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National Validation Forum II

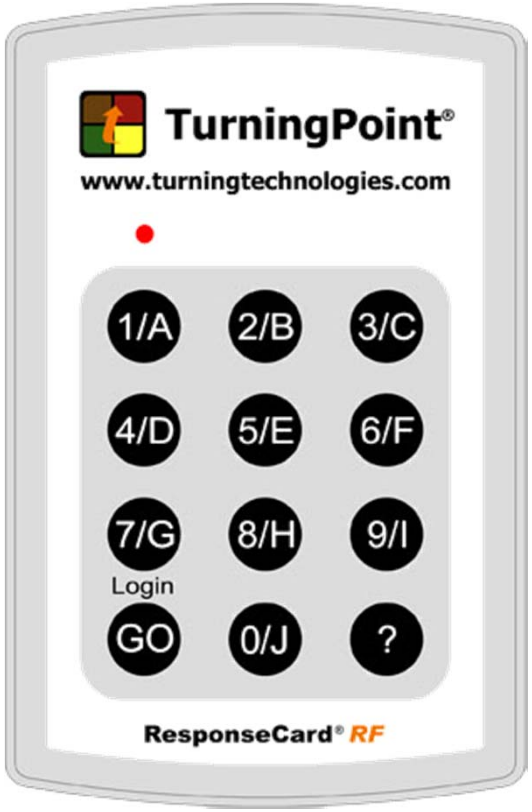
Keepad Questions

How to use the Keypads

1. Choose your response from the corresponding keypad button.

2. The light will go GREEN to confirm your response has been received.

3. You can change your answer (whilst voting is open) simply by pressing your new response button.



(The system will only count the last vote unless the question requires more than one response)

Note: Your response is completely anonymous

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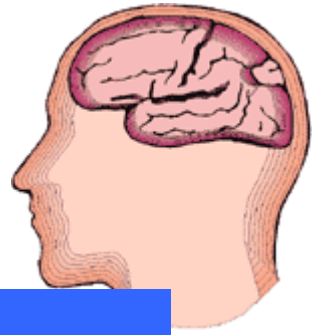
Count every " F "in the following text:

FINISHED FILES ARE THE RE
SULT OF YEARS OF SCIENTI
FIC STUDY COMBINED WITH
THE EXPERIENCE OF YEARS...

