16th Annual EUR Bioassay Conference

27-29 September 2023

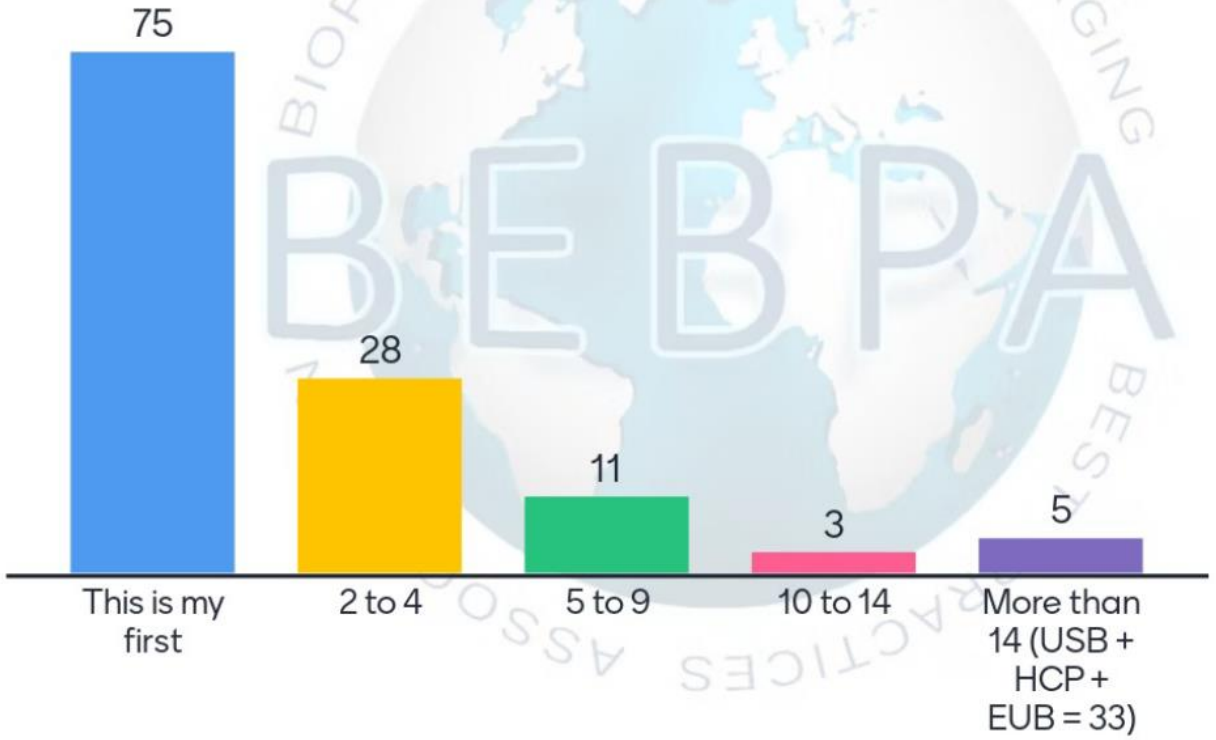
Bled, Slovenia

Welcome Back & Introduction

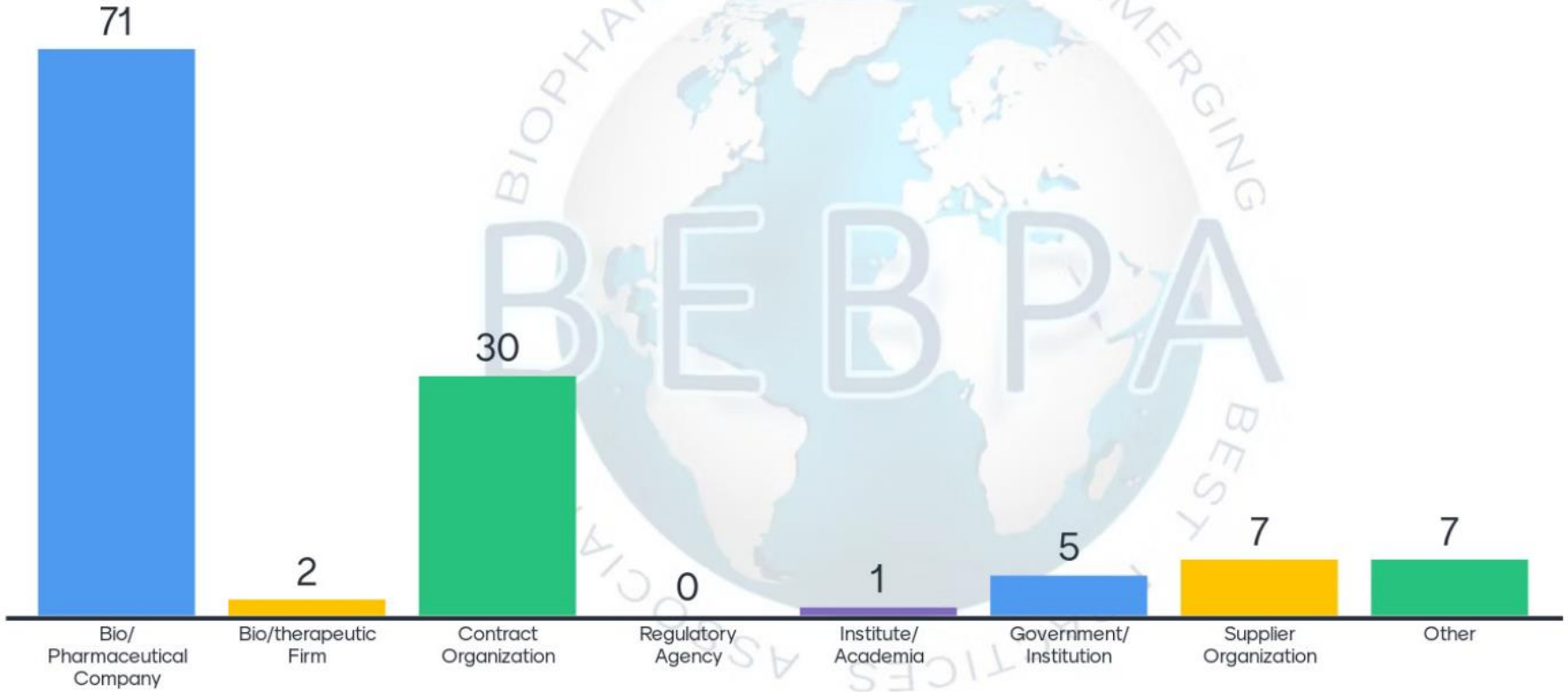
Siân Estdale
Head of Scientific Affairs, CTTS
Labcorp
BEBPA Scientific Committee

Audience Surveys

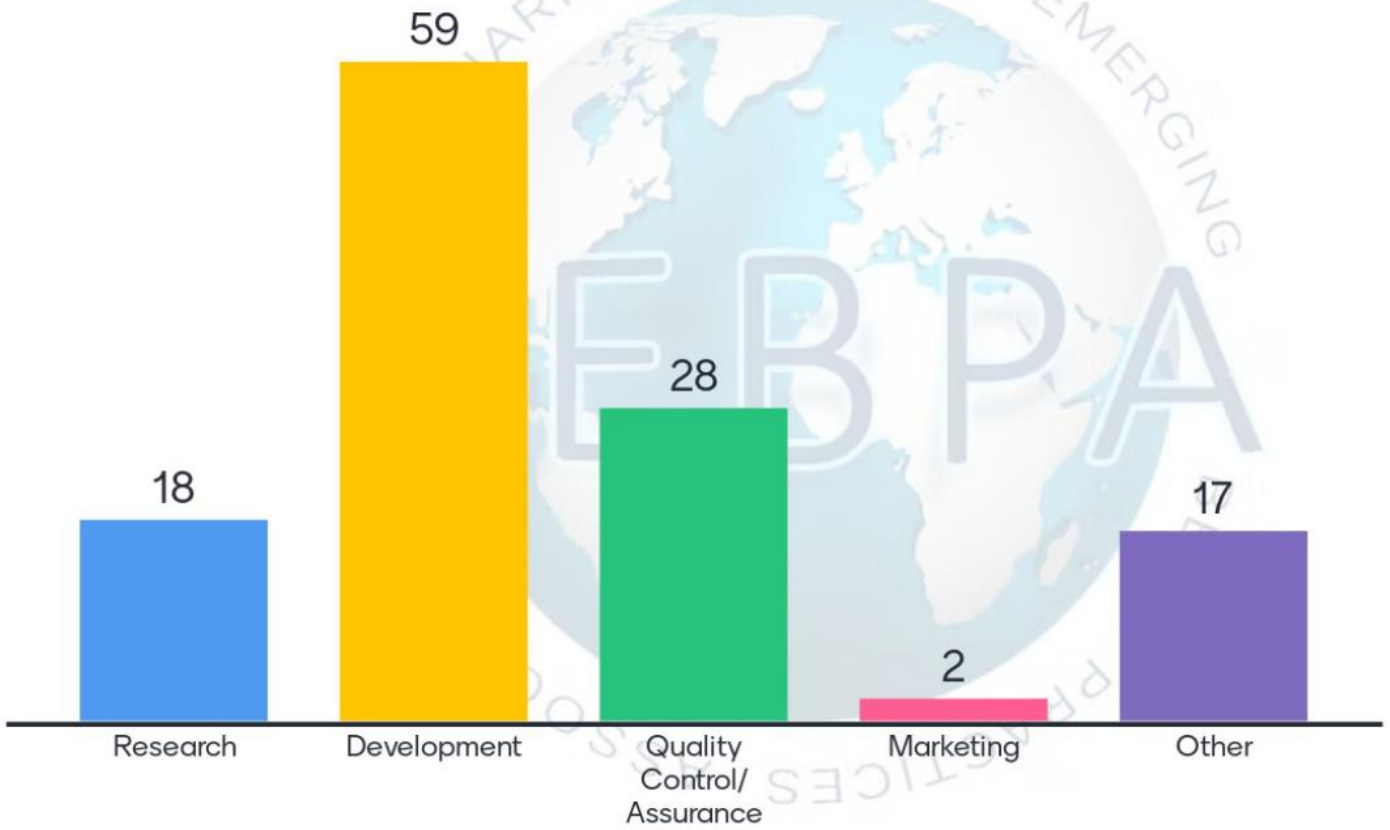
i.1 How many BEBPA Conferences have you attended?



