

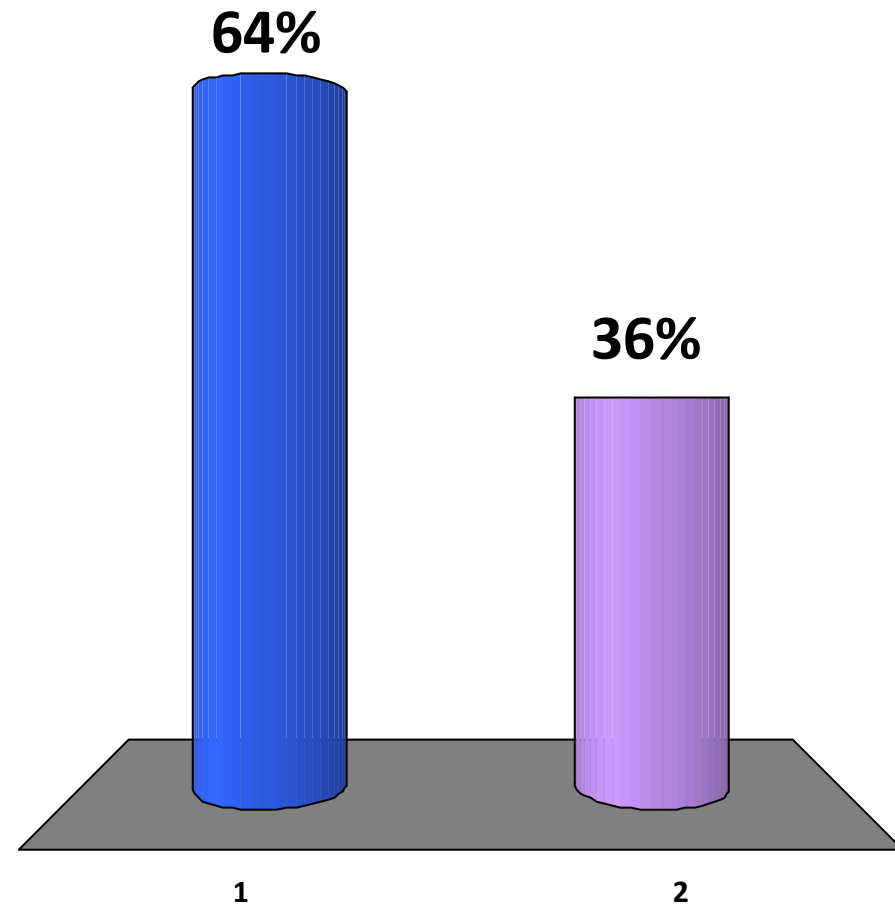


# National Validation Forum II

## Keypad Questions II

# First Off Demographic – Which stream were you in?

1. Sterile
2. Non Sterile



Compare with what your background  
is?

Sterile – 54%

Non Sterile – 46%

# Who were the smartest guys in the room?

First Question – Find the “F”s. Who got it right?