33%	1. Three
5%	2. Four
12%	3. Five
42% ✓	4. Six
8%	5. Seven



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Forum Demographics

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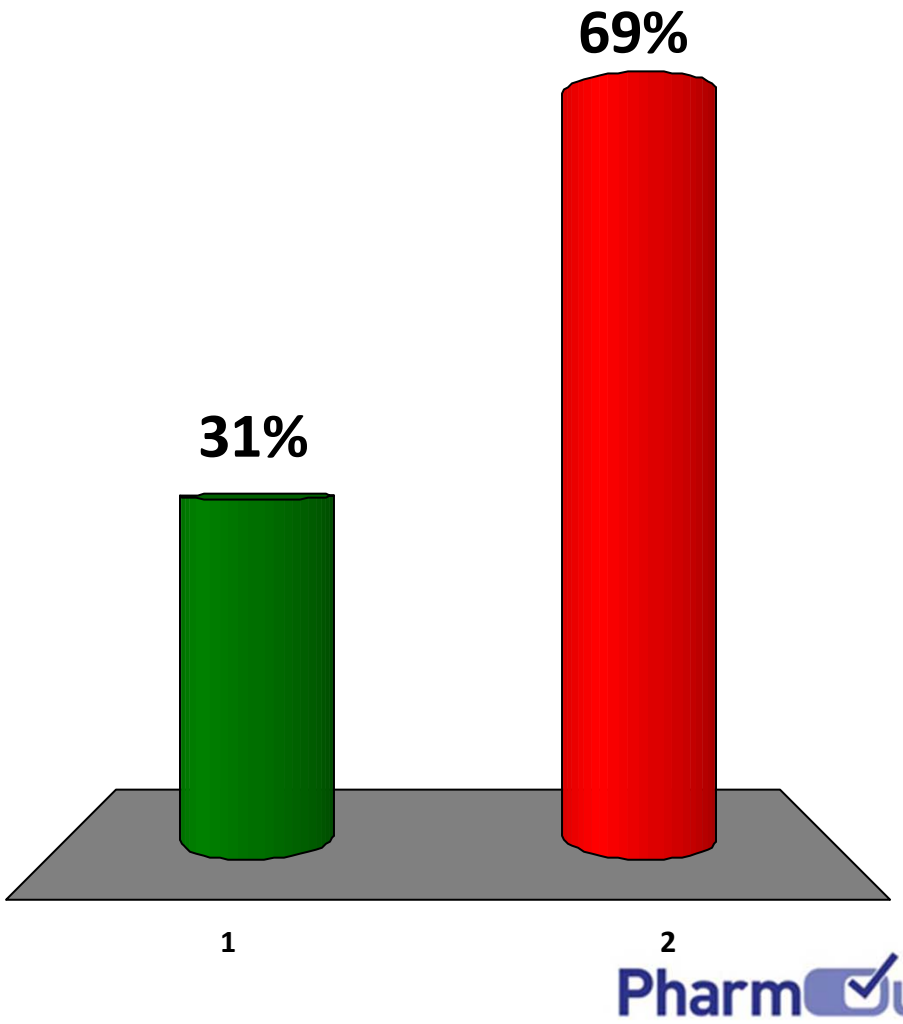
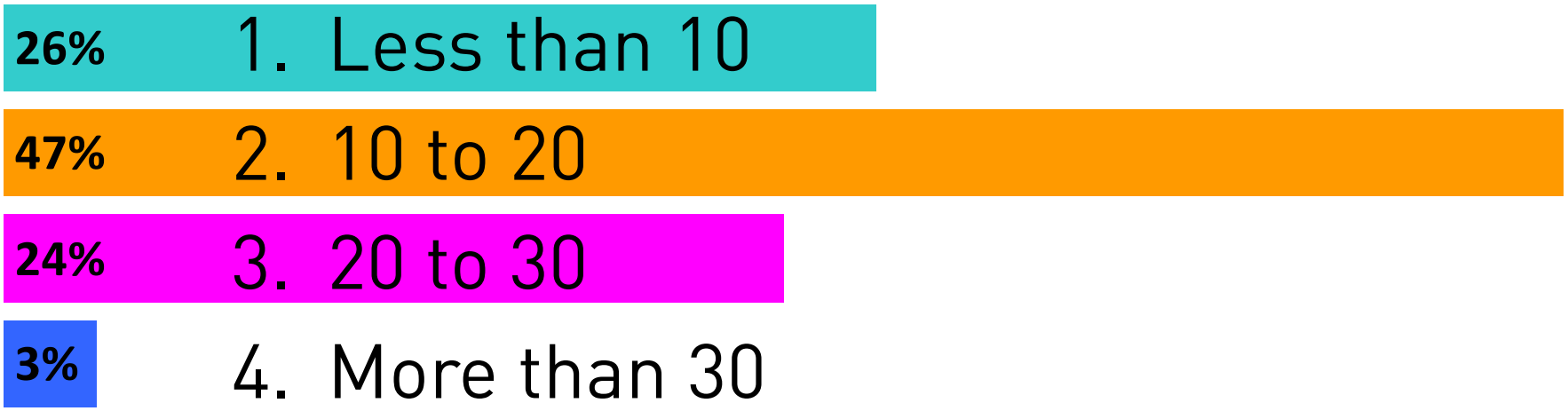
Did you attend NVF I?

1. Yes
2. No



How many years have you worked in a GMP regulated industry?



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What is your current core role in your company?

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In what part of the Life Science Industry have you spent the key part of your career?

46% 1. Non Sterile Pharmaceuticals

54% 2. Sterile Pharmaceuticals

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Do you:

68%	1. Work directly for a manufacturer?
1%	2. Work directly for a supplier/vendor?
24%	3. Work as a GMP consultant?
7%	4. Other

