Reference Material Webinar

BEBPA Free Technical Webinar Series

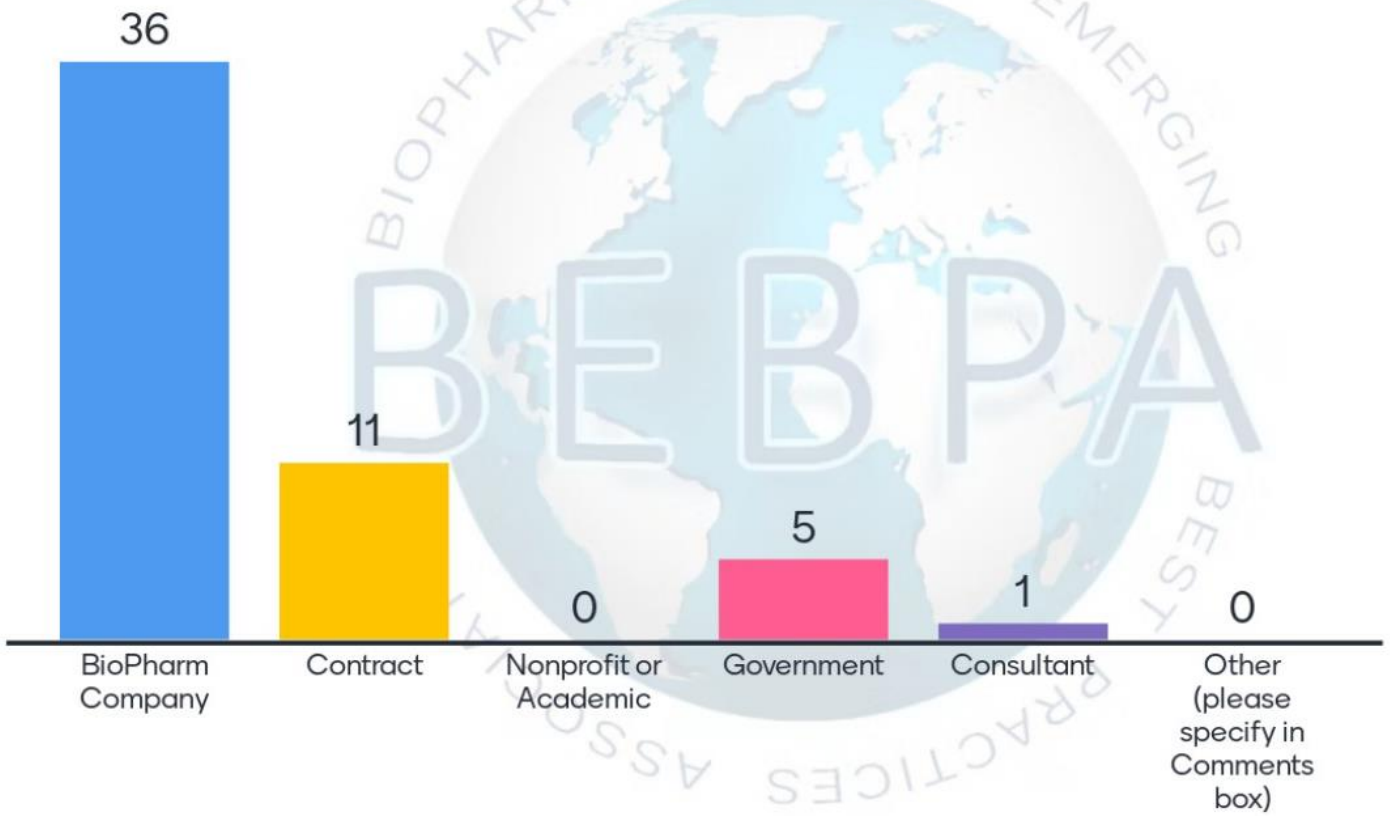
15 November 2023

Welcome & Introduction

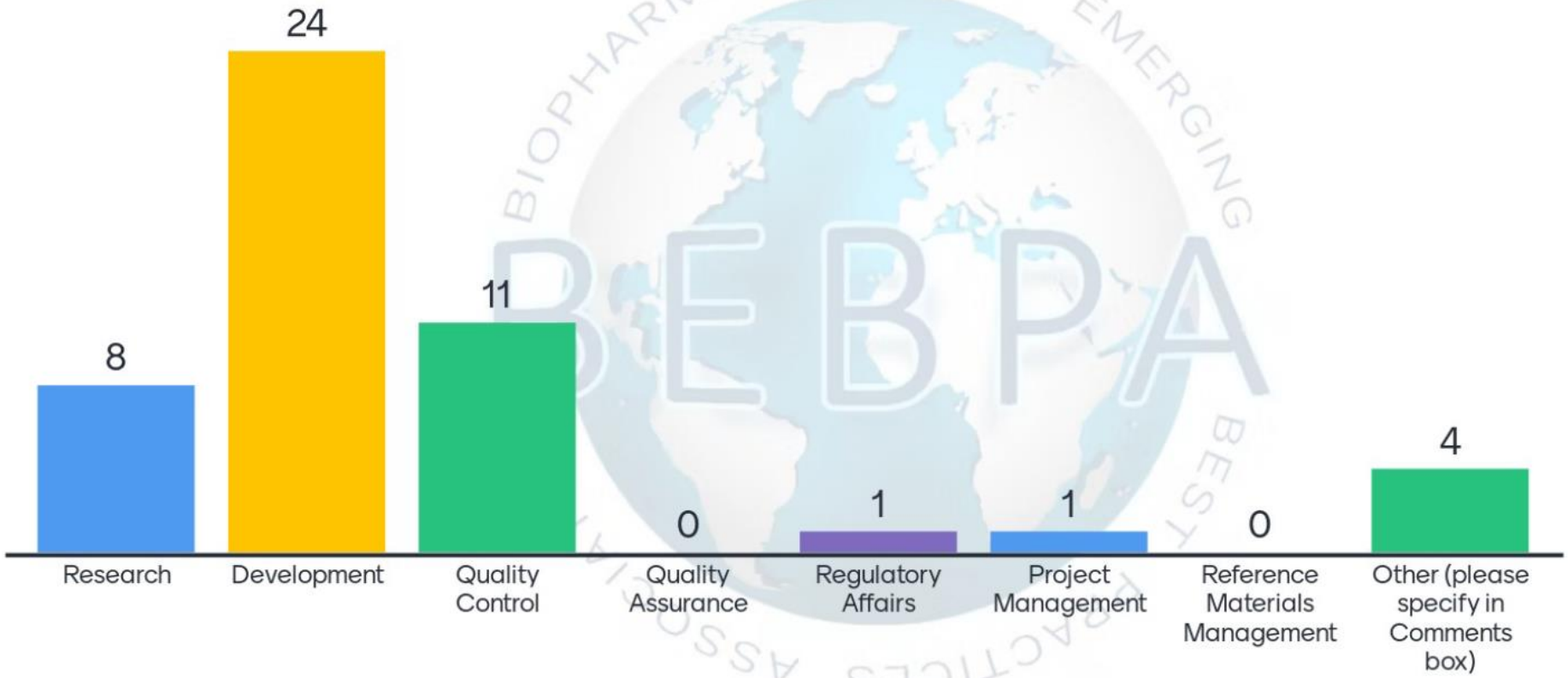
Laureen Little
President
BEBPA

Audience Surveys

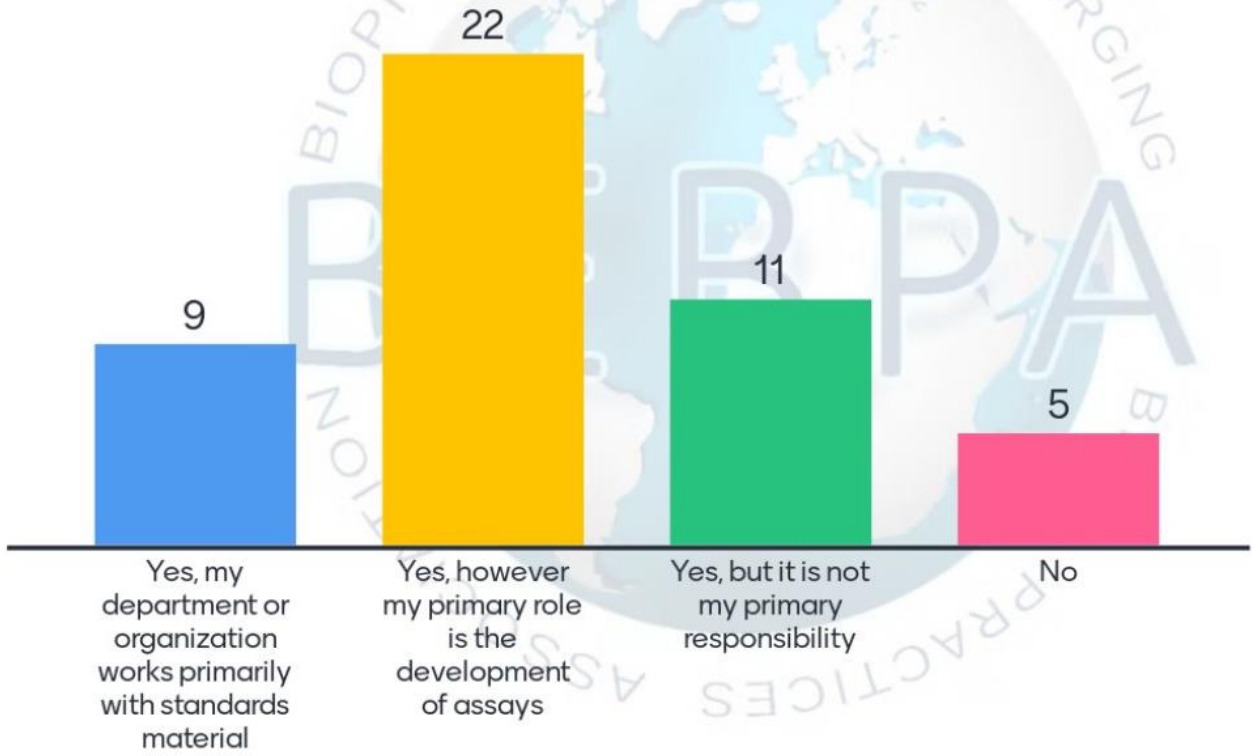
i.1. What type of organization do you work for?



i.2. What part of the organization do you work with?



i.3. Do you work directly with establishing or maintaining Reference Material?

