

# 10th Annual USB Bioassay Conference

23-26 March 2026  
College Park, MD, USA



# Concurrent Workshop 1: Bioassay Basics

Workshop 1 Leaders:

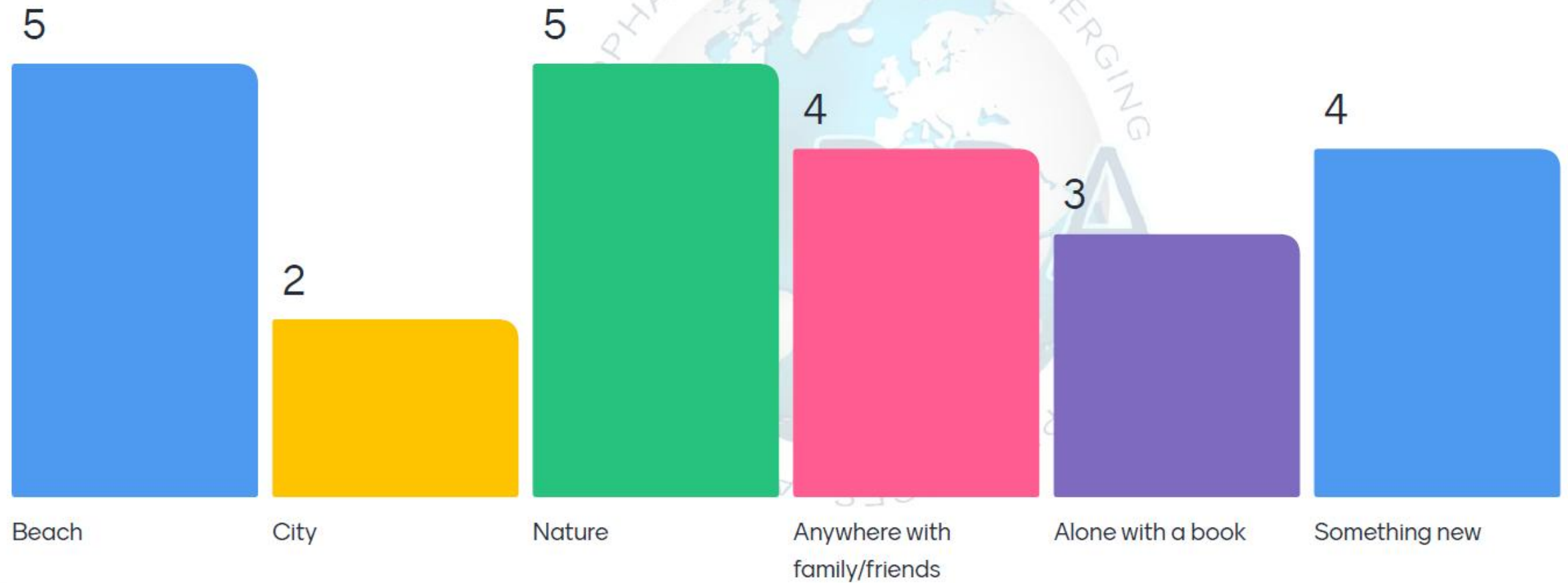
Anton Stetsenko, BioQual Consulting

Mike Merges, Autolus Therapeutics

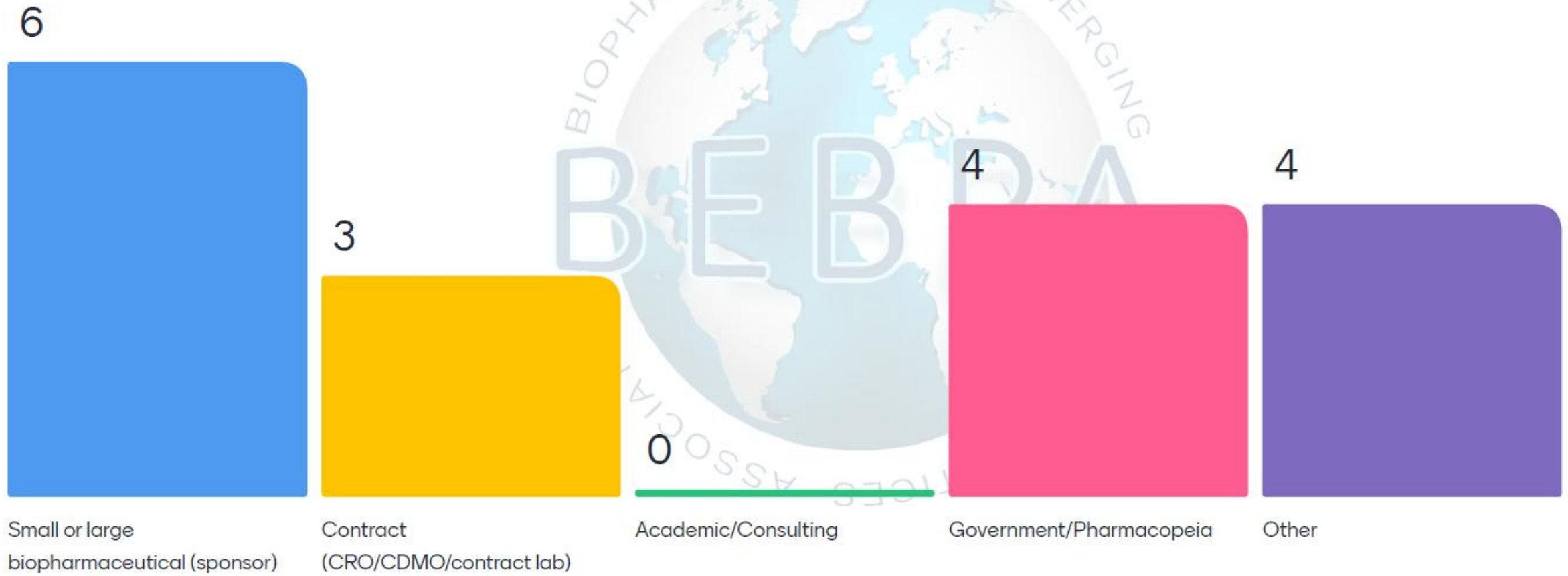
Leslie Wagner, US FDA

Audience Surveys

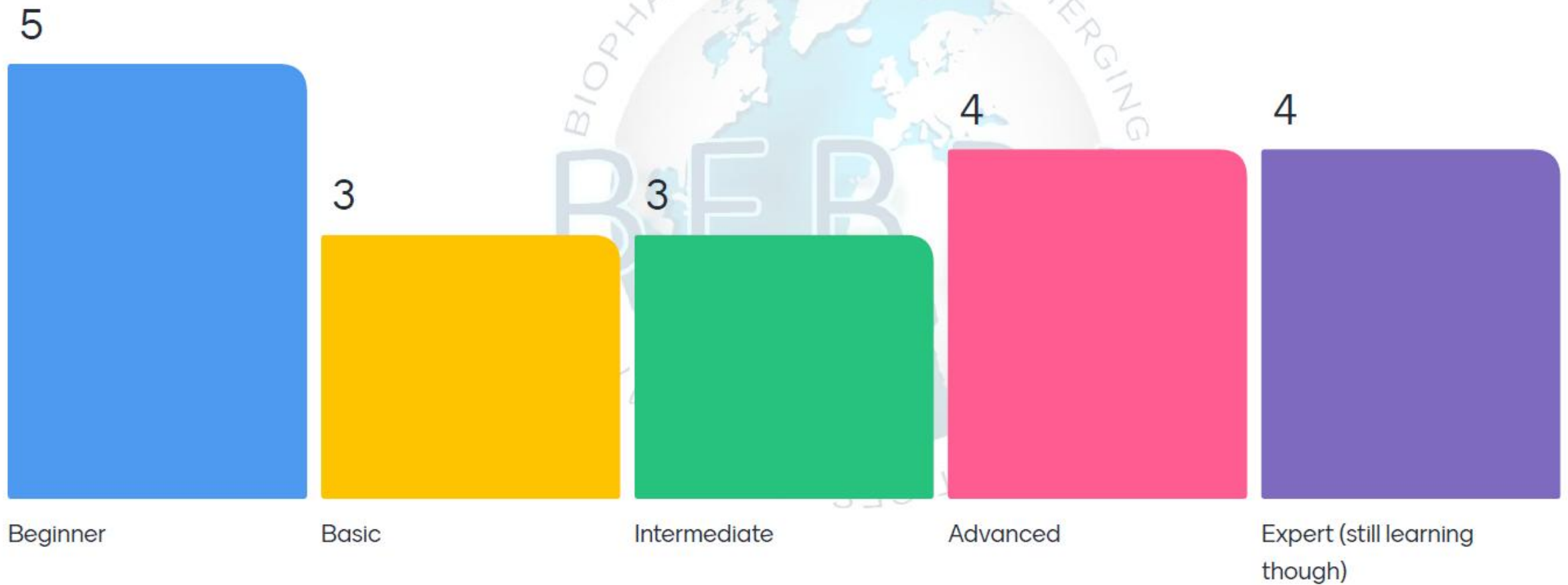
# W1.1 What is your favorite vacation?