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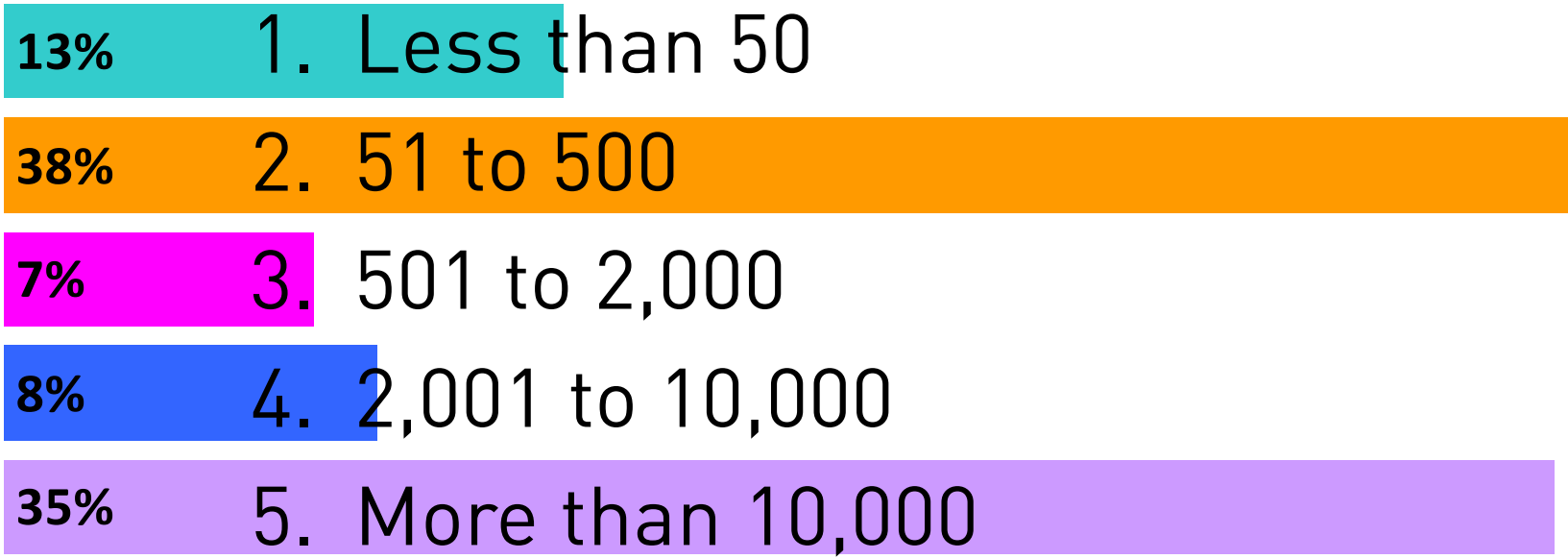
How many people work in your company, globally?



What countries/regions do you supply to?

30%	1. Australia & New Zealand
1%	2. Europe
10%	3. Asia
3%	4. US
54%	5. All
3%	6. None

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How relevant are the US FDA's regulations and guidelines to you?