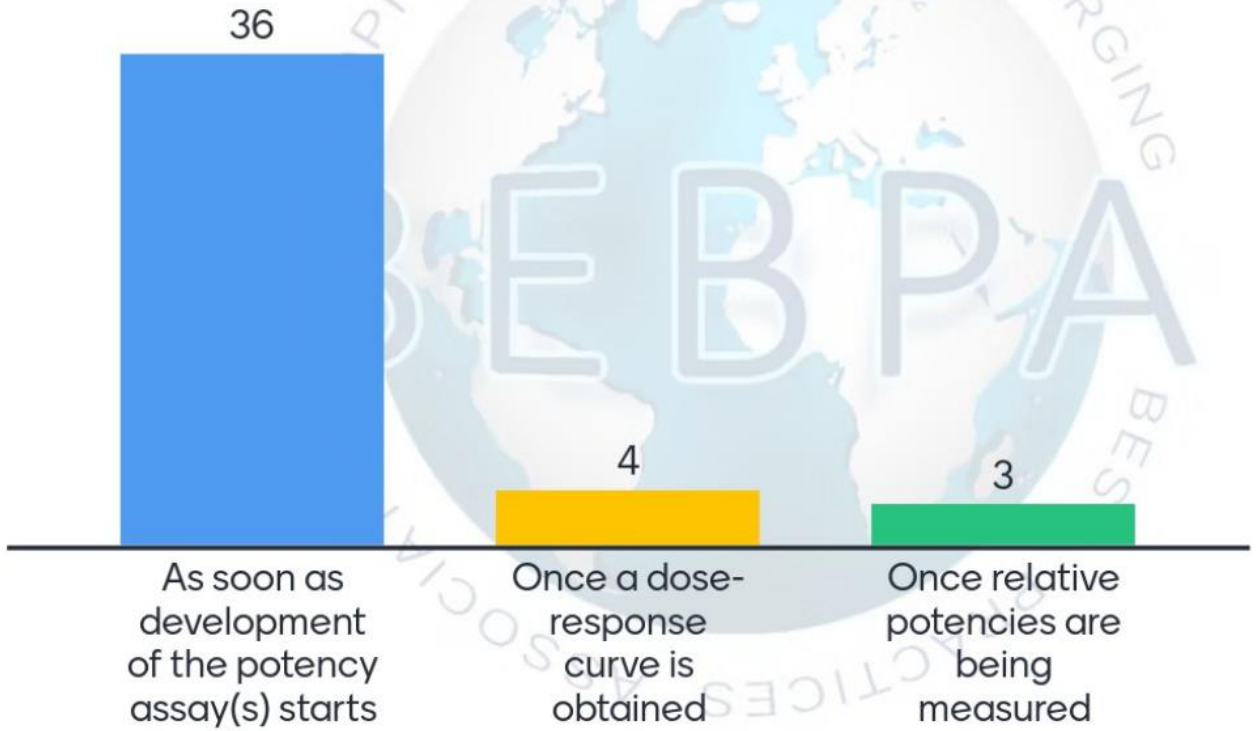


Session 1: Developing a Potency Assay

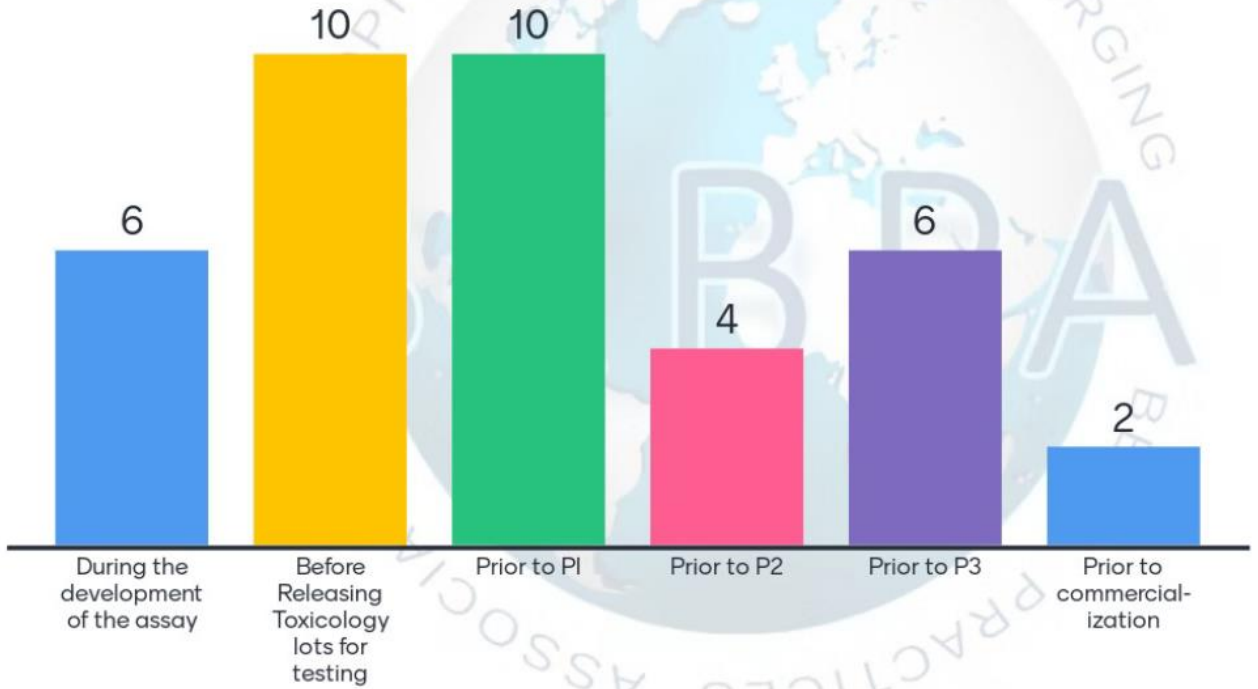
Jane Robinson
BEBPA

Audience Surveys

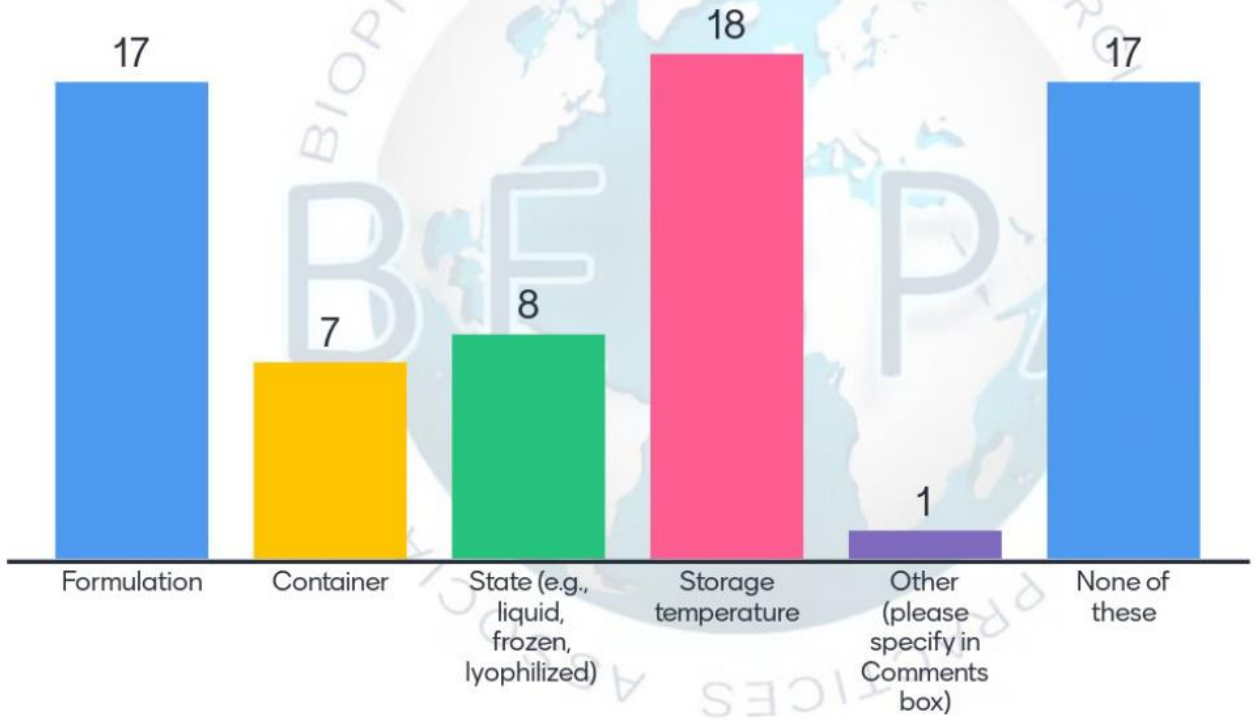
1.1 When do you start the development of a potency reference standard?



