

Question Details

001

Score: 0%

Responses Received: 48



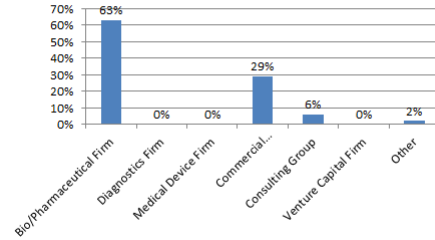
BEBPA 2014: Validation Survey

Question: What type of firm do you work for?

1. Bio/Pharmaceutical Firm
2. Diagnostics Firm
3. Medical Device Firm
4. Commercial Research/Manufacturing/Testing Organization
5. Consulting Group
6. Venture Capital Firm
7. Other

10

What Type of Firm Do You Work for?



002

Score: 0%

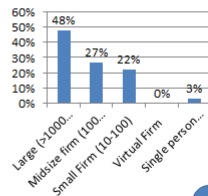
Responses Received: 63



BEBPA 2014: Validation Survey

Question: What size is the firm you work for?

1. Large (>1000 employees)
2. Midsize firm (100 to 1000 employees)
3. Small Firm (10-100)
4. Virtual Firm
5. Single person company



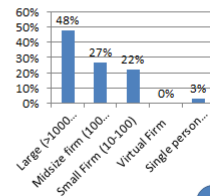
10



BEBPA 2014: Validation Survey

Question: What size is the firm you work for?

1. Large (>1000 employees)
2. Midsize firm (100 to 1000 employees)
3. Small Firm (10-100)
4. Virtual Firm
5. Single person company



10

Question Details

017

Score: 0%

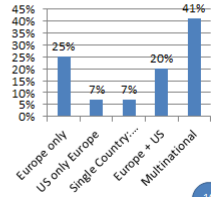
Responses Received: 59



BEBPA 2014: Validation Survey

Where Does Your BioAssay Testing Occur?

1. Europe only
2. US only Europe
3. Single Country: Non Europe /US
4. Europe + US
5. Multinational



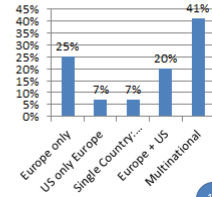
10



BEBPA 2014: Validation Survey

Where Does Your BioAssay Testing Occur?

1. Europe only
2. US only Europe
3. Single Country: Non Europe /US
4. Europe + US
5. Multinational



10

003

Score: 0%

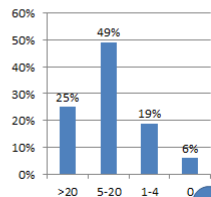
Responses Received: 63



BEBPA 2014: Validation Survey

Question: How many products do you have which require a potency assay?

1. >20
2. 5-20
3. 1-4
4. 0



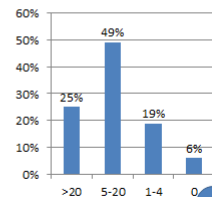
10



BEBPA 2014: Validation Survey

Question: How many products do you have which require a potency assay?

1. >20
2. 5-20
3. 1-4
4. 0



10

Question Details

004

Score: 0%

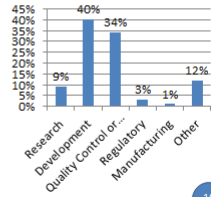
Responses Received: 67



BEBPA 2014: Validation Survey

Question: What part of the organization do you work in?

1. Research
2. Development
3. Quality Control or Quality Assurance
4. Regulatory
5. Manufacturing
6. Other



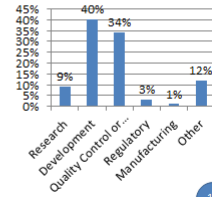
10



BEBPA 2014: Validation Survey

Question: What part of the organization do you work in?

1. Research
2. Development
3. Quality Control or Quality Assurance
4. Regulatory
5. Manufacturing
6. Other



10

008

Score: 0%

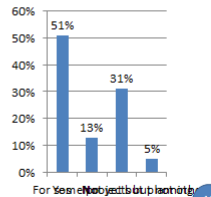
Responses Received: 61



BEBPA 2014: Validation Survey

Question : Do you do formal robustness studies?

1. Yes
2. No
3. For some projects but not others
4. Not yet but planning on it



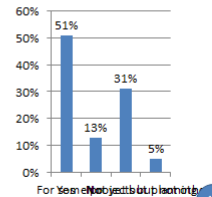
10



BEBPA 2014: Validation Survey

Question : Do you do formal robustness studies?

1. Yes
2. No
3. For some projects but not others
4. Not yet but planning on it



10

Question Details

011

Score: 0%

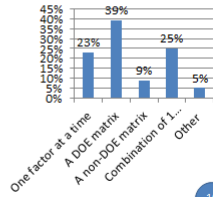
Responses Received: 57



BEBPA 2014: Validation Survey

Question: If you do a formal robustness study, how do you set it up?

1. One factor at a time
2. A DOE matrix
3. A non-DOE matrix
4. Combination of 1 and 2
5. Other



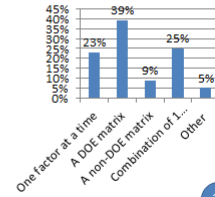
10



BEBPA 2014: Validation Survey

Question: If you do a formal robustness study, how do you set it up?