# W1.2 What organization do you represent?

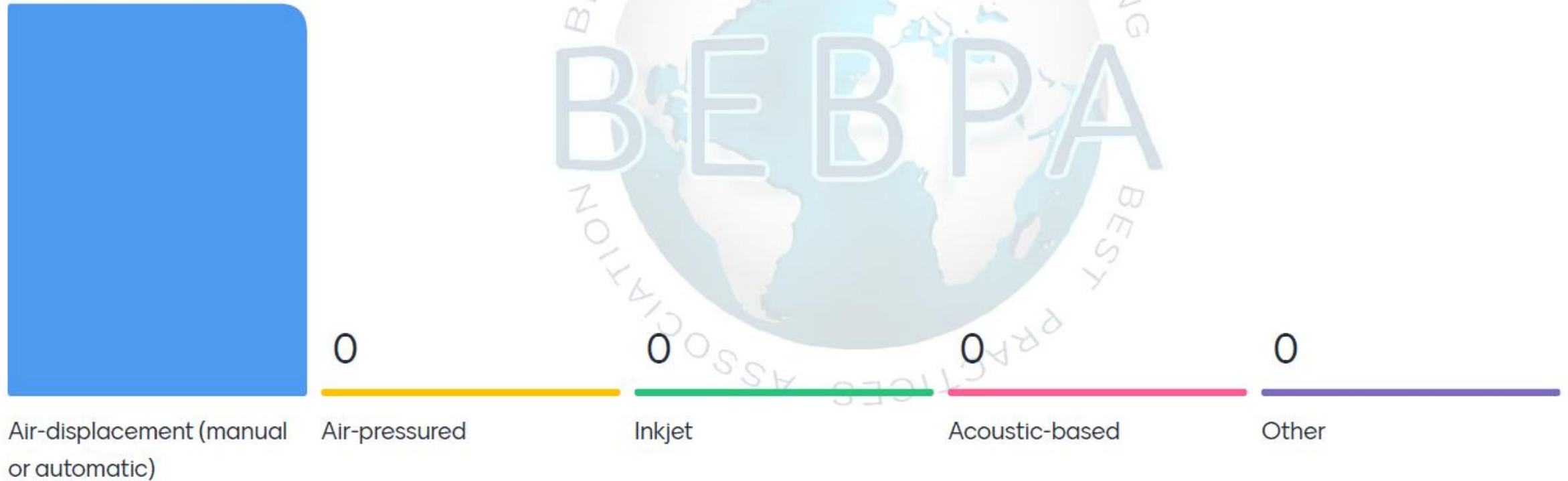


# W1.3 How would you rate your proficiency level in bioassays?

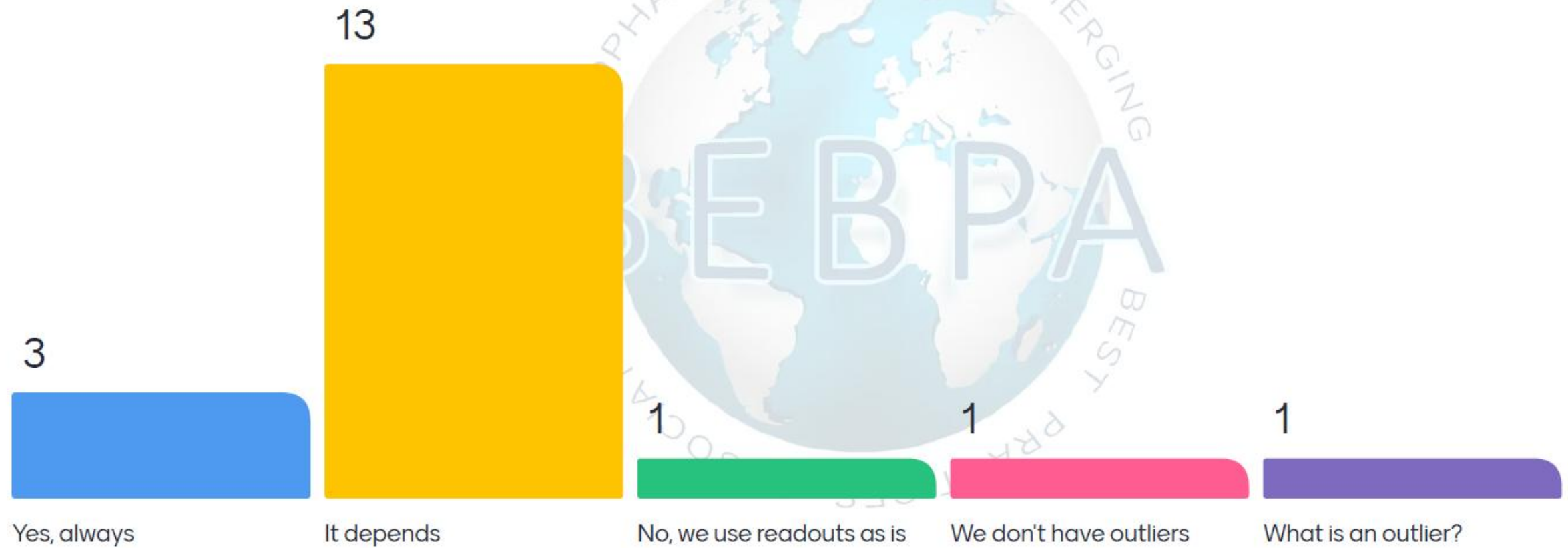


# W1.4 Which dispensing mechanism do you use most often for your dose dilutions preparation?

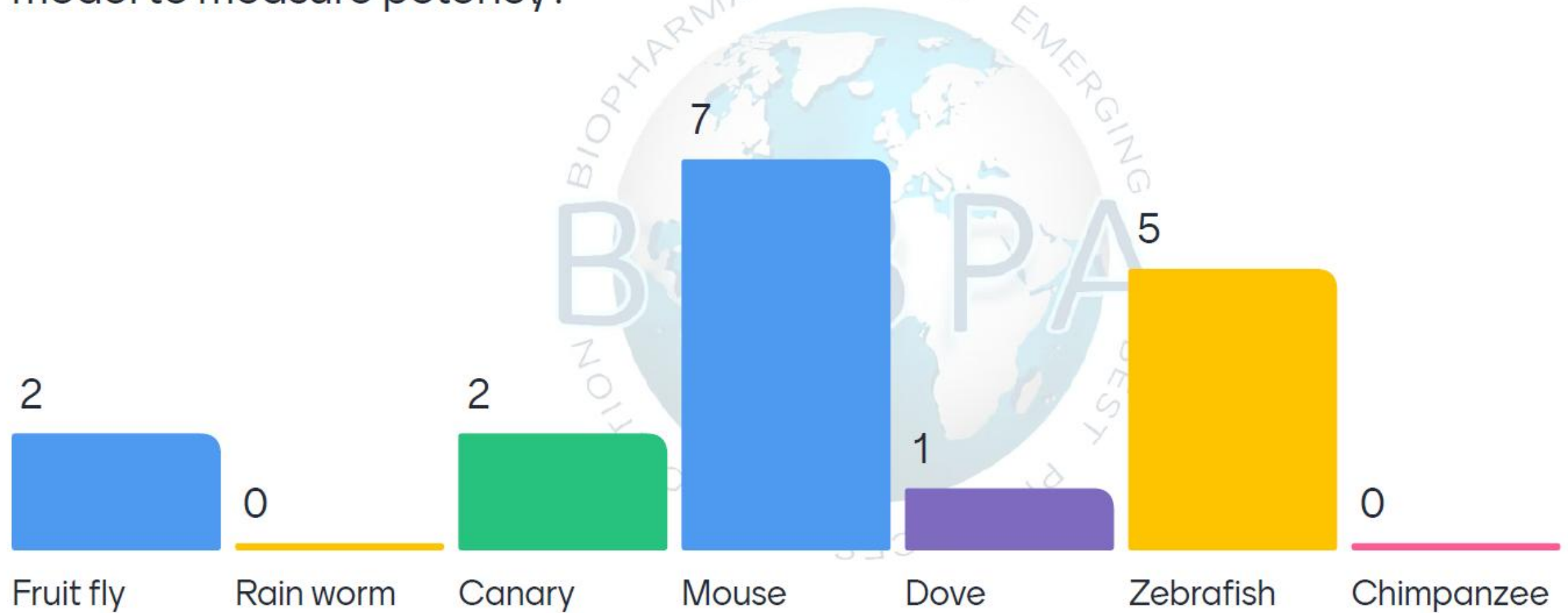
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# W1.5 Do you use an outlier's detection for your assay's readouts?



W1.6 Which organism was first documented in the literature as an in vivo model to measure potency?