Quality – 36%

Operations – 43%

Validation – 48%

Engineering – 60%

Companies with <2000 people – 50%

Companies with >2000 people – 32%

# How relevant are the US FDA's Regulations and Guidelines?

Companies with <2000 people – 44%

Companies with >2000 people – 81%

# Who are the most cynical about their validation procedures in the room?

People with <10 years experience – 26%

People with >10 years experience – 8%

# Who is embracing CPV?

## Traditional 3 Golden Batches

Sterile – 58%

Non Sterile – 28%

## Continuous Process Verification

Sterile – 0%

Non Sterile – 13%

## Hybrid

Sterile – 35%

Non Sterile – 50%

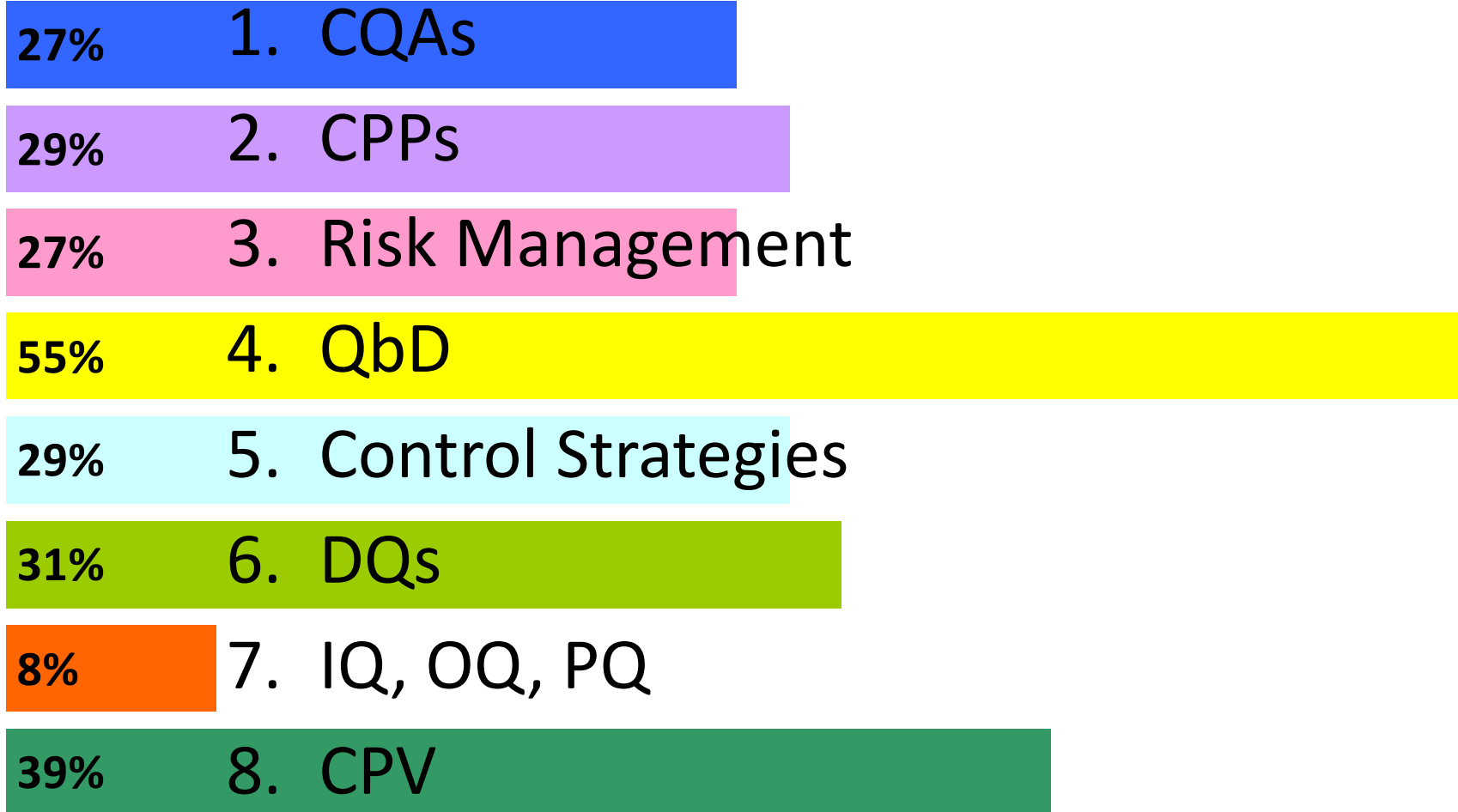
# Product Quality Reviews

Does a Product Quality Review occur:

	Quality	Validation
Annually?	72%	88%
More than annually?	8%	12%
As a result of adverse circumstances?	20%	0%



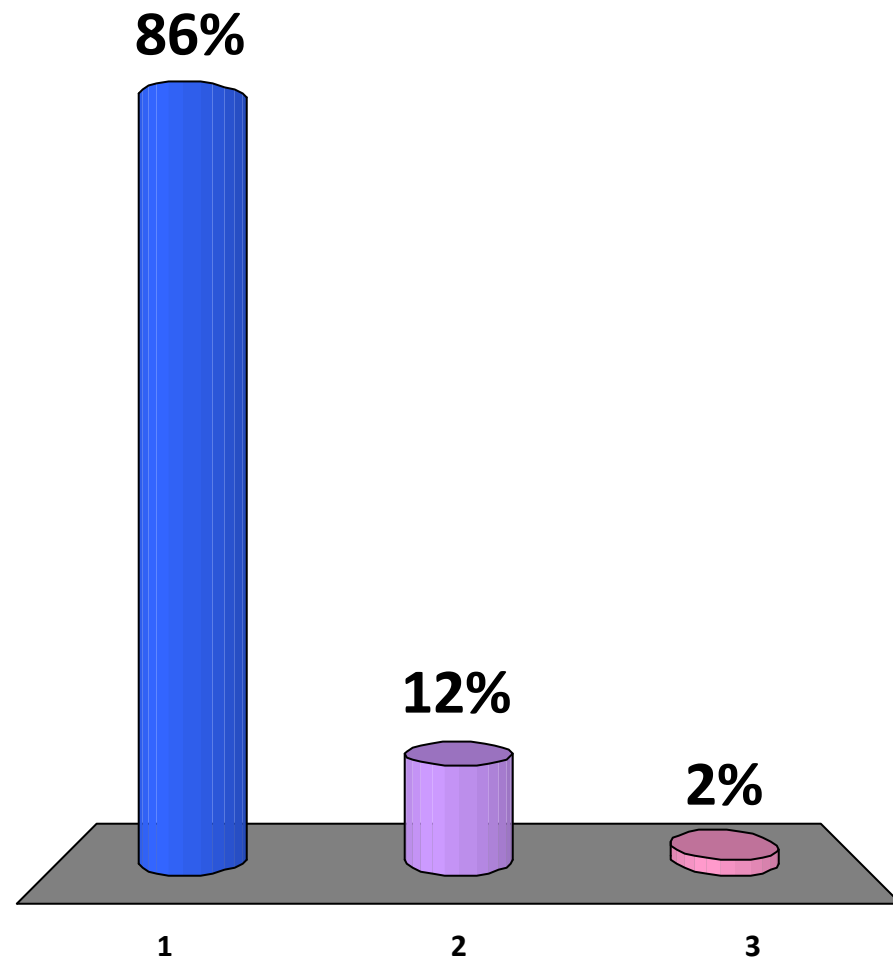
# The Validation components that still do my head in are:



Note: Choose all that apply

# From this forum has your understanding of the new paradigms in PV changed?

1. Improved.
2. About the same.
3. Worsened.



From what I have learned at this forum, my company's validation procedures are:

16% 1. Right on track

71% 2. In need of a few minor adjustments

14% 3. In need of a major overhaul

# Does the risk based approach to validation:

30% 1. Make validation more complicated

70% 2. Make validation simpler

# Do you think the risk based approach to Process Validation:

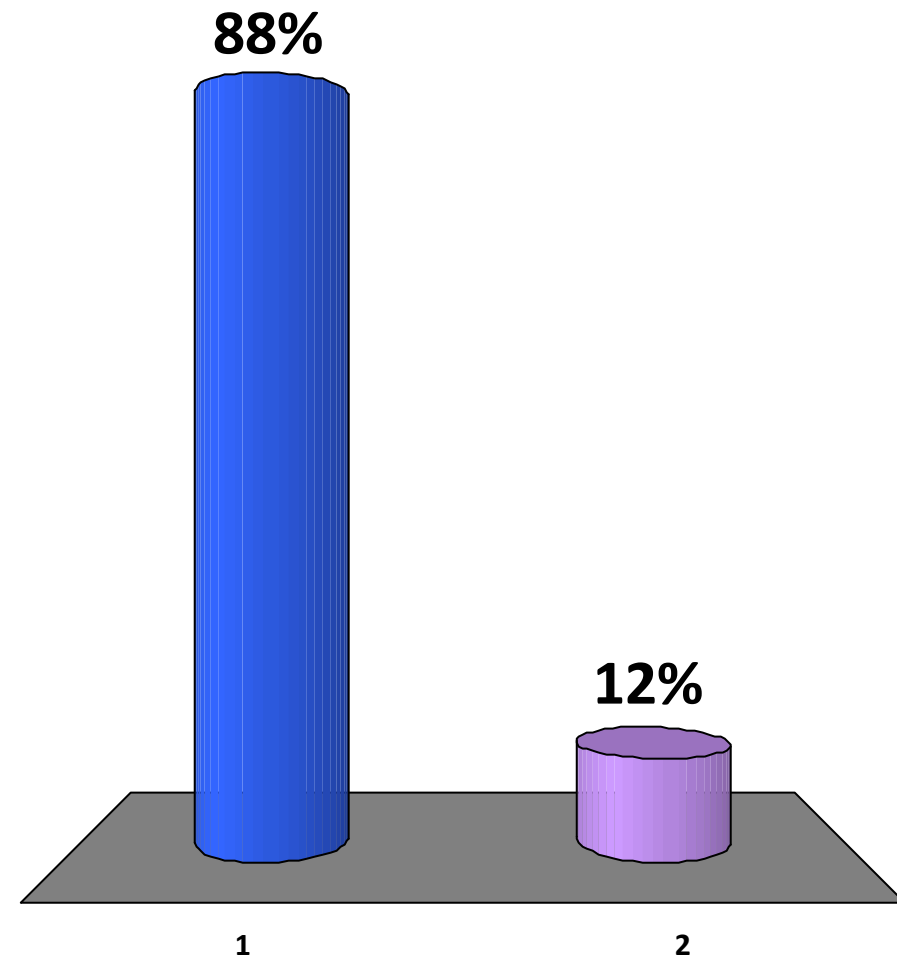
53% 1. Takes more effort

22% 2. Takes less effort

25% 3. About the same

Do you feel more confident in your ability to justify your risk based validation approach to regulators / business partners?

- 1. Yes
- 2. No



# Do you think the new approach to PV will achieve any of the following?

- 59% 1. Improve patient safety
- 84% 2. Improve product quality assurance
- 70% 3. Allow me to increase efficiency, reduce waste, or reduce costs

Note: Choose all that apply

# Has this forum improved your understanding of how to use Risk Management?

70% 1. Yes it has helped

2% 2. No it hasn't

28% 3. About the same



# Has this forum helped you to mesh risk based approaches into Annex 15?

71% 1. Yes it has helped

4% 2. No it hasn't

25% 3. No change

If there was no regulatory impetus, what would induce you to adopt these new PV approaches?

58% 1. I can make better products.

28% 2. I can make more profit (reduce costs).

13% 3. I'm already doing it!

# Has this forum met your expectations?

60%

1. Yes

2%

2. No

39%

3. Somewhat

# Keepad Survey

**Thank you!**