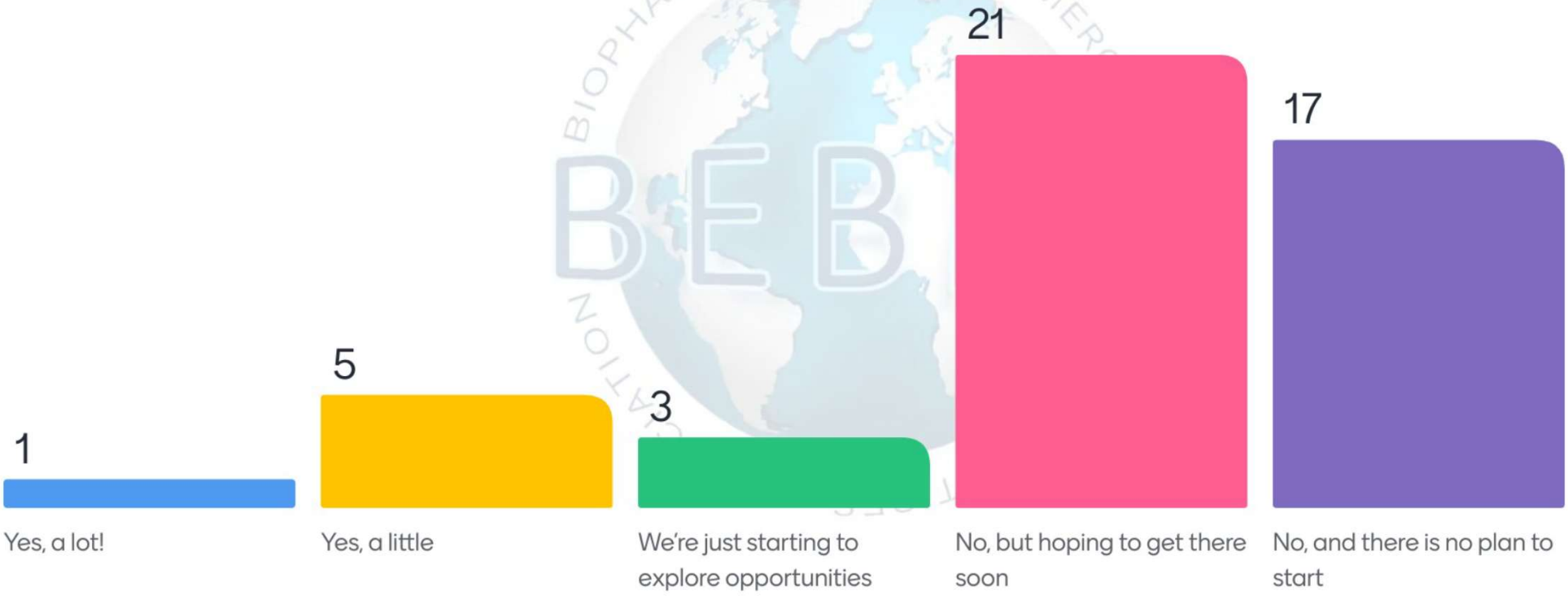
2.6 What types of method development have you successfully platformed?