# Day 3 Audience Surveys

Intro

Session 1: Regulatory Updates

Session 2: Critical Rare Reagents

Session 3: Quality Assurance Aspects of Potency Assays

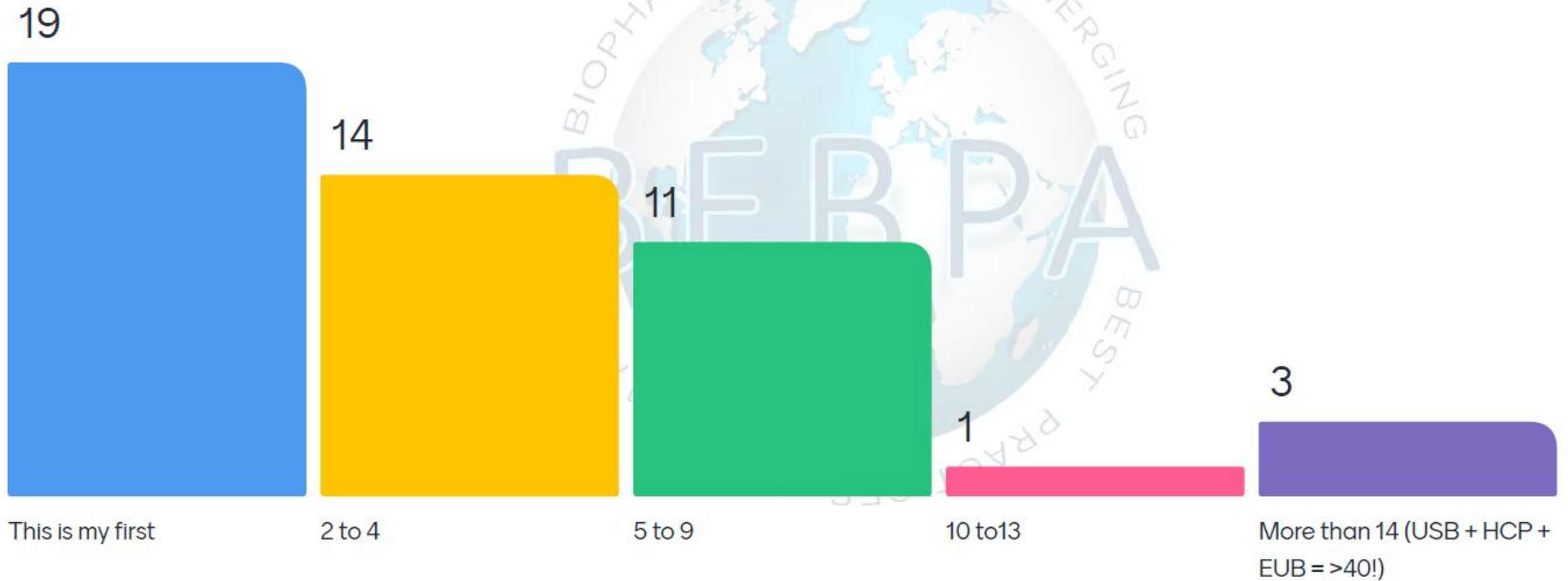
Session 4: Platform Bioassays/ Automation



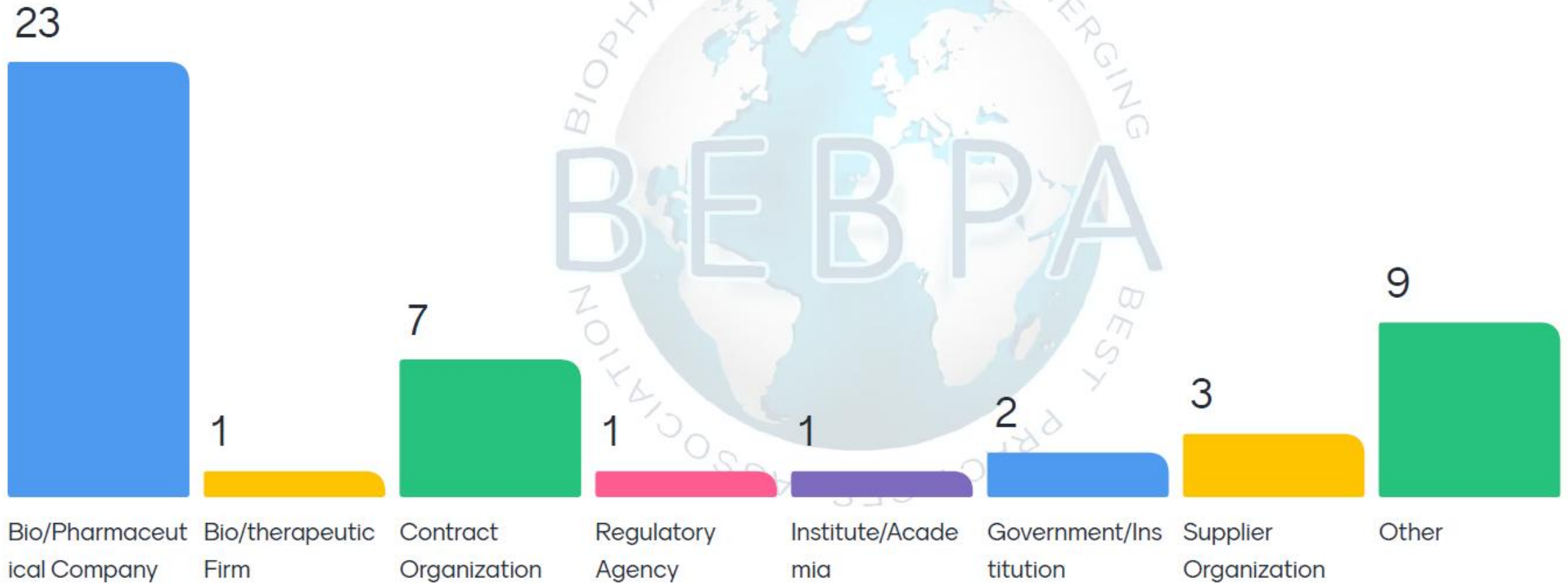


# Intro Survey

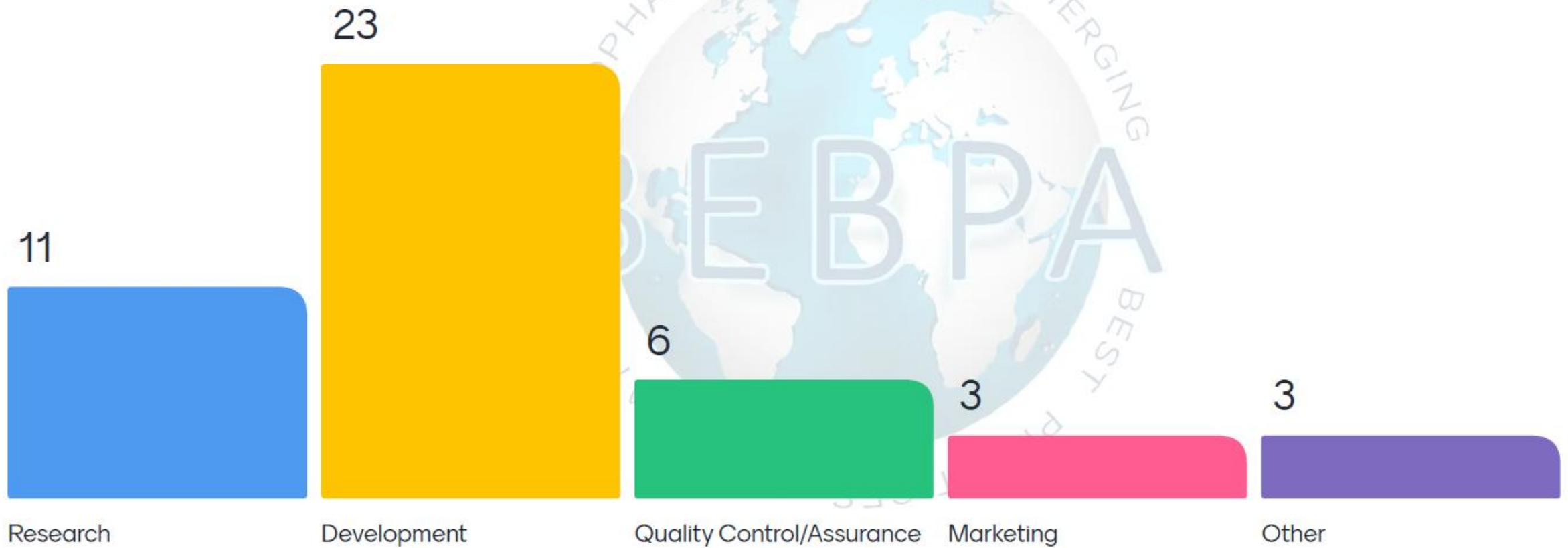
# i.1 How many BEBPA Conferences have you attended?



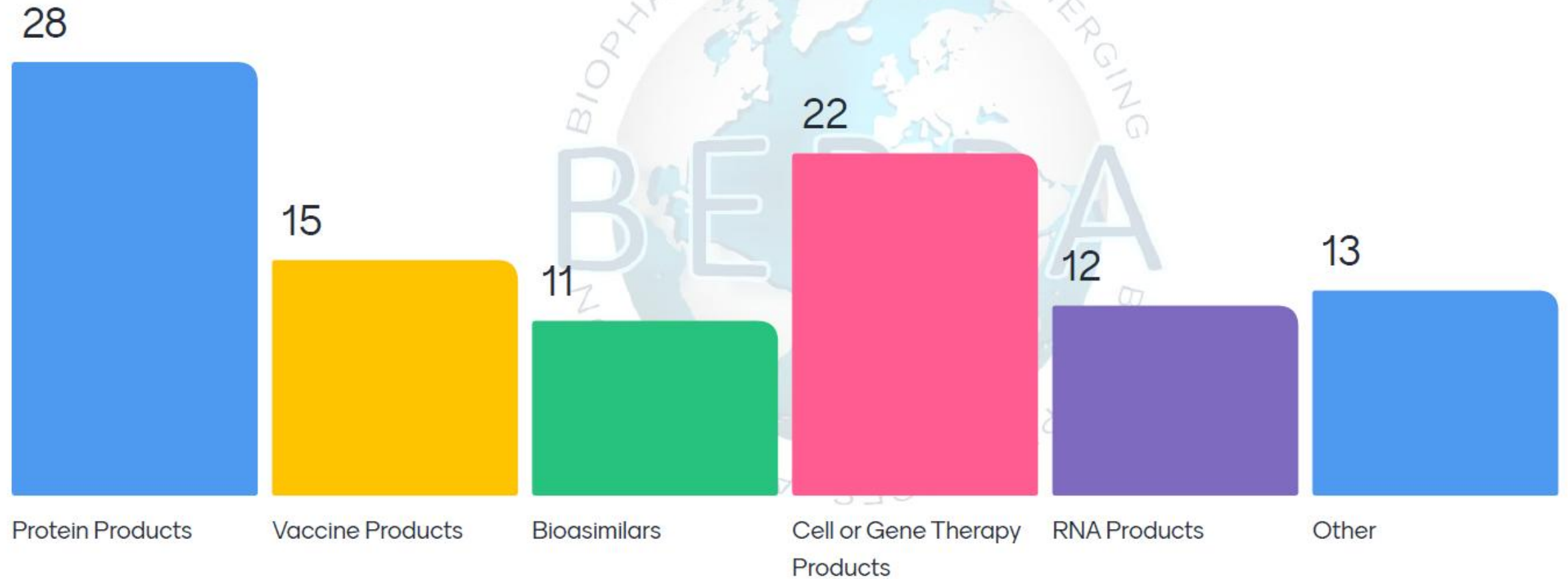
## i.2 What type of organization do you work for?



