BEBPA 2024 Reference Material Conference

24-28 June 2024

Virtual Event

DAY 2: Challenges with The First Relative Potency IRM

Tuesday, 25 June 2024

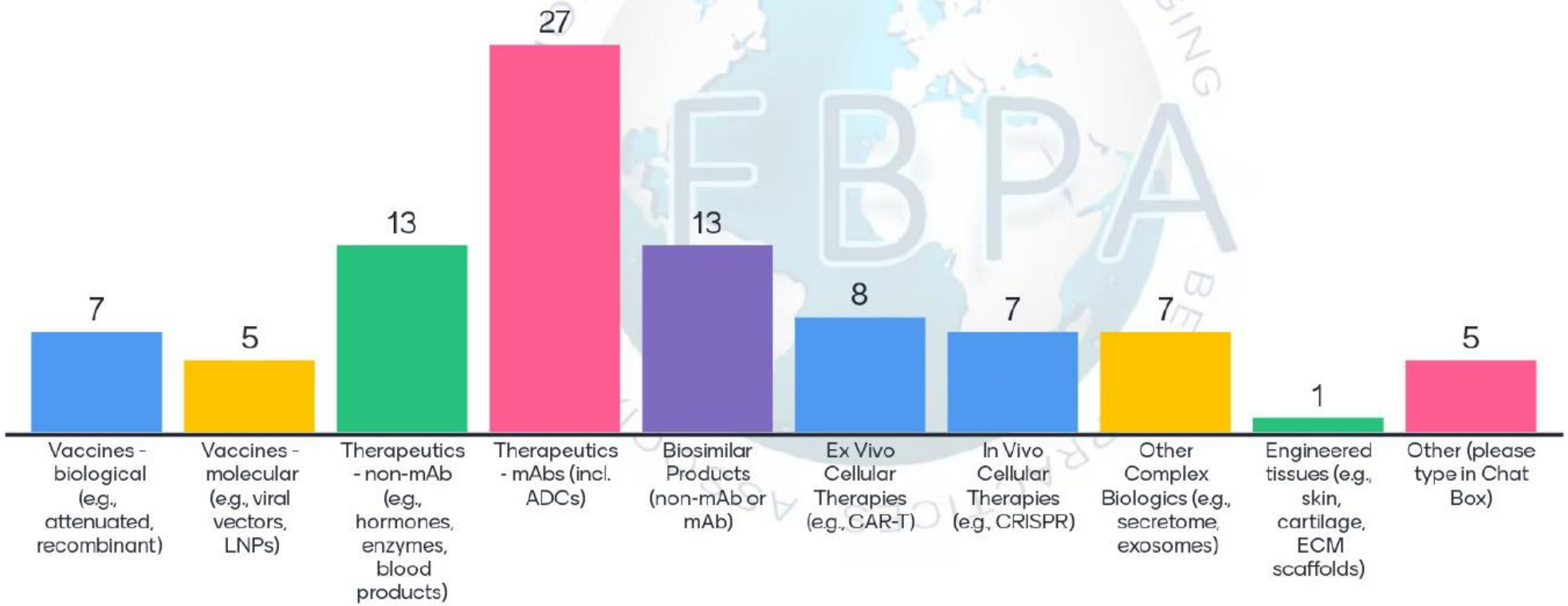
Session Chair: Nadine Ritter

President

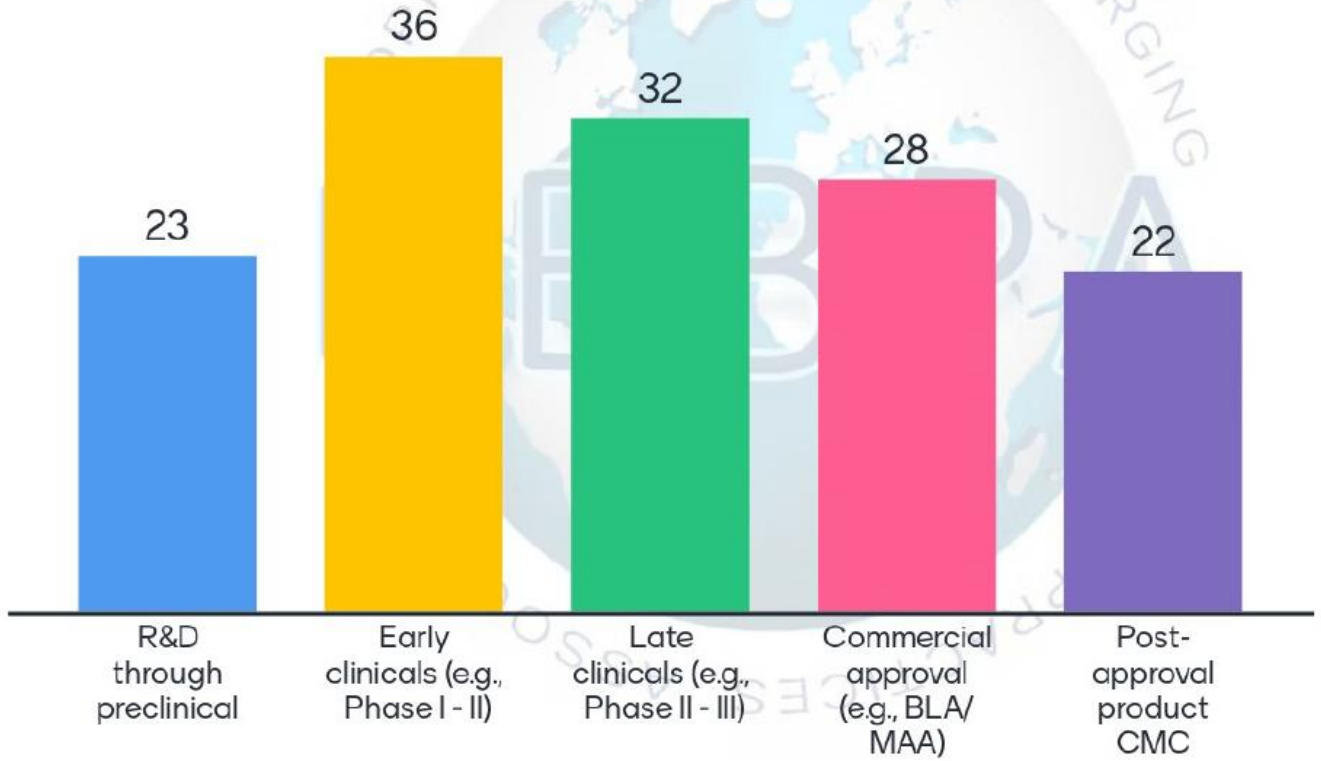
Global Biotech Experts

Audience Surveys

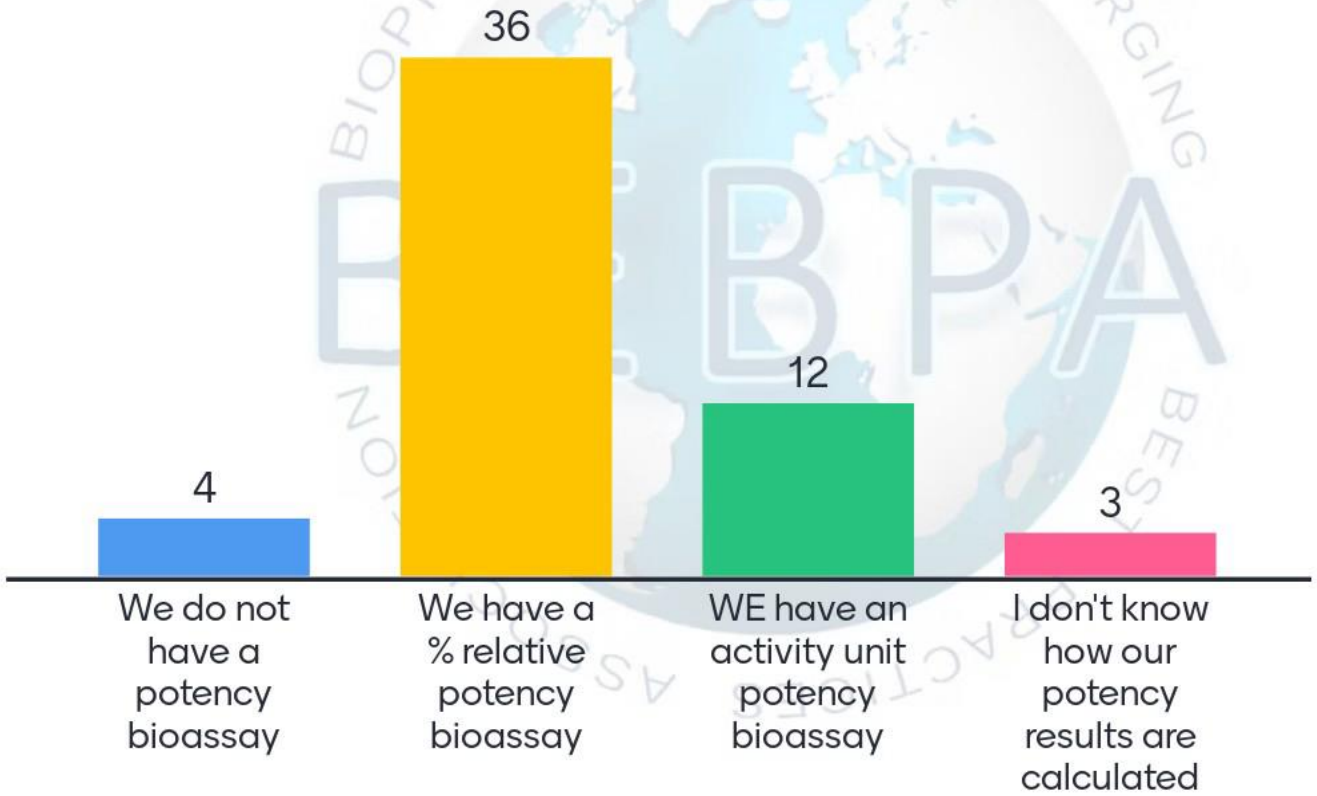
2.1 Which biological product modalities do you mostly work on? Check all that apply