1.2 At what point during product development do you typically manufactured your RS under GMPs?



1.3 For your Development Reference Standard, do you routinely investigate optimum:

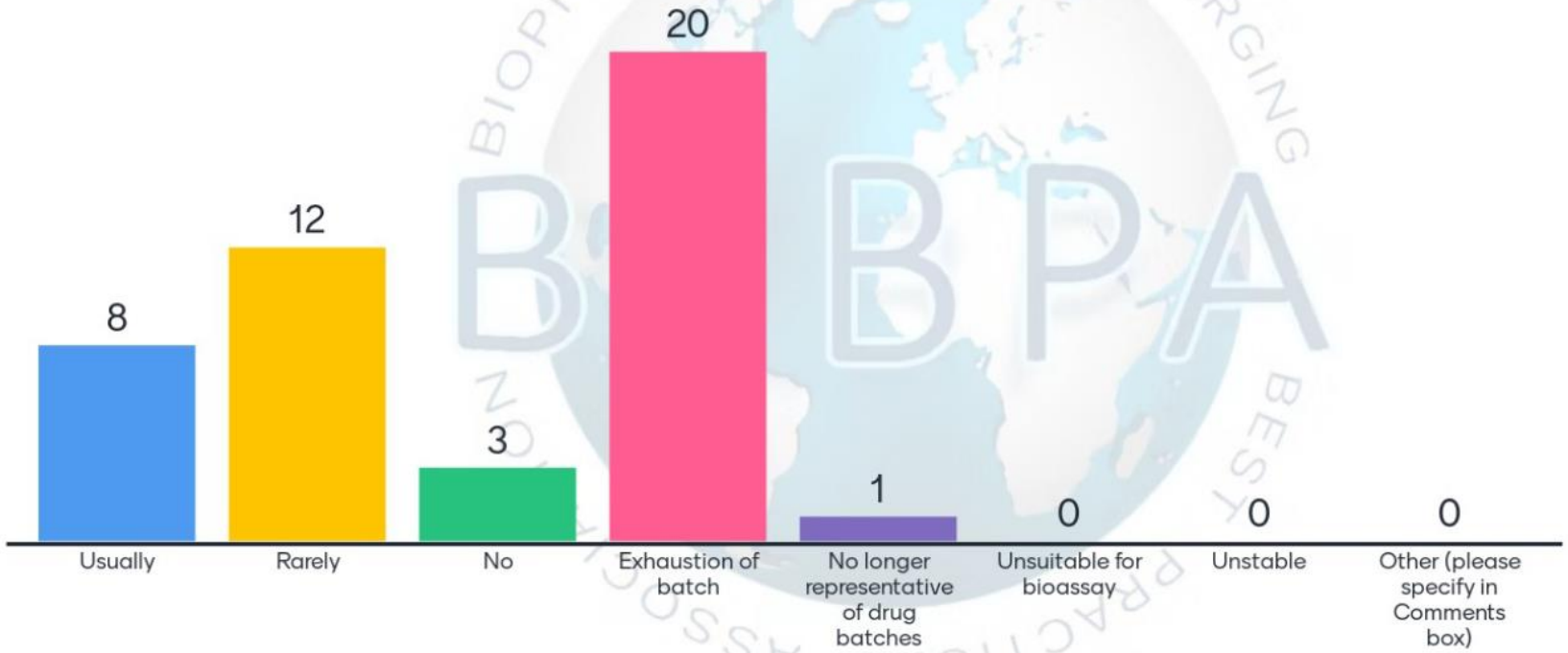


Session 2: Reference Standards During Clinical Studies