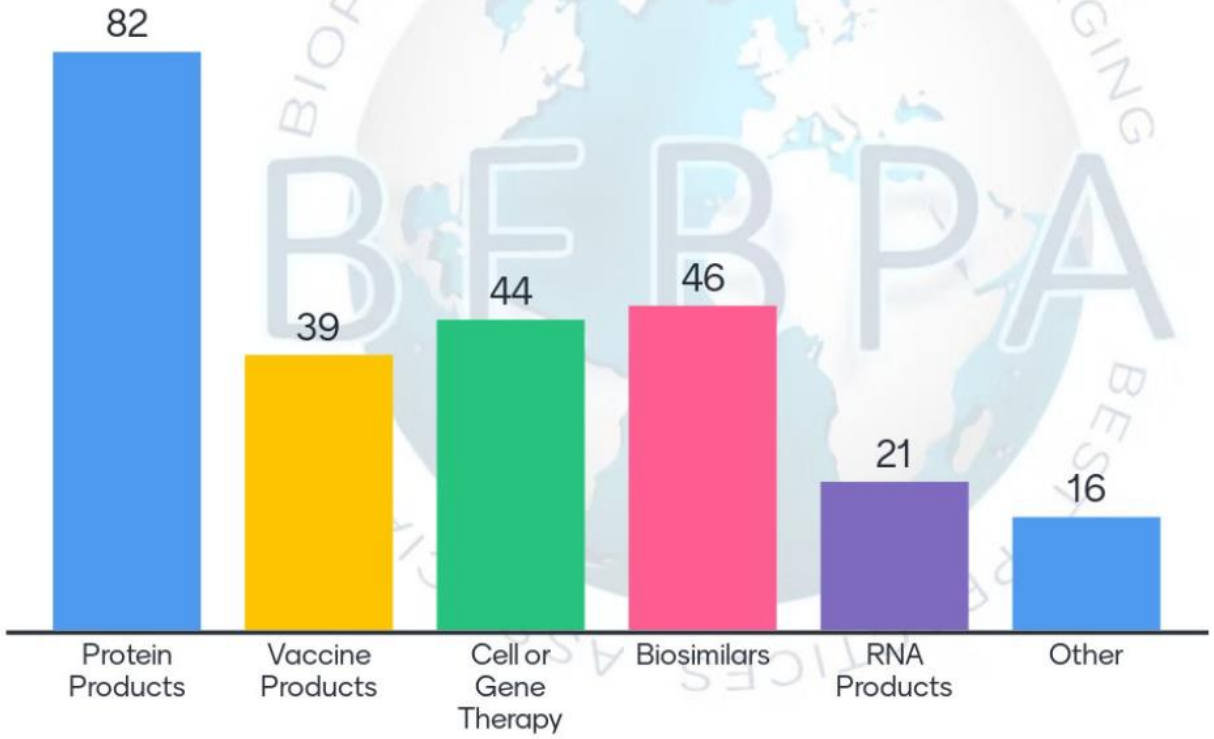
i.2 What type of organization do you work for?



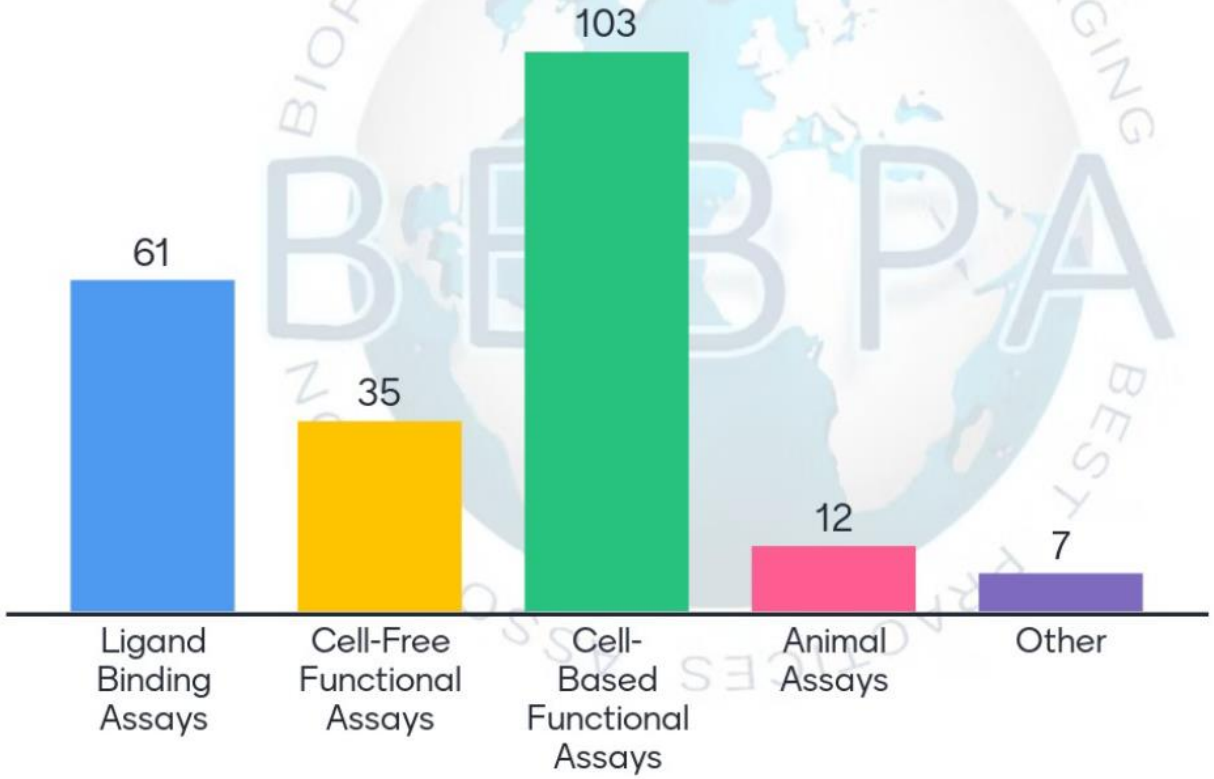
i.3 What part of the organization do your work for?



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)