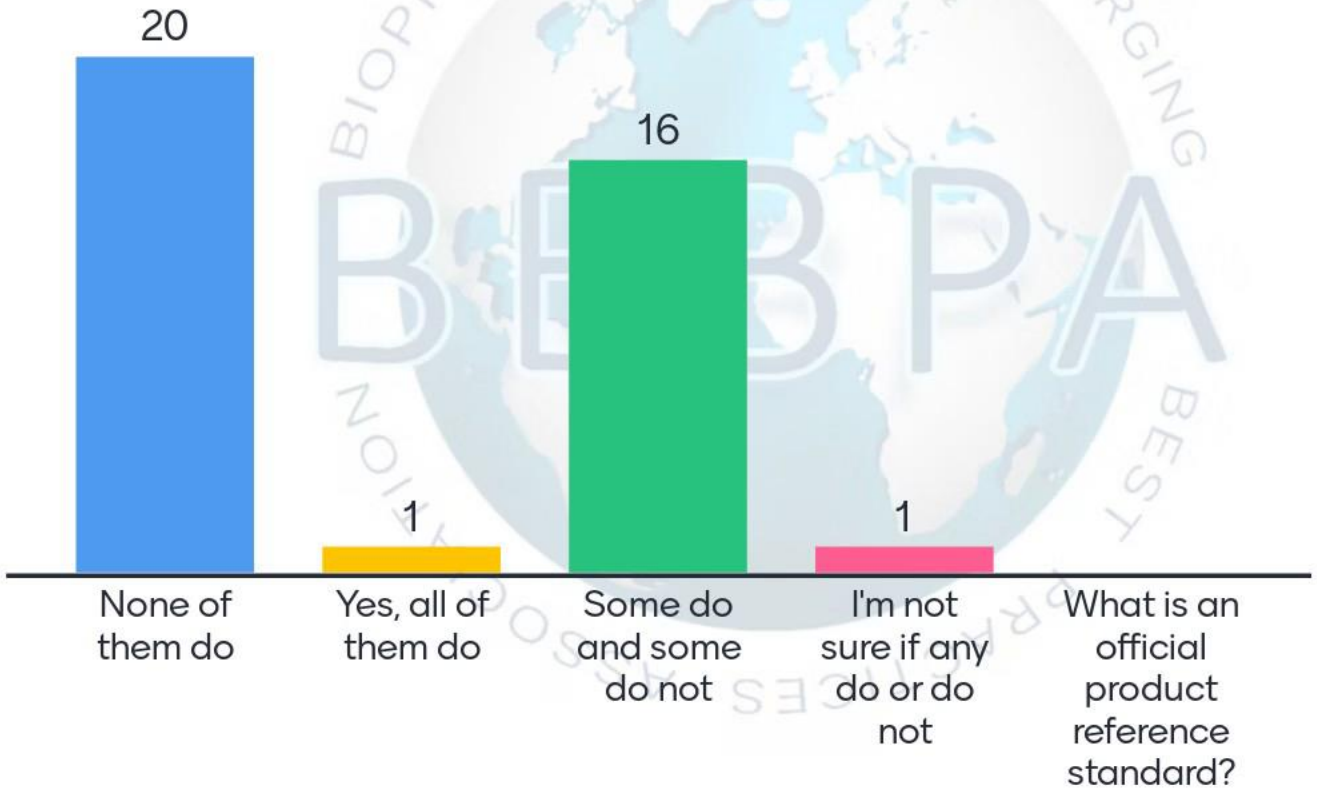
2.2 What phase(s) of CMC product development are the products you mostly work on? Check all that apply



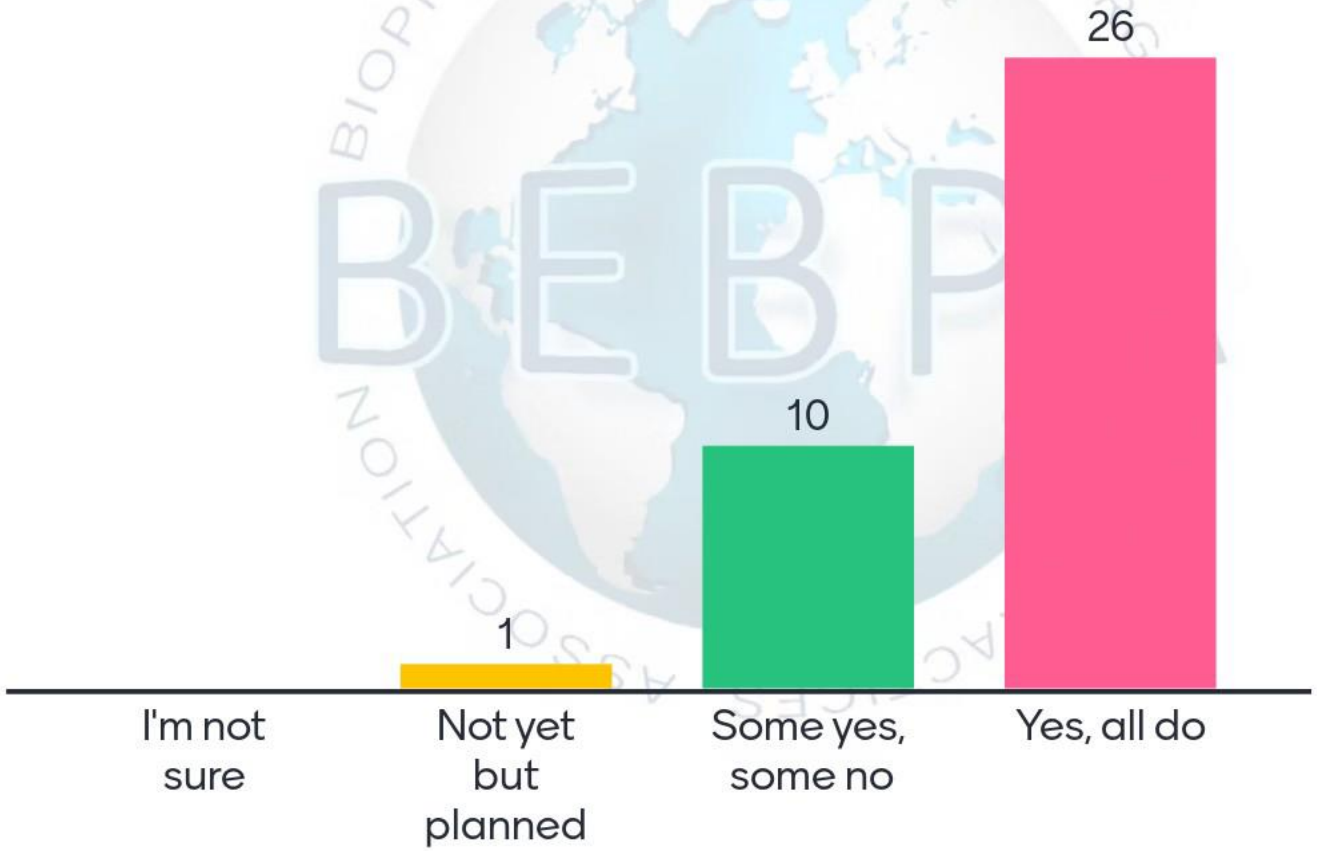
2.3 Do you have (or plan to have) potency assays for your products? If yes, are reportable results calculated as % RP or U of activity?



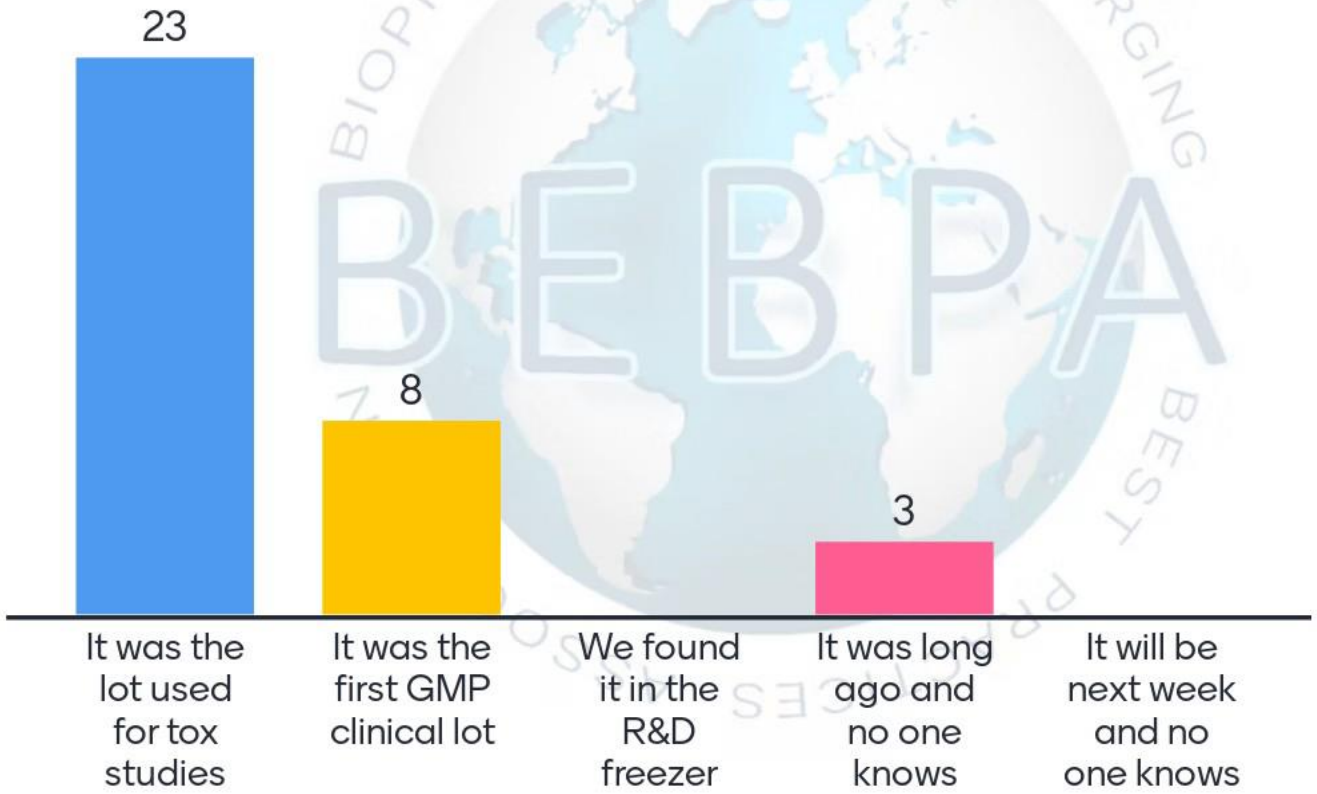
2.4 Do any of the products you work on have an official product reference standard (e.g., WHO, USP, EDQM, NIBSC)?



2.5 For products that you mostly work on, is there an in-house reference material established for the product's potency assay(s)?



2.6 How was the FIRST lot of interim product reference material chosen for use in the potency bioassay?



DAY 3: Potency IRM Bridging and Stability Challenges

Wednesday, 26 June 2024

Session Chairs:

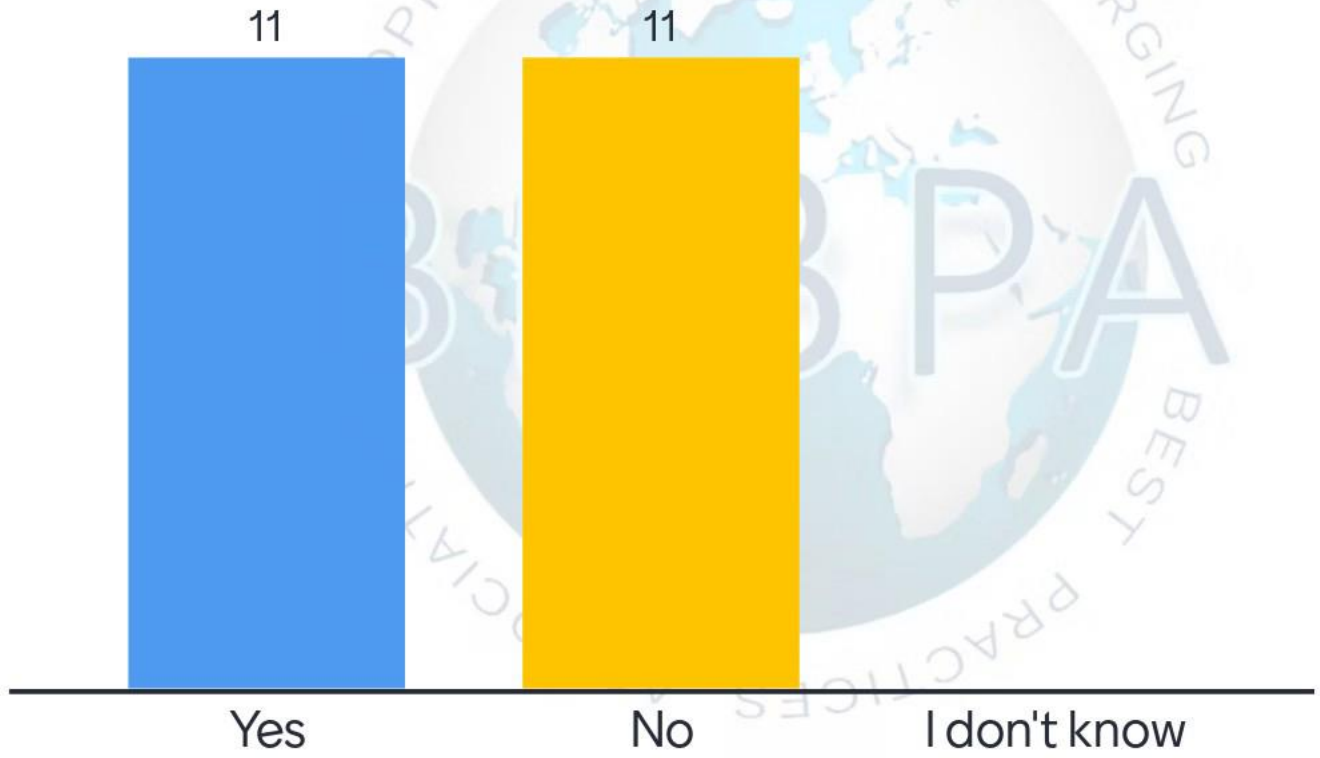
Matt Borer, Executive Director, CRSO

Seth Foltz, Sr. Principal Scientist, CRSO

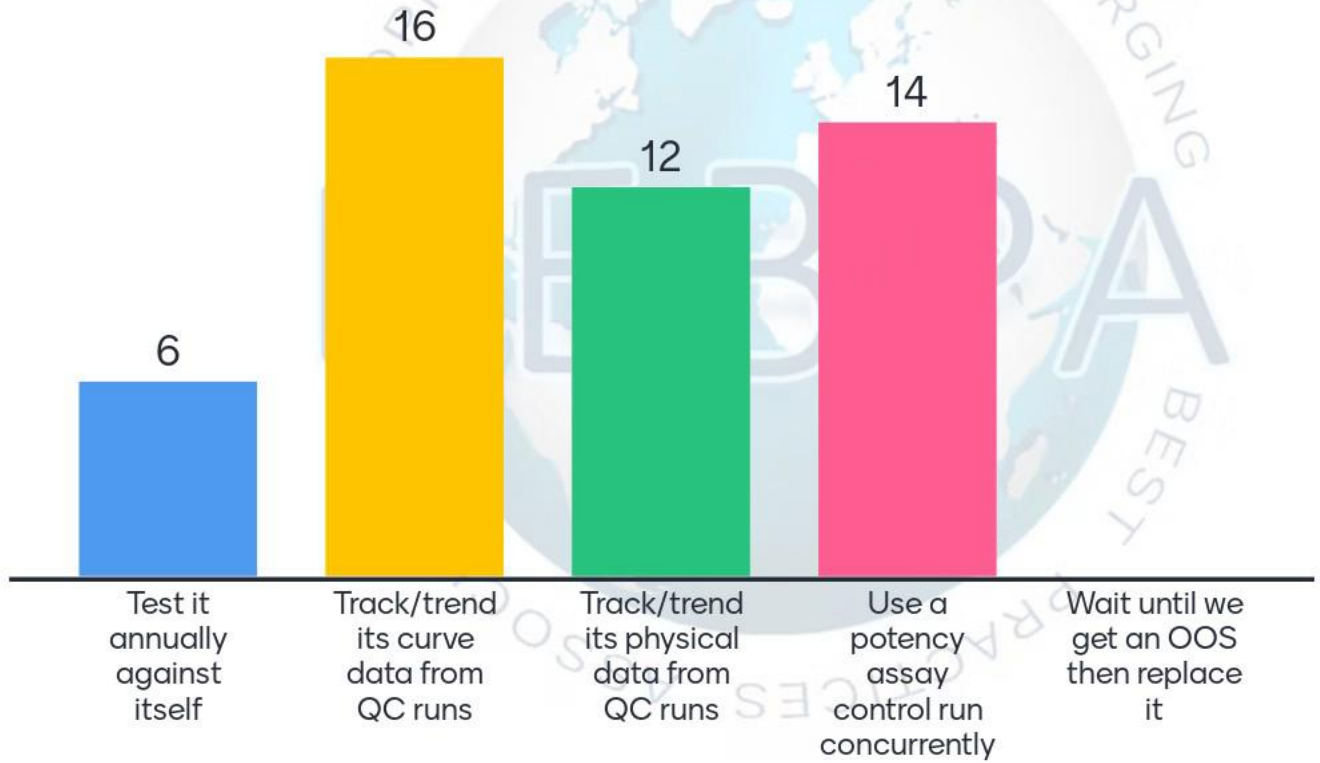
Eli Lilly and Company

Audience Surveys

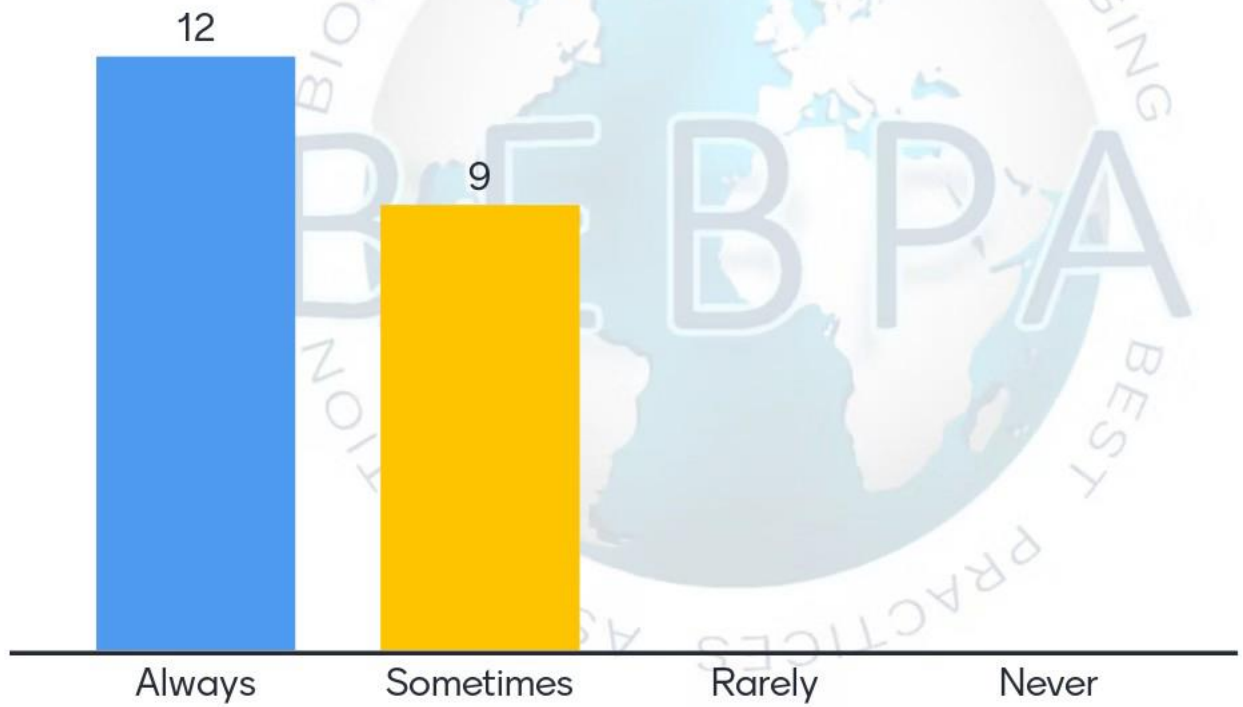
3.1 Have you experienced a stability problem with your reference material during clinical development?



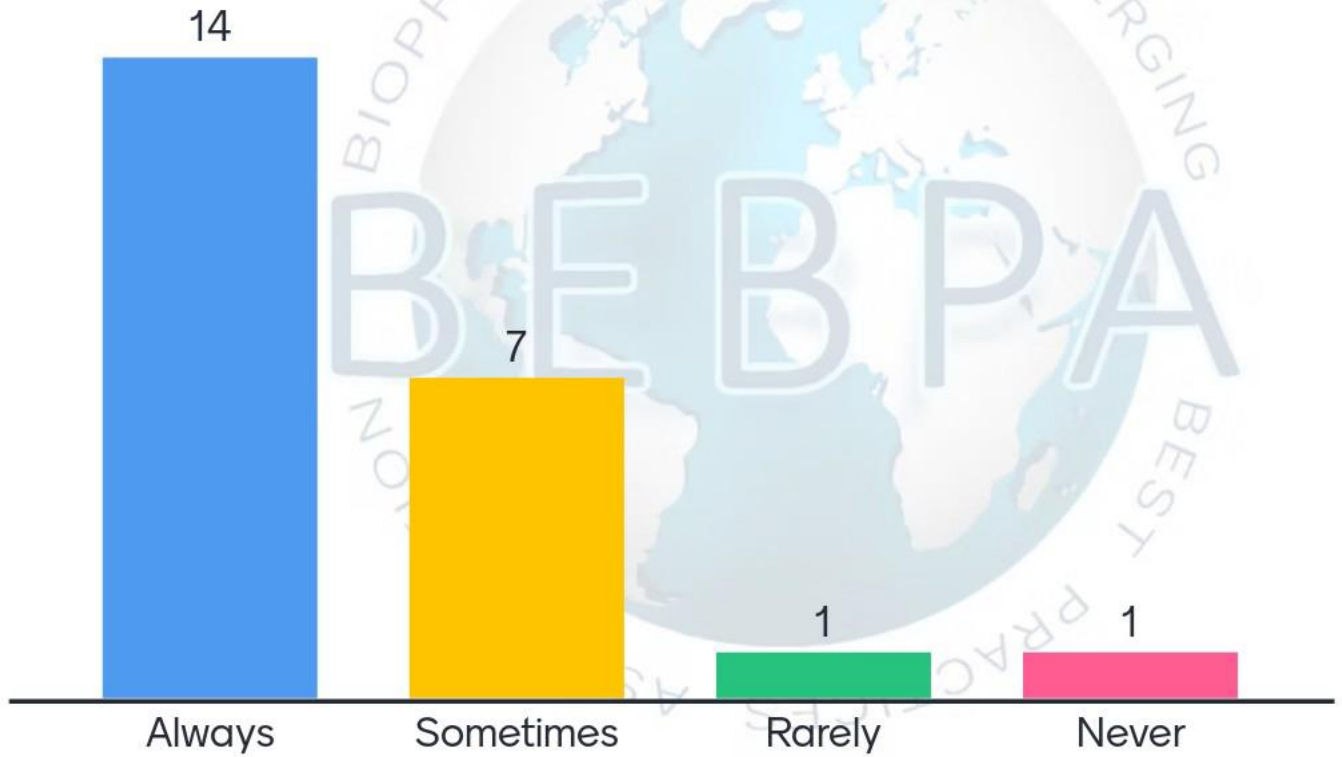
3.2 How do you assess the stability of your in-house potency reference standards? Check all that apply