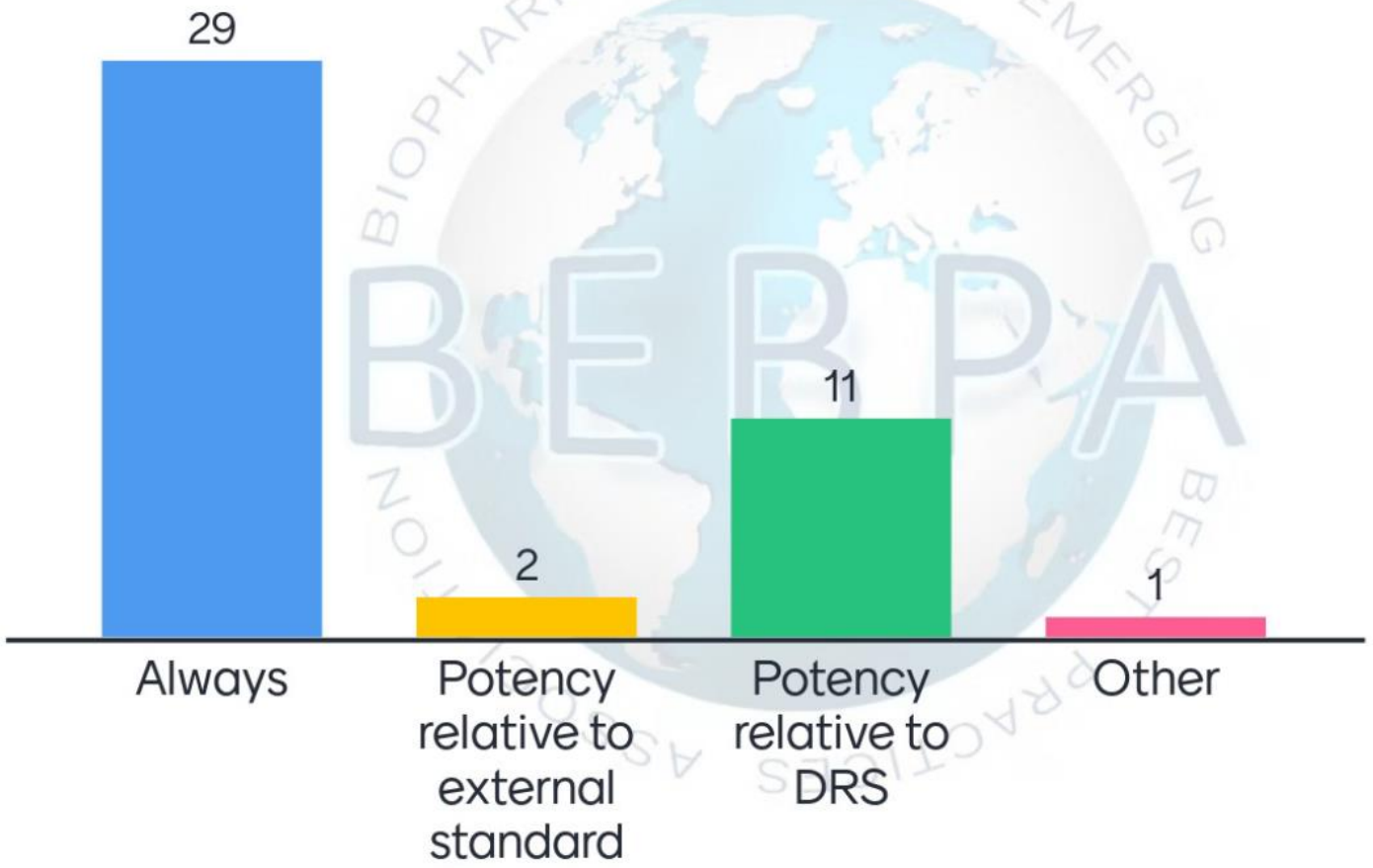
Jane Robinson
BEBPA

Audience Surveys

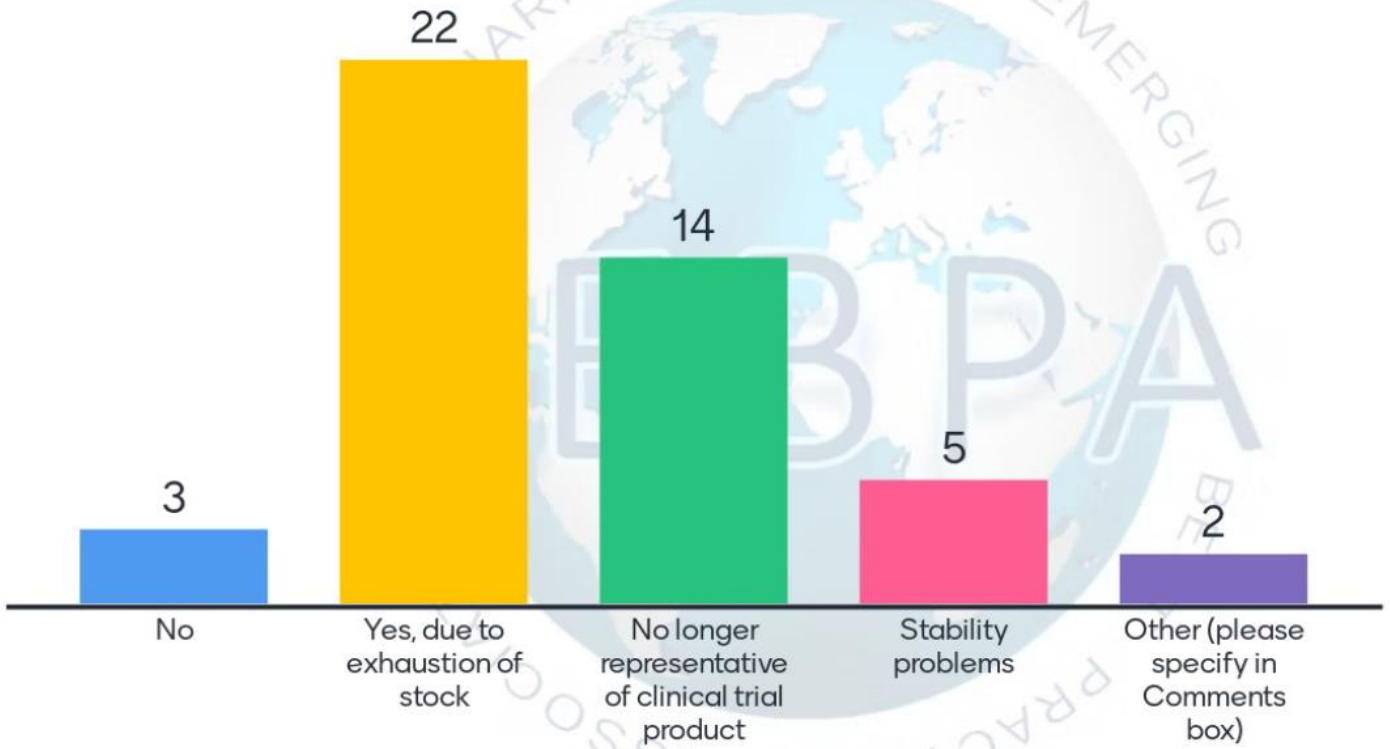
2.1 During method development have you needed to replace the DRS?



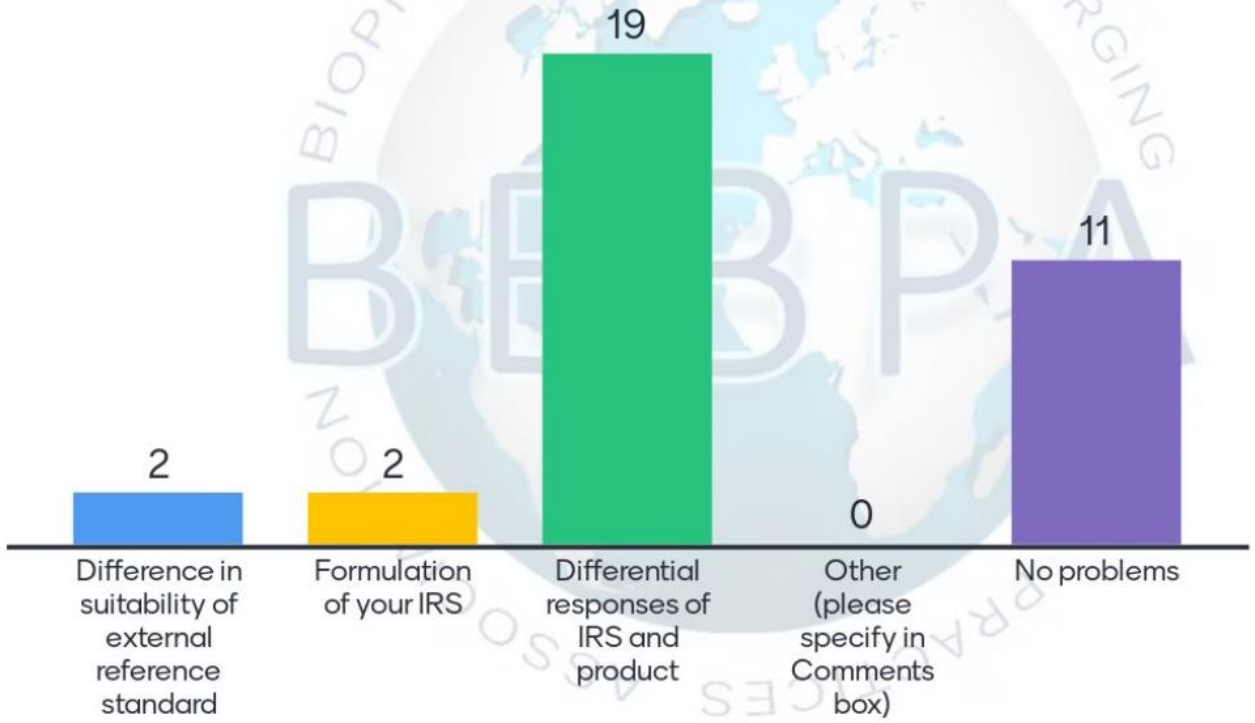
2.2 Do you assign your First IRS 100% potency?



