



CCS Reality Check: Connecting Risk, Control, and the Path Forward.

Vanessa Vasadi Figueroa

VVF Science[®]

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Disclosure

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Agenda

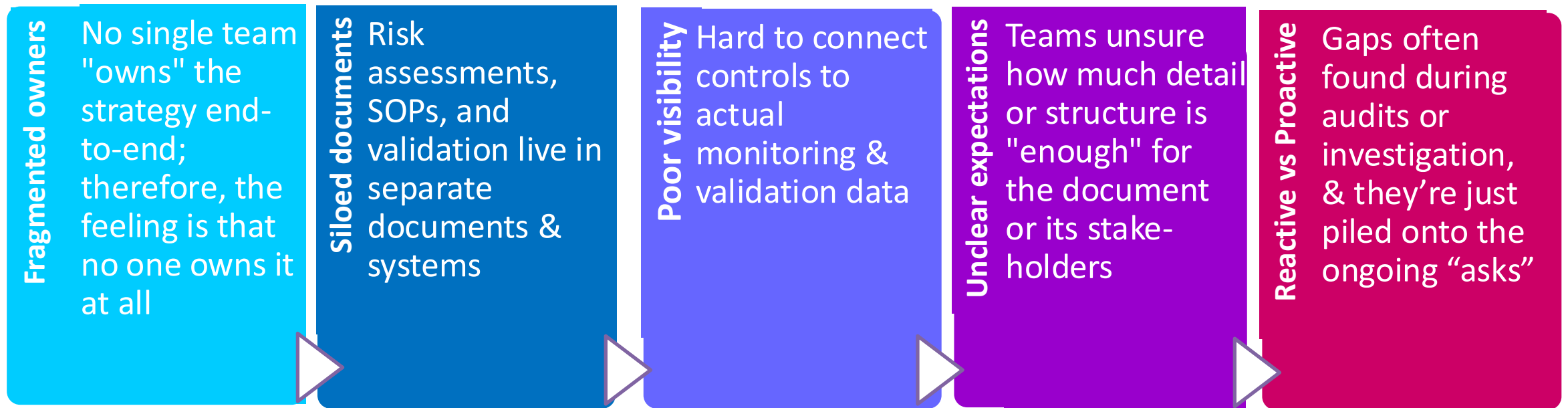
1. Why CCS Still Feels So Challenging
2. Risk Management as the Hidden Gap
3. Global Expectations: What the Regulations Require
4. Core Elements of a Strong CCS
5. Step-by-Step Development Process
6. Looking Forward: CCS Maturity & Integration
7. Final Reflections + Q&A

Let's start at the beginning

ACKNOWLEDGE THE ASK

- What is it? → A Contamination Control Strategy
- Who does it? → Not just Microbiology
- Why is it needed? → Demonstrate controls to manage contamination risk
- When was it required? → ~August 2023

Why CCS may feel challenging for some



IS RISK MANAGEMENT THE MISSING LINK?

- ✓ Everyone agrees that contamination control should be risk-based.
- ✓ But when it comes to building the CCS... where exactly is the *risk thinking*?
- ✓ Are we using risk to guide structure, depth, and priority?
- ✓ Do the risk assessments only feed the CCS? How many of them?
- ✓ Leverage PDA/ANSI-03 standard for industry setting process



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Poll #1

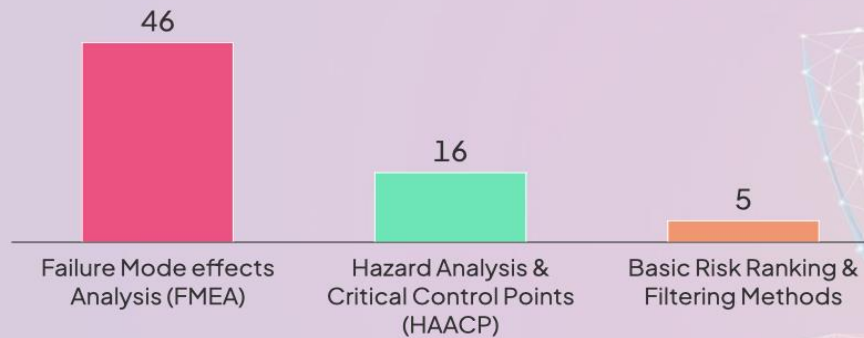
What type of risk management tool do you incorporate into the development of your Contamination Control Strategy?