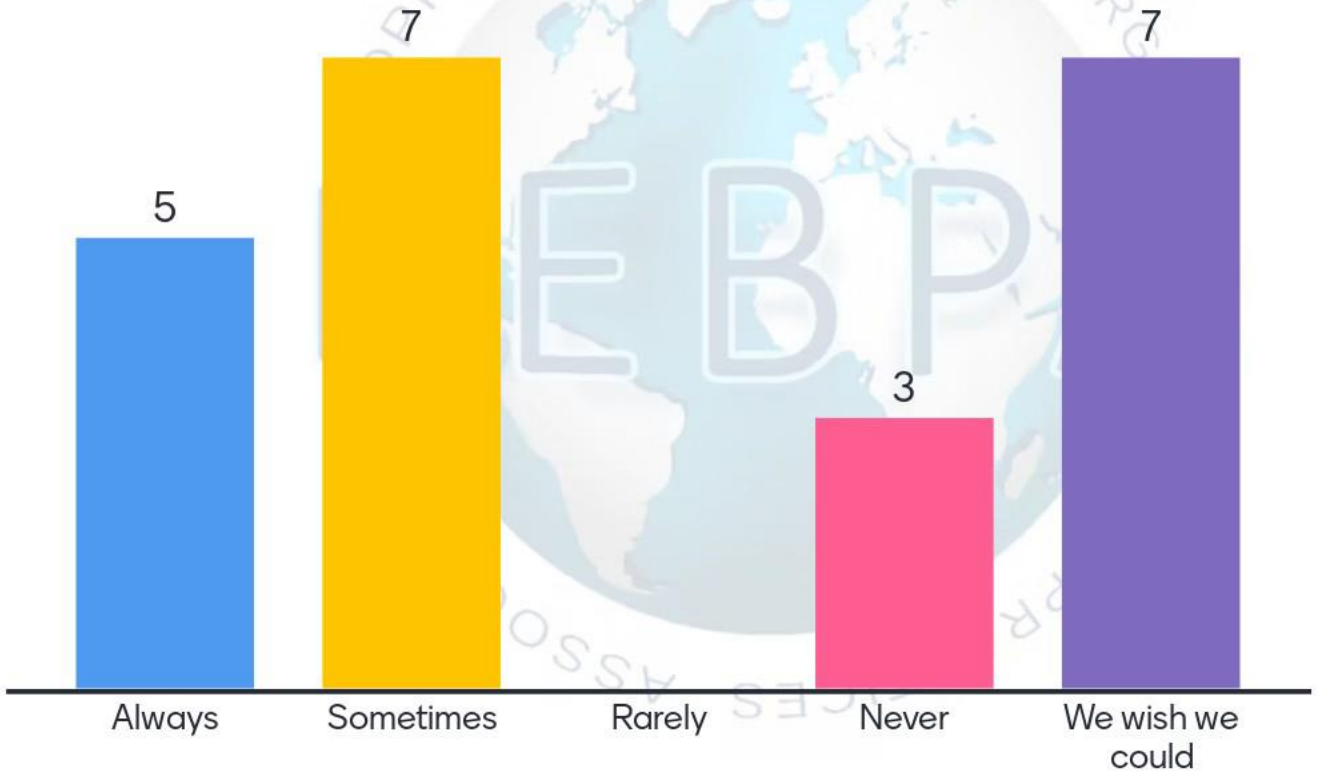
3.3 Do you have formal bridging protocols for references used to support PI and PII studies?



3.4 Do you use formal bridging protocols for changing in-house interim product reference standard lots during Phase II and Phase III clinical studies?



3.5 Do you involve a statistician to help design reference bridging studies between references used to support PI and PII studies



DAY 4: Relative Potency IRM Challenges New Modalities

Thursday, 27 June 2024

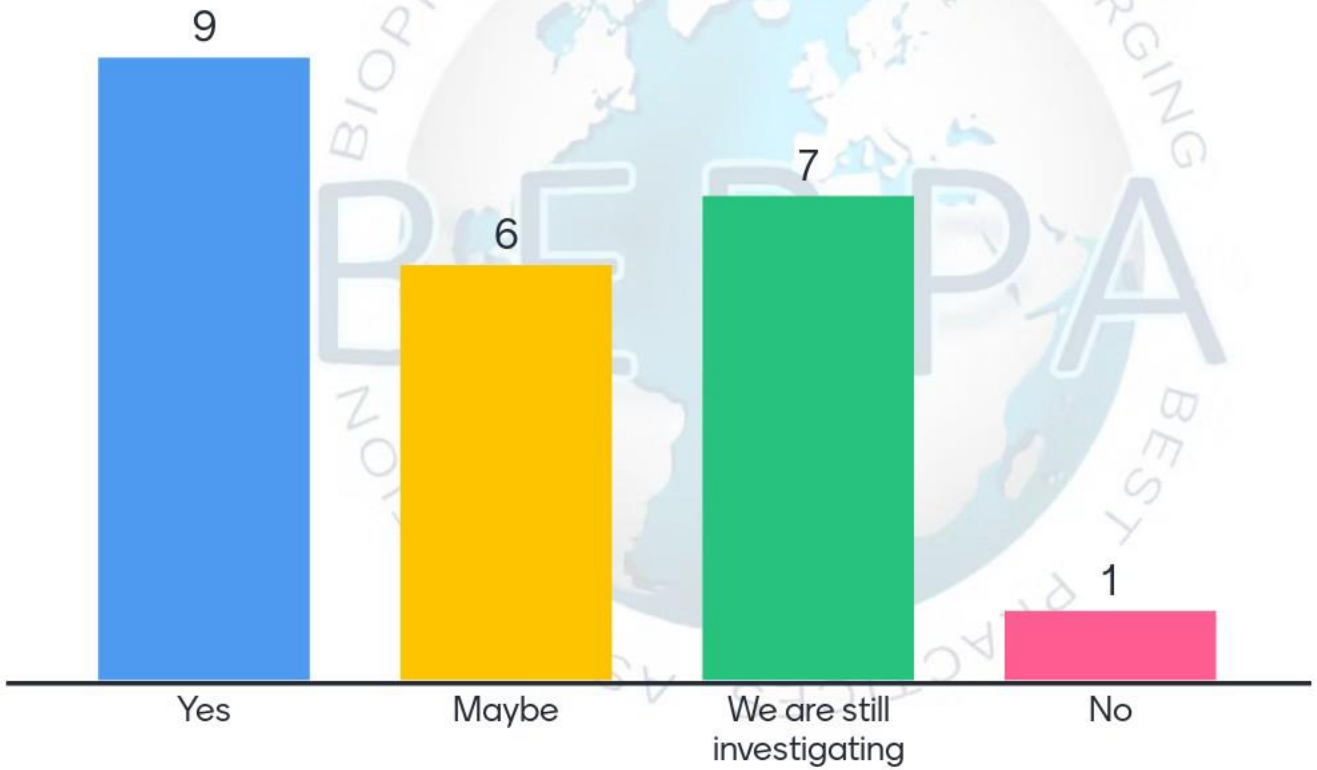
Session Chair: Nadine Ritter

President

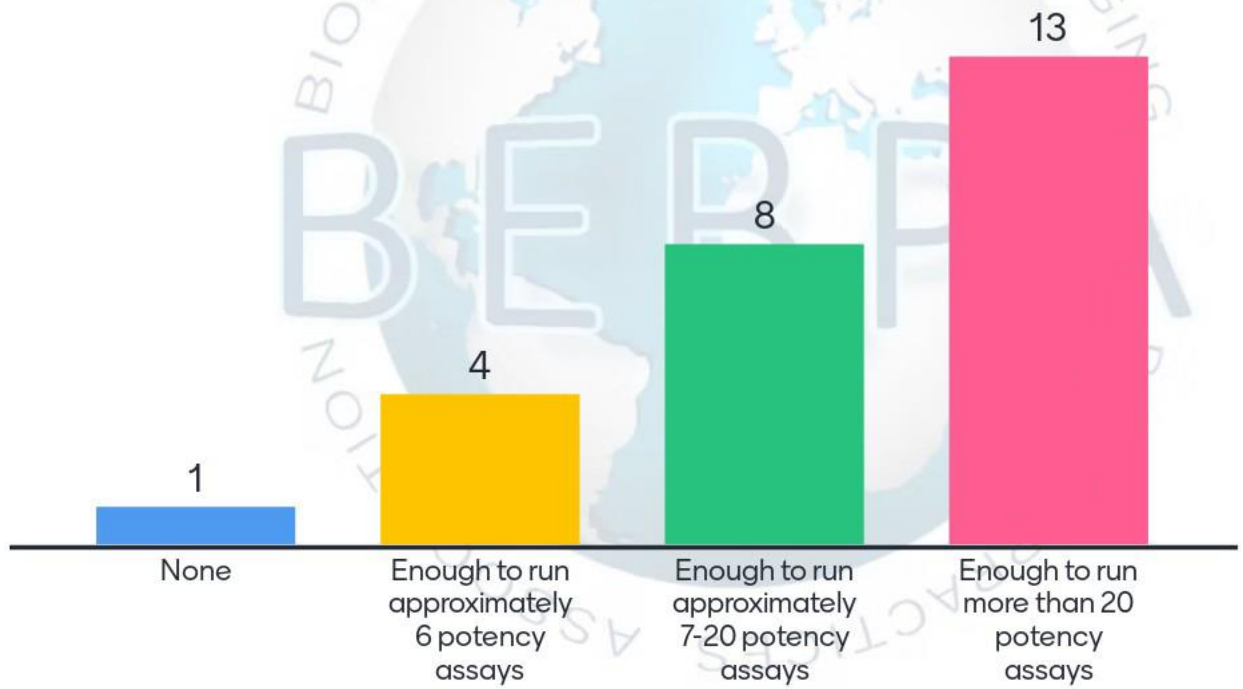
Global Biotech Experts

Audience Surveys

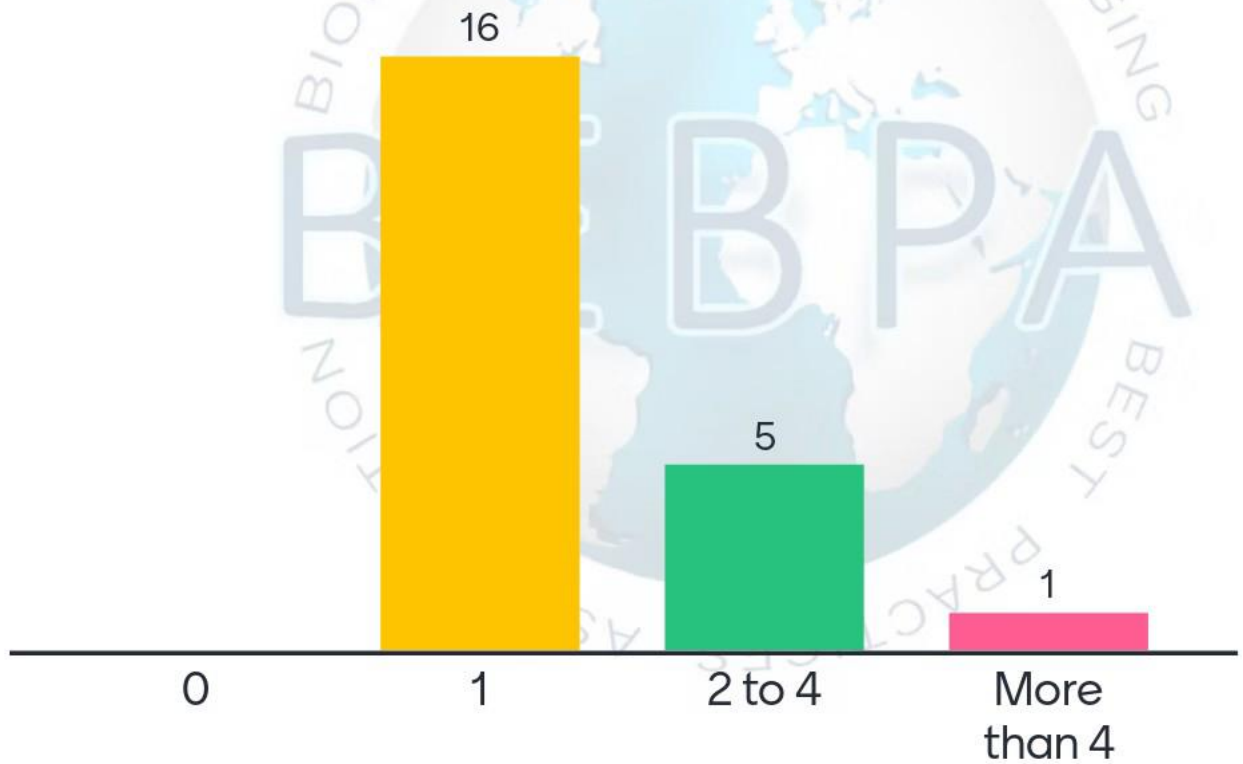
4.1 For your cellular or complex product is there sufficient product stability to potentially develop a two-tier reference program?