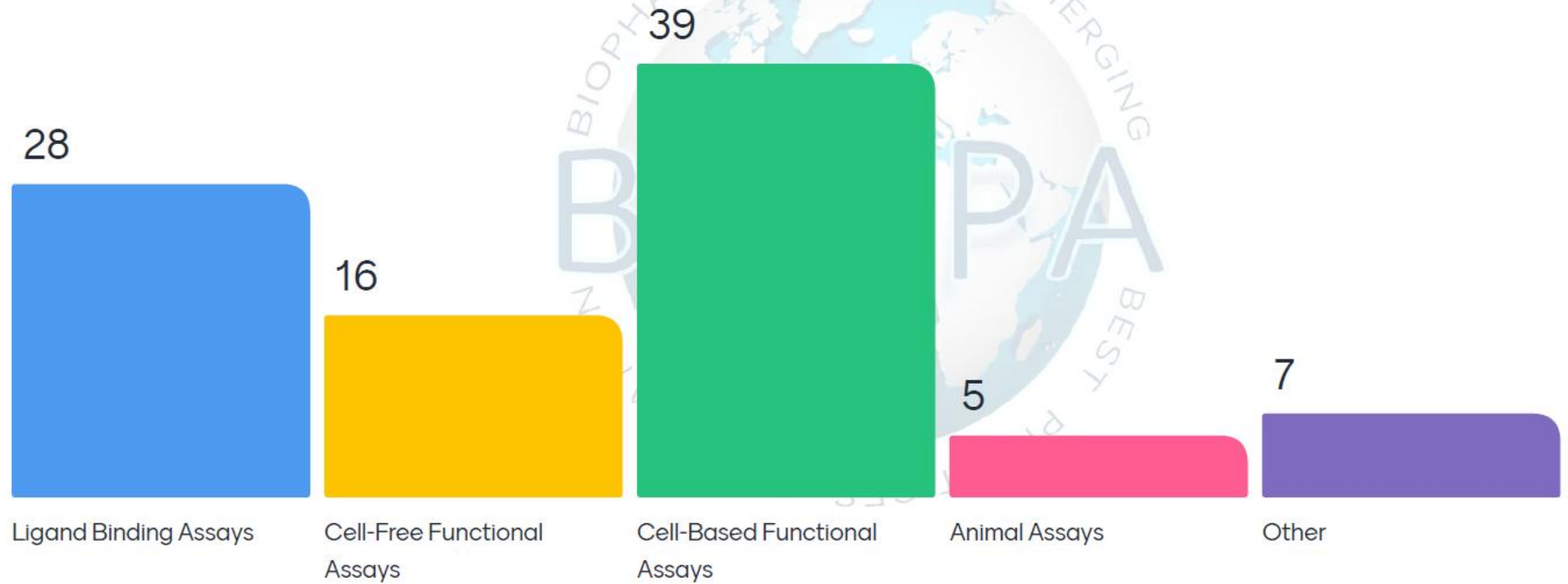
### i.3 What Part of the Organization do you work in?



## 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)



A large, light blue watermark logo is centered on the page. It consists of a globe with the text 'BIOPHARMACEUTICAL EMERGING BEST PRACTICES ASSOCIATION' curved around it. Overlaid on the globe is the acronym 'BEBPA' in large, bold, blue letters.

# Day 3 Survey

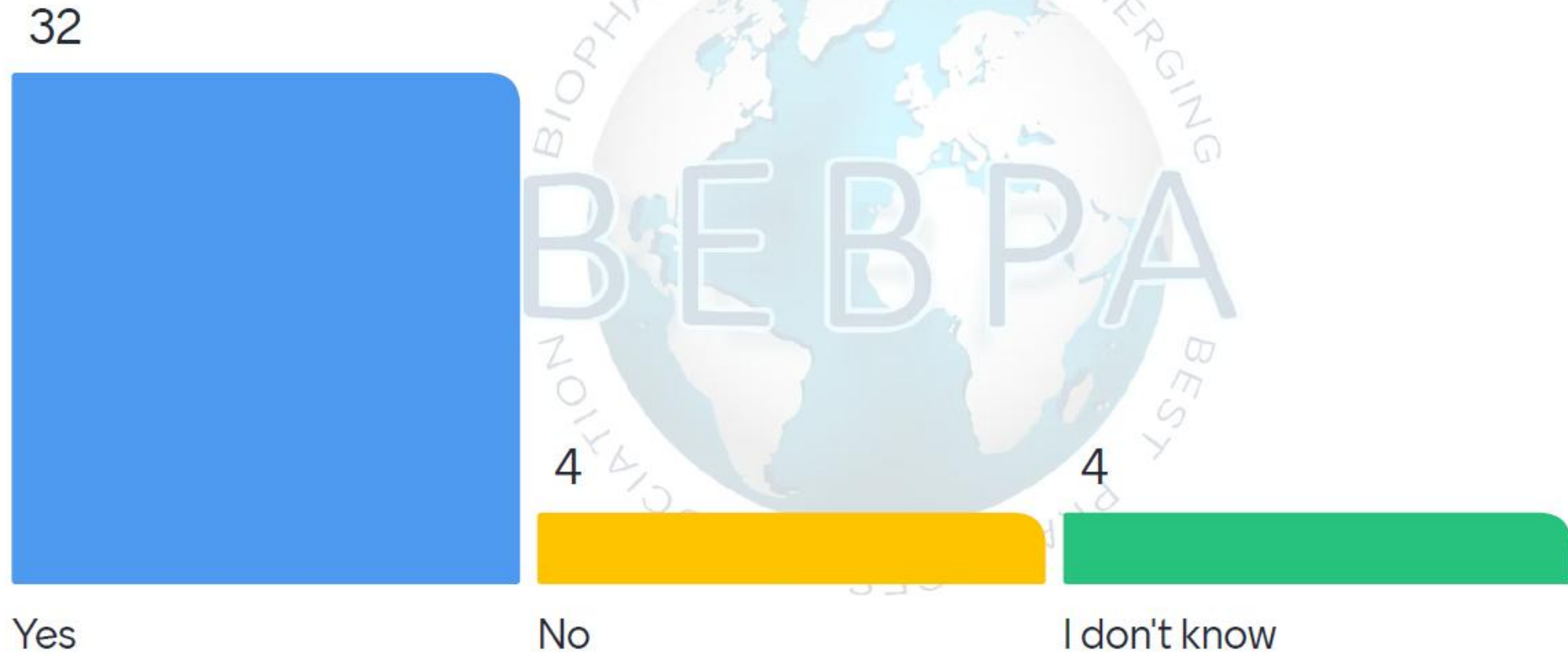
Session 1: Regulatory Updates

Session 2: Critical Rare Reagents

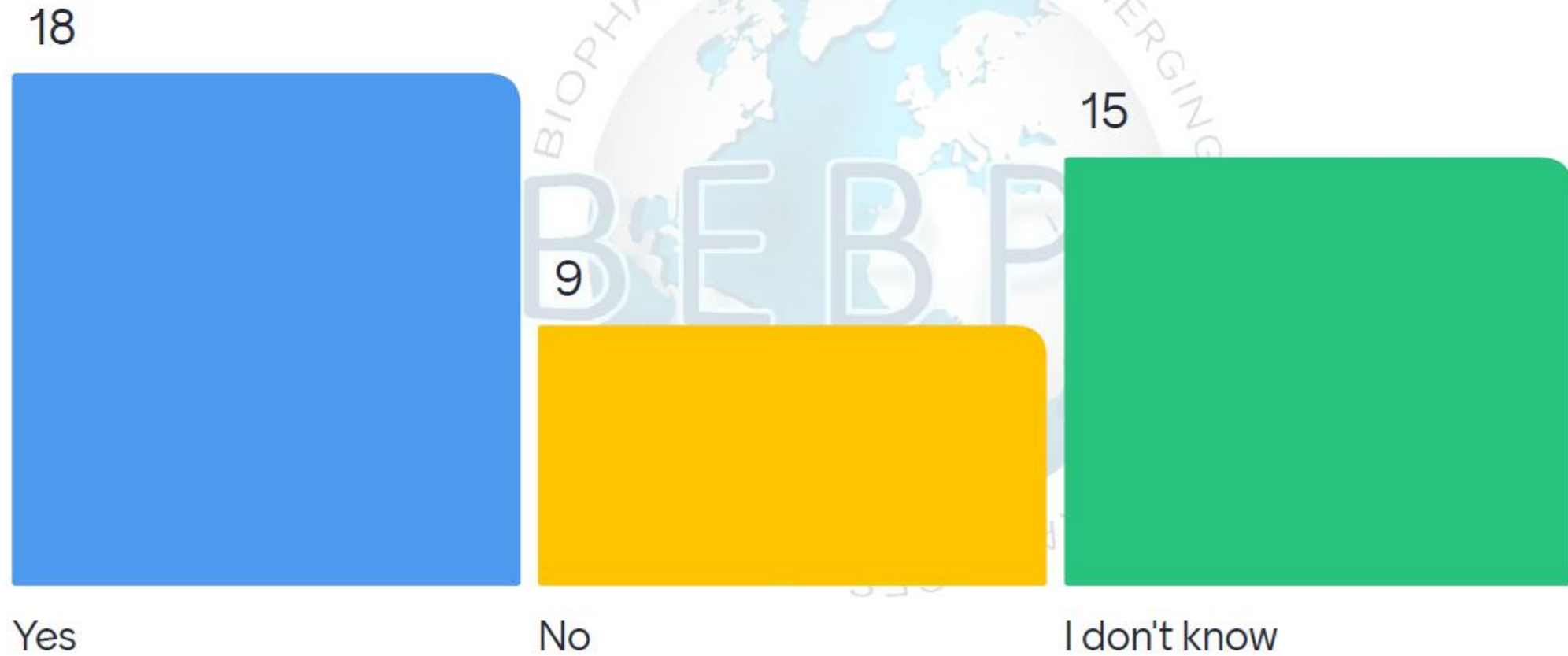
Session 3: Quality Assurance Aspects of Potency Assays