60% 1. Extremely important, they influence the markets I work in

32% 2. Important, I like to keep abreast of their expectations

8% 3. Unimportant

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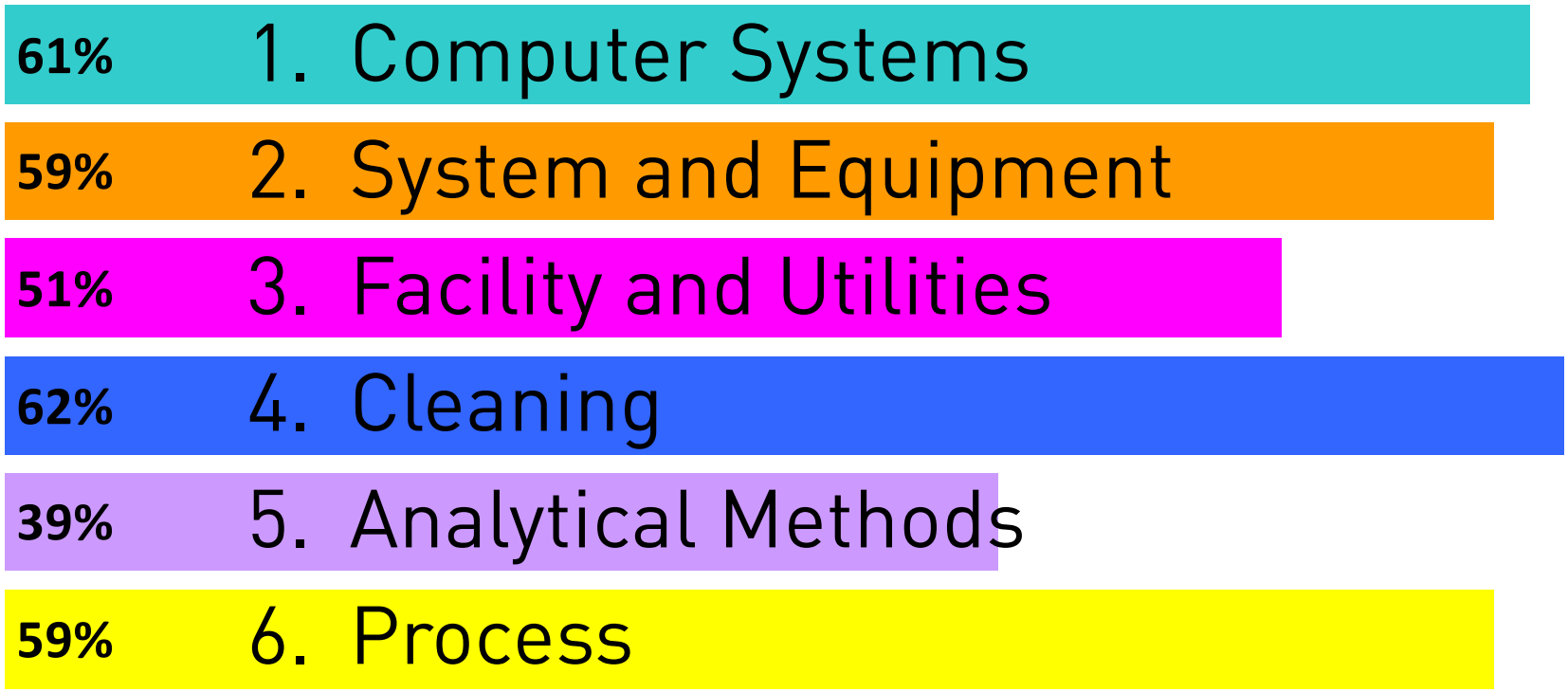
Which areas of validation do you need/ want training on?



Note: Choose all that apply

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What technical training do you need / want?

45%	1. Quality Management Systems
20%	2. Energy Efficiency
45%	3. Equipment and Facility
32%	4. Critical Utilities
41%	5. Lean Manufacturing
72%	6. Risk Management
35%	7. Aseptic Practices
30%	8. Good Documentation Practices

Note: Choose all that apply

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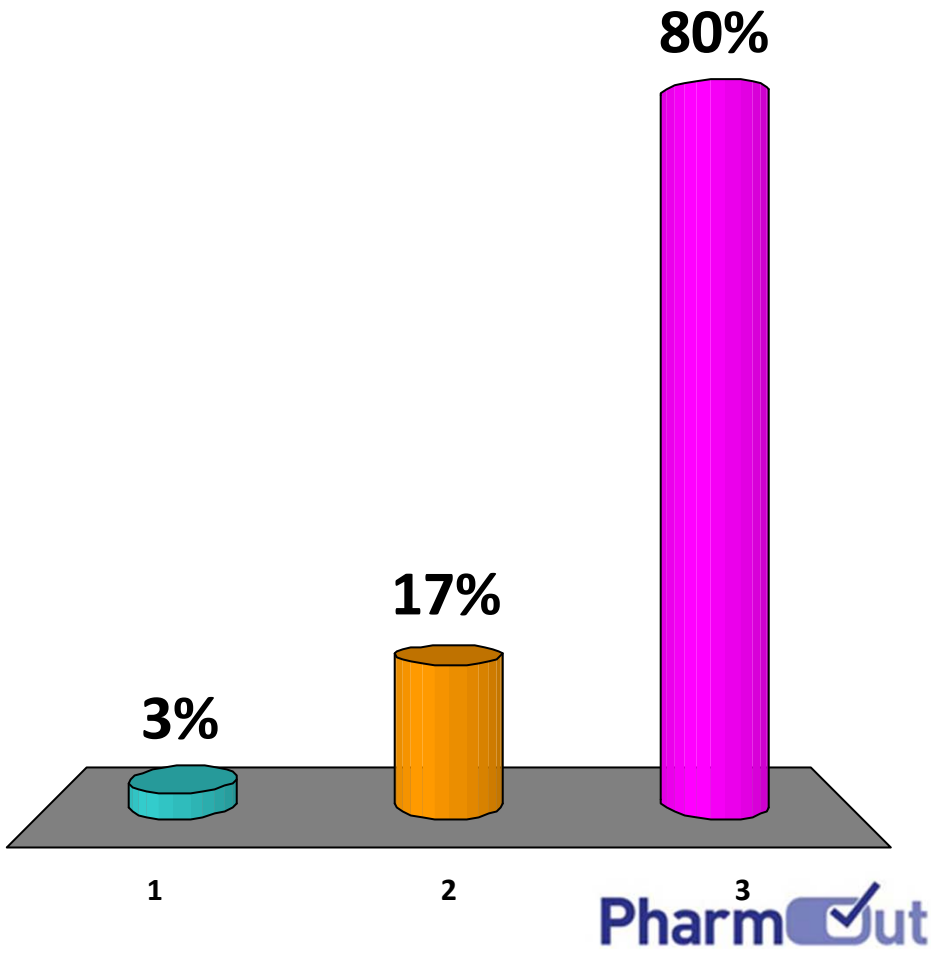
How have you received most of your validation training?