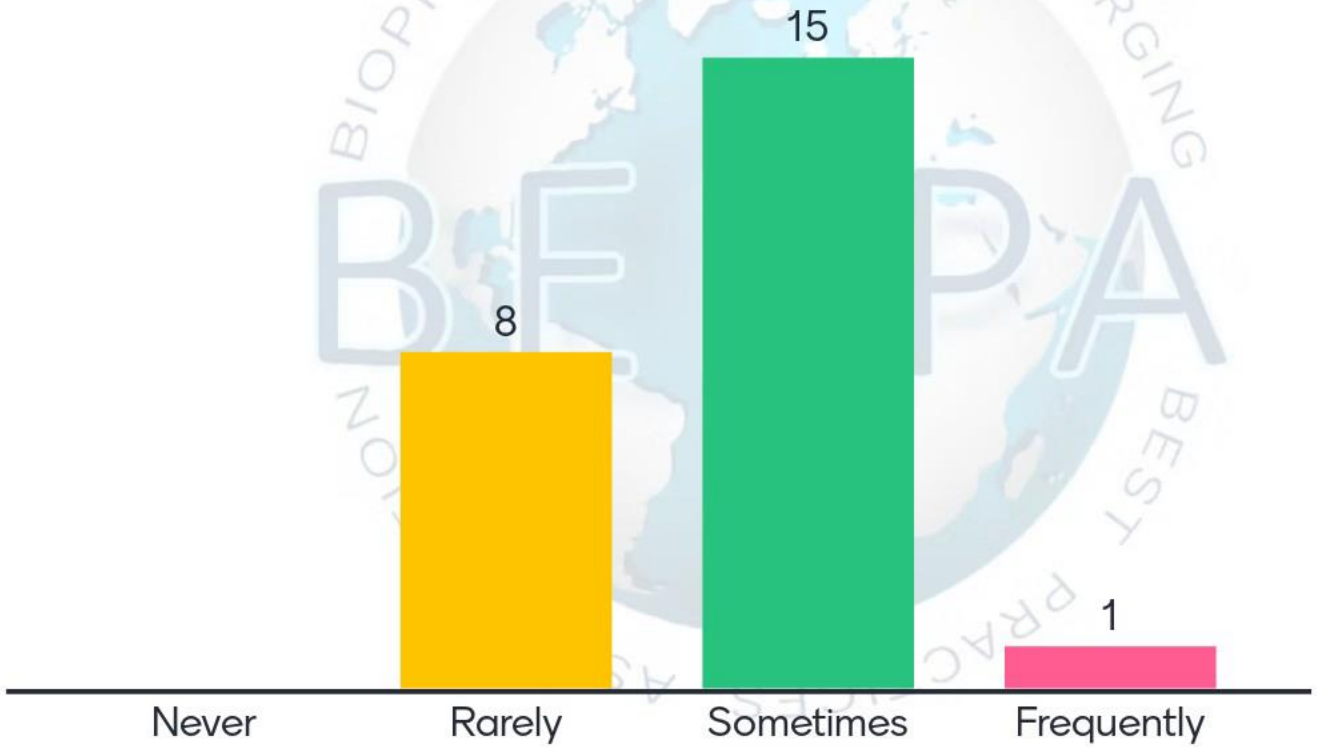
4.2 How many retention samples do you keep of your PI reference material?



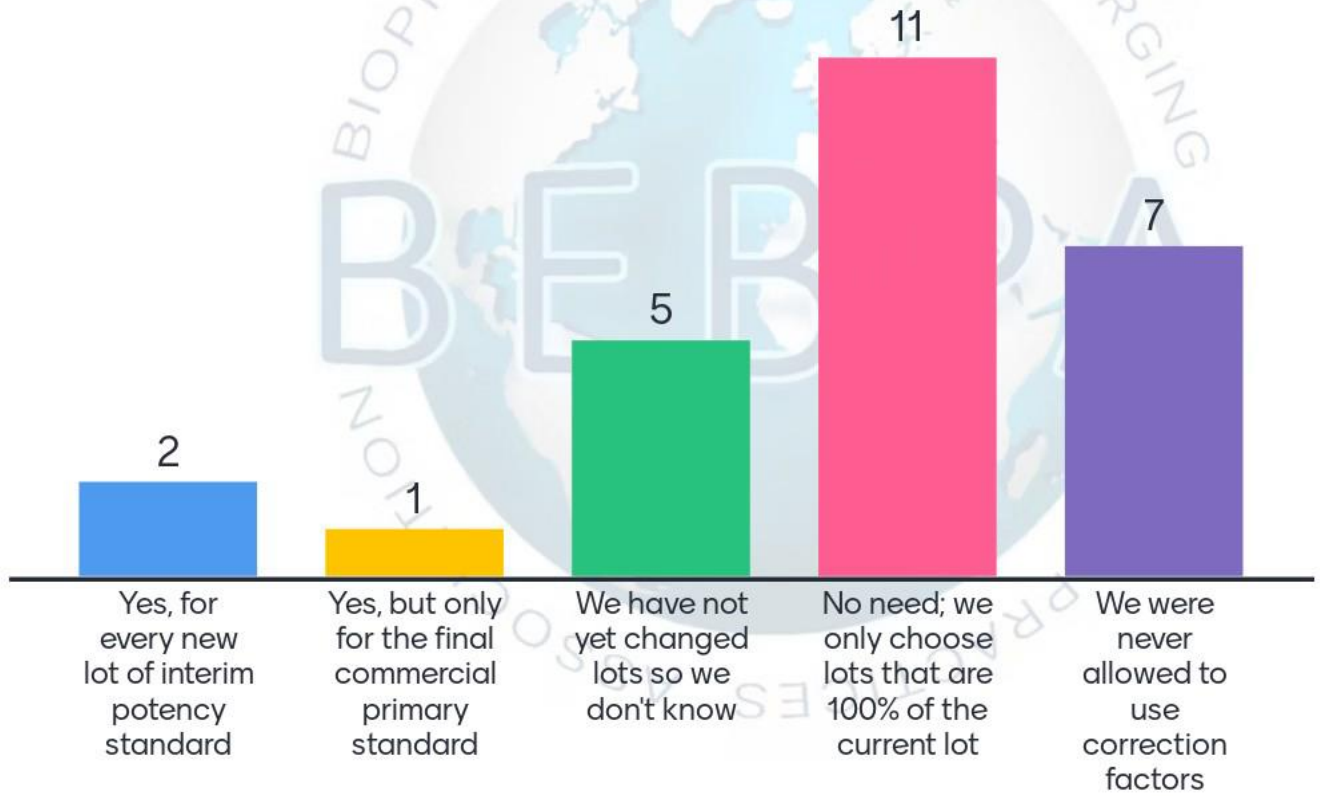
4.3 How many reference lots do you typically need to support PI studies?



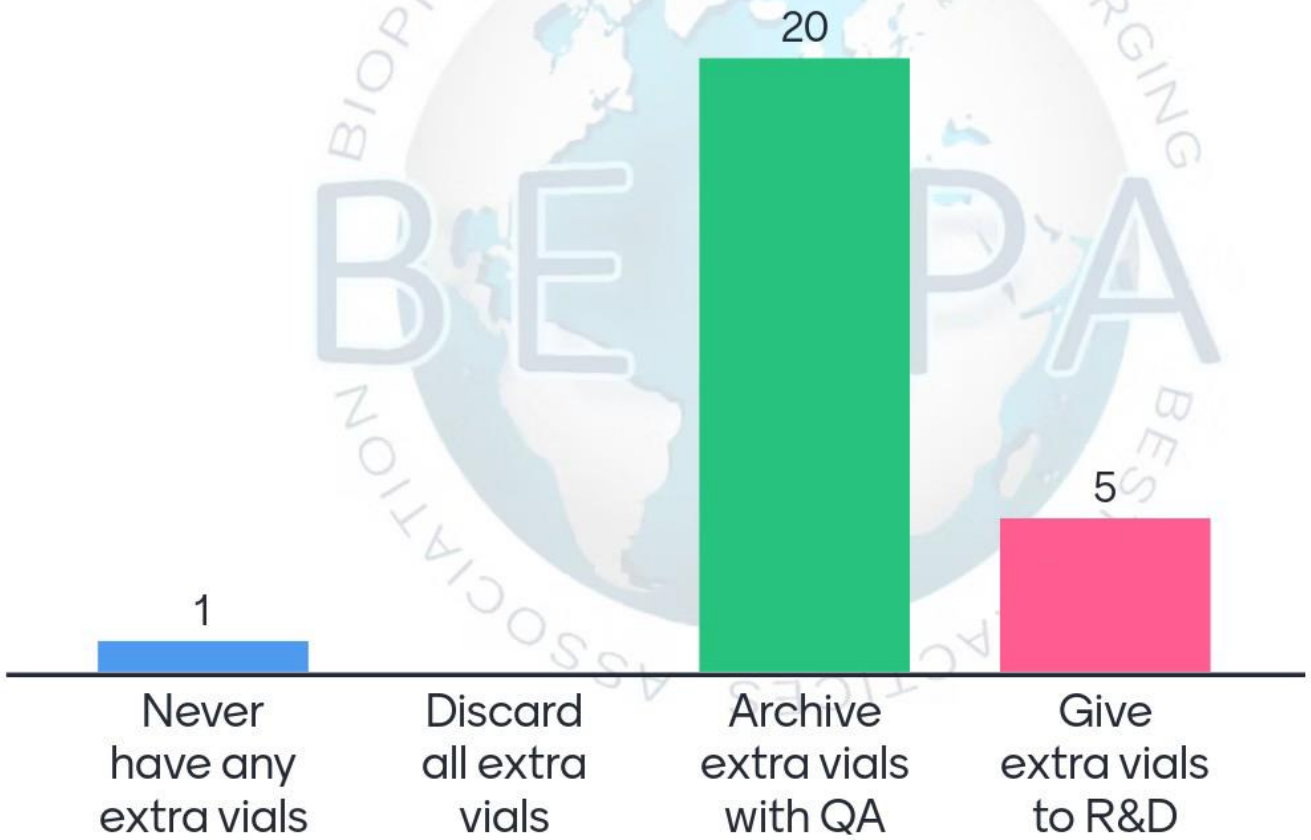
4.4 About how many times have you changed interim potency reference standard lots during clinical development?