2.3 Have you needed to replace a first IRS?



2.4 If you have made changes to your bioassay(s), have you encountered any problems with:



Session 3: Commercial Reference Standards

Perceval Sondag
Senior Director - Scientific Analytics
Novo Nordisk

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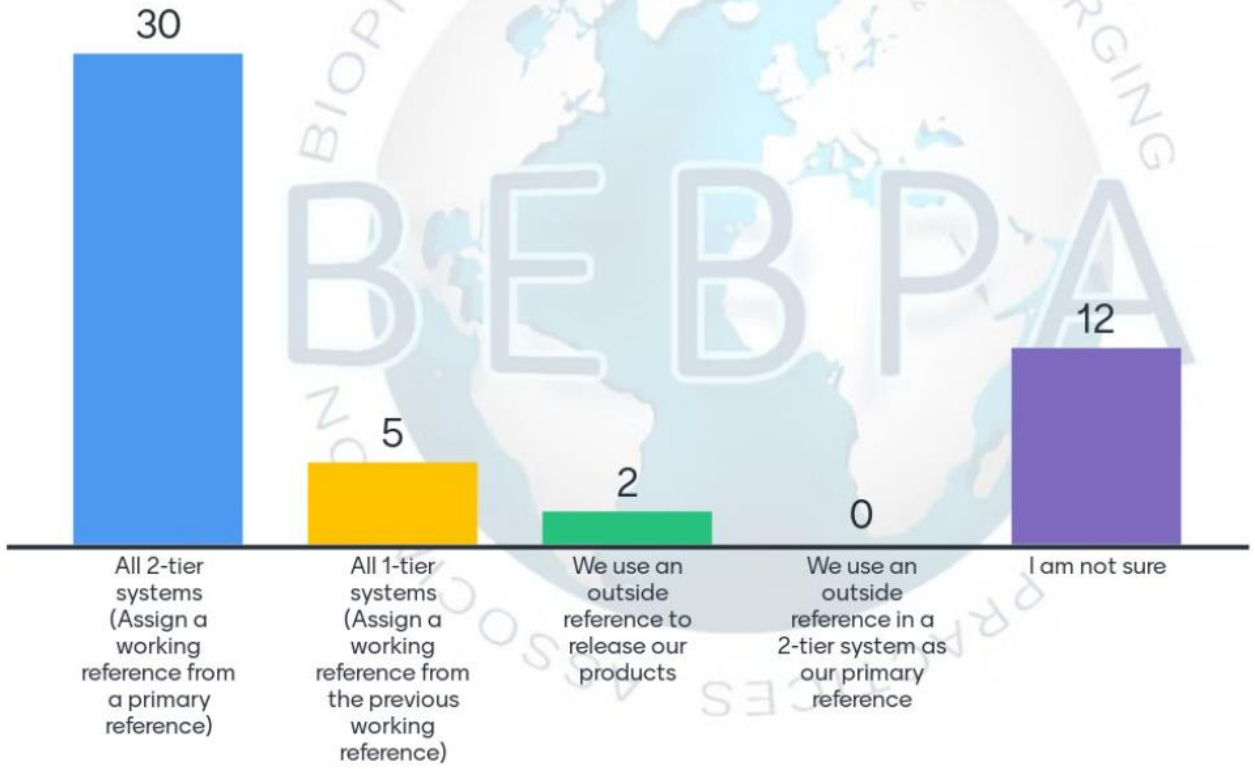
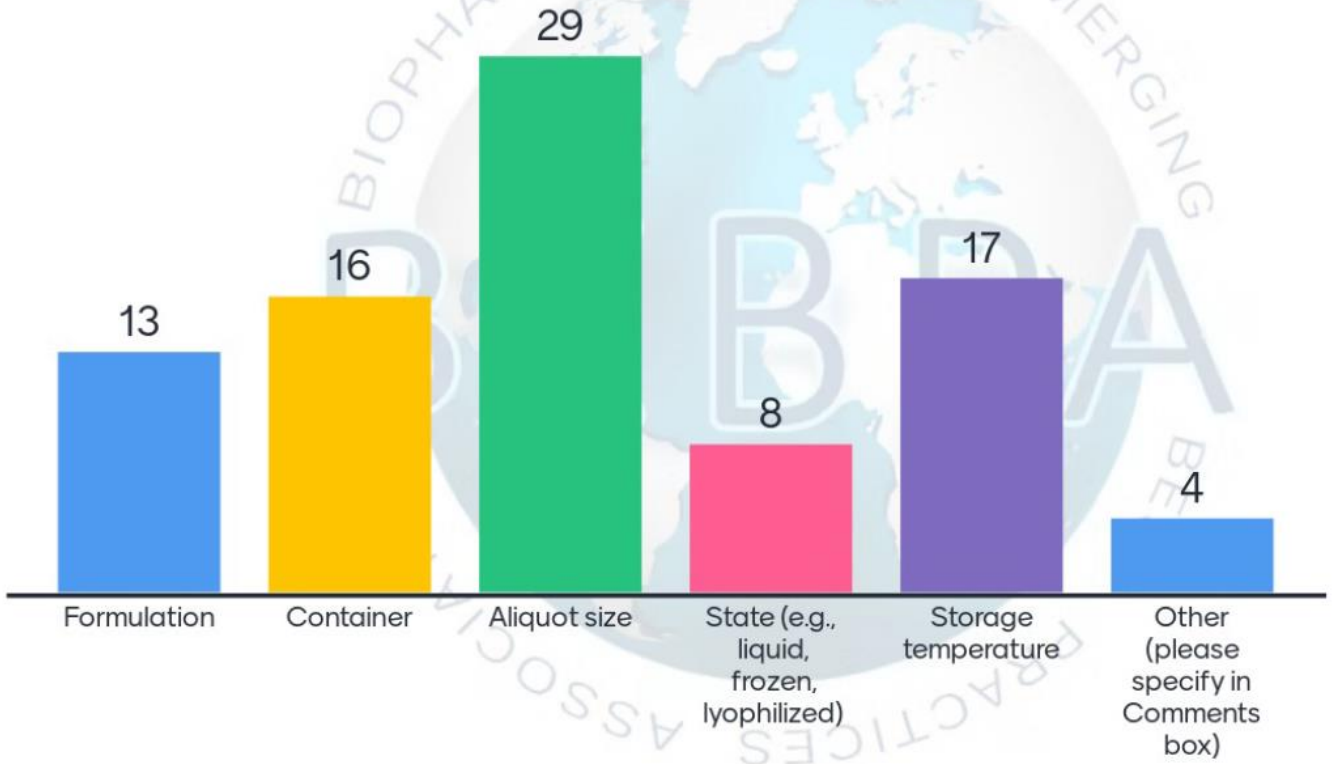
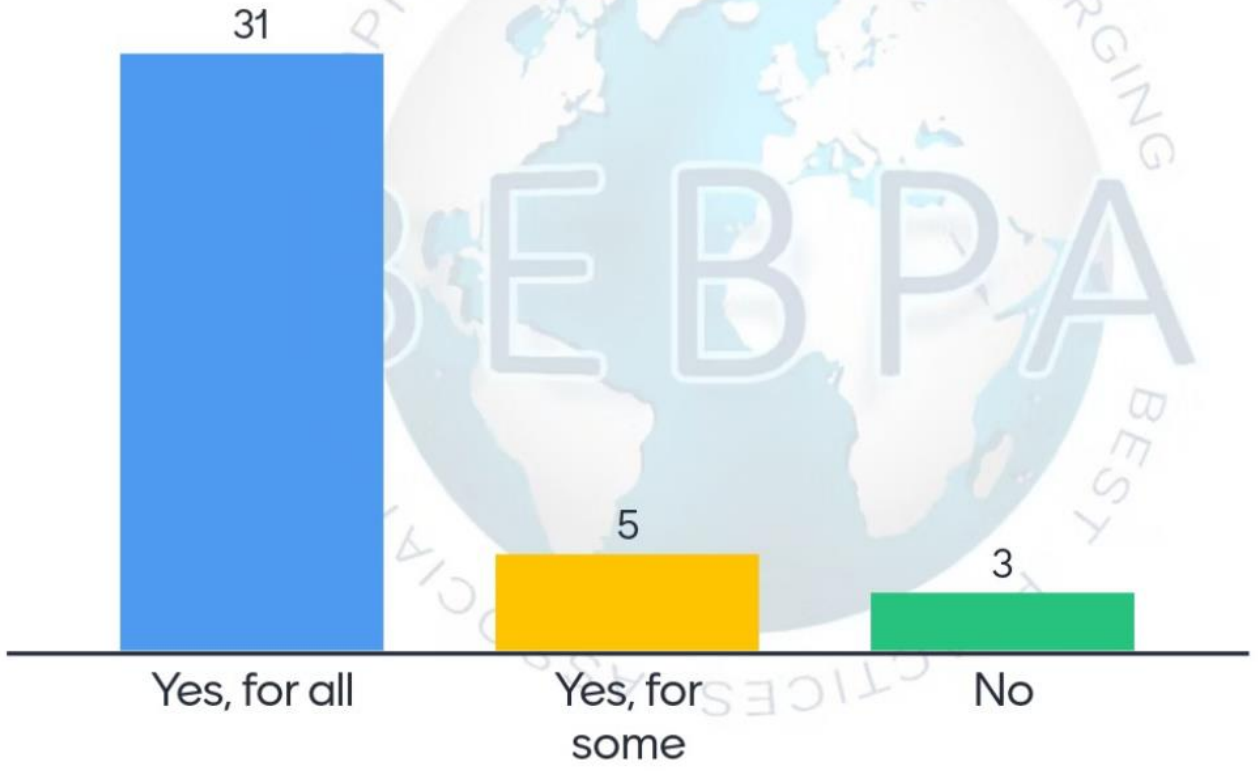
3.1 Is your current RS program system to support commercial products:



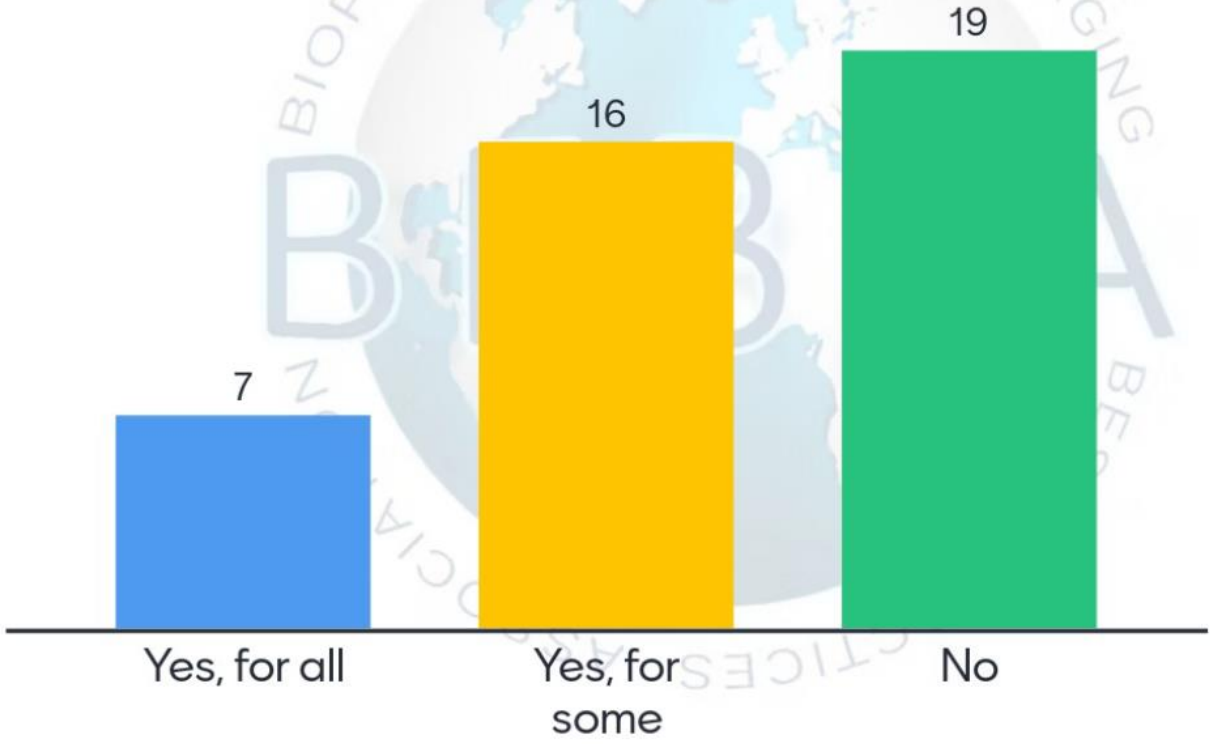
3.2 For any of your products, does your reference standard differ from your drug substance or drug product in