1. Institutional (Uni or College)
2. Commercial course
3. On the job



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Validation

How would you describe your level of validation knowledge?

15% 1. Recognised subject matter expert (SME)

28% 2. Extensive and thorough understanding

31% 3. Good working, applied knowledge with a few gaps

20% 4. Good understanding, but limited experience

6% 5. Basic understanding

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How would you describe your company's validation procedures?

28%	1.	Appropriate
10%	2.	Over the top / overly complicated
49%	3.	Needs some work, but heading in the right direction
7%	4.	Barely functional
6%	5.	Non-existent

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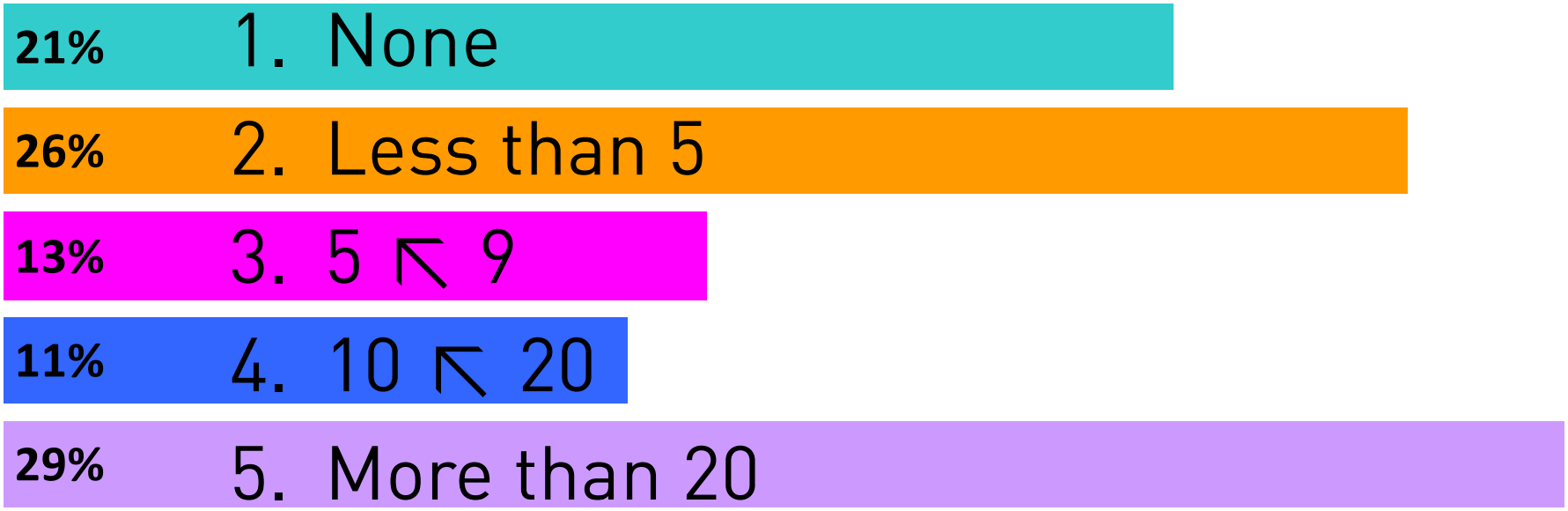
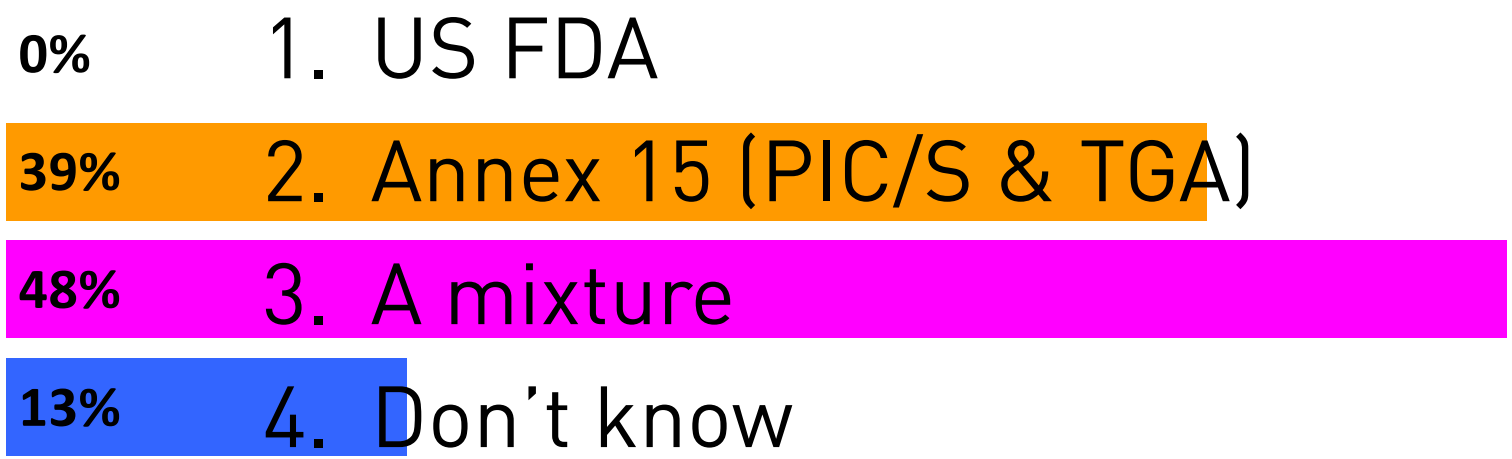
How many staff do you have working on validation full time?



For your TGA licensed products, are your validation procedures aligned with:



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Have you abandoned the "three golden batches" approach for process validation?

42% 1. Traditional approach – "Three Golden Batches

6% 2. Continuous Process Verification

43% 3. Hybrid of 1. & 2.

9% 4. Need to understand more about the options

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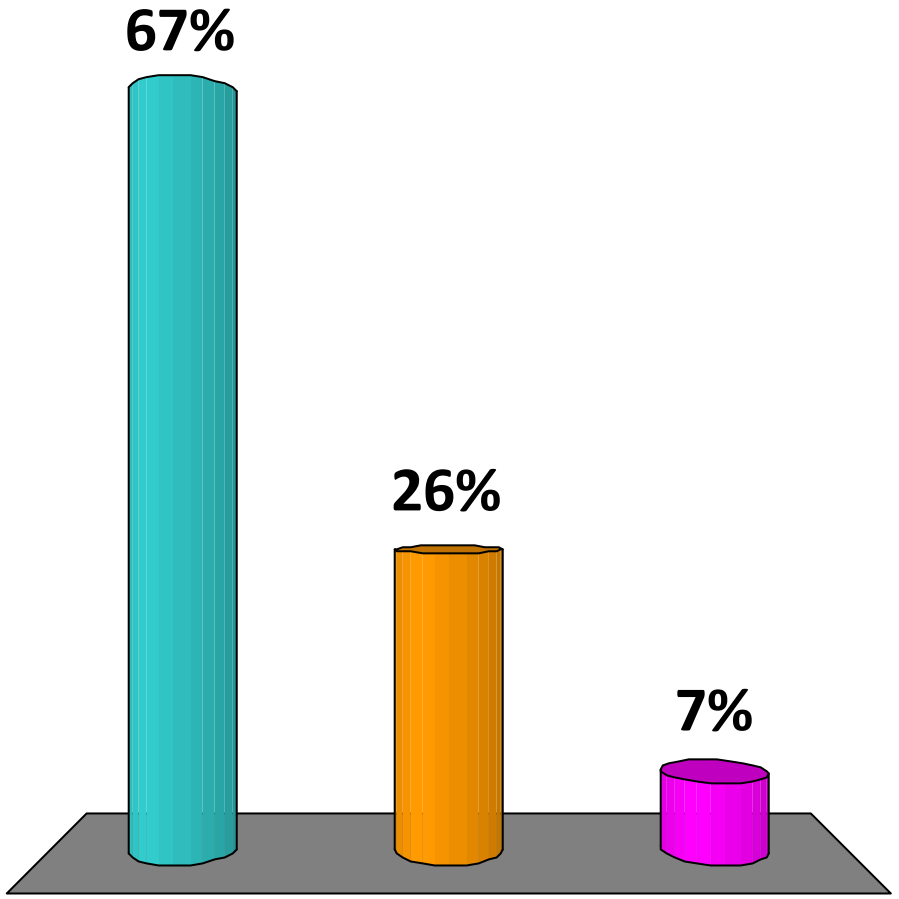
Risk Management