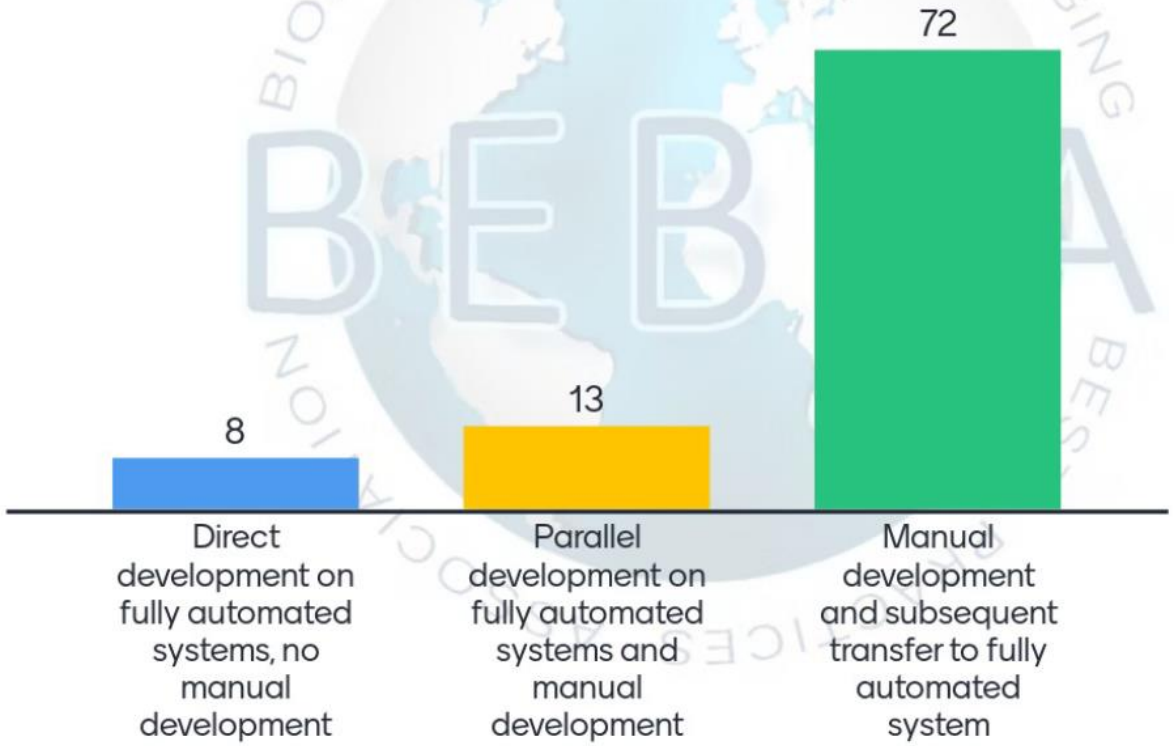


Session 1: Current Trends in Bioassays

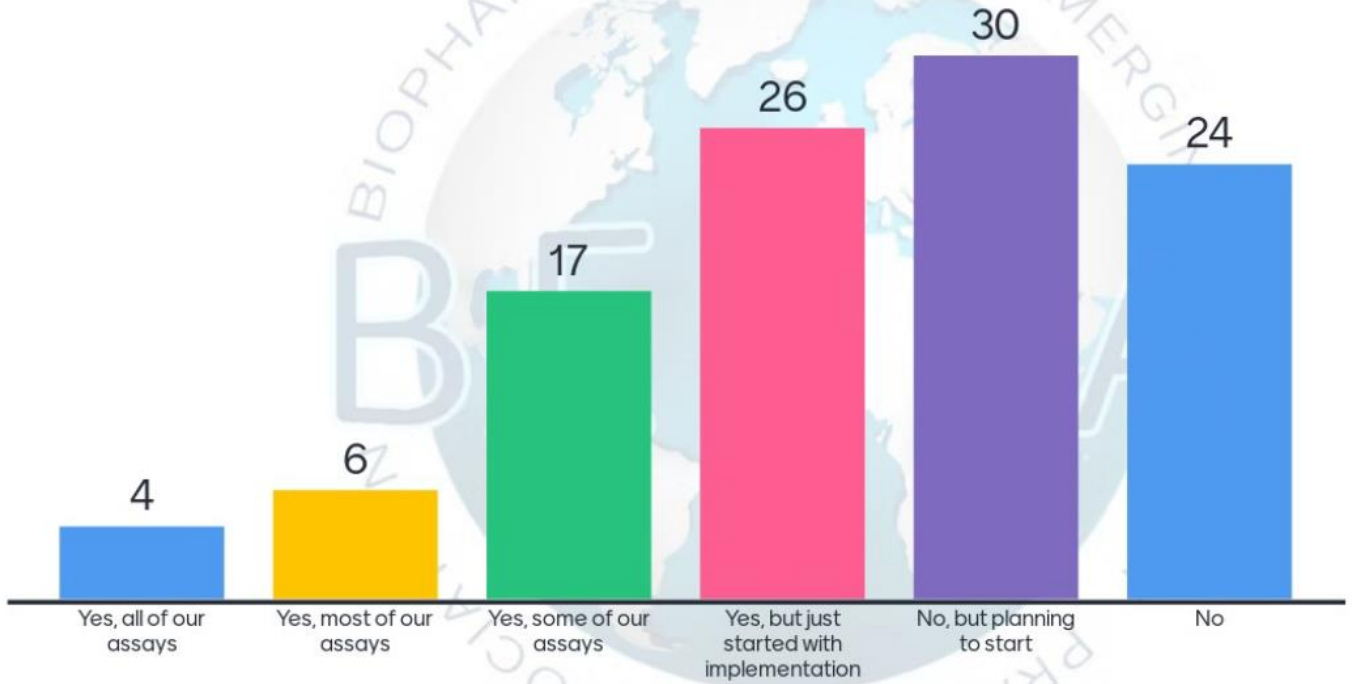
Session Chair: Siân Estdale
Head of Scientific Affairs, CTTS
Labcorp
BEBPA Scientific Committee

Audience Surveys

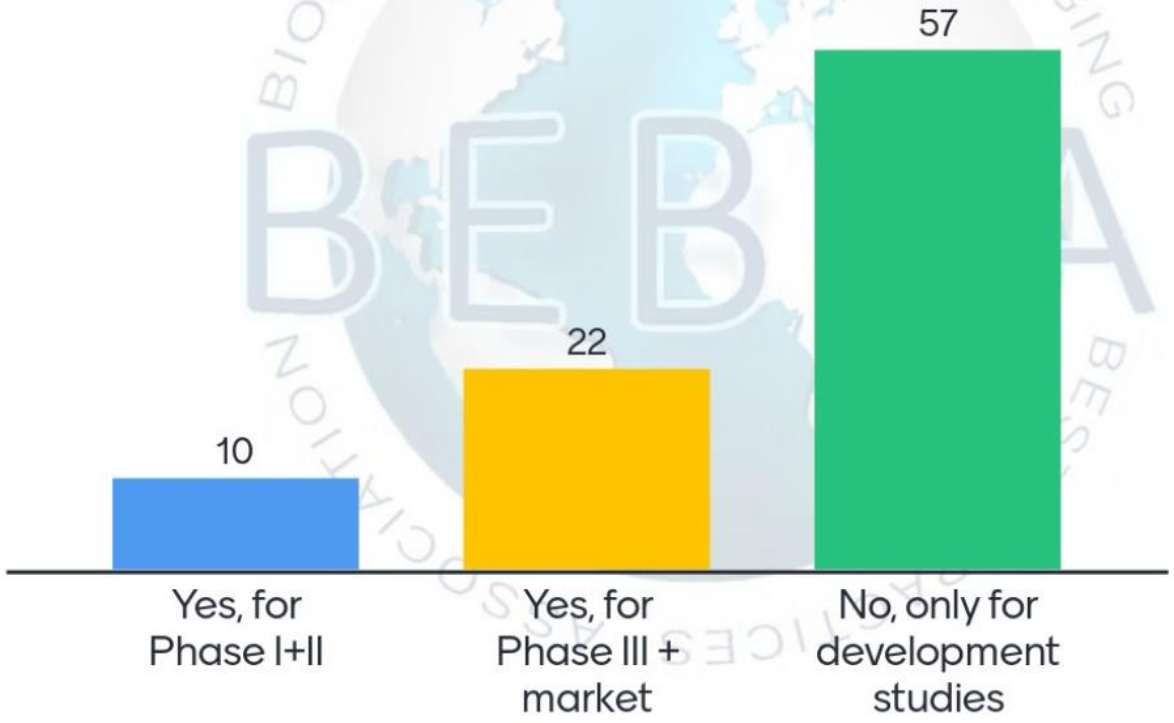
1.1 Do you directly develop bioassays on a fully automated system or do you perform a transfer?



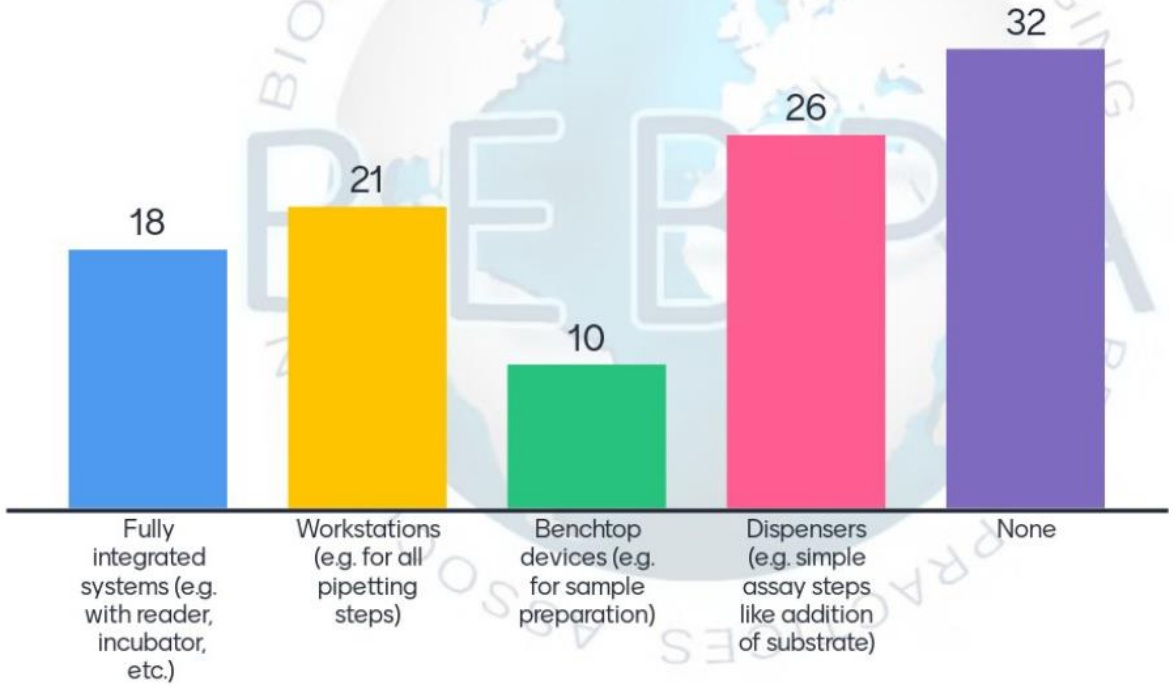
1.2 Do you automate your bioassays?



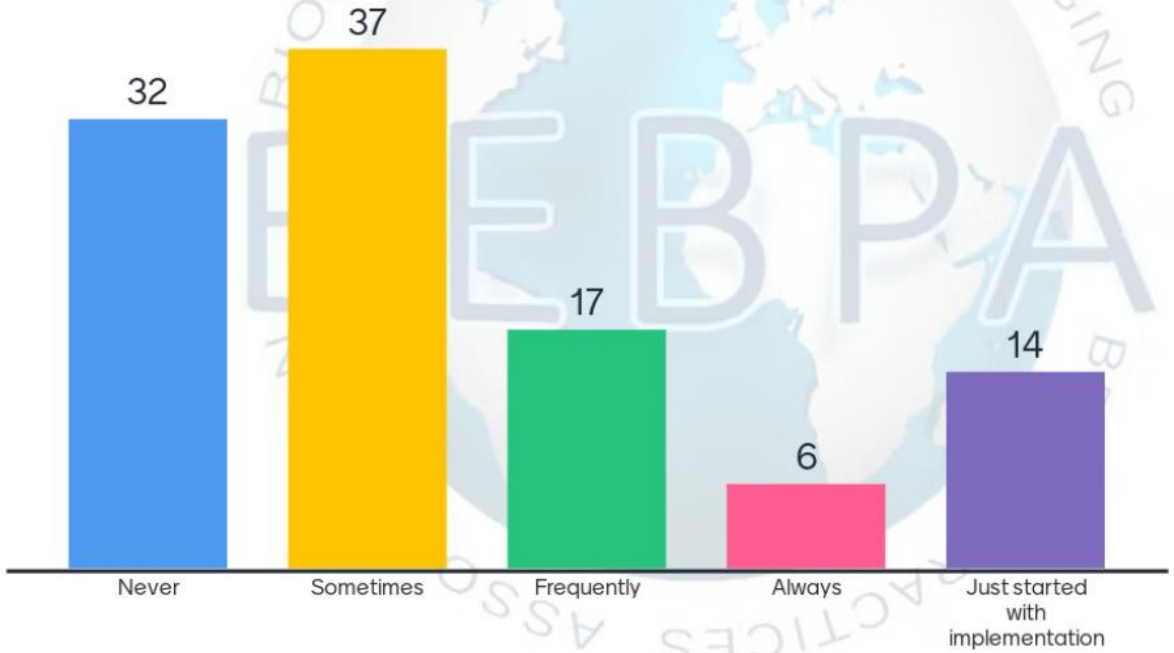
1.3 Do you use fully automated systems under GMP conditions?