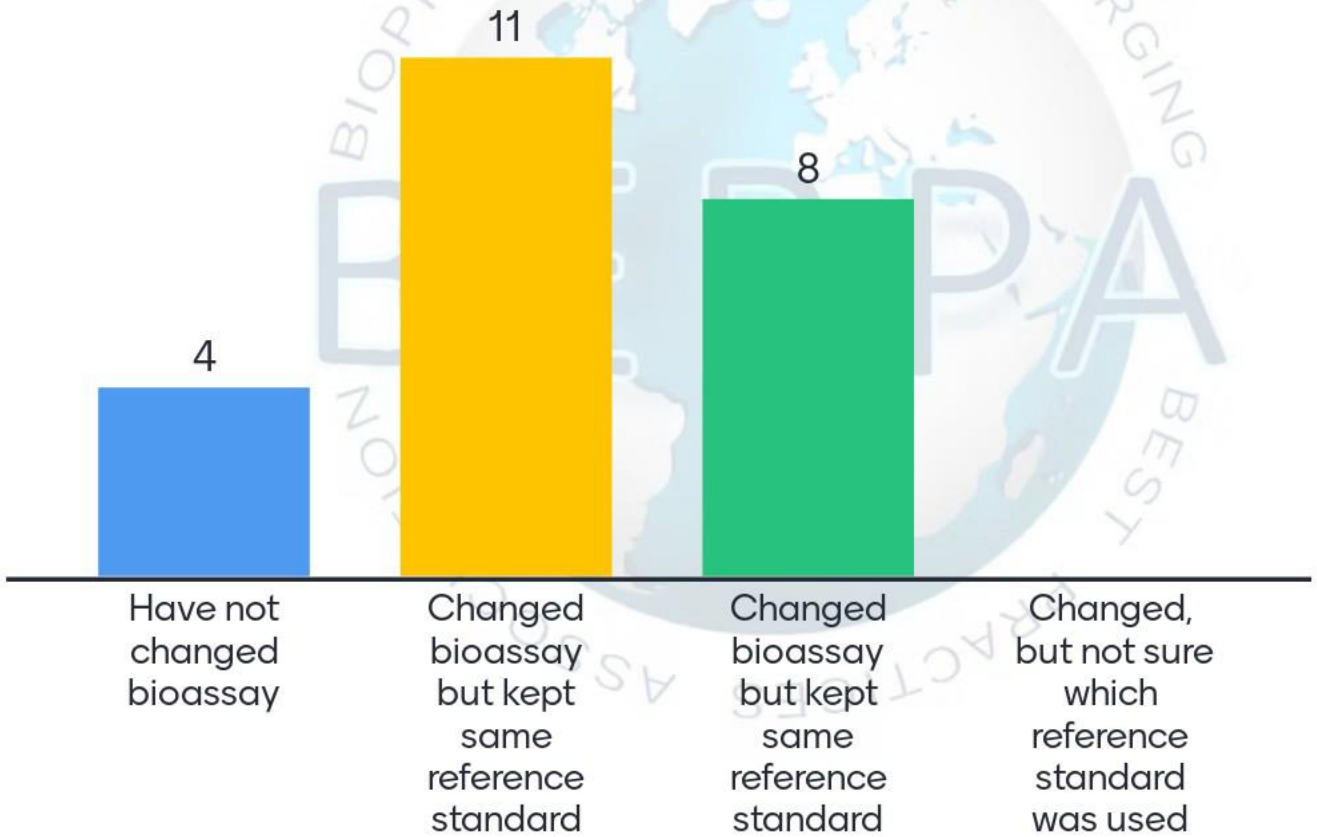
4.5 During clinical development, have you used a correction factor to adjust each new lot of interim product reference standards to '100% potency'?



4.6 When you change in-house interim product reference standard lots, what do you do with the extra vials of the previous lot?



4.7 Have you changed potency bioassays during clinical development? If so, did you use the same potency reference standard?



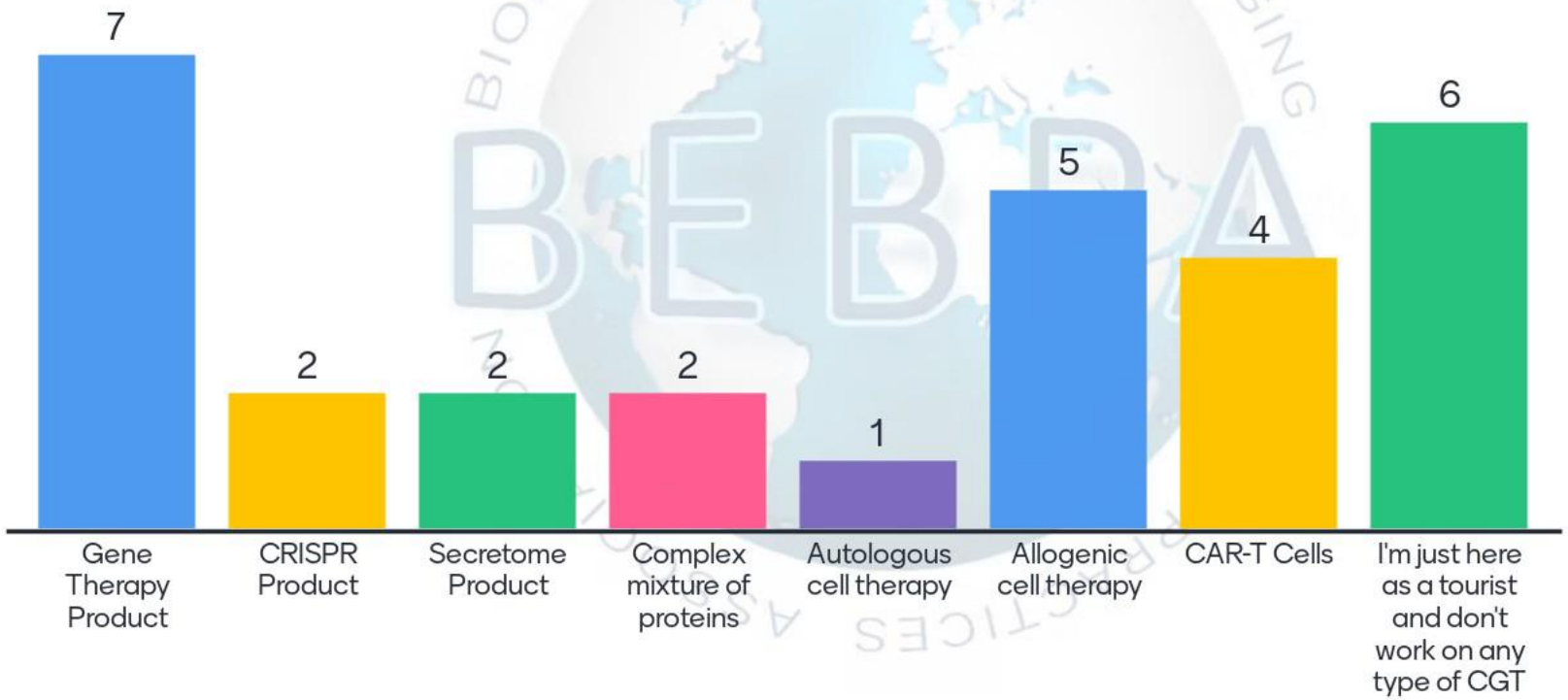
Workshop 2: Cell & Gene Therapy Reference Standards

Friday, 28 June 2024

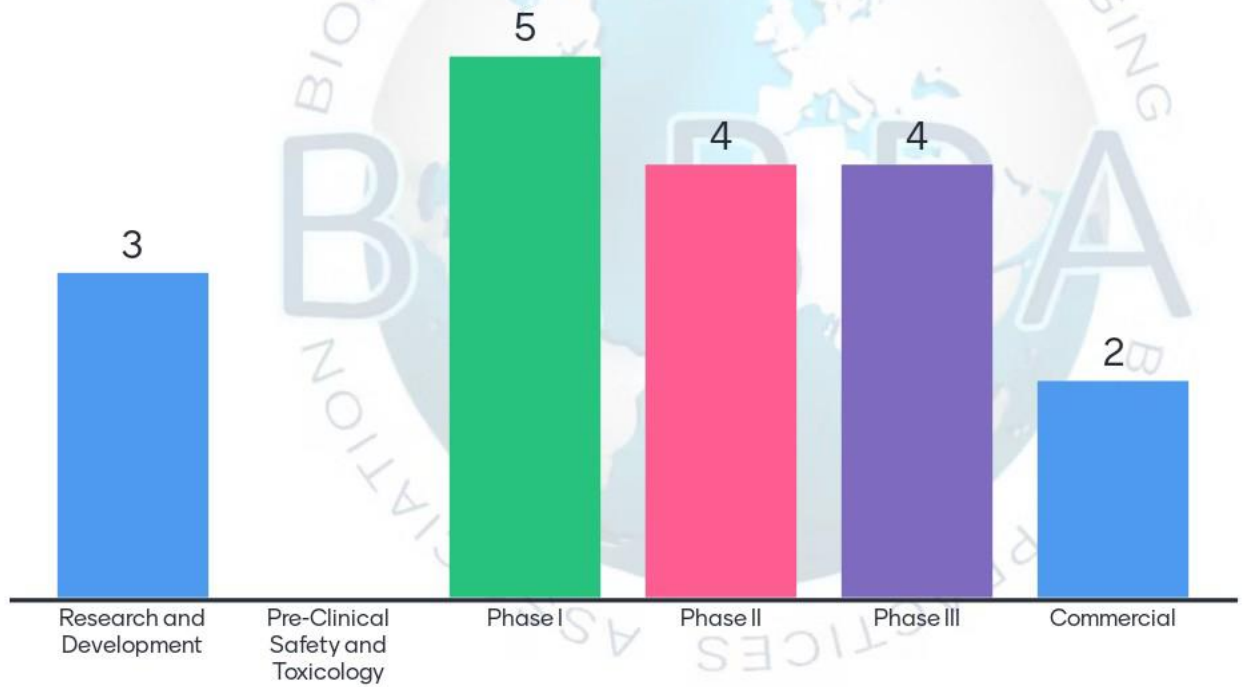
Laureen Little
Principal Consultant, Quality Services
President, BEBPA

Audience Surveys

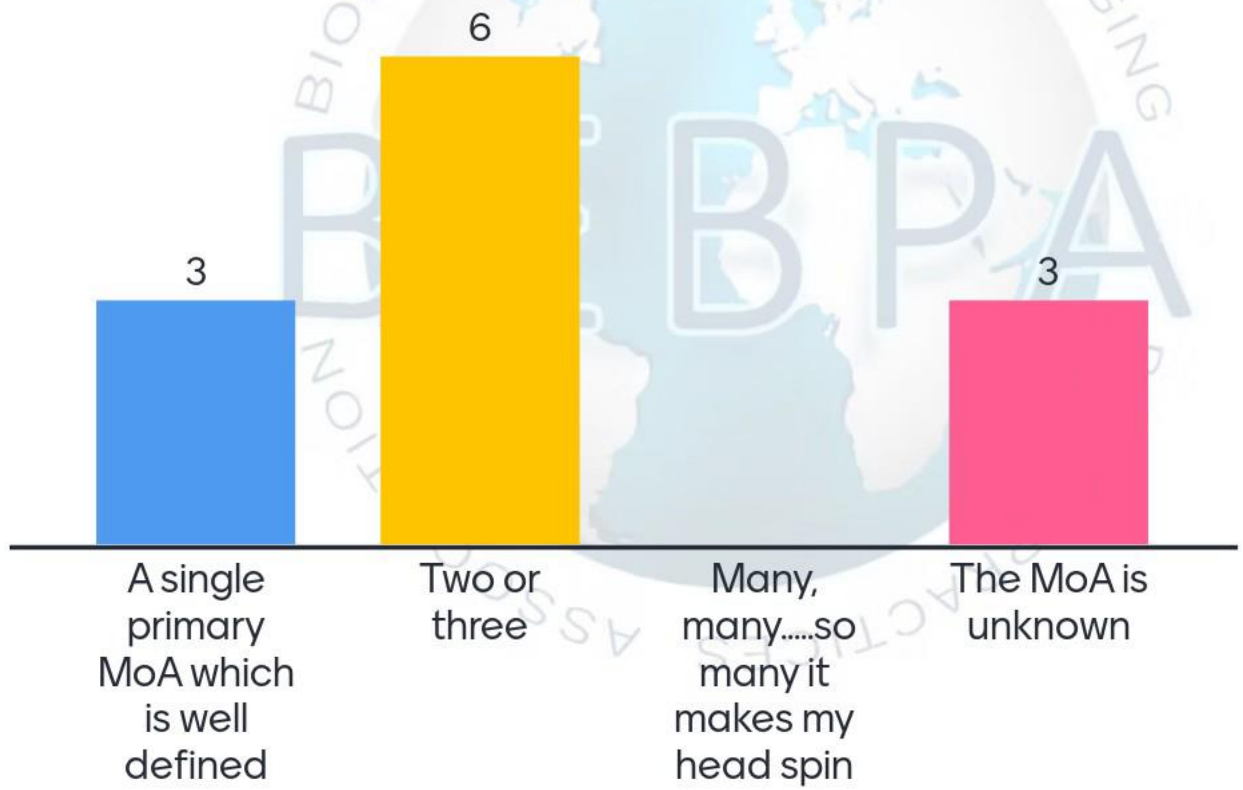
W2.1 What type of products do you work on? (Check all that apply)