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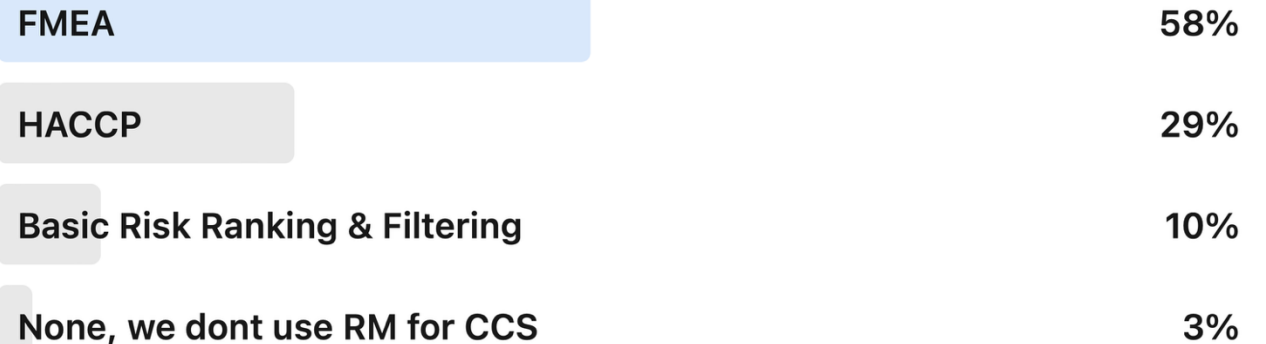
Polling Question 1- Other recent Industry results

What type of risk management tool do you incorporate into the development of your Contamination Control Strategy?



What type of risk management tool did/do you use for your Contamination Control Strategy (CCS)?

You can see how people vote. [Learn more](#)



125 votes • Poll closed

The CCS is not a single, standalone risk assessment; it's the structured, documented strategy that connects all the risk-based decisions an organization has already made.

But once you see it all together, they may find the total of all controls in place do not fully cover the risk.

That's where strategic thinking comes in.

CCS Requirements around the globe



U.S. FDA, Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing, (2004)

An aseptic processing facility should be designed to minimize the potential for contamination of the sterile drug product. Key elements include adequate separation of processing areas, cleanroom classification, and air handling systems designed to protect critical operations.



European Commission EU Guidelines for GMP, Annex 1: Manufacture of Sterile Medicinal Products, (2022)

A contamination control strategy (CCS) should be implemented across the facility in order to define all critical control points and assess the effectiveness of all the controls (design, procedural, technical and organizational) that are in place to manage risks to medicinal product quality and safety.



ISO 13408 – Aseptic Processing of Health Care Products (2023)

The manufacturer shall establish, implement and maintain a documented system to identify, evaluate, and control contamination risks associated with aseptic processing. The system shall be designed to ensure a state of control based on risk assessment, validation of critical parameters, and monitoring activities.

Regulations & evolution of quality maturity

FDA's QMM

encourages manufacturers to ***voluntarily demonstrate maturity***, showing how deeply quality, risk management, & contamination control are embedded in culture & quality systems

**REGULATORY
GLOBAL
CONVERGENCE:
contamination
control is now a
measurable
indicator of quality
maturity &
leadership
accountability.**