2.7 Is your company investing in Artificial Intelligence (AI)?



2.8 Are you using ***generative*** AI to help with your bioassay work?

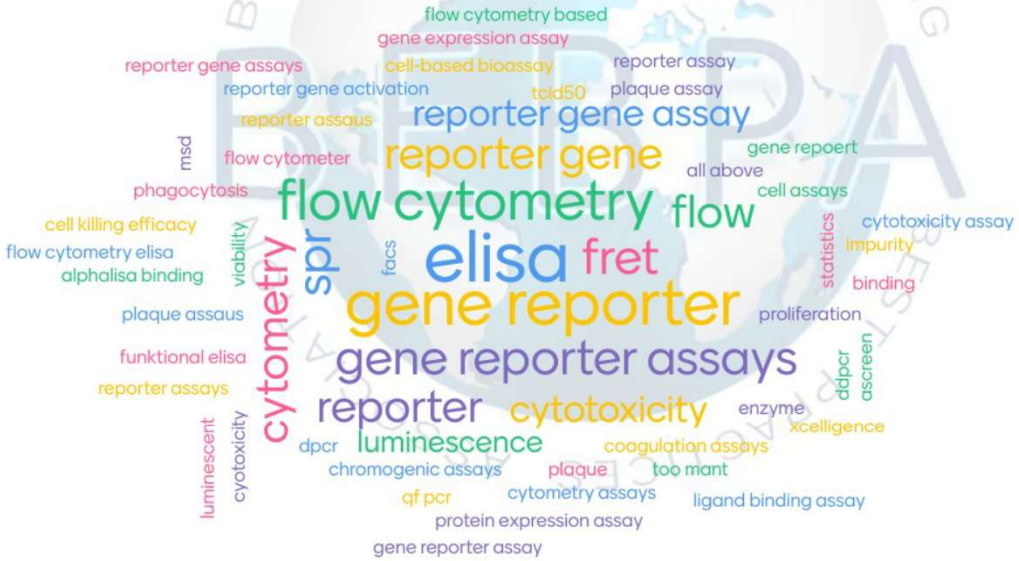


Day 3 Audience Surveys

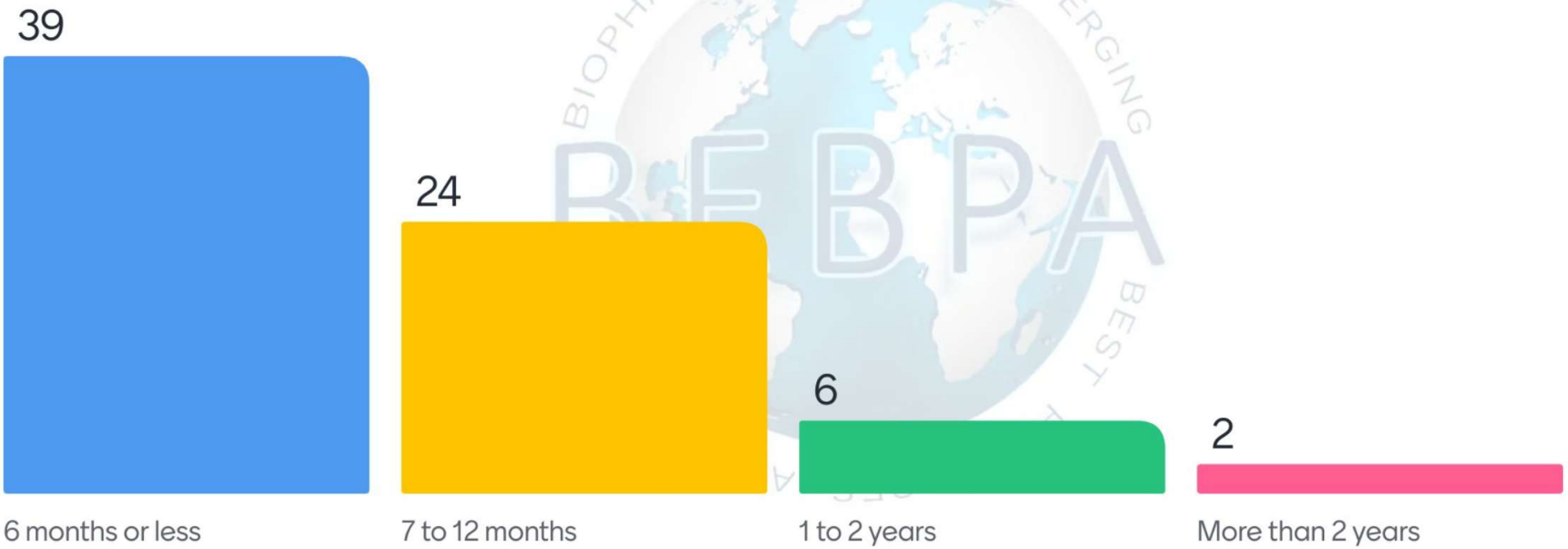
Session 6: New Approaches to Old Problems

3.1 What type of technologies have you used to develop bioassays? (e.g., gene reporter assays, cytometry, Fret assays, plaque assays, etc.)