Session 4: Platform Bioassays/ Automation

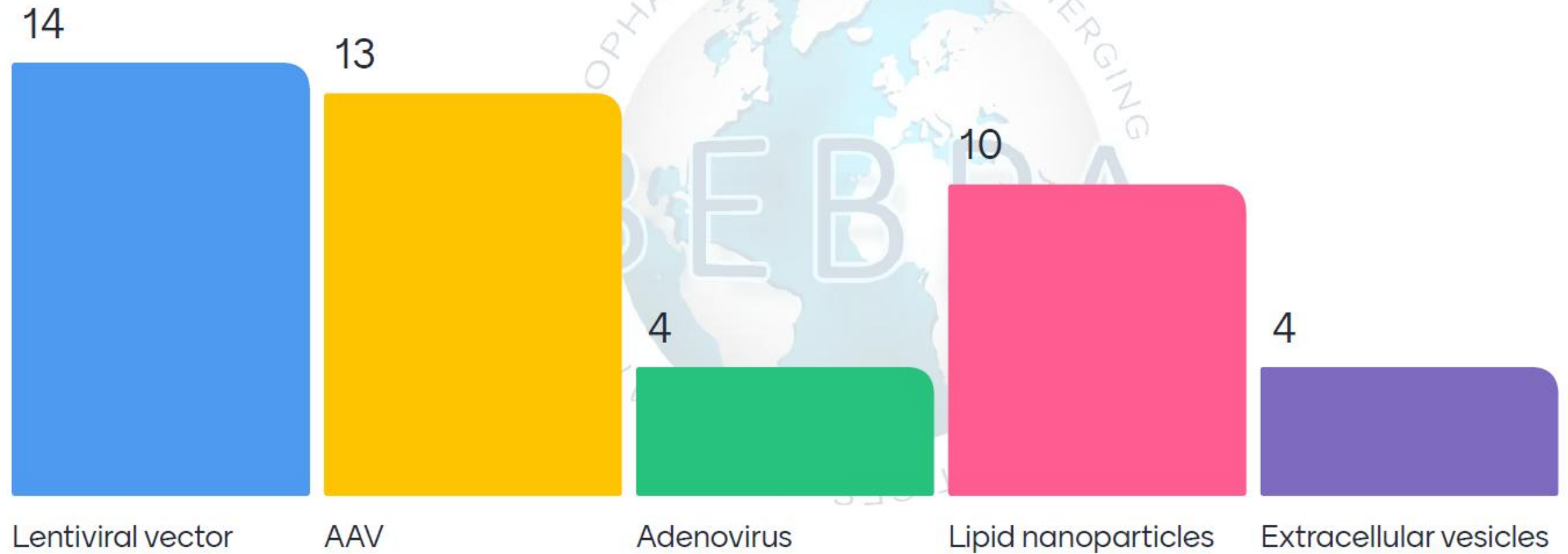
3.1 Do you use commercial/institutional cell lines that are allowed for commercial use if they are available?



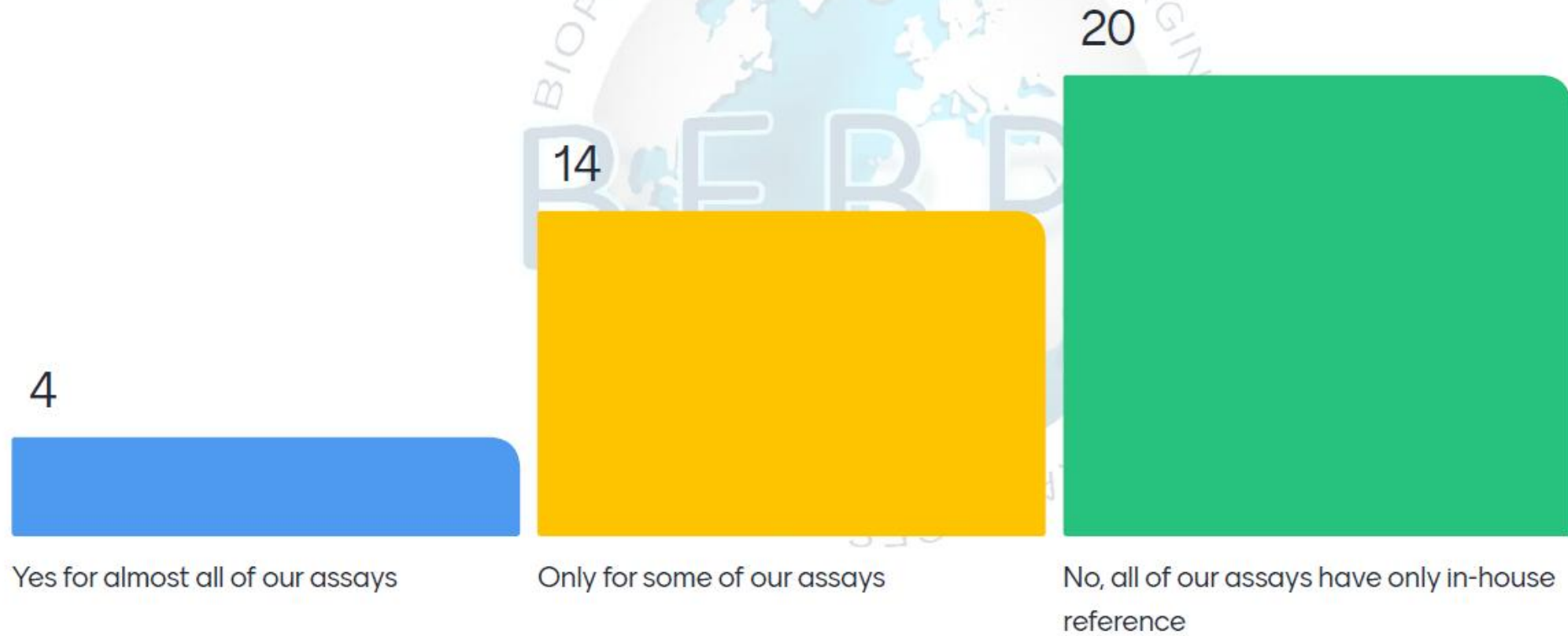
3.2 Is gene transfer vector (such as lentivirus, AAV, lipid nanoparticles, or extracellular vesicles) reference materials needed?



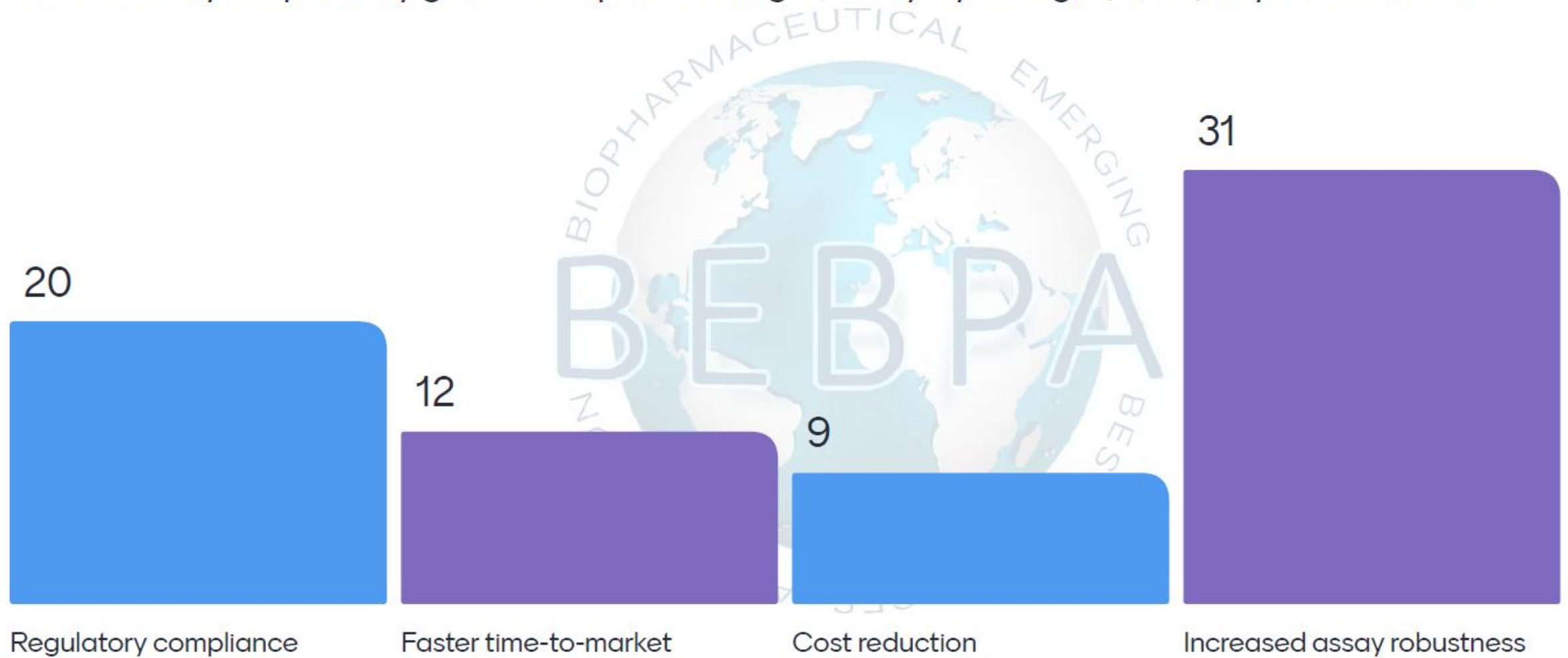
### 3.3 Which gene transfer vector do you use for cell & gene therapy for cell line engineering?