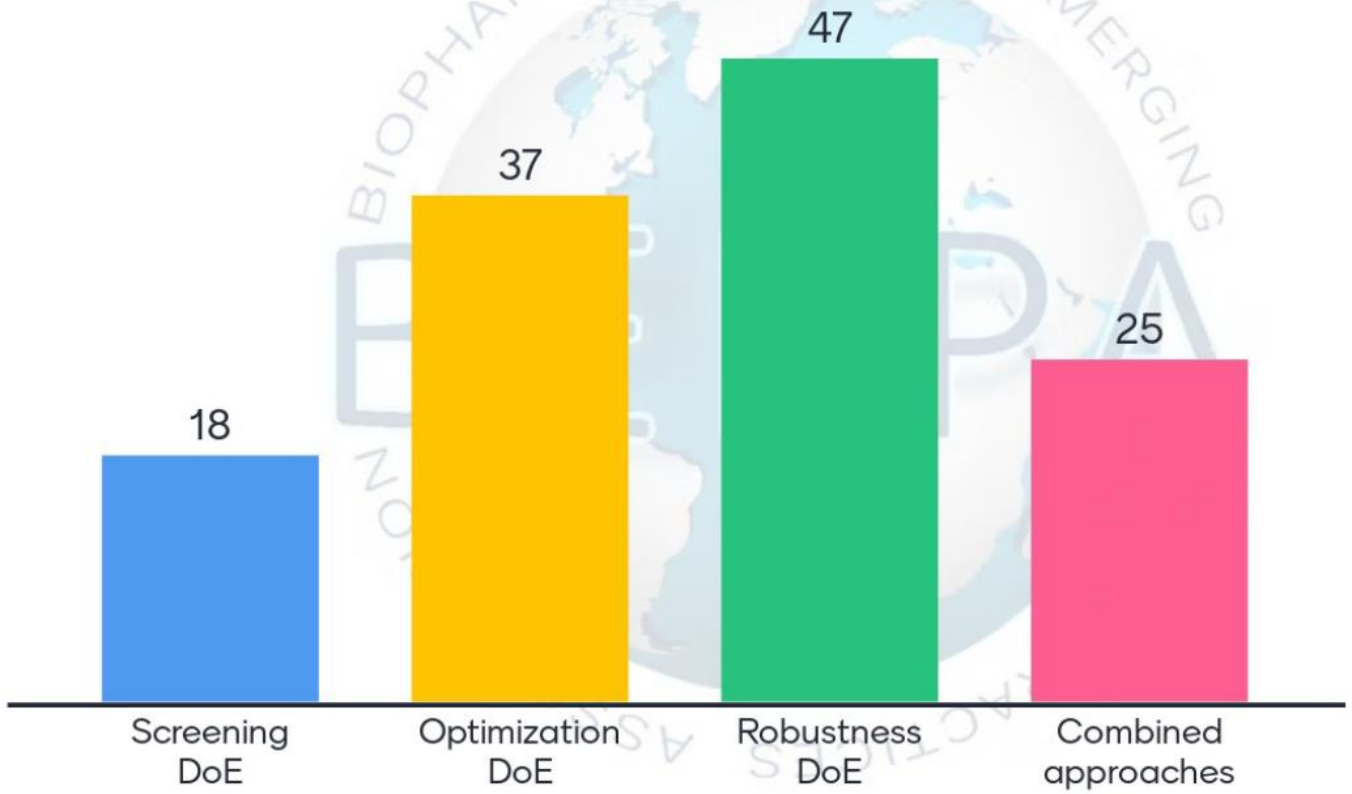
1.4 What type of automation systems do you use for bioassays?



1.5 How often do you use DoE during bioassay development?

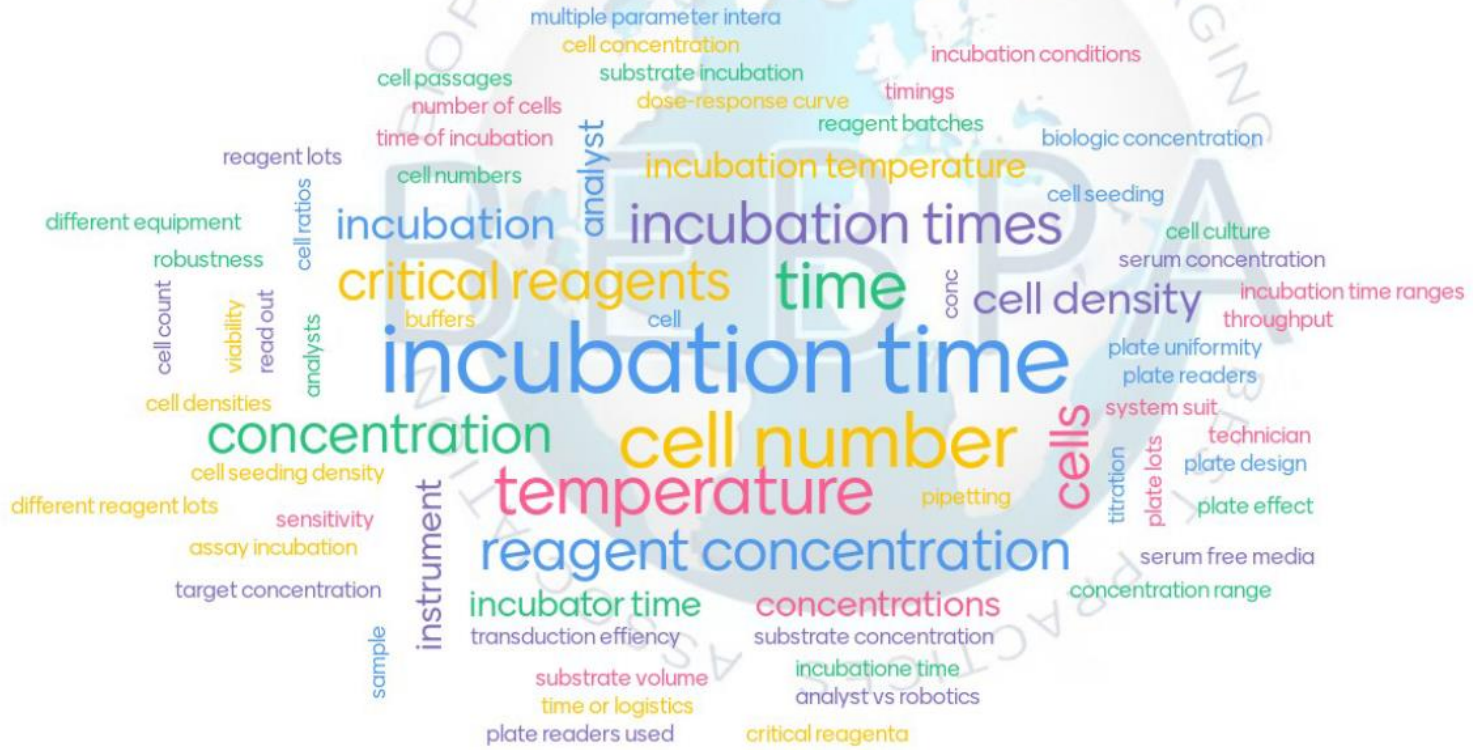


1.6 What type of DoE designs do you use?



1.7 What are typical factors you assess in a bioassay DoE?

150 responses



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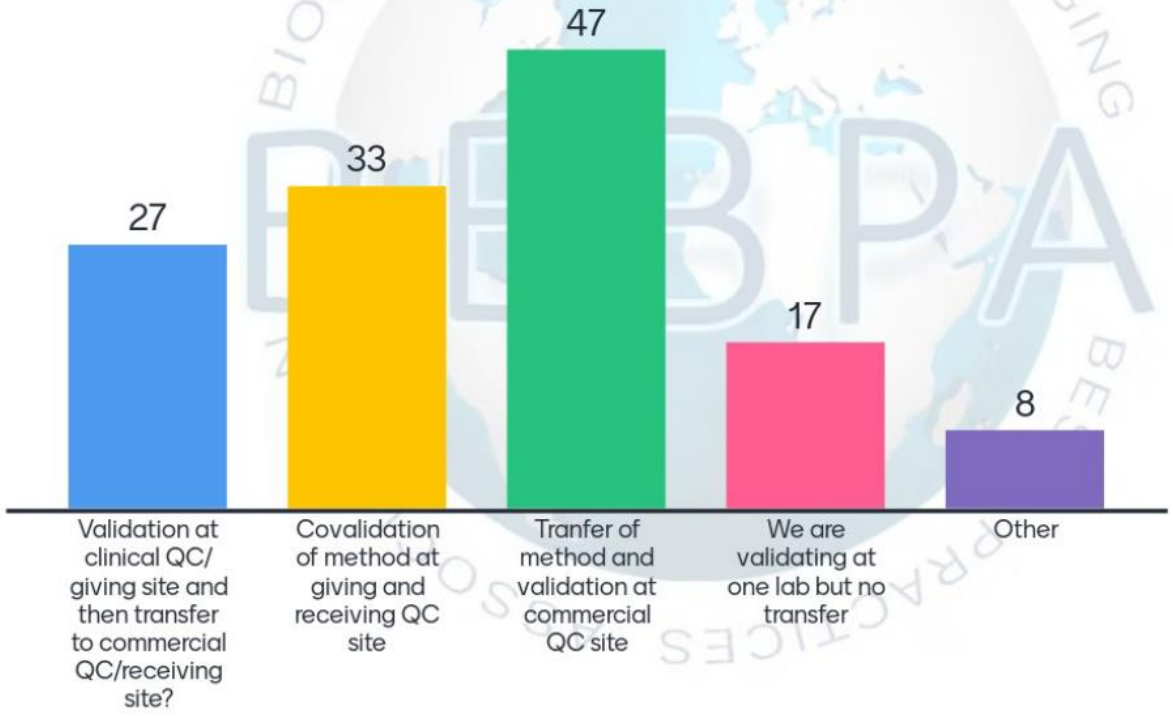
Session 2: Validation of Potency Assays