Are Risk Assessments a requirement for all projects?

1. Yes
2. No
3. Don't know



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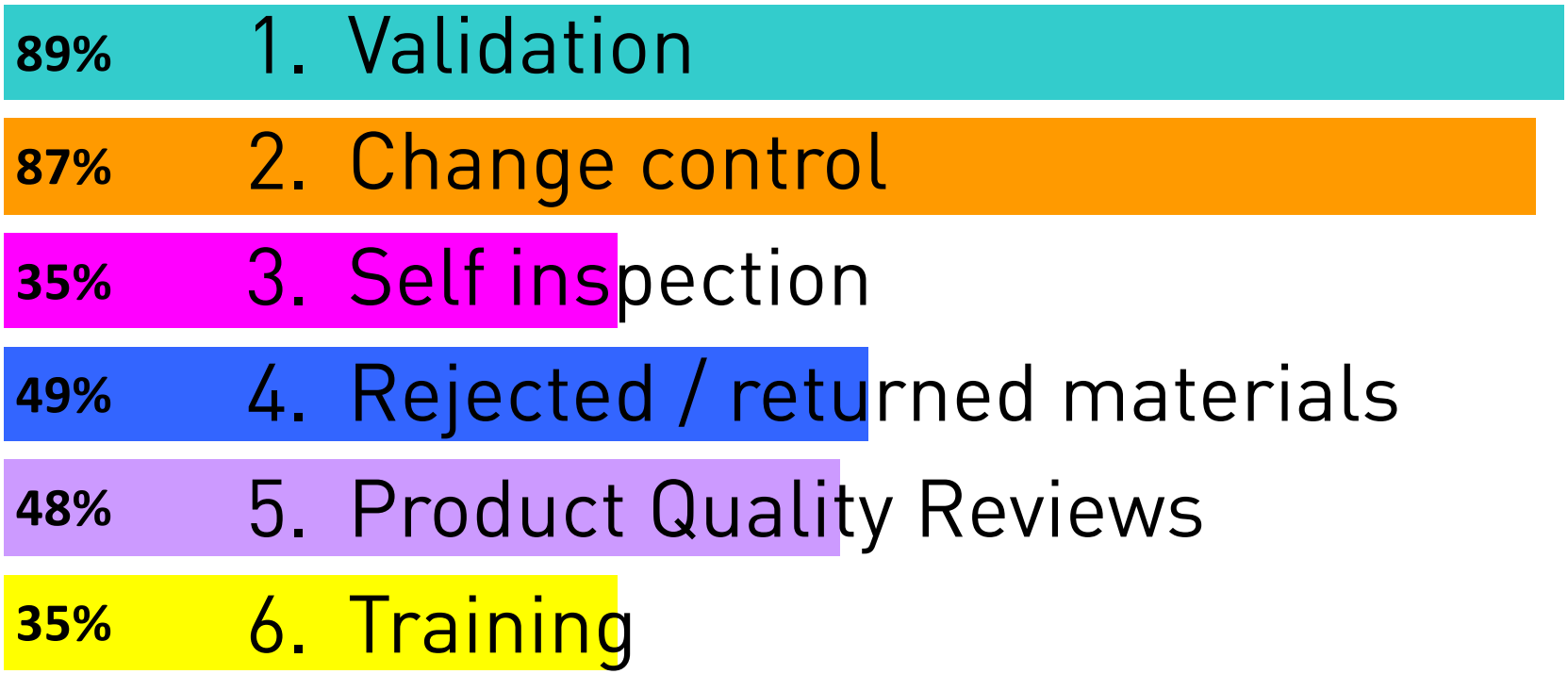
Is Risk Assessment a requirement in your following SOPs?



