Pigeonhole Live

Poll (Multiple Choice)

PV STATS Polling - General 1

09 Sep 2017, 08:00 - 15 Sep 2017, 23:59

45	43	21
Participants	Total votes	Highest vote

Q: Has the issuance of the FDA PV Guidance increased use of statistics in support of PV lifecycle, at your company?

Yes, quite a bit	48.8%	21 Votes
Yes, somewhat	18.6%	8 Votes
Yes, a little	18.6%	8 Votes
No - have historically relied heavily on use of statistics in PV	7%	3 Votes
No	2.3%	1 Vote
N/A	4.7%	2 Votes

0 Comments

No comments

Pigeonhole Live

Poll (Multiple Choice)

PV STATS Polling - General 2

09 Sep 2017, 08:00 - 15 Sep 2017, 23:59

45	44	30
Participants	Total votes	Highest vote

Q: If I had to pick one attitude, statistics in lifecycle process validation in my company is regarded as mostly a

Compliance exercise	31.8%	14 Votes
Opportunity to increase proc. under standing and proc. improvement	68.2%	30 Votes

0 Comments

No comments

Pigeonhole Live

Poll (Multiple Choice)

PV STATS Polling - General 3

09 Sep 2017, 08:00 - 15 Sep 2017, 23:59

46	44	22
Participants	Total votes	Highest vote

Q: How does your firm determine the number of batches/lots to be used for Stage 2 (Process Performance Qualification)?

Use risk assessment incorporating process and platform knowledge	13.6%	6 Votes
Defaulting to 3 with adjustments based on process knowledge	50%	22 Votes
A statistical approach	0%	0 Votes
Defaulting to 3 w/ limited scientific/ statistical justification	36.4%	16 Votes

0 Comments

No comments

Pigeonhole Live

Poll (Multiple Choice)

PV STATS Polling - General 4

09 Sep 2017, 08:00 - 15 Sep 2017, 23:59

41	38	13
Participants	Total votes	Highest vote

Q: Which application of statistics is the most challenging?

Application of DOE in Stage 1	7.9%	3 Votes
Determining the number of lots in S tage 2	13.2%	5 Votes
Determining acceptance criteria in Stage 2	34.2%	13 Votes
Use of Statistical Process Control in Stage 3	23.7%	9 Votes
Evaluating Content Uniformity and Blend Uniformity in Stages 1-3	5.3%	2 Votes
Don't Know	15.8%	6 Votes

0 Comments

No comments

Pigeonhole Live

Poll (Multiple Choice)

PV STATS Polling - General 5

09 Sep 2017, 08:00 - 15 Sep 2017, 23:59

45	38	14
Participants	Total votes	Highest vote

Q: What are greatest obstacles to employing statistical approaches in PV lifecycle?

Use of Risk Assessment in lieu of statistical approach	21.1%	8 Votes
Too many statistical approaches – no clear best practices	28.9%	11 Votes
Not having access to statistical expertise	36.8%	14 Votes
No obstacles	0%	0 Votes
Other	13.2%	5 Votes

1 Comment

Anonymous • 14 Sep 2017 13:30 • Voted for: **Other**

Other: acces to data

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Poll (Multiple Choice)

PV STATS Polling - General 6

09 Sep 2017, 08:00 - 15 Sep 2017, 23:59

46	45	22
Participants	Total votes	Highest vote

Q: Does your firm utilize statistical methods to demonstrate comparability using quality attributes of a drug product for situations such as process changes or licensing of biosimilar/generic products?

Yes	48.9%	22 Votes
Yes, but only for biosimilar/generic product licensing	8.9%	4 Votes
No	22.2%	10 Votes
Don't know	20%	9 Votes

0 Comments

No comments

Pigeonhole Live

Poll (Multiple Choice)

PV STATS Polling - General 7

09 Sep 2017, 08:00 - 15 Sep 2017, 23:59

48	71	27
Participants	Total votes	Highest vote

Q: Which statistics methods do you use for comparability assessments of quality attribute data (select all that apply)?