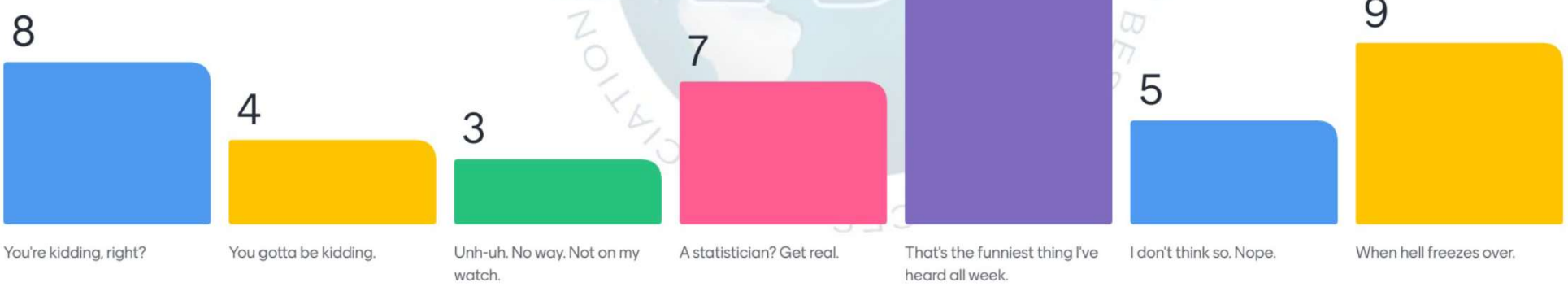
116 responses



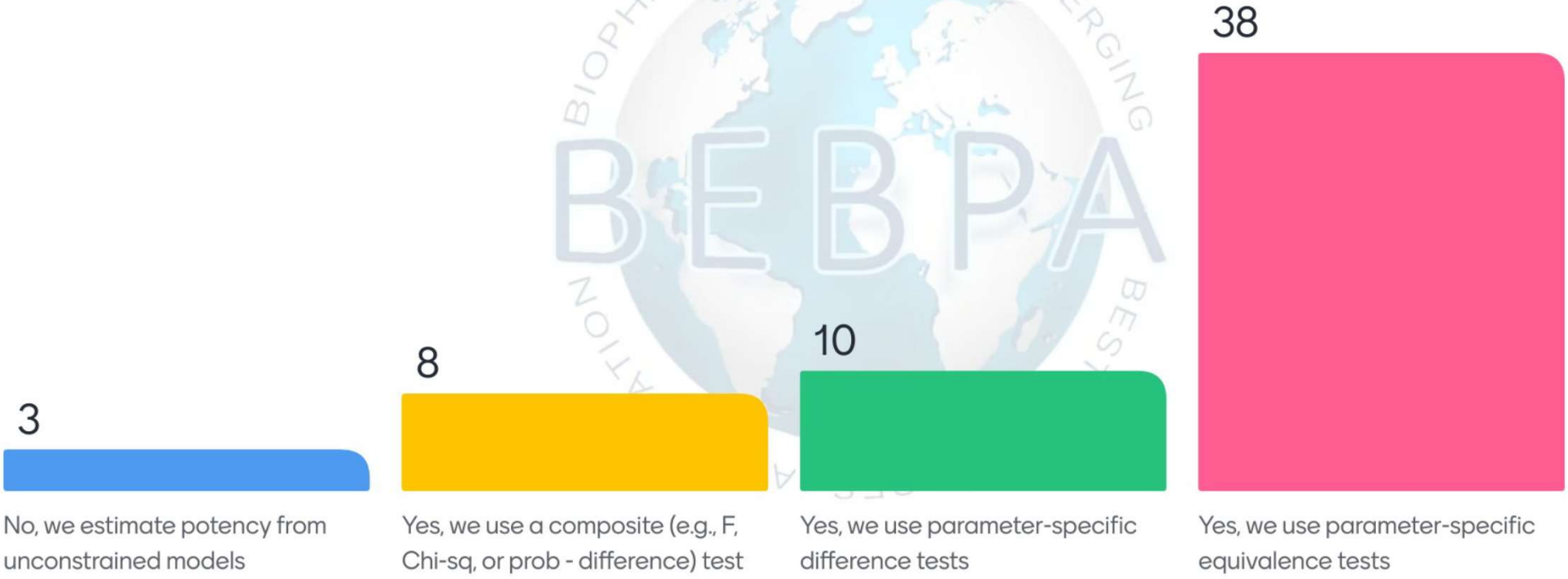
3.2 How long do you usually have to develop a potency assay?