1. One factor at a time
2. A DOE matrix
3. A non-DOE matrix
4. Combination of 1 and 2
5. Other



10

009

Score: 0%

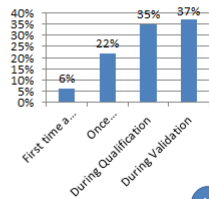
Responses Received: 54



BEBPA 2014: Validation Survey

Question: If you perform formal robustness studies, when do you usually perform them?

1. First time a method is transferred into the laboratory.
2. Once development is completed.
3. During Qualification
4. During Validation



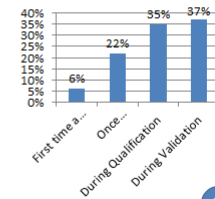
10



BEBPA 2014: Validation Survey

Question: If you perform formal robustness studies, when do you usually perform them?

1. First time a method is transferred into the laboratory.
2. Once development is completed.
3. During Qualification
4. During Validation



10

Question Details

006

Score: 0%

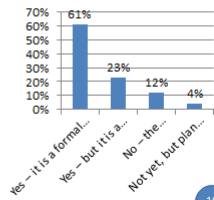
Responses Received: 57



BEBPA 2014: Validation Survey

Question : Do you do a qualification or characterization of the method prior to formal validation?

1. Yes – it is a formal study.
2. Yes – but it is a notebook study
3. No – the validation is the first formal characterization of the method.
4. Not yet, but plan to in the future



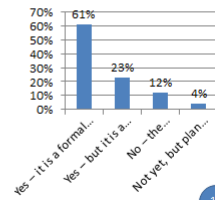
10



BEBPA 2014: Validation Survey

Question : Do you do a qualification or characterization of the method prior to formal validation?

1. Yes – it is a formal study.
2. Yes – but it is a notebook study
3. No – the validation is the first formal characterization of the method.
4. Not yet, but plan to in the future



10

007

Score: 0%

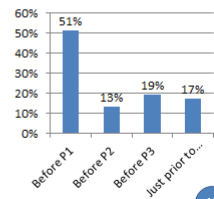
Responses Received: 53



BEBPA 2014: Validation Survey

Question : If you do a formal qualification when do you usually perform it?

1. Before P1
2. Before P2
3. Before P3
4. Just prior to validating the process.



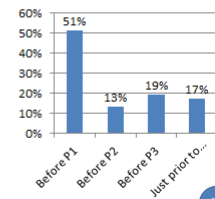
10



BEBPA 2014: Validation Survey

Question : If you do a formal qualification when do you usually perform it?

1. Before P1
2. Before P2
3. Before P3
4. Just prior to validating the process.



10

Question Details

005

Score: 0%

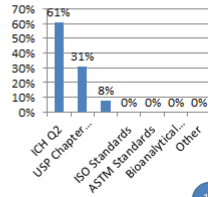
Responses Received: 59



BEBPA 2014: Validation Survey

Question: What is your primary regulatory guidance for validation?

1. ICH Q2
2. USP Chapter <1033>
3. FDA Guidance: 2014 Guidance for Industry: Analytical Procedures and Methods Validation for Drugs and Biologics
4. ISO Standards
5. ASTM Standards
6. Bioanalytical Validation Guidance
7. Other



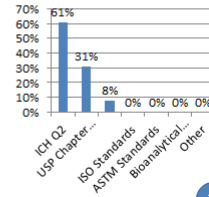
10



BEBPA 2014: Validation Survey

Question: What is your primary regulatory guidance for validation?

1. ICH Q2
2. USP Chapter <1033>
3. FDA Guidance: 2014 Guidance for Industry: Analytical Procedures and Methods Validation for Drugs and Biologics
4. ISO Standards
5. ASTM Standards
6. Bioanalytical Validation Guidance
7. Other



10

019

Score: 0%

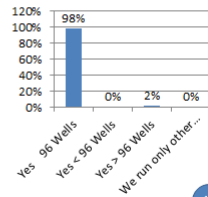
Responses Received: 63



BEBPA 2014: Validation Survey

Question: Are most of your bioassays plate based methods?

1. Yes 96 Wells
2. Yes < 96 Wells
3. Yes > 96 Wells
4. We run only other non-plate based method



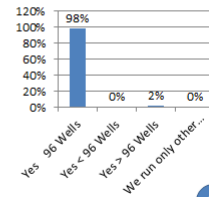
10



BEBPA 2014: Validation Survey

Question: Are most of your bioassays plate based methods?

1. Yes 96 Wells
2. Yes < 96 Wells
3. Yes > 96 Wells
4. We run only other non-plate based method



10

Question Details

016

Score: 0%

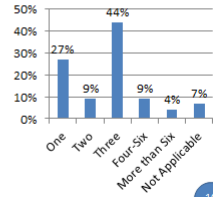
Responses Received: 45



BEBPA 2014 Validation Survey

How many plates do you have to run to get a reportable value for your cell based assay?