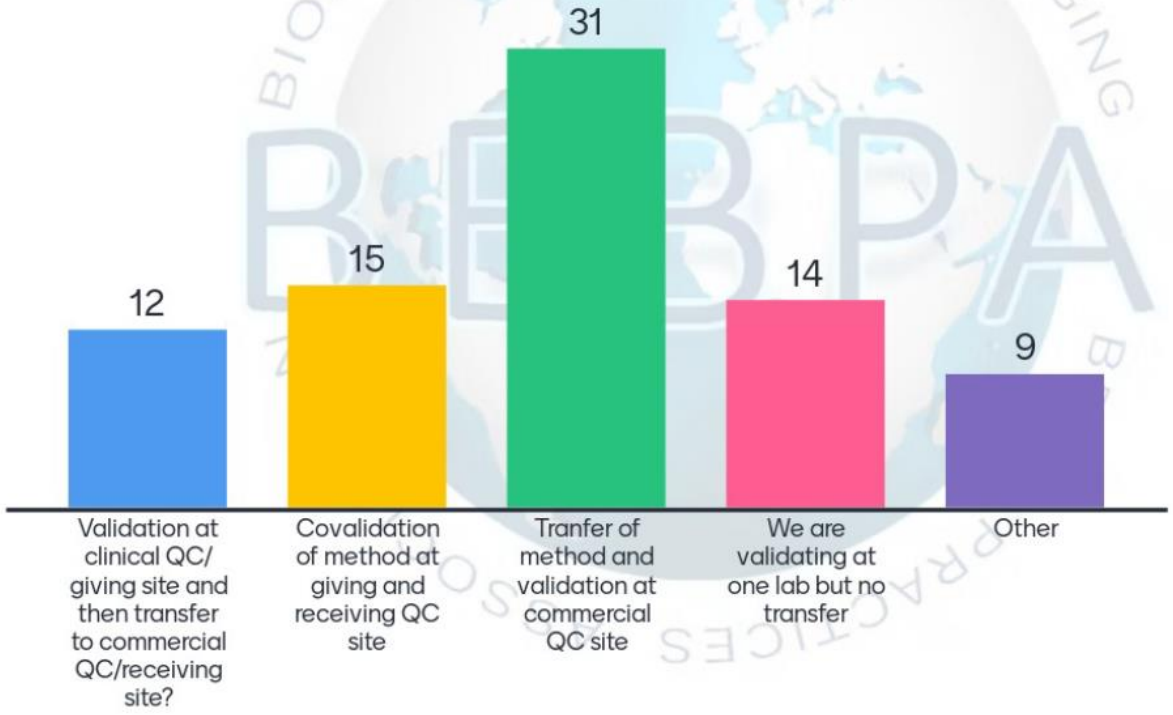
Session Chair: Hans-Joachim Wallny
Executive Director Scientific and Strategic Excellence TPPM
Novartis Pharma AG Switzerland
BEBPA Board of Directors

Audience Surveys

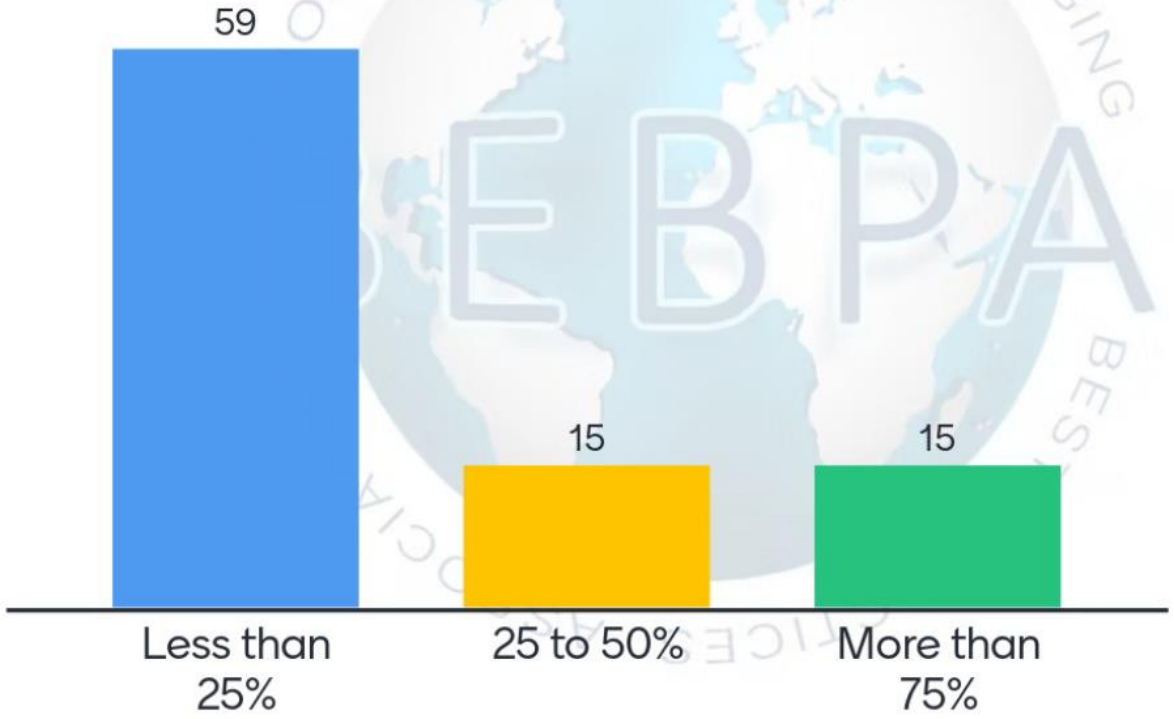
2.1 What stategies are you using for validation and transfer for bioassays?



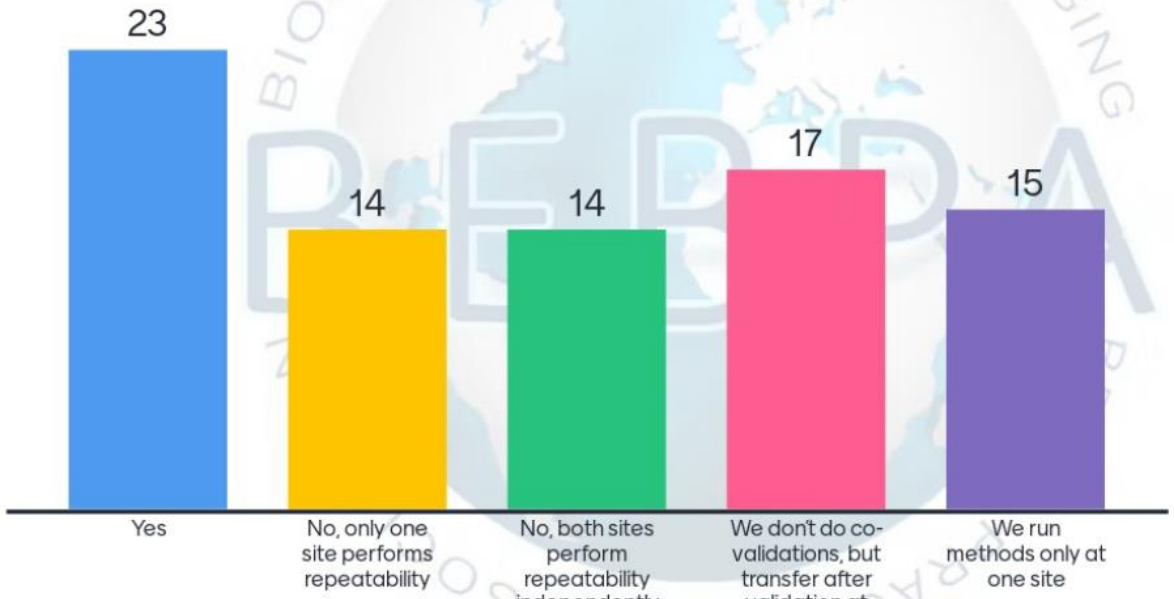
2.2 What is your most common approach for assay validation and transfer?



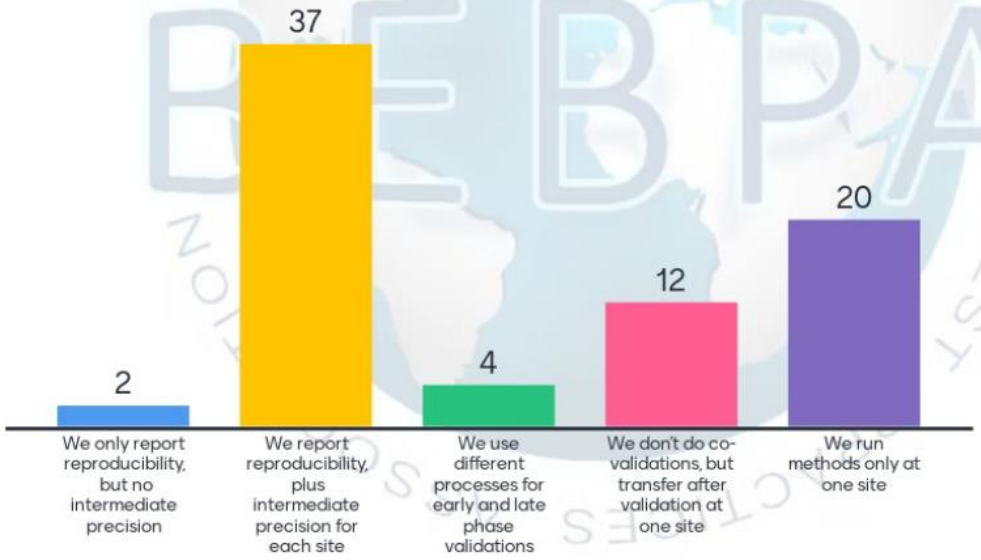
2.3 How often do you use the co-validation approach?