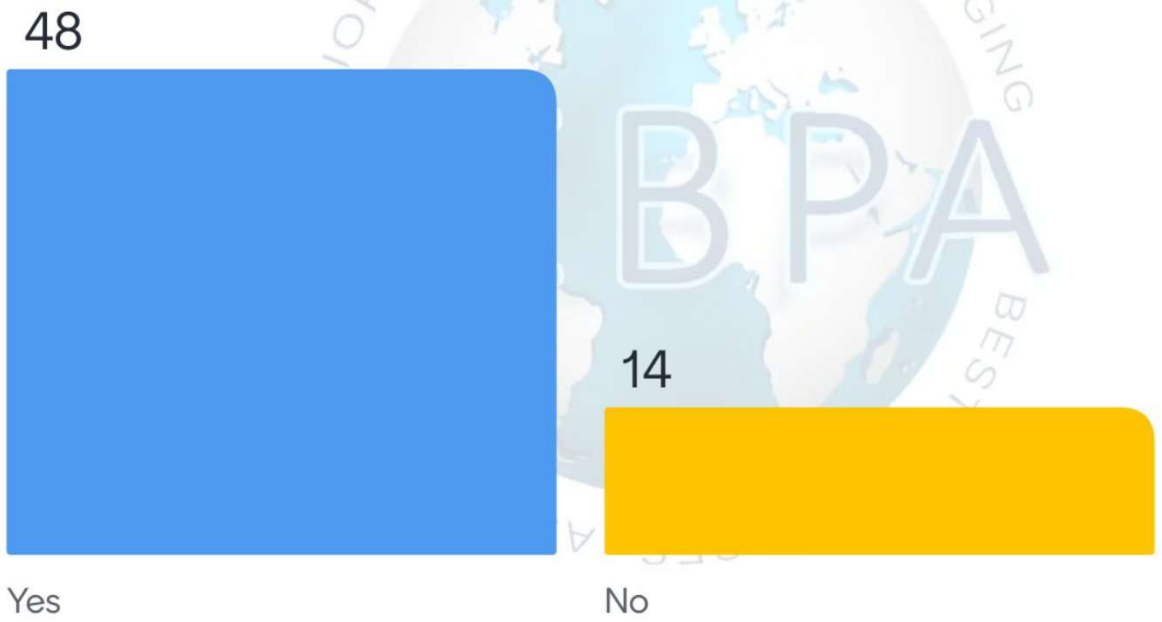
3.3 Would you trust a statistician to supply profoound knowledge of your field?