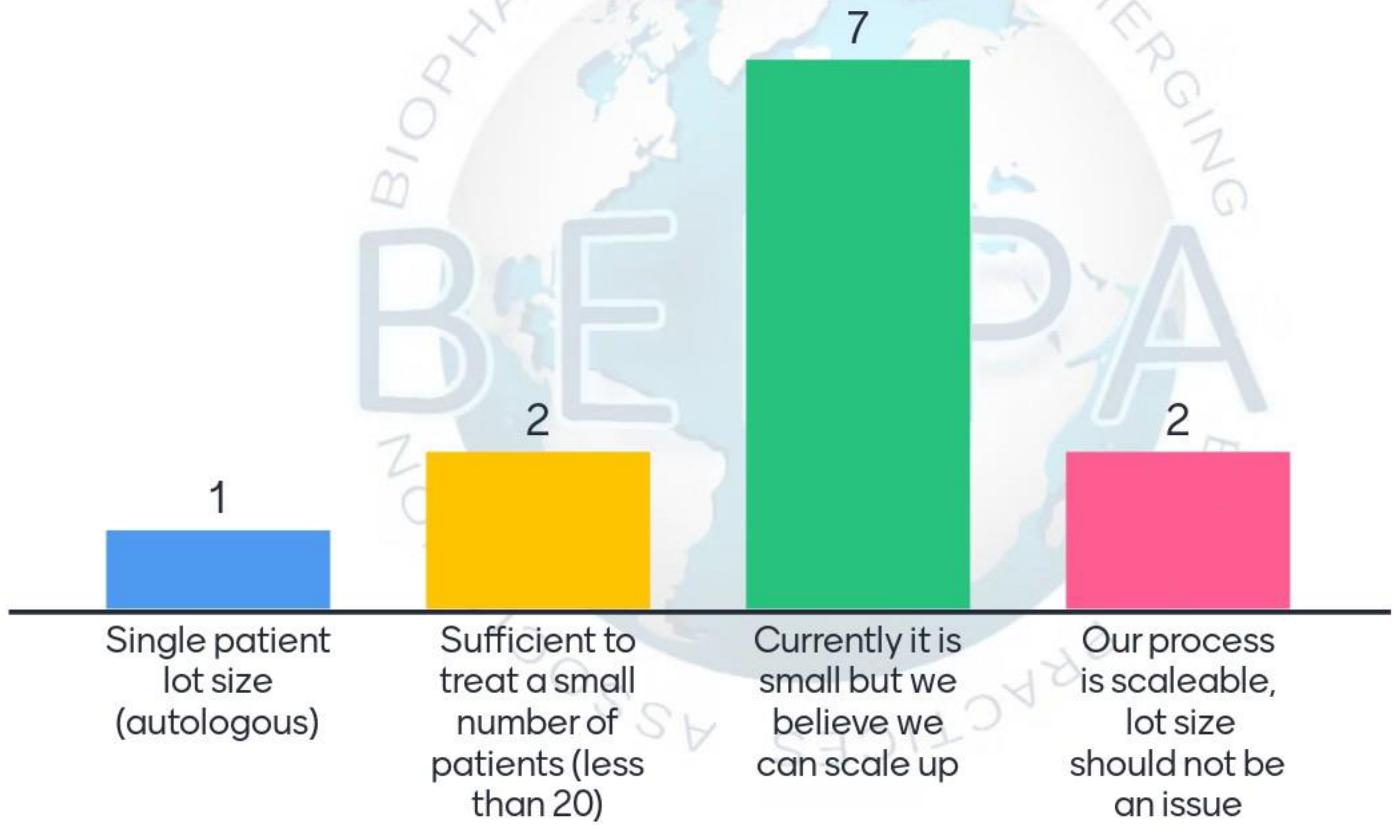
W2.2 What phase of development is the product on which you spend most of your time?



W2.3 How many mechanisms of action are there for the product on which you spend most of your time?



W2.4 Are your batch sizes limited? (Check all that apply)

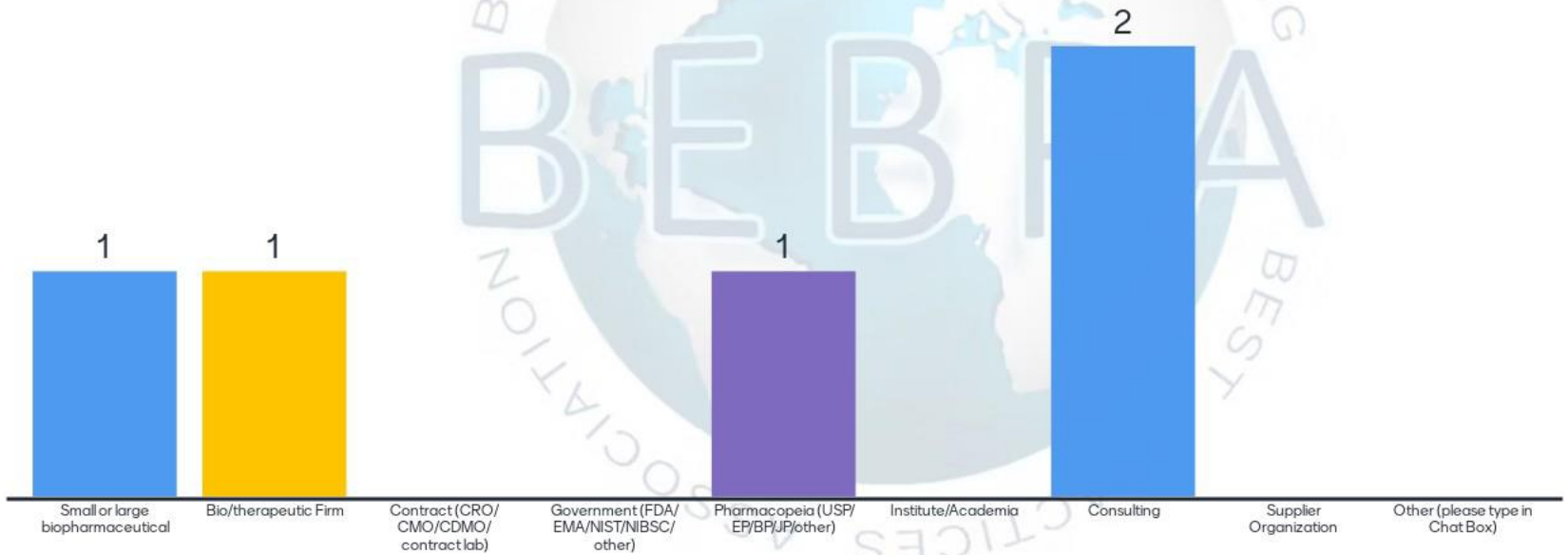


Workshop 3: Biosimilar Reference Standards

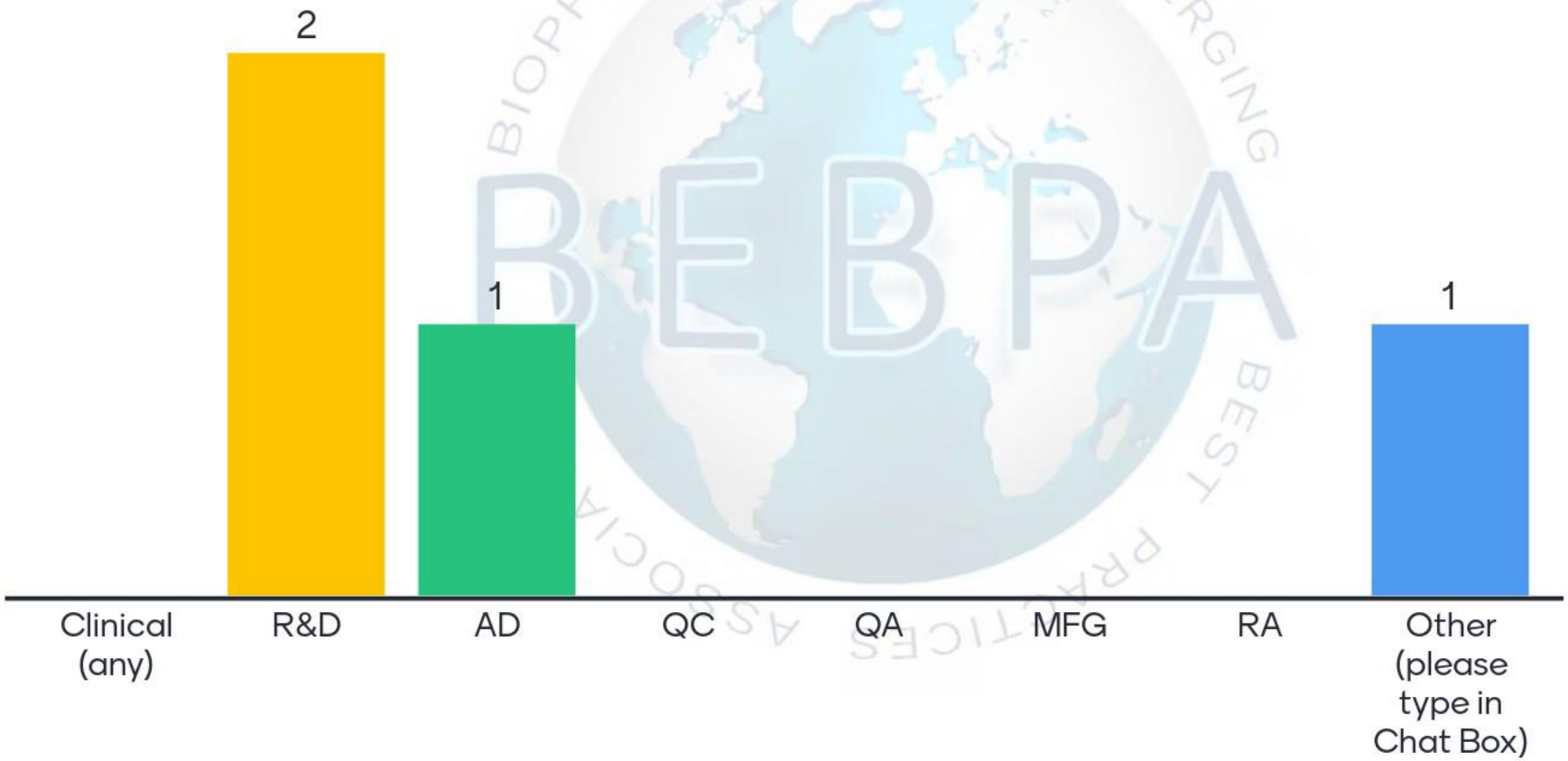
Friday, 28 June 2024
Anton Stetsenko
Principal Consultant
BioQual Consulting

Audience Surveys

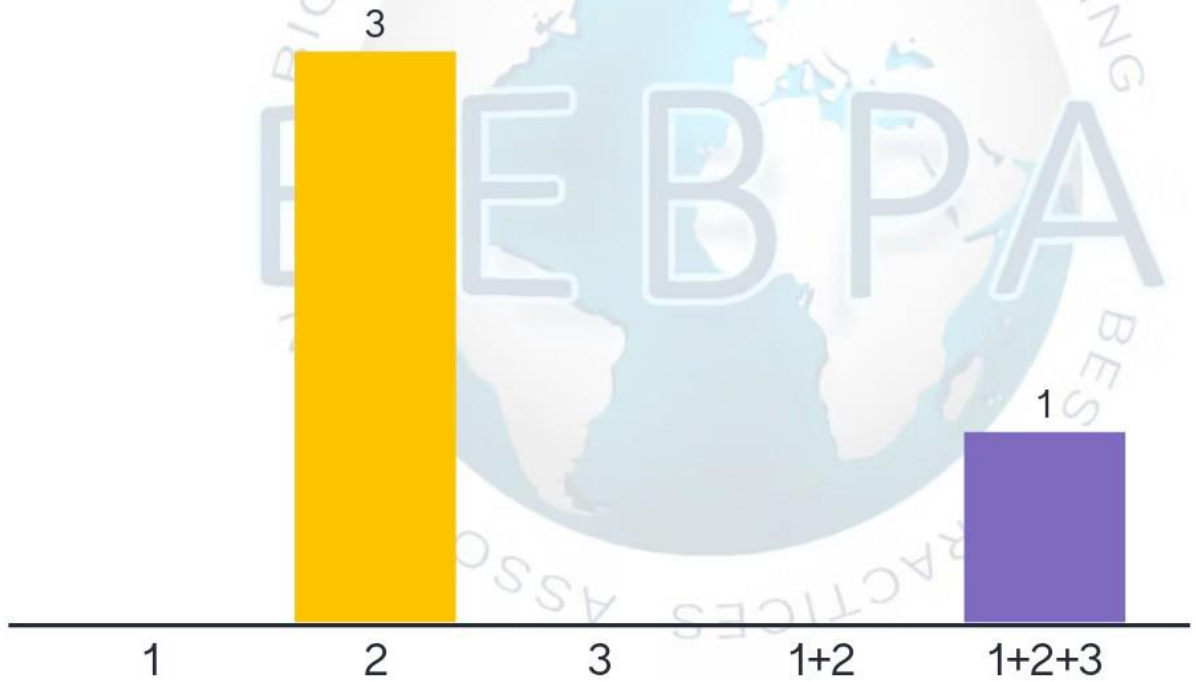
W3.1 What organization do you represent?