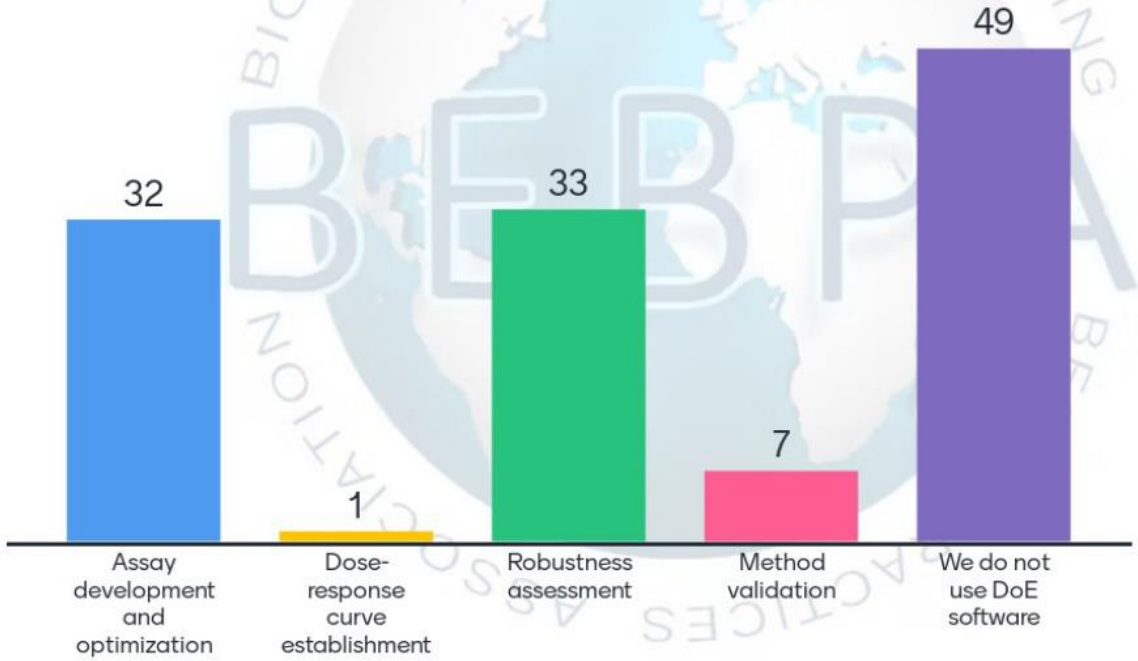
2.4 When running co-validations, do you run repeatability experiments across different sites?



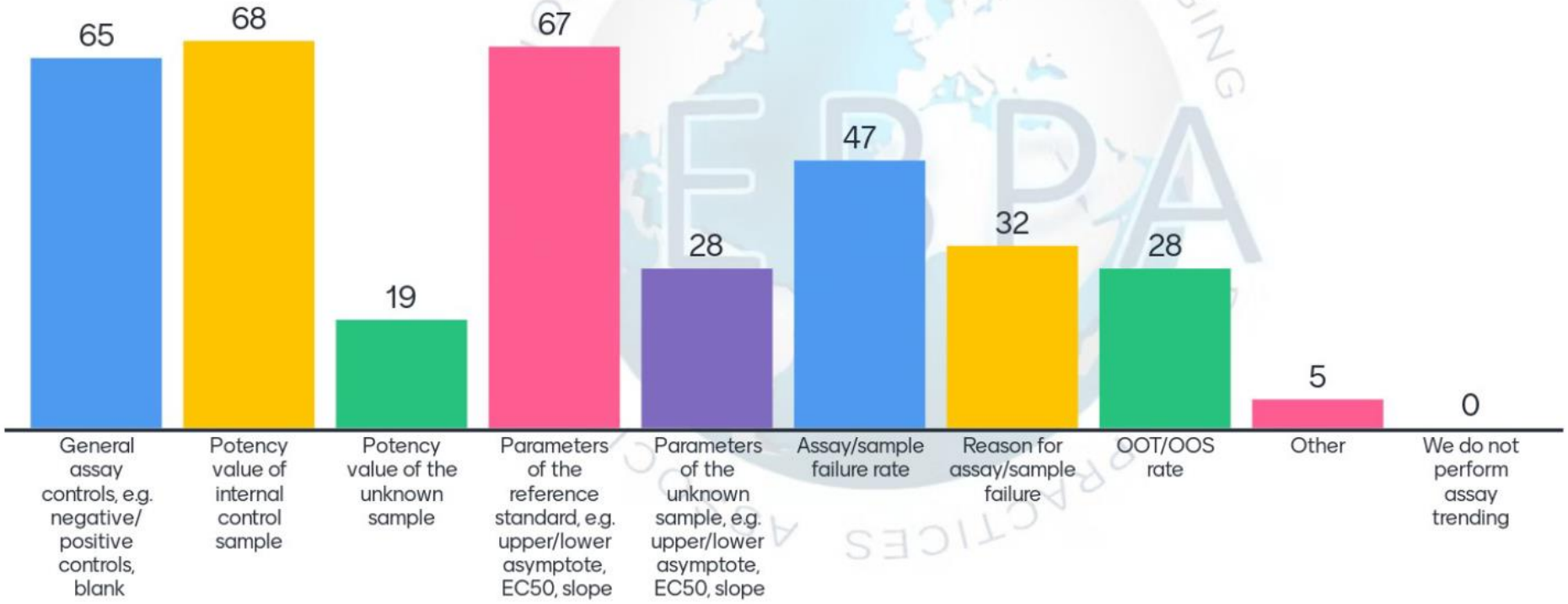
2.5 When running co-validations, how do you report intermediate precision and reproducibility?



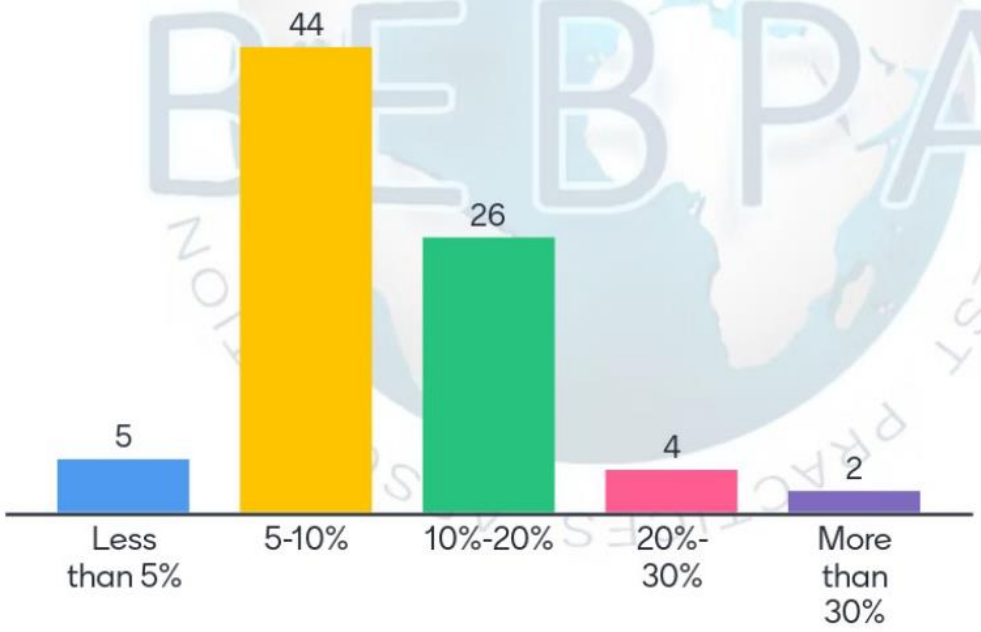
2.6 Are you using DoE software for bioassays?



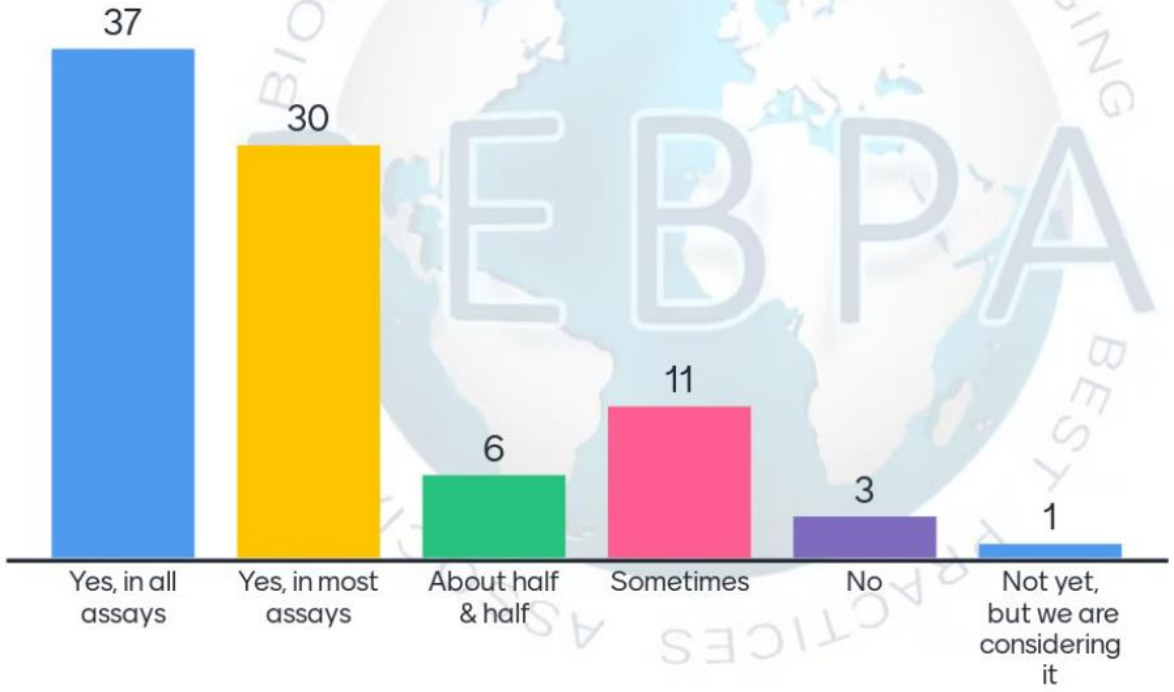
2.7 Which parameters do you monitor during QC sample routine analysis?