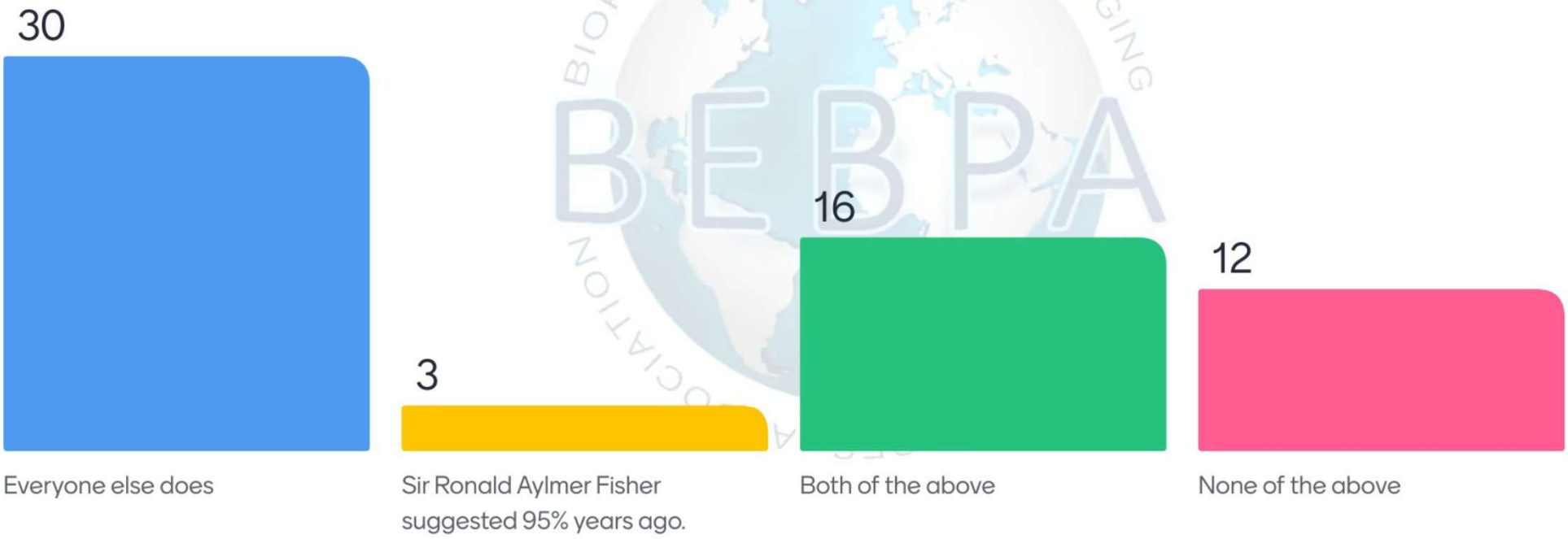
3.4 Do your bioassays usually require similarity before estimating relative potency?



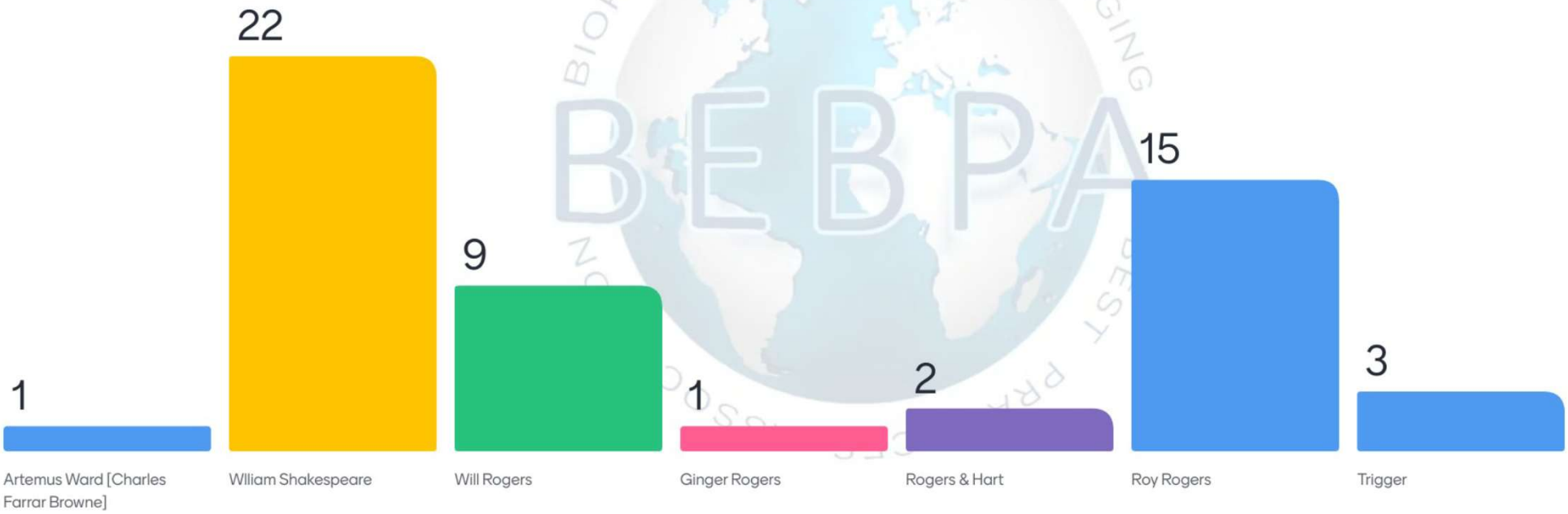
3.5 Are you concerned about bias in relative potency due to allowed non-similarity