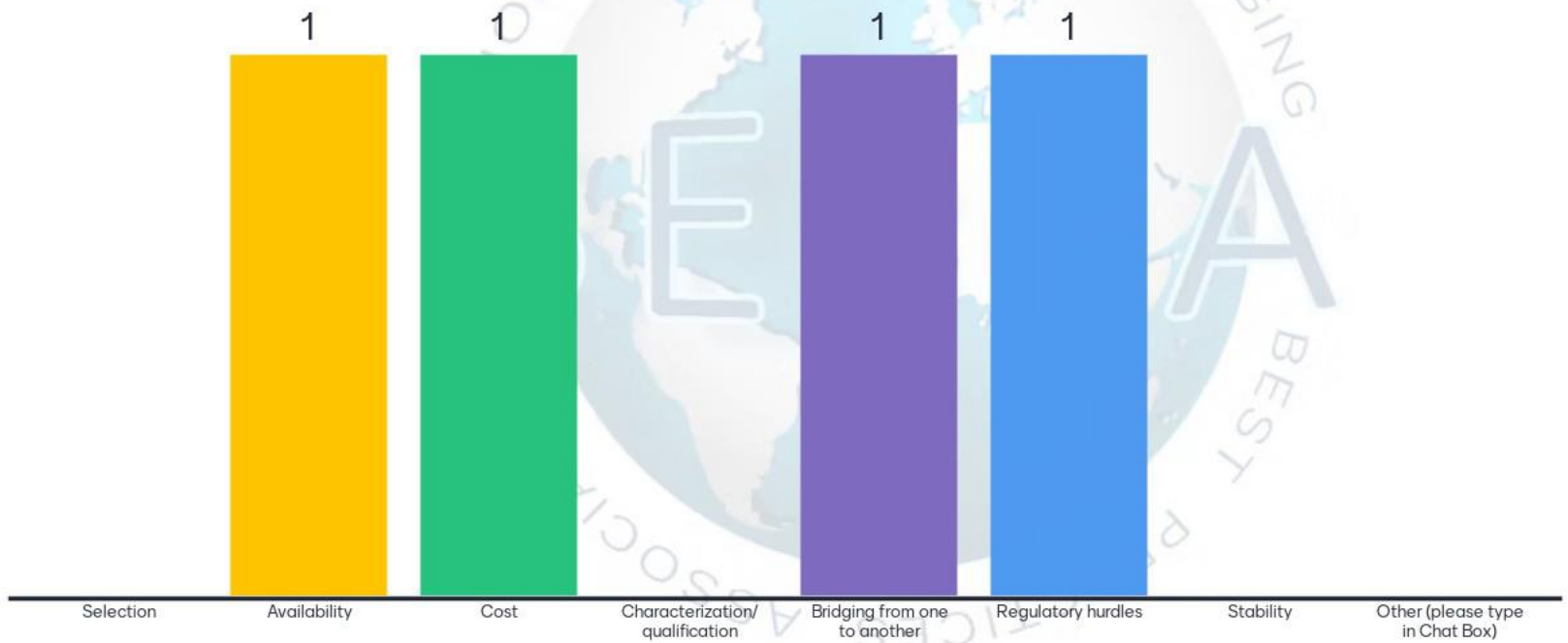
W3.2 What is your primary function?



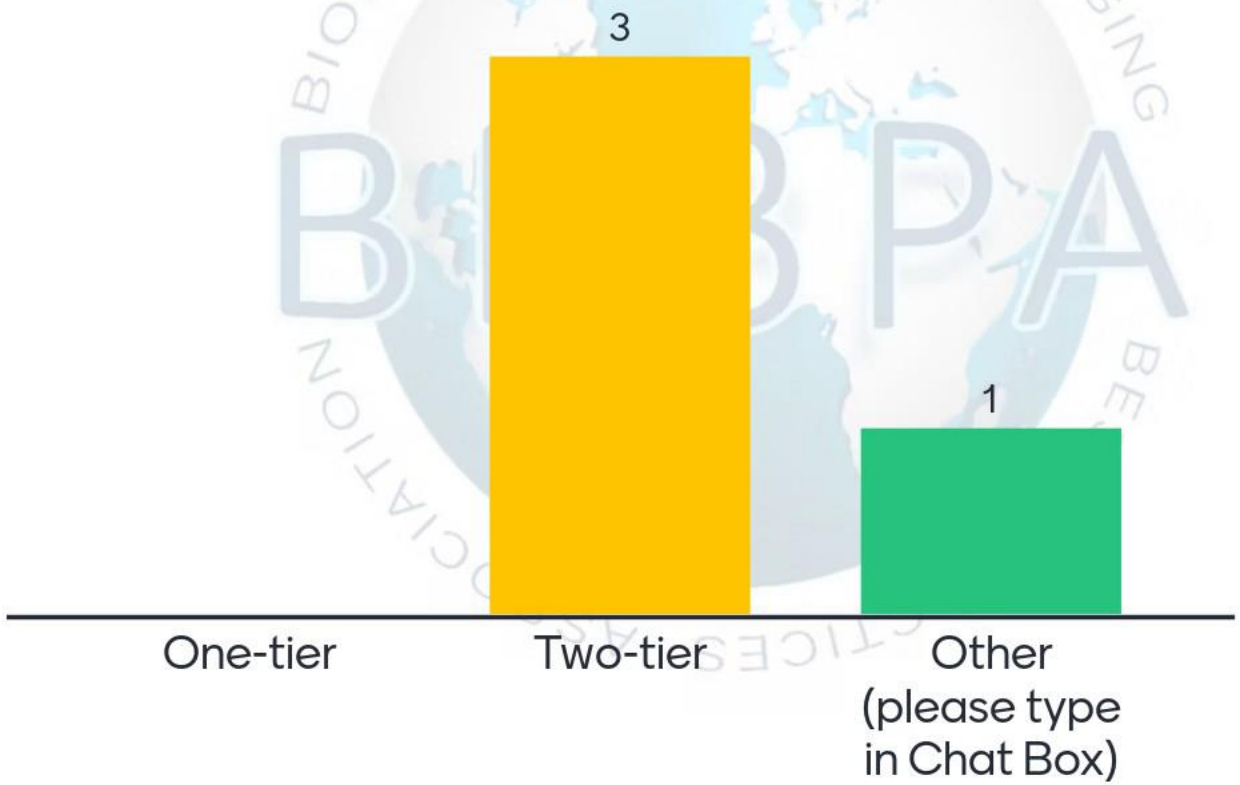
W3.3: Is your biosimilar product(s) a first (1), second (2), next (3) generation biosimilar, or combination?



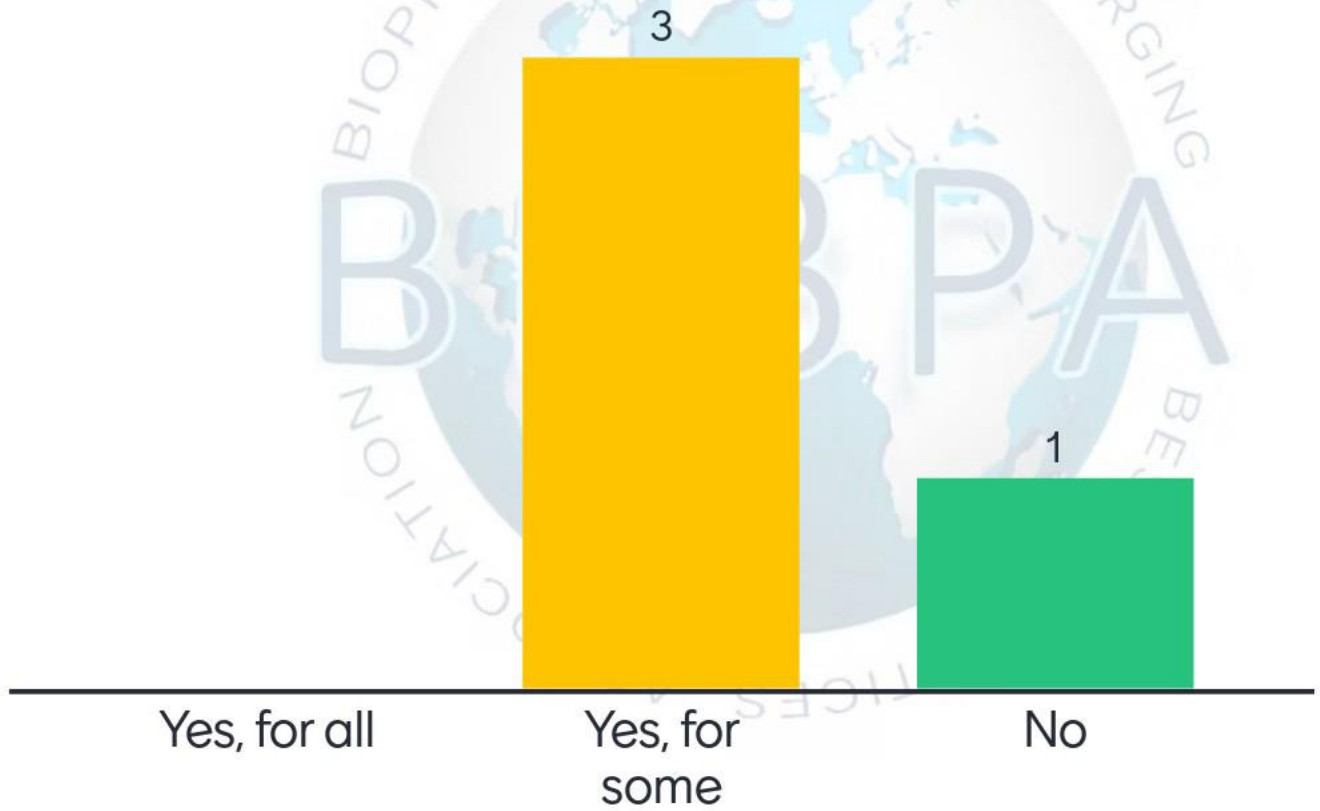
W3.4 What is your biggest challenge related to Reference Standards?



W3.5 What type of Reference Standard program do you currently use?



W3.6 Are you utilizing an official, externally sourced reference standard for your biosimilar product(s)?

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Thank you!!