Equivalence Testing	35.2%	25 Votes
T-Tests	9.9%	7 Votes
Graphical/Visual analysis	38%	27 Votes
Do not use statistical approaches	2.8%	2 Votes
Other	4.2%	3 Votes
Don't know	9.9%	7 Votes

0 Comments

No comments

Pigeonhole Live

Poll (Multiple Choice)

PV STATS Polling - General 8

09 Sep 2017, 08:00 - 15 Sep 2017, 23:59

34	31	18
Participants	Total votes	Highest vote

Q: Are you including statistically based intra-batch (within) variability acceptance criteria in your protocols? (e.g. Tolerance Interval, ASTM 2709)

Yes	58.1%	18 Votes
No	22.6%	7 Votes
No – but planning to implement	12.9%	4 Votes
For drug product but not API/Drug Substance	6.5%	2 Votes
Don't know	0%	0 Votes

0 Comments

No comments

Pigeonhole Live

Poll (Multiple Choice)

PV STATS Polling - General 9

09 Sep 2017, 08:00 - 15 Sep 2017, 23:59

35	35	20
Participants	Total votes	Highest vote

Q: Are you including statistically based inter-batch (between) variability acceptance criteria in your protocols? (e.g. limits on variance estimates, Ppk/Cpk)

Yes	57.1%	20 Votes
No	34.3%	12 Votes
For drug product but not API/Drug Substance	0%	0 Votes
Don't know	8.6%	3 Votes

0 Comments

No comments

Pigeonhole Live

Poll (Multiple Choice)

PV STATS Polling - General 10

09 Sep 2017, 08:00 - 15 Sep 2017, 23:59

38	36	21
Participants	Total votes	Highest vote

Q: Do you incorporate patient impact and higher risk into statistically based acceptance criteria for PPQ?

Yes	58.3%	21 Votes
No	25%	9 Votes
Other	0%	0 Votes
Don't know	16.7%	6 Votes

0 Comments

No comments

Pigeonhole Live

Poll (Multiple Choice)

PV STATS Polling - General 11

09 Sep 2017, 08:00 - 15 Sep 2017, 23:59

36	32	14
Participants	Total votes	Highest vote

Q: After successful validation of the blend uniformity, does your company continue blend sampling during CPV?

Yes	12.5%	4 Votes
No	43.8%	14 Votes
Yes, but not for every lot	15.6%	5 Votes
Yes, if CU for final dosage units impact blend uniformity	0%	0 Votes
Don't know	28.1%	9 Votes

0 Comments

No comments

Pigeonhole Live

Poll (Multiple Choice)

PV STATS Polling - General 12

09 Sep 2017, 08:00 - 15 Sep 2017, 23:59

37	30	11
Participants	Total votes	Highest vote

Q: When do you use statistically based routine release criteria?

Until variability estimates have been established for the process	6.7%	2 Votes
A defined number of batches post PPQ (in Stage 3)	10%	3 Votes
For high risk processes only CQAs	23.3%	7 Votes
We only use compendial/USP testing – no plans to implement	36.7%	11 Votes
Don't know	23.3%	7 Votes

0 Comments

No comments

Pigeonhole Live

Poll (Multiple Choice)

PV STATS Polling - General 13

09 Sep 2017, 08:00 - 15 Sep 2017, 23:59

35	28	14
Participants	Total votes	Highest vote

Q: Do you establish internal release limits (IRLs) to account for long-term degradation over the shelf life? If so, do you use them as part of acceptance criteria during PPQ and CPV?

Use IRLs for PPQ sampling/acceptance criteria	10.7%	3 Votes
Use IRLs for CPV metrics, e.g. process capability	10.7%	3 Votes
Use IRLs in both PPQ and CPV	50%	14 Votes
Use IRLs only in context of commercial product release	10.7%	3 Votes
We do not compute internal release limits.	10.7%	3 Votes
What is an internal release limit?	7.1%	2 Votes

0 Comments

No comments

Pigeonhole Live

Poll (Multiple Choice)

PV STATS Polling - General 14

09 Sep 2017, 08:00 - 15 Sep 2017, 23:59

36	34	13
Participants	Total votes	Highest vote

Q: What is the current state for Continuous Manufacturing within your organization?

Currently have validated continuous manufacturing (CM) processes	20.6%	7 Votes
Will have validated CM in the next 6 months to 1 year	14.7%	5 Votes
Will have validated CM in the next 2 to 3 years	11.8%	4 Votes
We are not currently pursuing CM	38.2%	13 Votes
Don't know	14.7%	5 Votes

0 Comments

No comments

Pigeonhole Live

Poll (Multiple Choice)

PV STATS Polling - General 15

09 Sep 2017, 08:00 - 15 Sep 2017, 23:59

38	35	11
Participants	Total votes	Highest vote

Q: Do you utilize a QbD/Lifecycle approach to Analytical Method Development and Validation?

Yes	31.4%	11 Votes
No	28.6%	10 Votes
Plan to implement	20%	7 Votes
Don't know	20%	7 Votes

0 Comments

No comments