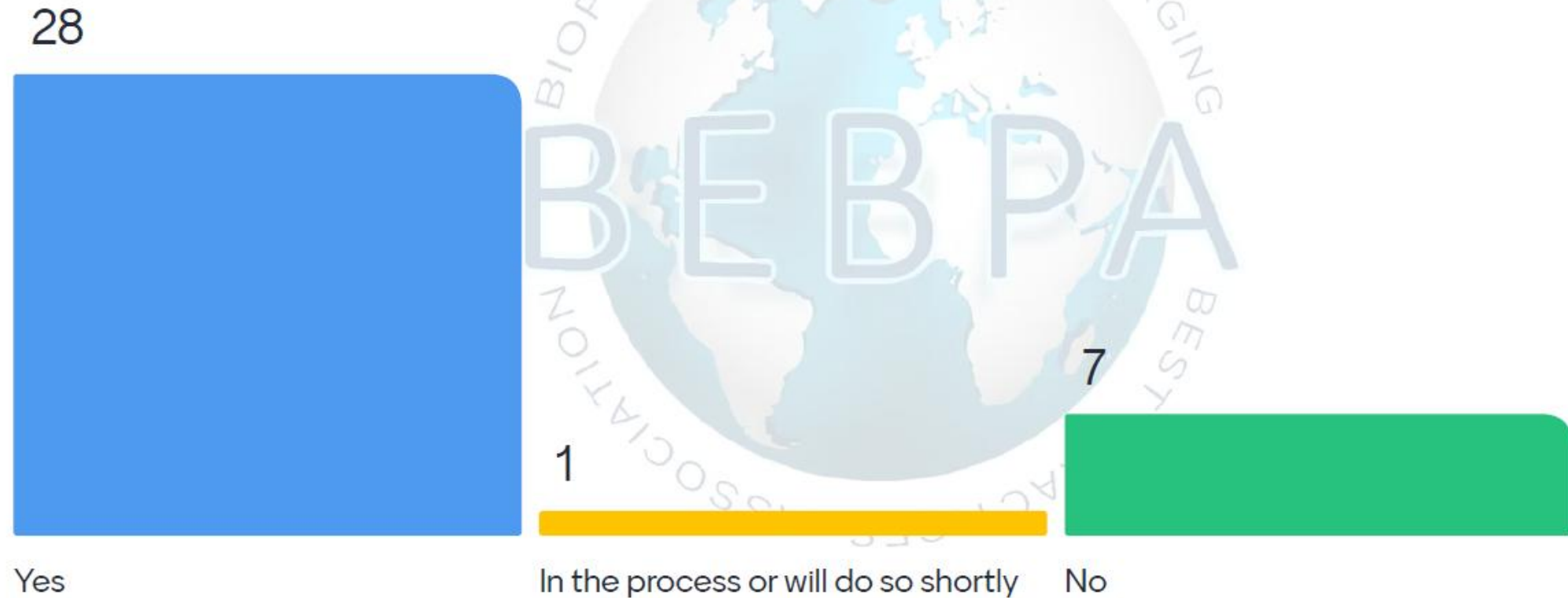
### 3.4 Is there a "commercially available" reference material for your potency assay?



### 3.5 What is your primary goal for implementing Quality by Design (QbD) in your workflow?



3.6 Have you ever transferred a potency assay to a GMP laboratory to release clinical material?



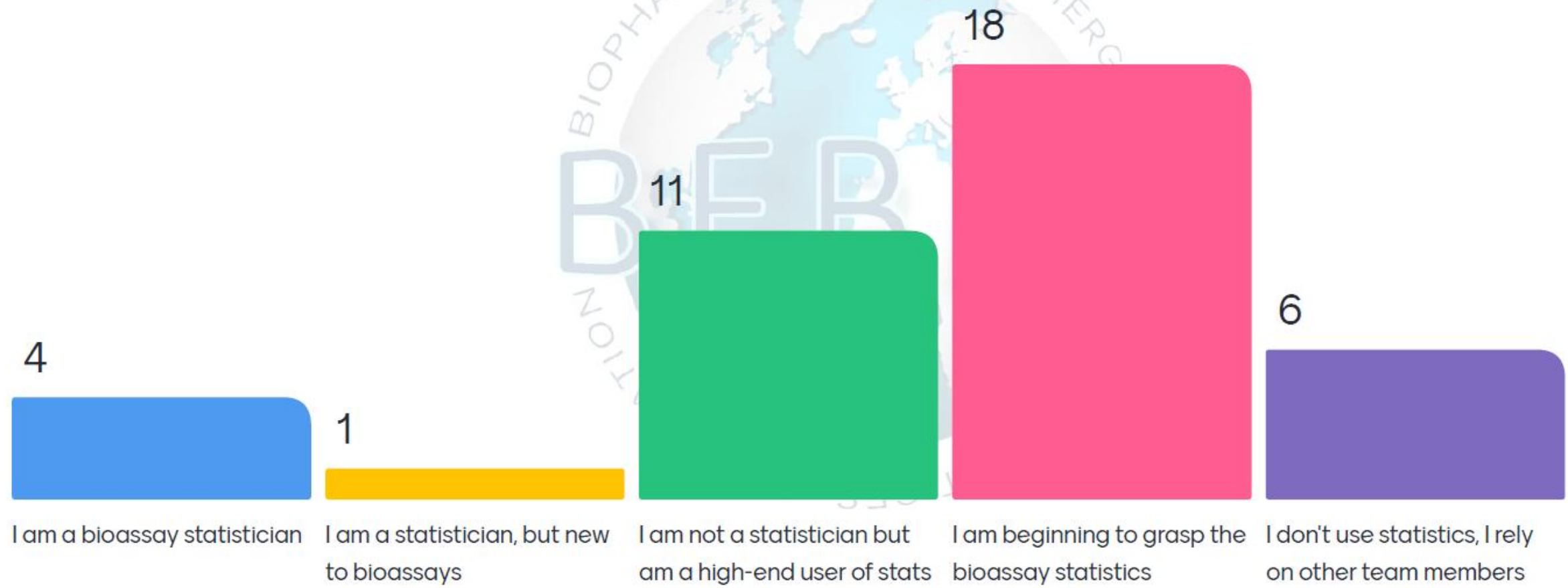
A large, faint watermark of the BEBPA logo is centered on the page. It consists of a globe with the text 'BIOPHARMACEUTICAL EMERGING BEST PRACTICES ASSOCIATION' and 'BEBPA' overlaid on it.

# Day 4 Audience Surveys

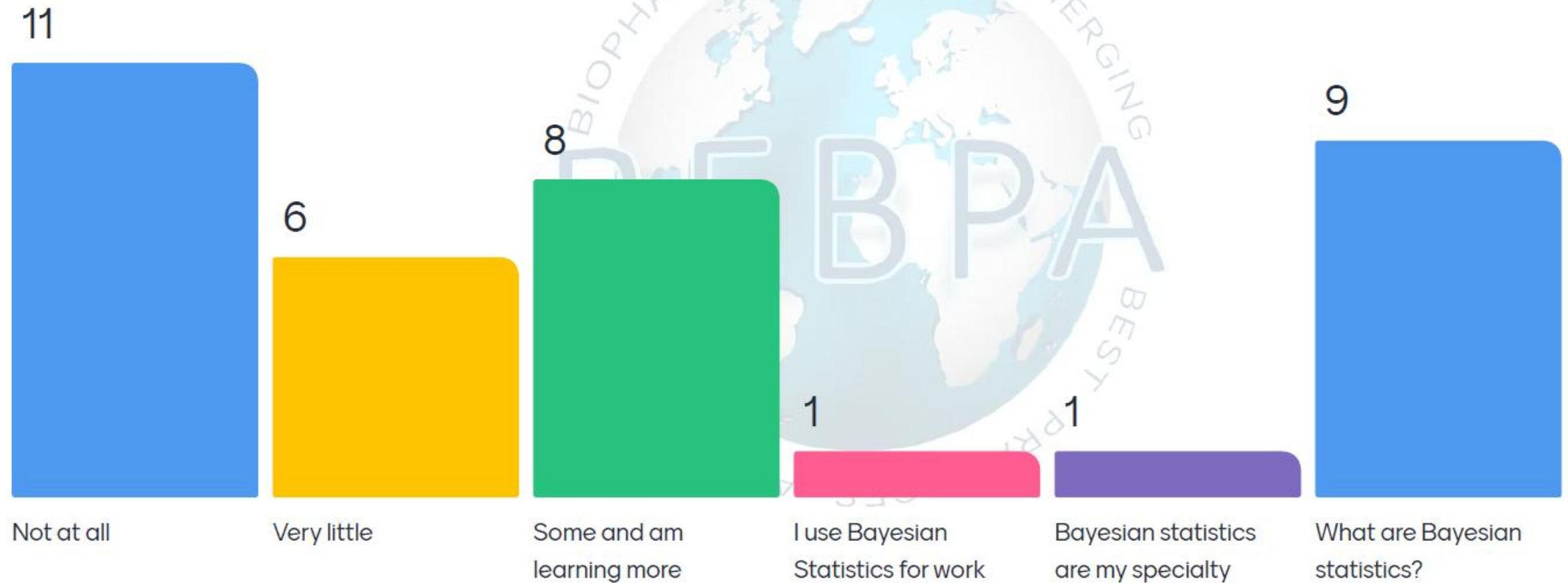
Session 5: Statistical Tools for Bench Scientists