3.3 Do you use the same stock of aliquots of your RS for physico-chemical tests and for bioassays?



3.4 Do you store opened aliquots of your RS for use in further assays?



Session 4: Reference Standards Stability/Biosimilar

Siân Estdale
Head of Scientific Affairs, CTTS
Labcorp

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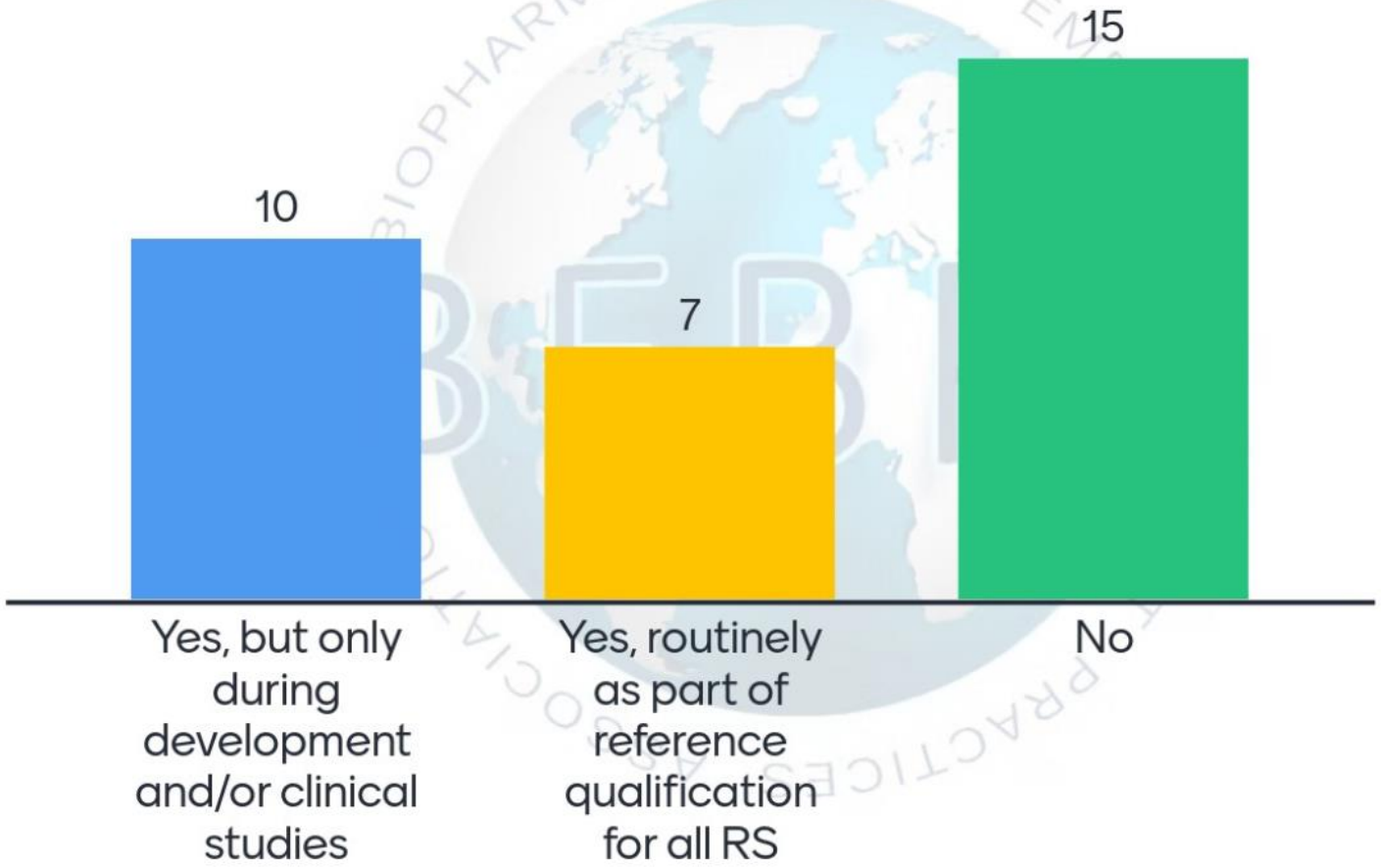
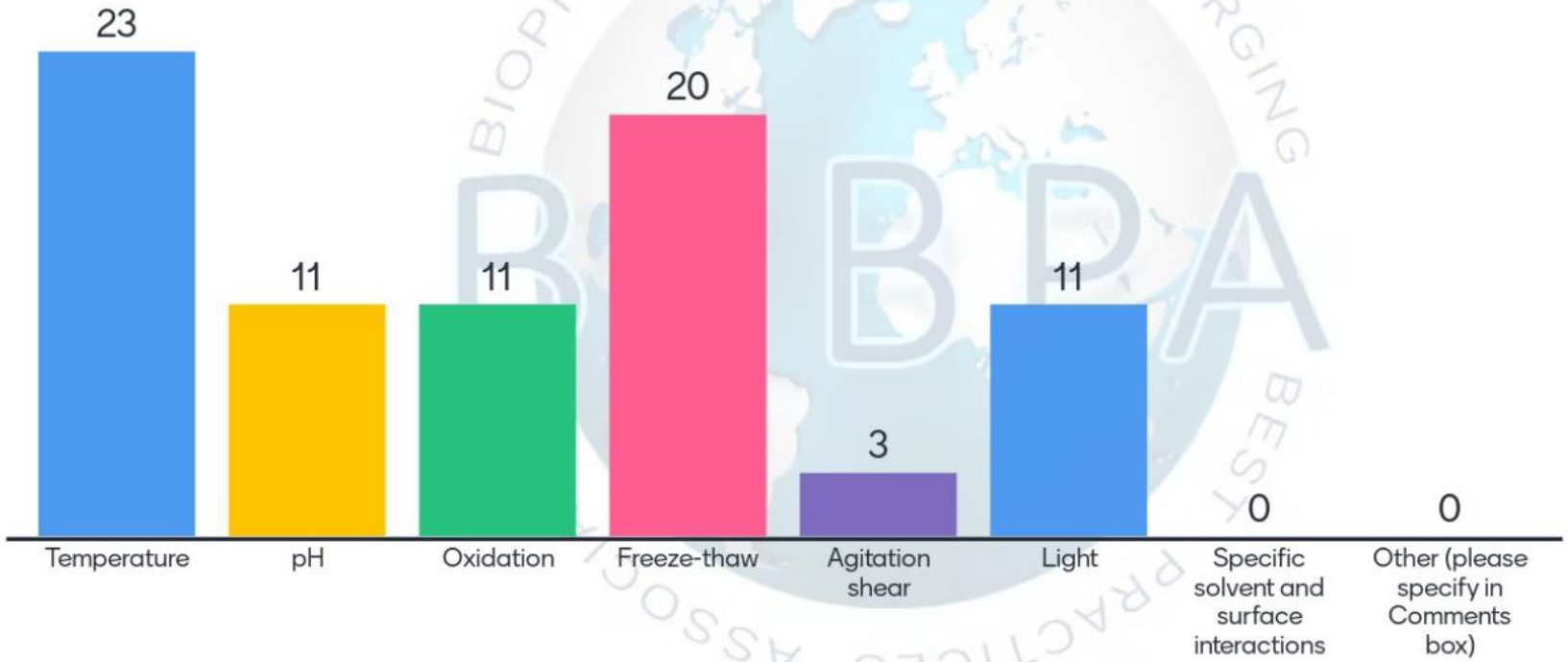
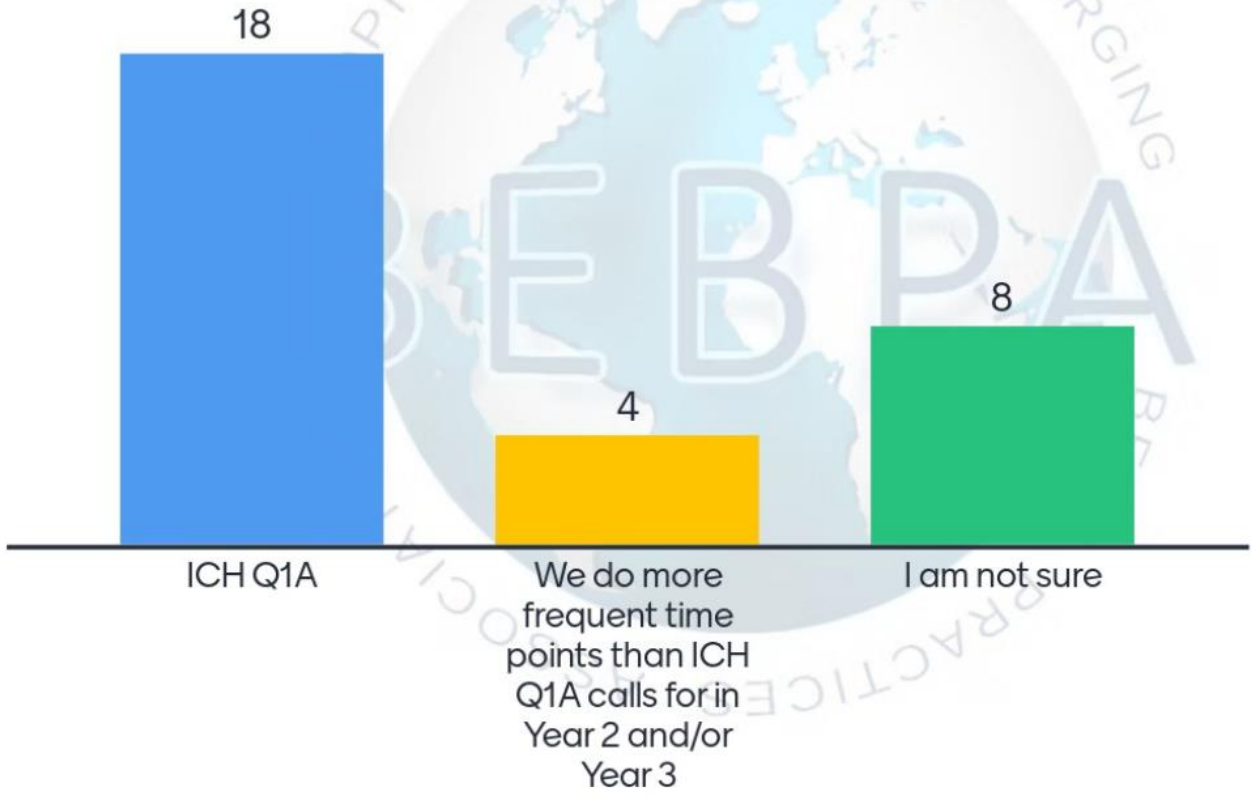
4.1 Do you perform accelerated stability on your RS?



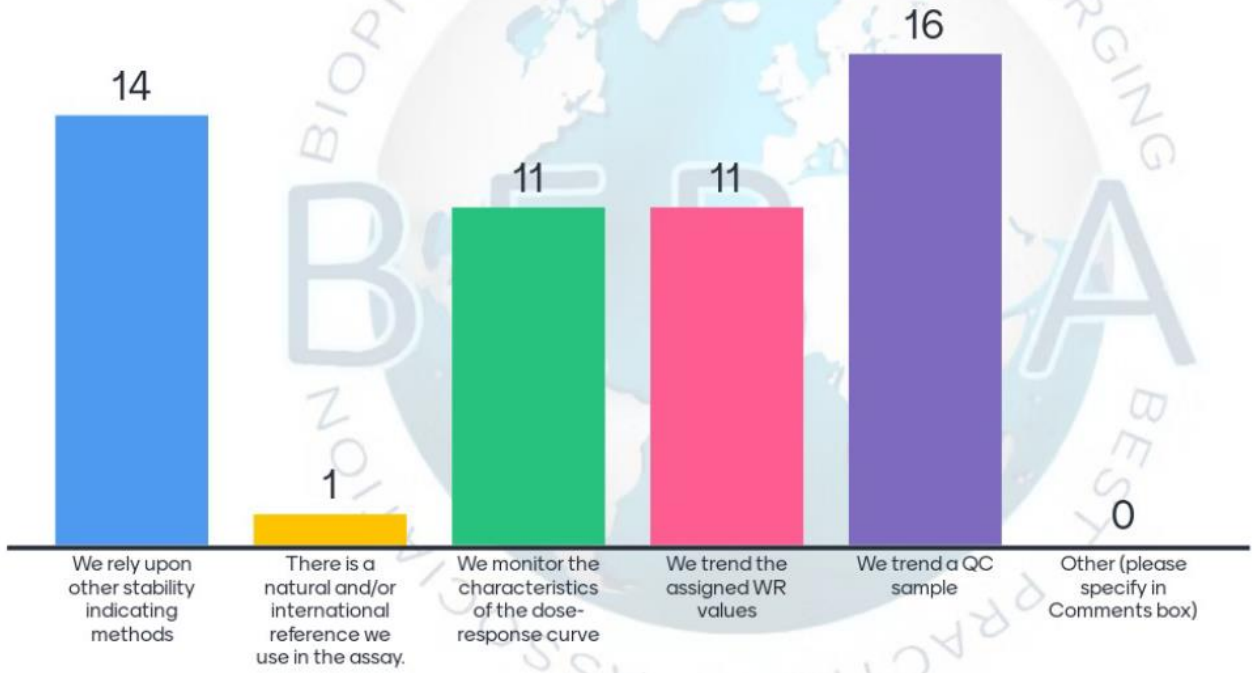
4.2 If you perform accelerated (forced degradation), what type do you usually do?