2.8 What repetition rate would you still find acceptable for potency assays during validation?



2.9 Do you use a quality control sample in your assays?

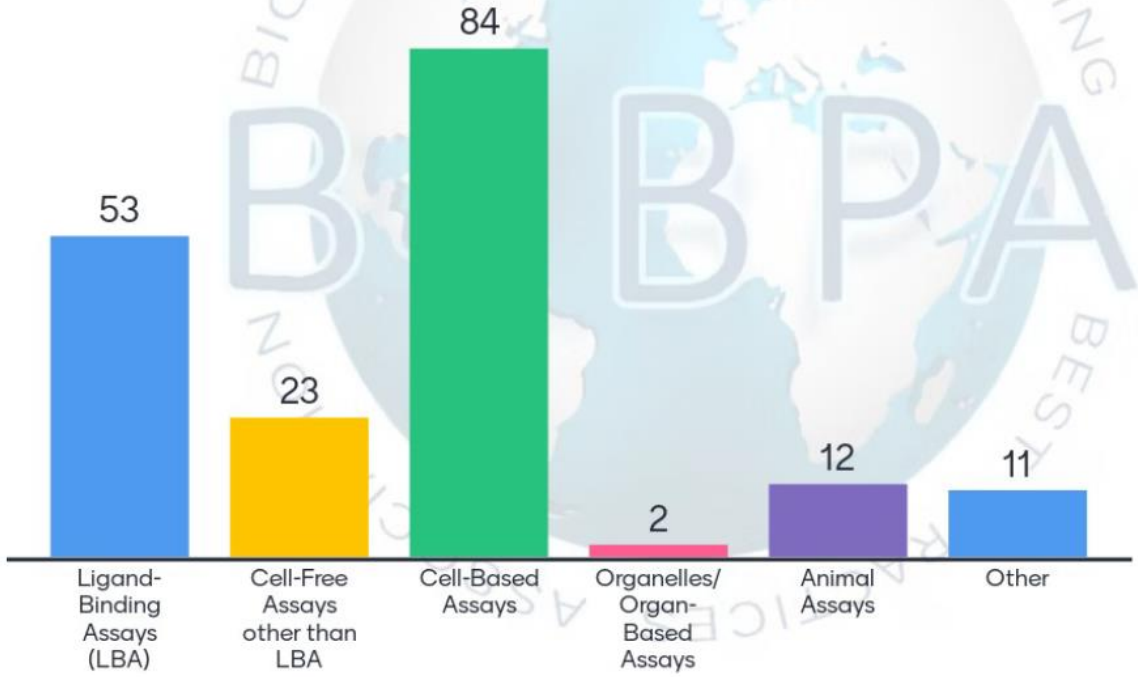


Session 3: From Animals to Molecules: Simplifying the Potency Assay

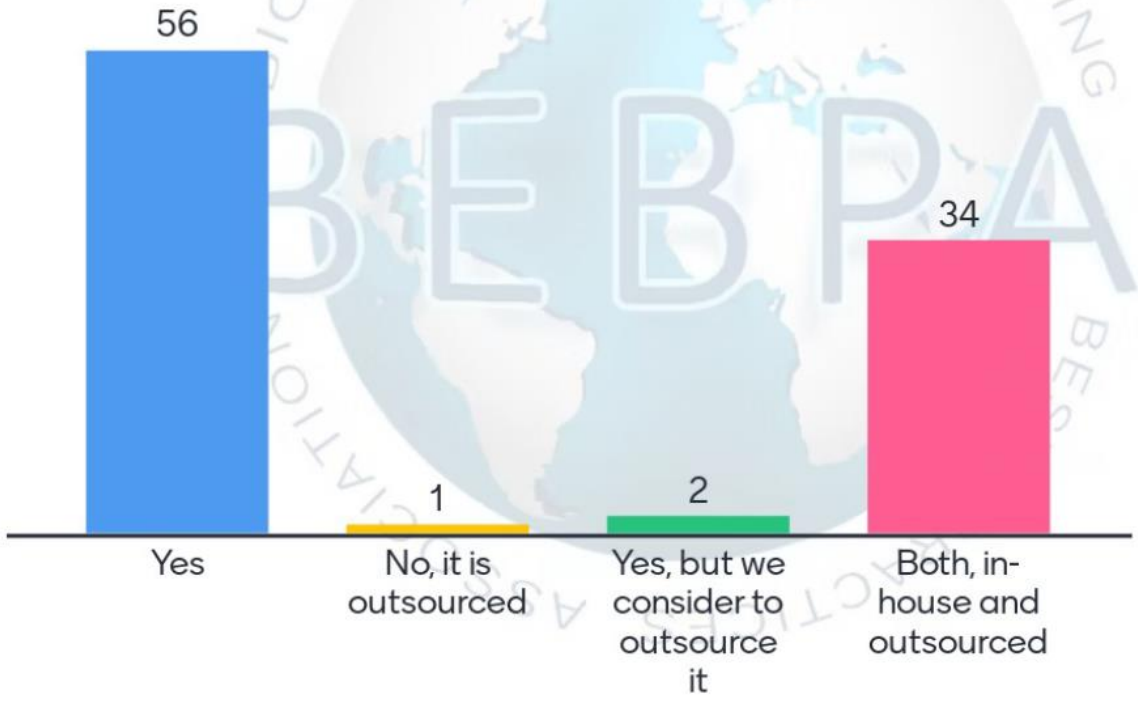
Session Chair: Bassam Hallis
Deputy Director, Vaccine Development, Evaluation and Preparedness
UK Health Security Agency
BEBPA Board of Directors

Audience Surveys

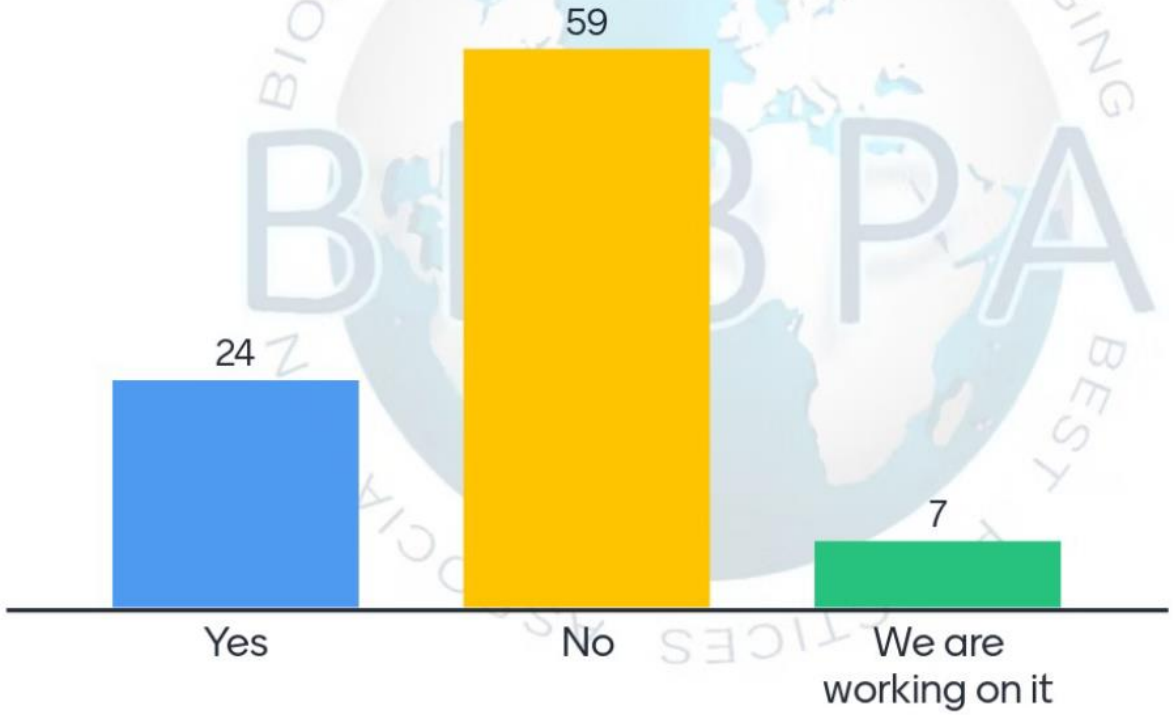
3.1 What type of potency assay(s) do you run?