Session 6: Product Specific Case Studies

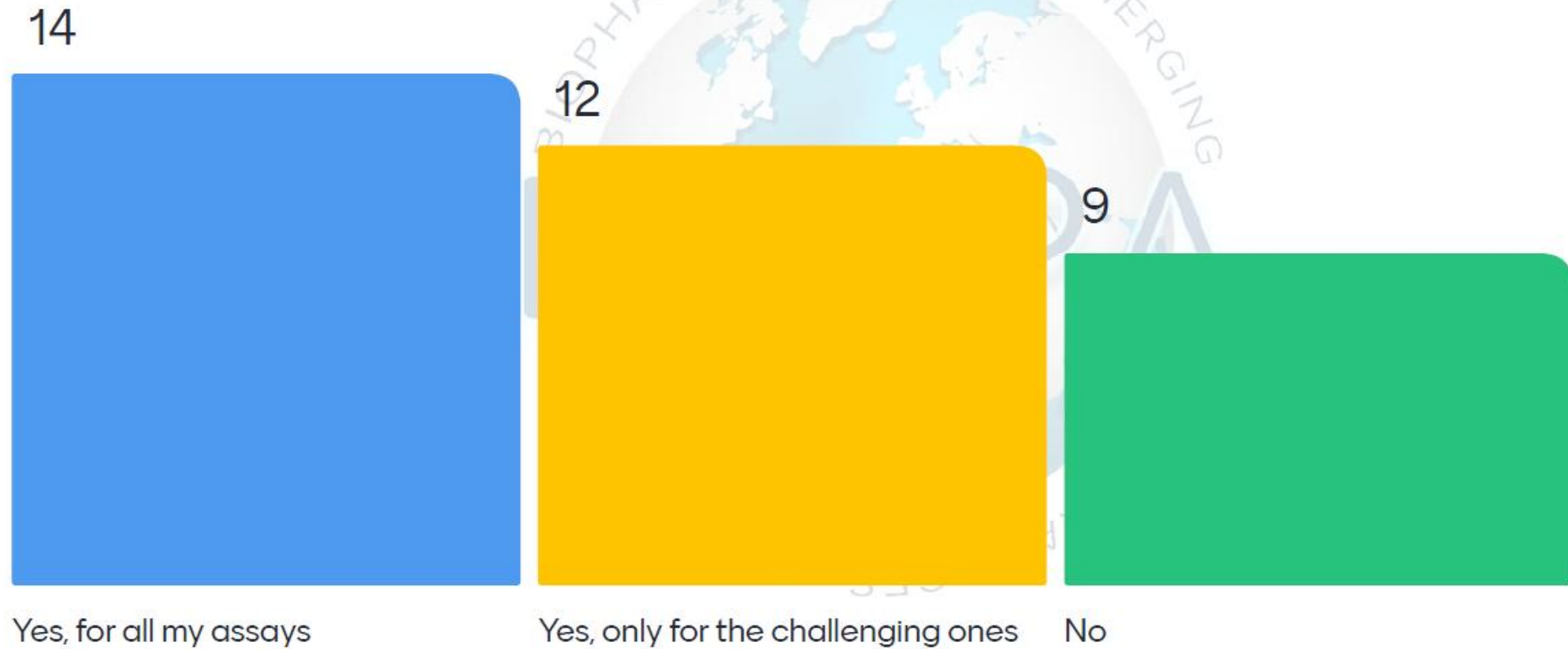
# 4.1 What is your level of statistical understanding/education?



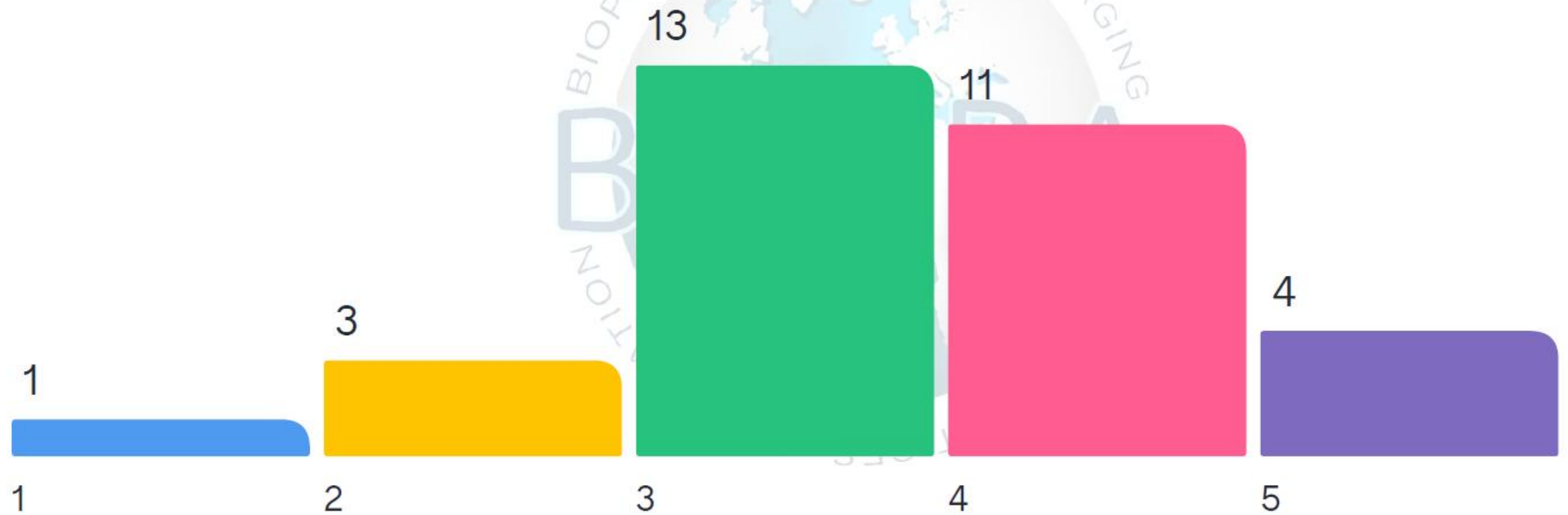
## 4.2 Do you understand/use Bayesian Statistics?



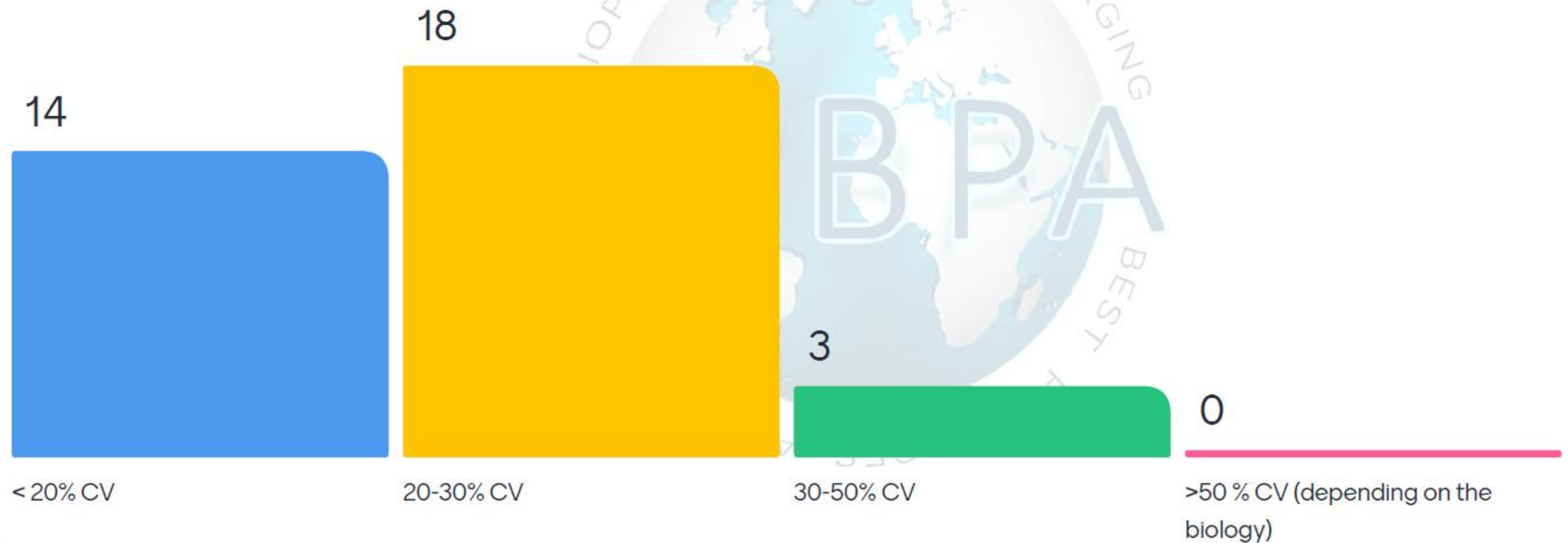
## 4.3 Do you use DoE for your assay development?



