CoP Session: C&Q COP

Trends and Current Initiatives

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Agenda

- Mission
- COP Structure
- Trends and Current Initiatives
- How You Can Get Involved
- Q&A

Survey

Adoption rate of ISPE Baseline Guide 5 C&Q approach

- QRM based integrated C&Q

Trends

Benchmarking

Mission

- Provide a community and forum to discuss and implement best practices
- Forums
  - Community website
  - Blogs
  - PE Magazine
  - Good Practice Guide
  - Webinars
  - Presentations
  - T40 Course

COP Structure

- COP
- Steering Committee
- Paperless Sub-Committee

Areas of Focus

Approach Used

Paperless Validation

Benchmarking

Drivers and Adoption

How does ISPE Improve?

Trends

Lack of understanding of BG5 Fundamentals – GCEs

- V-Model
- Risk Assessments & methods
- Role of Quality
- CPP definition and flexibility – product/process or just equipment

Definition of Risk Based Approach is variable

Definition of Hybrid Approach

Very little understanding of the cost of C&Q

SLIA and CCA still used

Lack of GEP Use – program established? Fundamental to Approach

Paperless is here and trend for rapid adoption

Next Steps

1. Need to define & measure cost of C&Q
2. Boundaries/definition for TIC
3. More application examples and education needed
4. What does RBA and Integrated approach mean to respondent?
5. Read the guide!

Current Initiatives

1. More application examples and education needed
2. New Survey in 2024 – better clarification of approaches
3. GAMP Alignment
4. PR, ECM and GEP Focus
5. Lack of Product/Process Definition and how to proceed
6. Upcoming education and guide on paperless tools and validation

Benchmarking - Claimed % TIC

		36	Robust measurement?			
	Total		Yes %TIC		no robust	
31%	3-5%	11	4%	1	3-5%	10
19%	5-8%	7	5-7%	1	5-8%	6
17%	10%	6	7-12%	1	10%	4
14%	15%	5	10%	1	15%	3
6%	20%	2	15%	1	20%	1
6%	25%	2	20%	1	25%	2
3%	30%	1			30%	1
3%	40%	1			40%	1
3%	50%	1			50%	1

What is included in TIC Analysis

Vendor Test Activities (purchased IOQ)	18
System Risk Assessments	18
PQ	18
SAT	17
Lab Instrument and Systems Qualification	16
FAT	15
Utility URS	15
Facility	15
Equipment	14
Design Review	14
Vendor/Supplier Qualification	13
Engineering/Water Runs	13
PPQ/PV	12
Media Fills	12
Automation Engineering and Implementation	12
Design Phase and Activities	9

Deep Dive Results

Clear Improvement Noted

Deliverable or Task / TIC% and Total Respondents	3-4% (11)	5-8% (7)		10-15% (10)	>16% (9)
Overall Process Risk Assessment	82%	71%		40%	44%
CAs/CDEs as identified through SRA	55%	43%		40%	0%
Design Review completed under GEPs	64%	71%		30%	33%
Design Qualification completed	91%	57%		70%	44%
DQ	55%	43%		40%	0%
Quality pre/post approval of verification protocols (FAT/SAT/IOV/CX)	18%	14%		50%	22%
No pre/post approval of executable (GEP) verification documents	64%	29%		30%	56%
GEP Oversees C&Q process w/QA auditing oversight	36%	14%		30%	11%
IOQ as summary report only	9%	29%		10%	11%

No Change Noted

	3-4% (11)	5-8% (7)	10-15% (10)	>16% (9)
Commissioning activities leveraged as Qualification activities	64%	71%	70%	78%
Critical Components as determined through SLIA/CCA	45%	29%	40%	67%
Quality pre/post approval of leveraged IOQ protocols	27%	43%	70%	44%
GEPs Established	36%	29%	20%	33%

Results of Implementation of RBA/QRM

Years RBA in place	%TIC	schedule savings	What was TIC before RBA	Comment
5		2-3 months		
2.5		12%		
10	5-7%	2-3 months	10-12%	
5	7-12%	15%	7-12%	no change in cost
1	20%	10%	20%	
2		25%		
10+	10%		15-20%	

Q&A