1. One
2. Two
3. Three
4. Four-Six
5. More than Six
6. Not Applicable



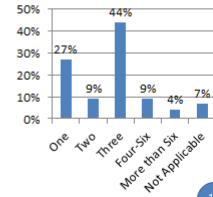
10



BEBPA 2014 Validation Survey

How many plates do you have to run to get a reportable value for your cell based assay?

1. One
2. Two
3. Three
4. Four-Six
5. More than Six
6. Not Applicable



10

018

Score: 0%

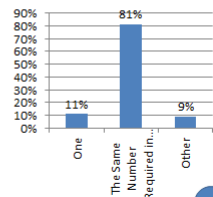
Responses Received: 47



BEBPA 2014: Validation Survey

For assays requiring multiple plates for a reportable value: during validation how many plates do you use for each validation run?

1. One
2. The Same Number Required in the Method Protocol
3. Other



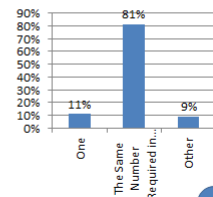
10



BEBPA 2014: Validation Survey

For assays requiring multiple plates for a reportable value: during validation how many plates do you use for each validation run?

1. One
2. The Same Number Required in the Method Protocol
3. Other



10

Question Details

012

Score: 0%

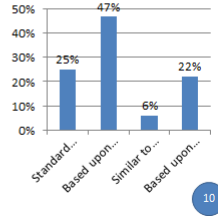
Responses Received: 32



BEBPA 2014: Validation Survey

Question: How do you determine your validation acceptance criteria?

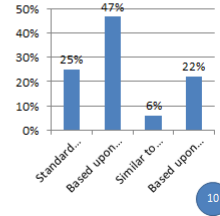
1. Standard requirements used by the company over the past decade
2. Based upon qualification results
3. Similar to specification
4. Based upon method capability vs. product specification calculations



BEBPA 2014: Validation Survey

Question: How do you determine your validation acceptance criteria?

1. Standard requirements used by the company over the past decade
2. Based upon qualification results
3. Similar to specification
4. Based upon method capability vs. product specification calculations



010

Score: 0%

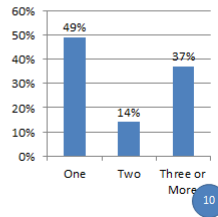
Responses Received: 57



BEBPA 2014: Validation Survey

Question: During the validation, how many lots of sample do you use for validation samples

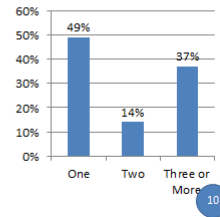
1. One
2. Two
3. Three or More



BEBPA 2014: Validation Survey

Question: During the validation, how many lots of sample do you use for validation samples

1. One
2. Two
3. Three or More



Question Details

013

Score: 0%

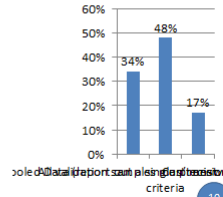
Responses Received: 58



BEBPA 2014: Validation Survey

Question: Do you use pooled data to assess the precision and accuracy of the method? (As discussed in the USP) Or do you require all samples to meet specific criteria

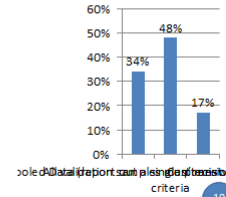
1. Pooled Data (report out a single precision value)
2. All validation samples must meet the specified criteria
3. Can't answer



BEBPA 2014: Validation Survey

Question: Do you use pooled data to assess the precision and accuracy of the method? (As discussed in the USP) Or do you require all samples to meet specific criteria

1. Pooled Data (report out a single precision value)
2. All validation samples must meet the specified criteria
3. Can't answer



015

Score: 0%

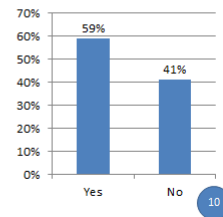
Responses Received: 59



BEBPA 2014: Validation Survey

Question: Do you include the stability indicating characteristics of the method in your validation protocol?

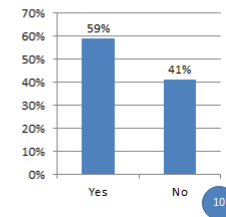
1. Yes
2. No



BEBPA 2014: Validation Survey

Question: Do you include the stability indicating characteristics of the method in your validation protocol?

1. Yes
2. No



Question Details

020

Score: 0%

Responses Received: 59



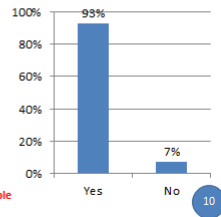
Last Question

Was this fun?

1. Yes
2. No

Thank you all for participating!

Please pass the clickers to the end of the table toward the aisle for collection.



10



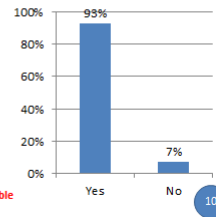
Last Question

Was this fun?

1. Yes
2. No

Thank you all for participating!

Please pass the clickers to the end of the table toward the aisle for collection.



10