4.3 What are your real-time stability time points based upon?



4.4 How do you handle assessing stability of the PR if your assay is a relative assay?



Session 5: External References

Laureen Little
President
BEBPA

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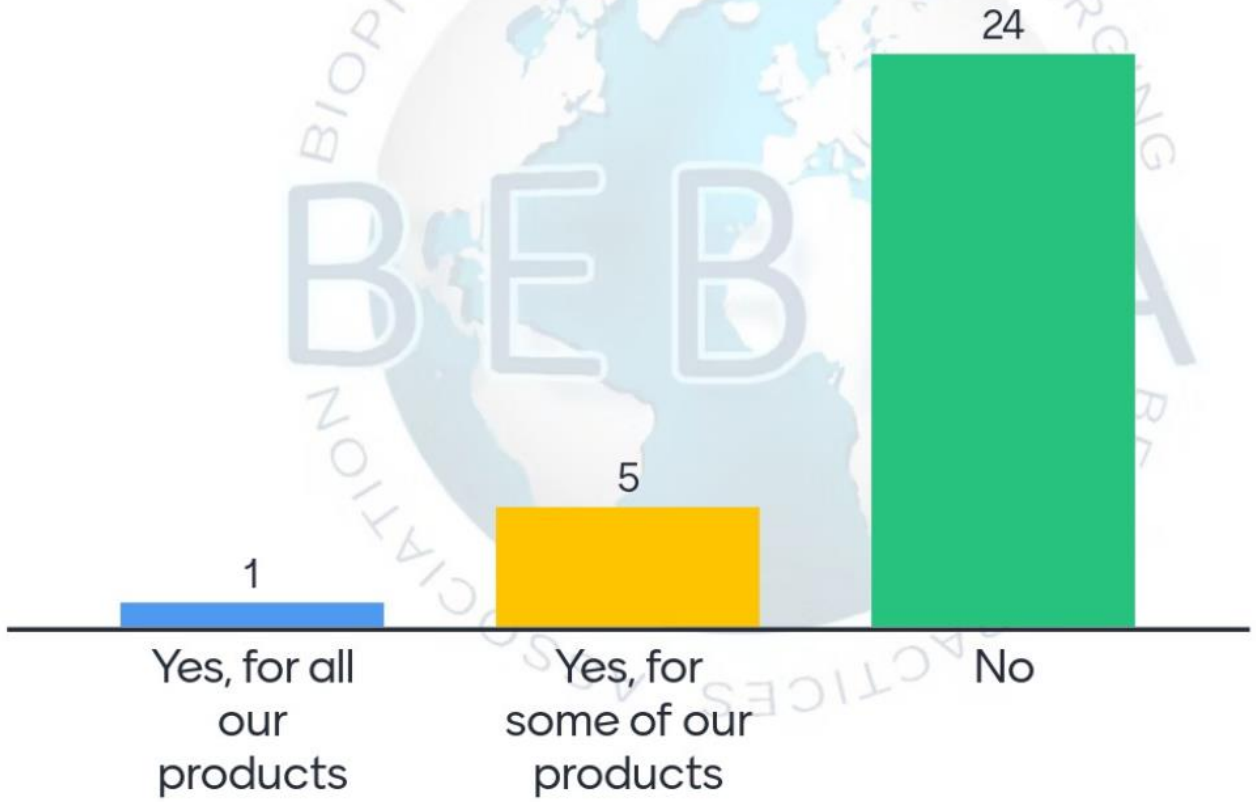
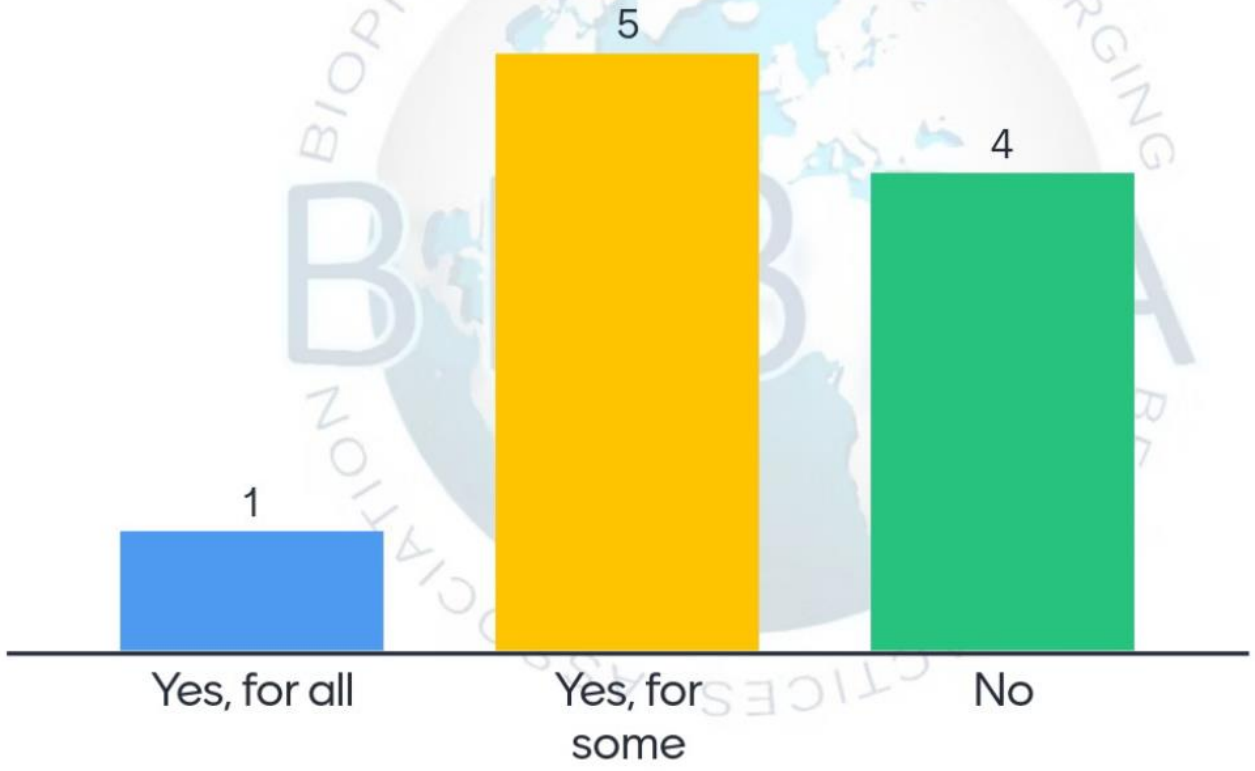
5.1 Is there an official (e.g., WHO, pharmacopeial, national) potency reference standard for your product(s)?



5.2 If there are official potency reference standards for any of your products, are they suitable for use in your bioassays?



Closing Comments

Laureen Little
President
BEBPA

Audience Surveys

6.1 What topics would you like to see included in this or future white papers?

Requalification of primary reference standard, what comparator to use, how to establish alignment with Primary RS is primary is degrading or otherwise unavailable.

Moving to secondary primary reference standards; how to demonstrate comparability, and what happens if the original PRS is no longer suitable for use, or representative of process?

Using method trending as part of requalification

Examples of statistics considerations in sampling size

Some specific attention to Gene And Cell therapy

Bridging and use of reference material in absolute potency assays.

Any parting comments?

Thank you for nice talks

The Session was very informative .Thank you. BEBPA Conference is very informative too but registration fees are too high.

This was fantastic, thank you :)

It was a great conference! Please do it again.Challenges in CBA Aand solutions

Thank you so much!

Thank you. I wonder when you should use a secondary reference, 1) how often do you need to retest the primary reference, 2) do you select the controls on the primary reference? Thank you so much!

5 6

Thank You!!