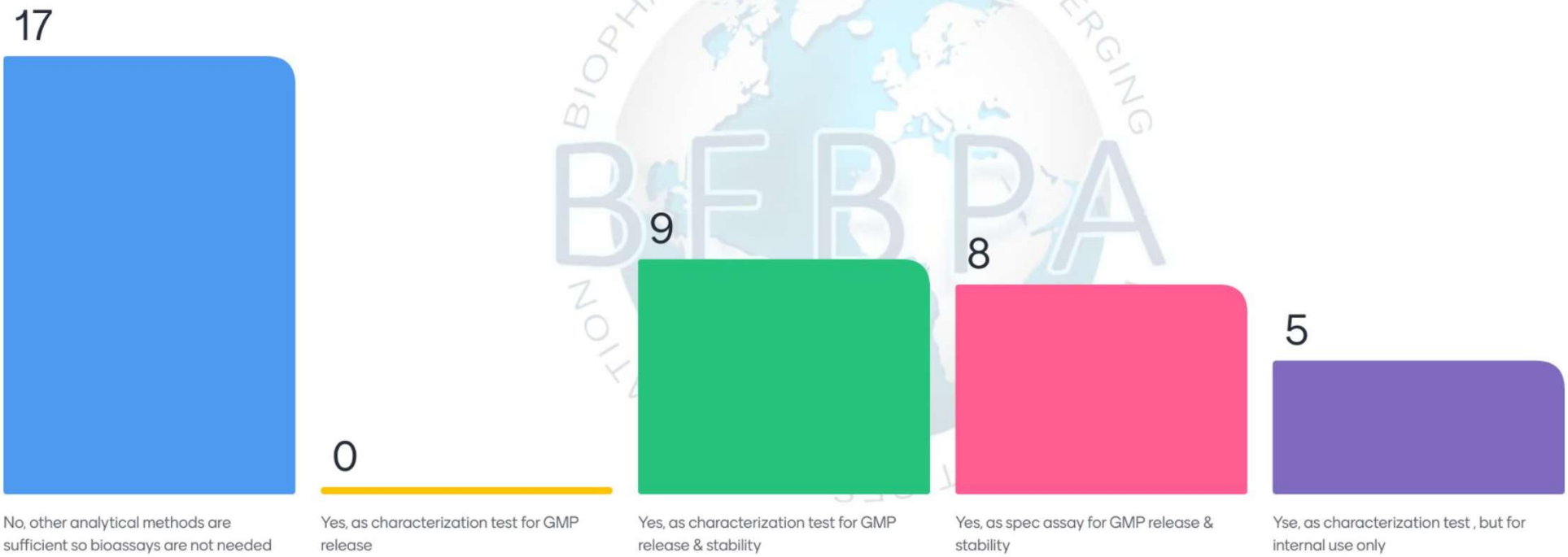
3.6 "Everyone" uses 95% as the level of confidence for statistical tests because:



3.7 Who said, "It ain't so much the things we don't know that gets us in trouble. It's the things we know that ain't so."