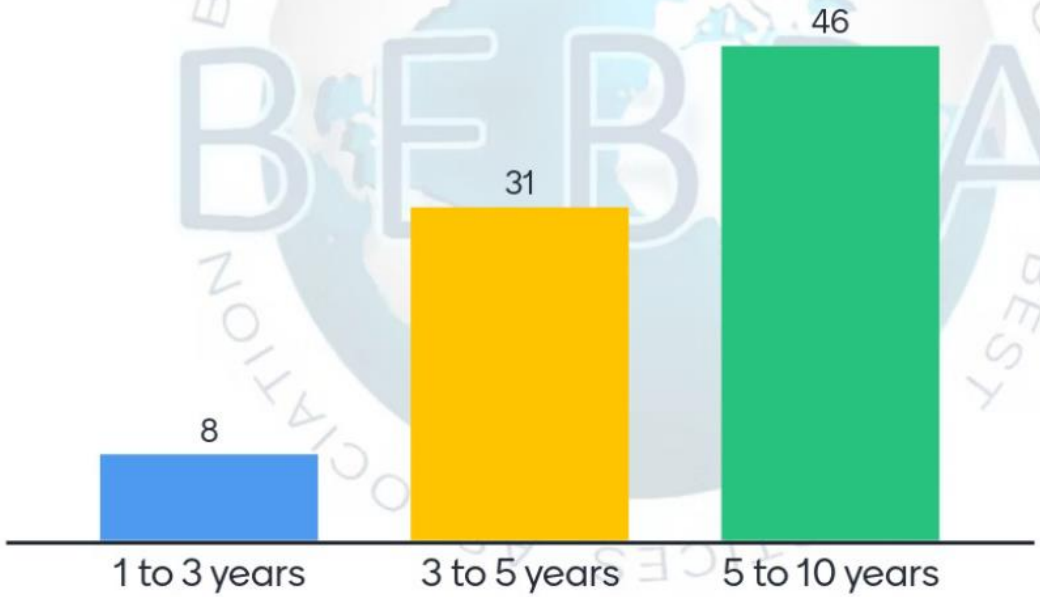
3.2 Do you run your potency assay(s) in-house?



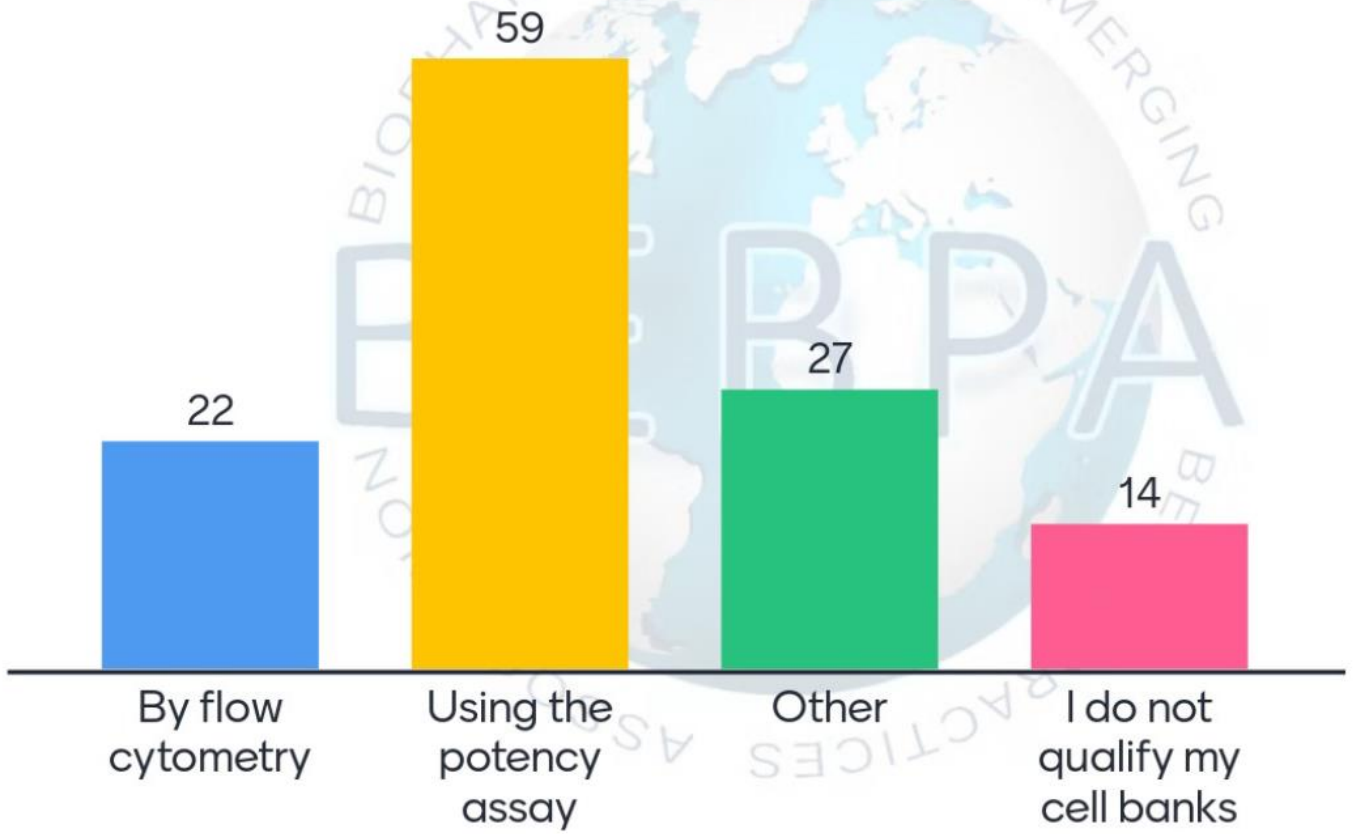
3.3 Have you experience on submission of an in vitro bioassay as alternative of an in vivo one?



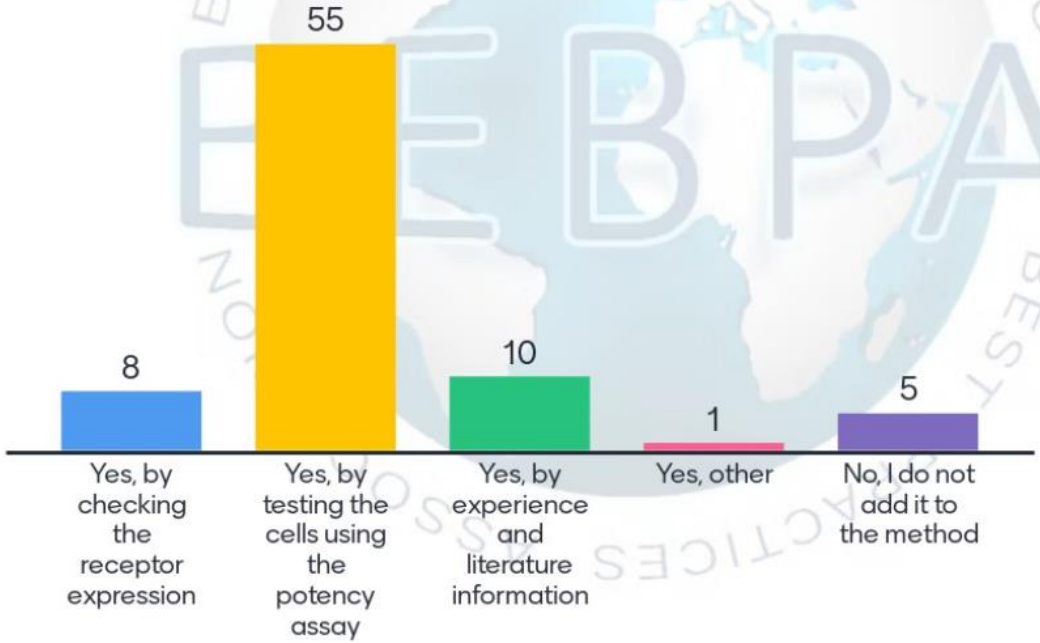
3.4 How long do you think it could take to introduce an in vitro test as alternative to an in vivo one, in a Pharmacopoeia monograph?



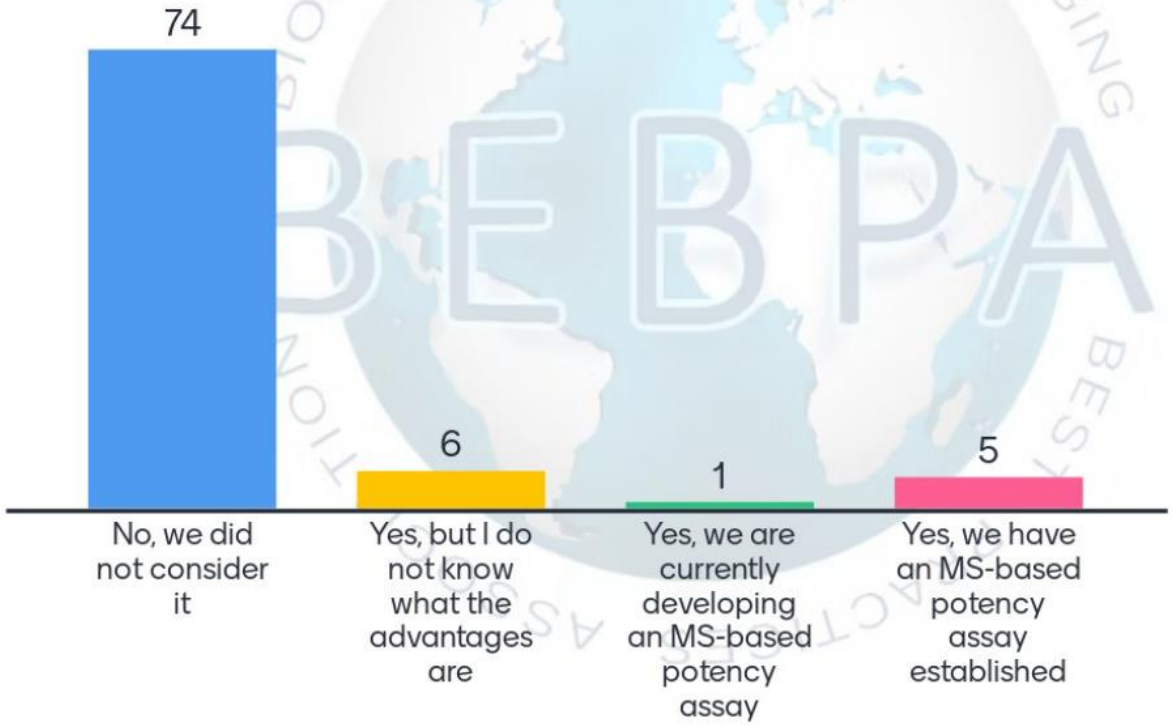
3.5 How do you qualify your cell bank?



3.6 Do you add to your method up to which cell passage the cell can be used in your potency assay? And how do you establish it?



3.7 Do you consider mass spectrometry as readout for your potency assay?

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Thank You!!