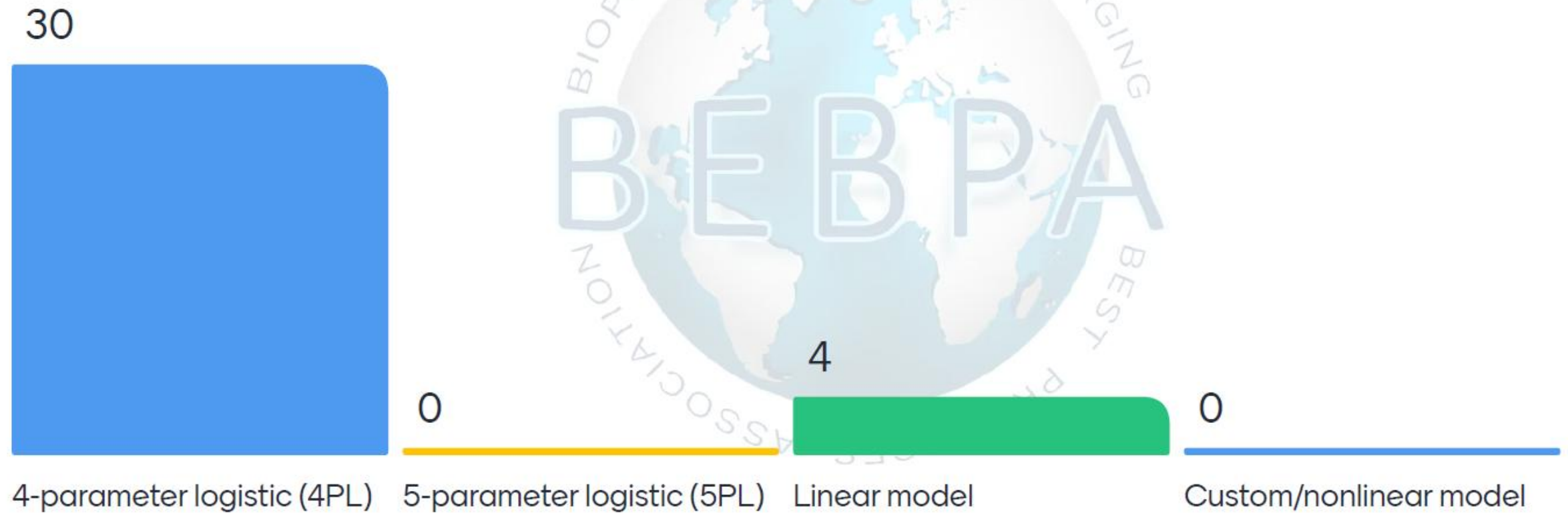
4.4 On a scale of 1–5, where 1 is not satisfied, how satisfied are you with the reproducibility of your current potency assays?



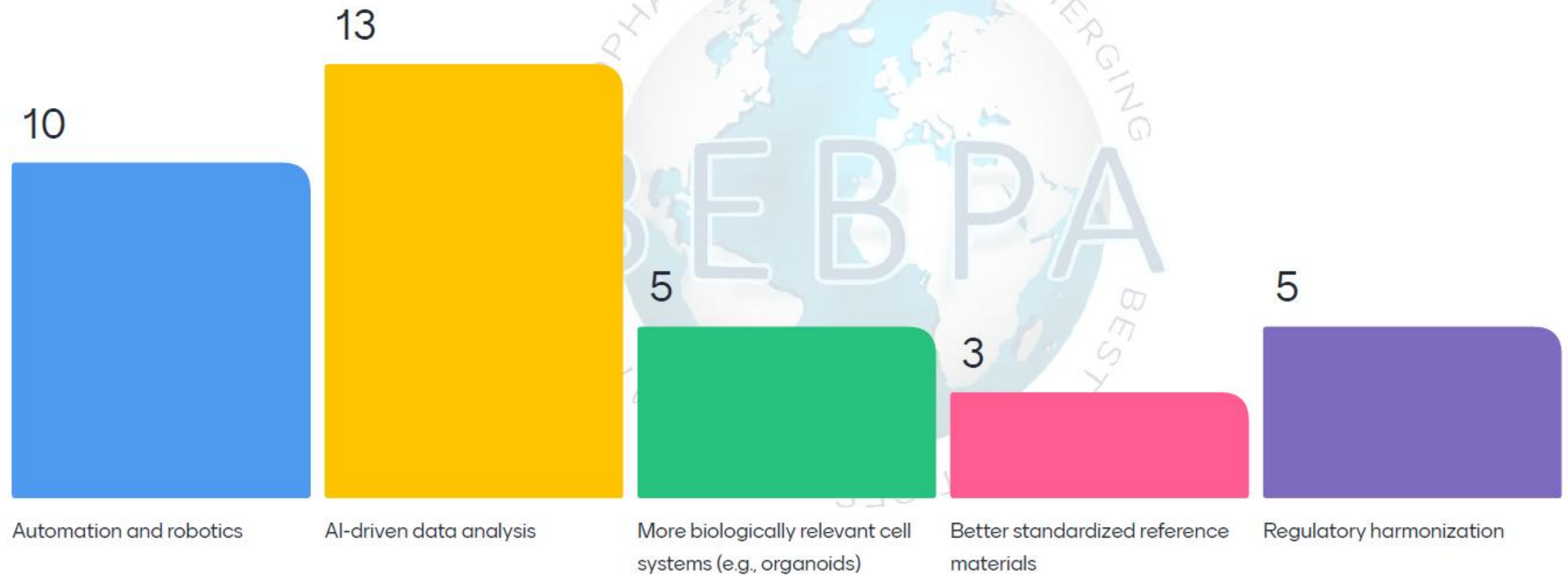
## 4.5 What level of variability do you consider acceptable for a cell-based potency or neutralization assay?



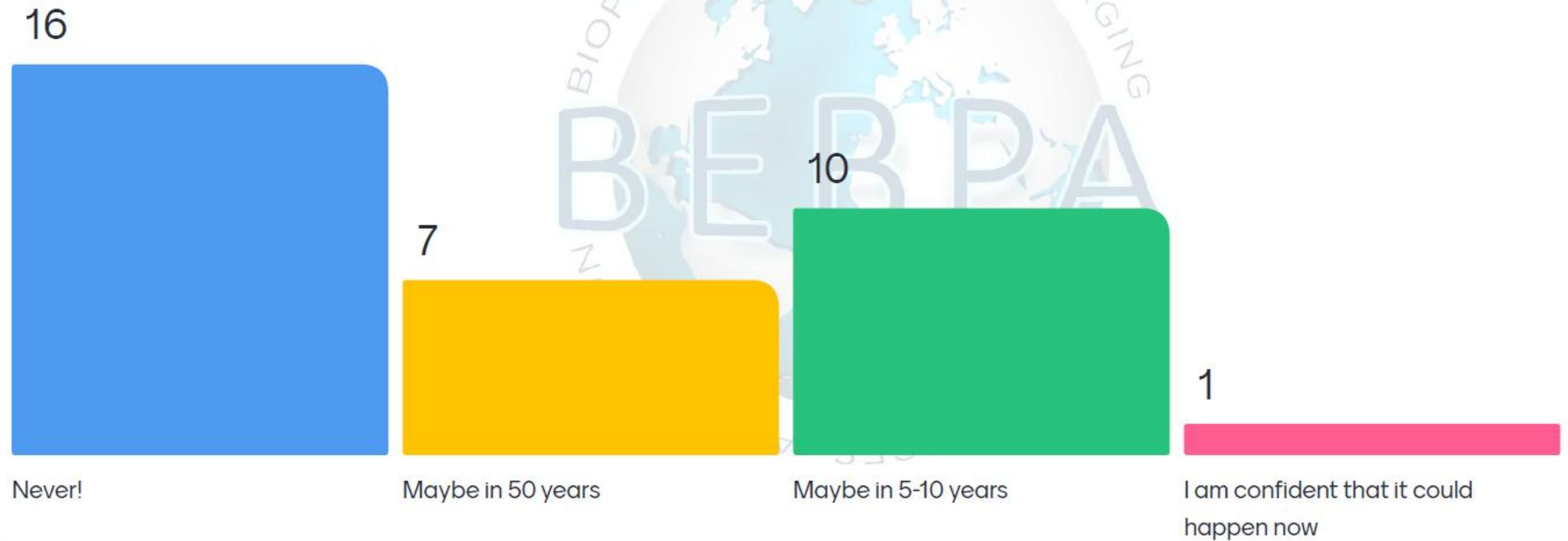
## 4.6 What model do you most commonly use for dose-response analysis?



## 4.7 What will have the biggest impact on bioassays in the next decade?



## 4.8 With continued advances in assay technology to reliably measure mAb binding and glycoanalysis, will cell-based potency assays ever be phased out?





***Thank you!!***