Note: Choose all that apply

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Annex 15 states that Risk Analysis is a "method to assess and characterise the critical parameters in the functionality of an equipment or process".

Therefore, during your Risk Analysis do you provide a justification for your risk evaluation (e.g. H, M, L)?

47%	1. All of the time
26%	2. Only for certain risks
16%	3. At your discretion
10%	4. Not sure/ don't know

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Annex 15 states that Risk Analysis is a "method to assess and characterise the critical parameters in the functionality of an equipment or process".

Therefore, during your Risk Analysis do you provide a justification for your risk control measures?

48%	1. All of the time
20%	2. Only for certain risks
15%	3. At your discretion
17%	4. Not sure/ don't know

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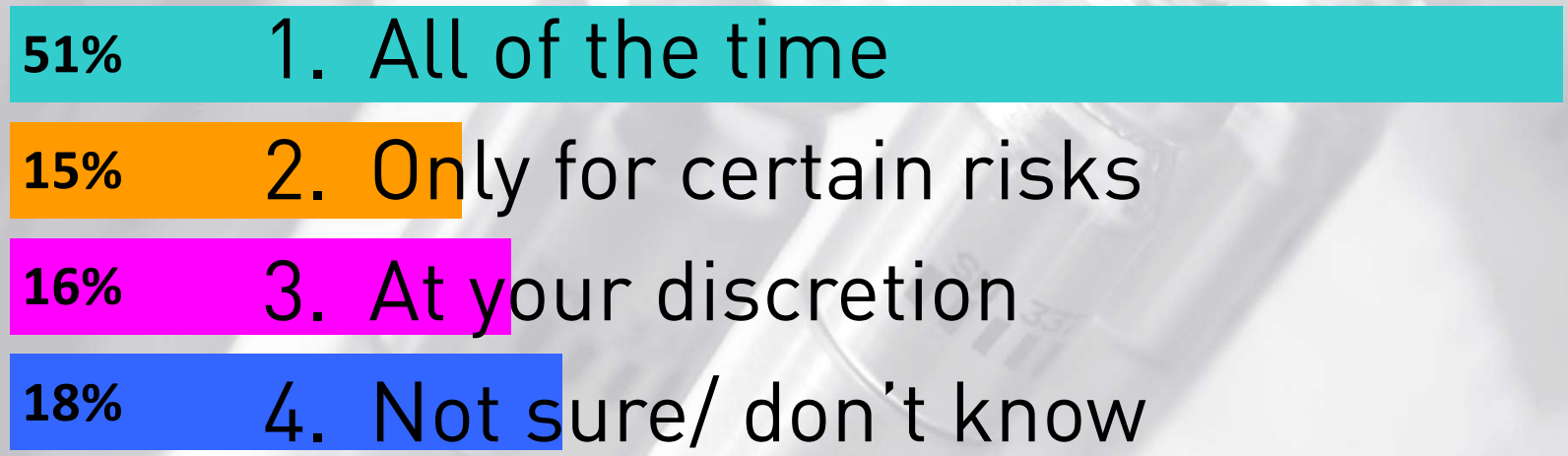
Annex 15 states that Risk Analysis is a "method to assess and characterise the critical parameters in the functionality of an equipment or process".

Therefore, during your Risk Analysis do you provide a justification for your Risk Review conclusion?



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Does a Product Quality Review…

81% 1. Occur as an annual event?

11% 2. Occur more frequently than annually?

8% 3. As a result of adverse circumstances?

Keepad Survey

Thank you!