3.8 Do you leverage bioassays for potency assessments for peptides less than 40 amino acids?



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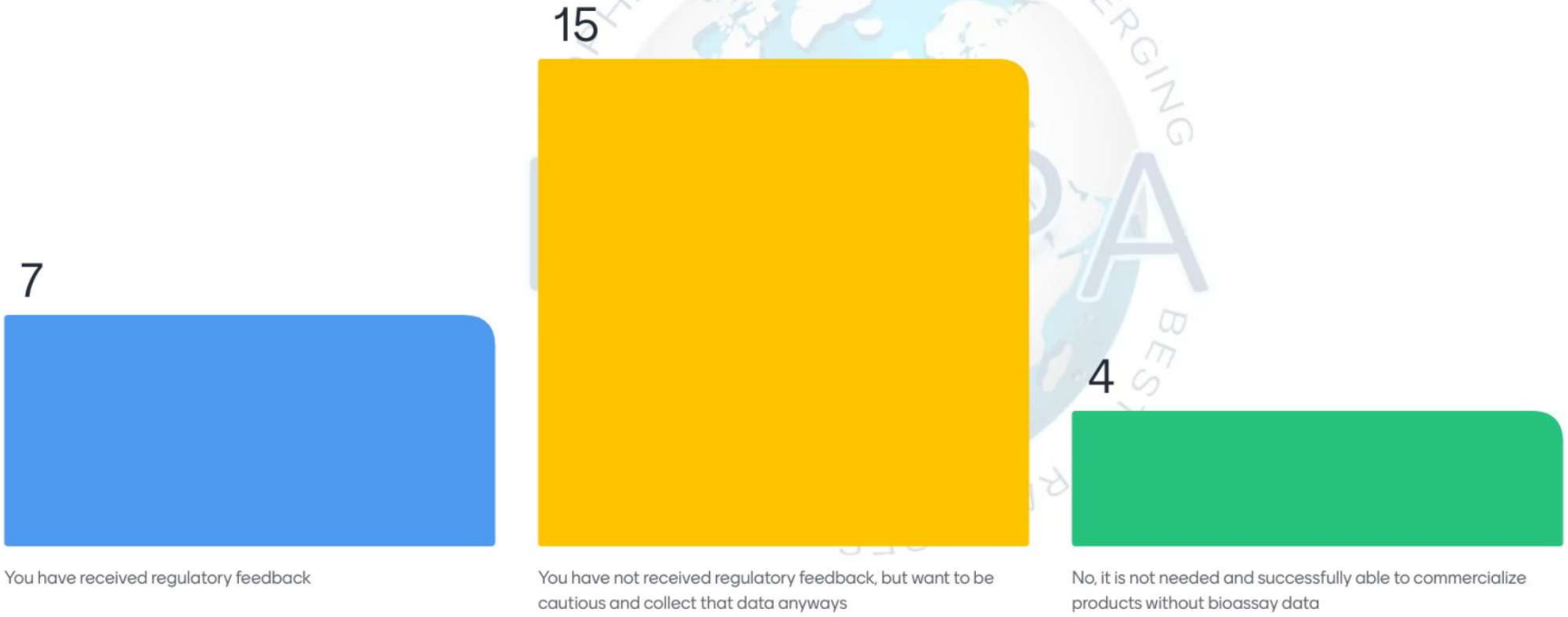
3.9 If you use bioassays for peptides less than 40 amino acids, you did so because:

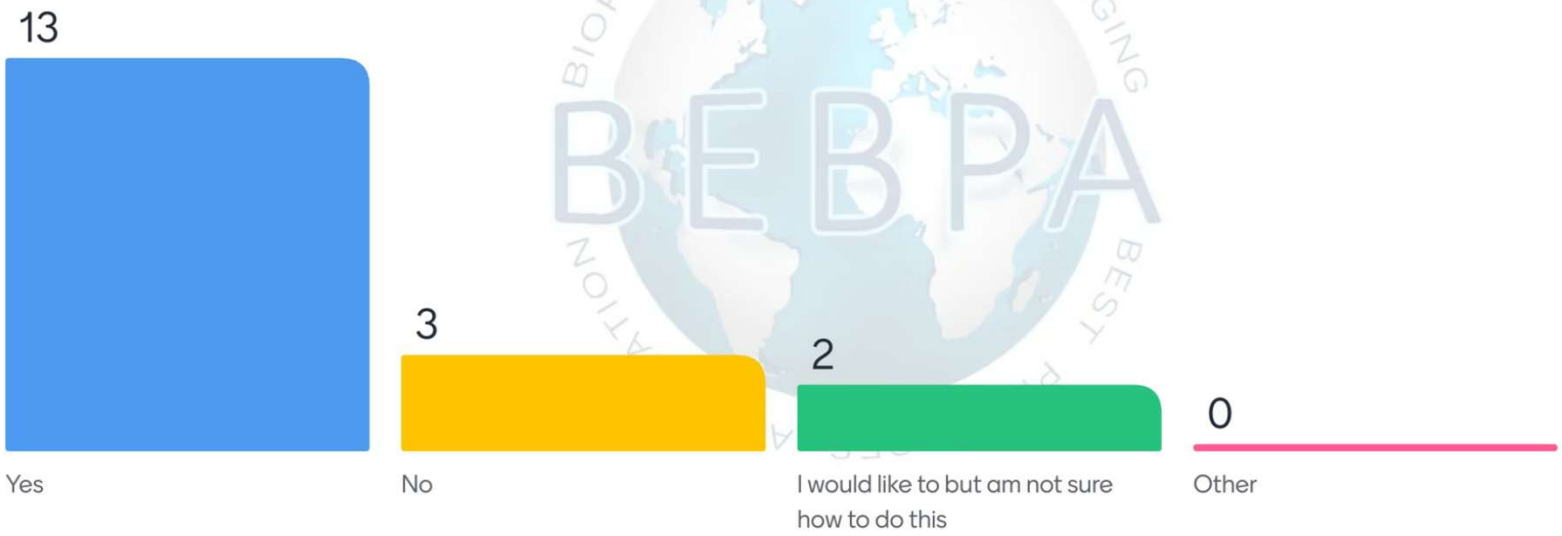


Workshop 1: Statistical Methods for Bioassay Qualification

Workshop Leader:
Perceval Sondag

Audience Surveys

W1.1 I use a single design to collect the data for accuracy, precision, and linearity



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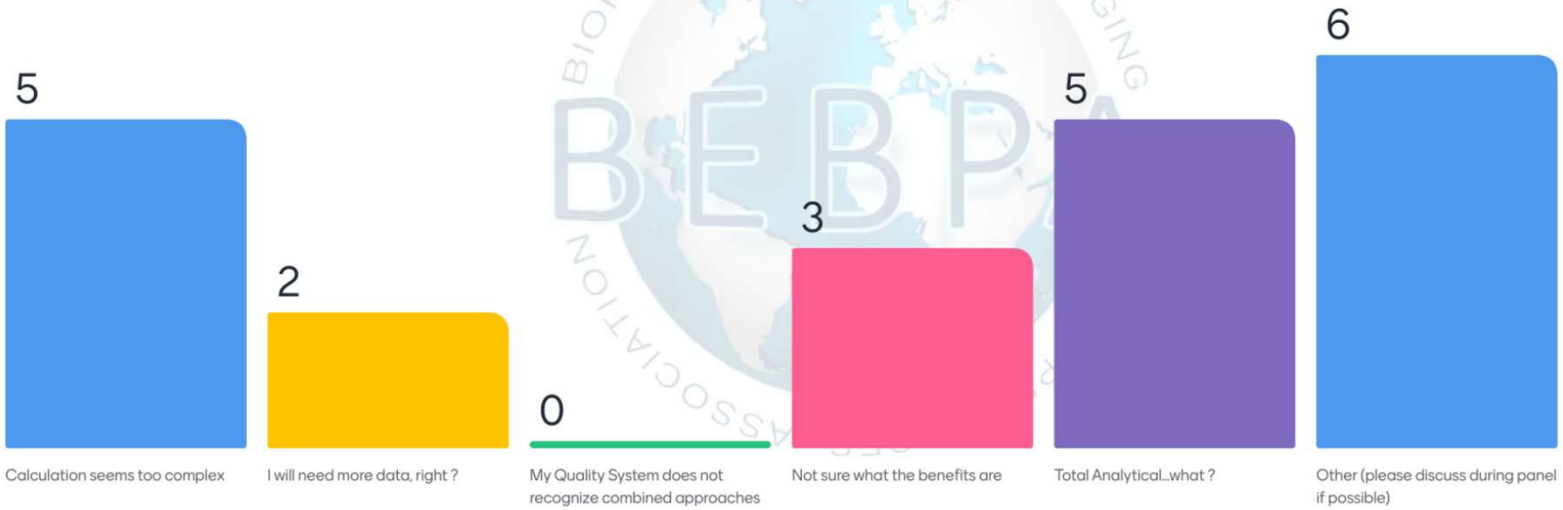
W1.2 What prevents you from implementing a Total Analytical Error Combined Approach for Accuracy and Precision ?



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Thank you!!