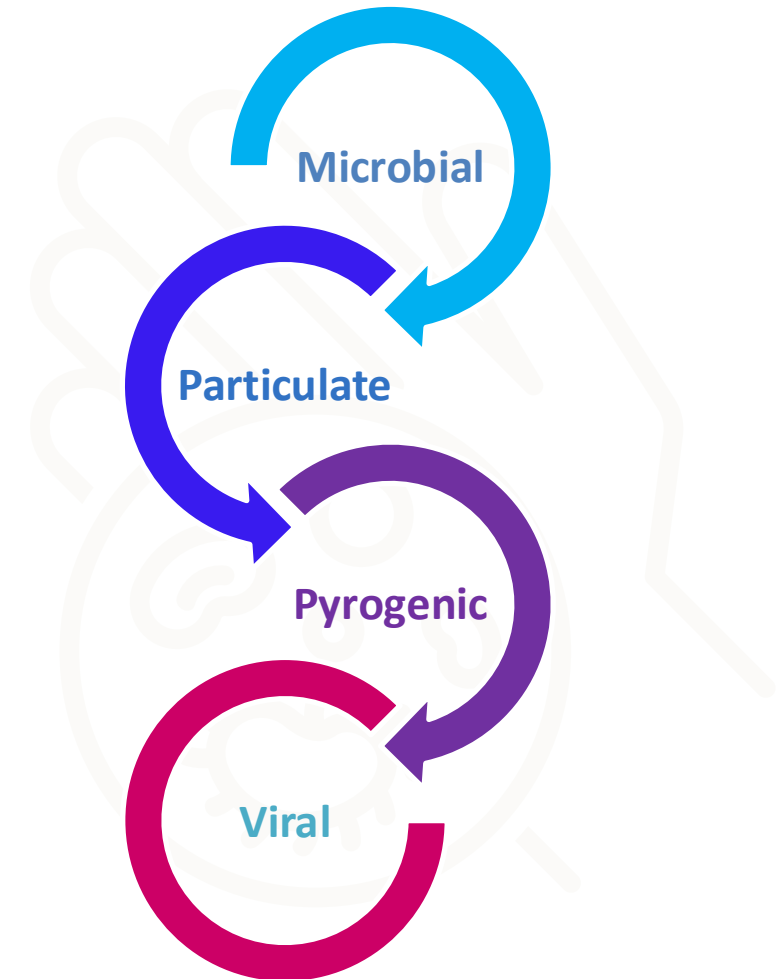
EU Annex 1

formalizes the same expectations through ***regulation***, requiring every sterile manufacturer to define and maintain a well-structured contamination control strategy within the pharma quality system

Types of contamination under focus

Things to Consider (depends on process):

- ✓ Points of ingress to the process for contaminants
- ✓ Points of proliferations to support growth of organisms that are present
- ✓ Potential for growth inherent to the process at each stage, and the environment
- ✓ Personnel practices and culture to prevent source of contamination
- ✓ Historical data for recovery of organisms



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Who should get involved?

People are at the core of our businesses; therefore, they will be at the core of the assessment process and control strategies

People are also performing the critical steps in their processes; & so, they are likely the #1 source of potential contamination



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Pharmaceutical Quality System elements that are required in a CCS



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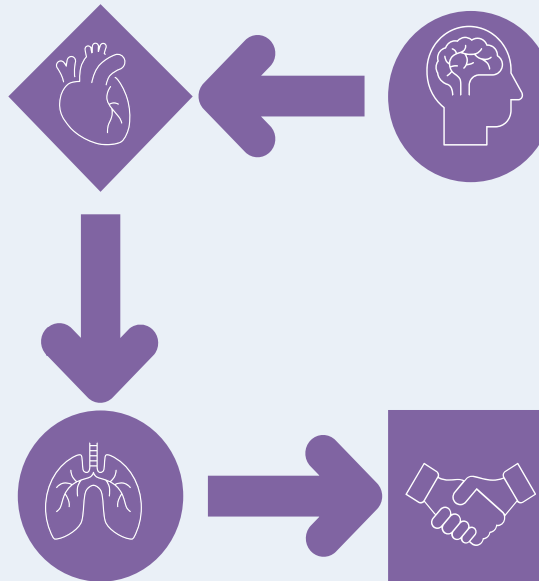
The Anatomy of a Strong CCS

CONNECTED:

integrates people, facilities, equipment, utilities, and process.

LIVING:

reviewed, trended, & adjusted using real data from controls.



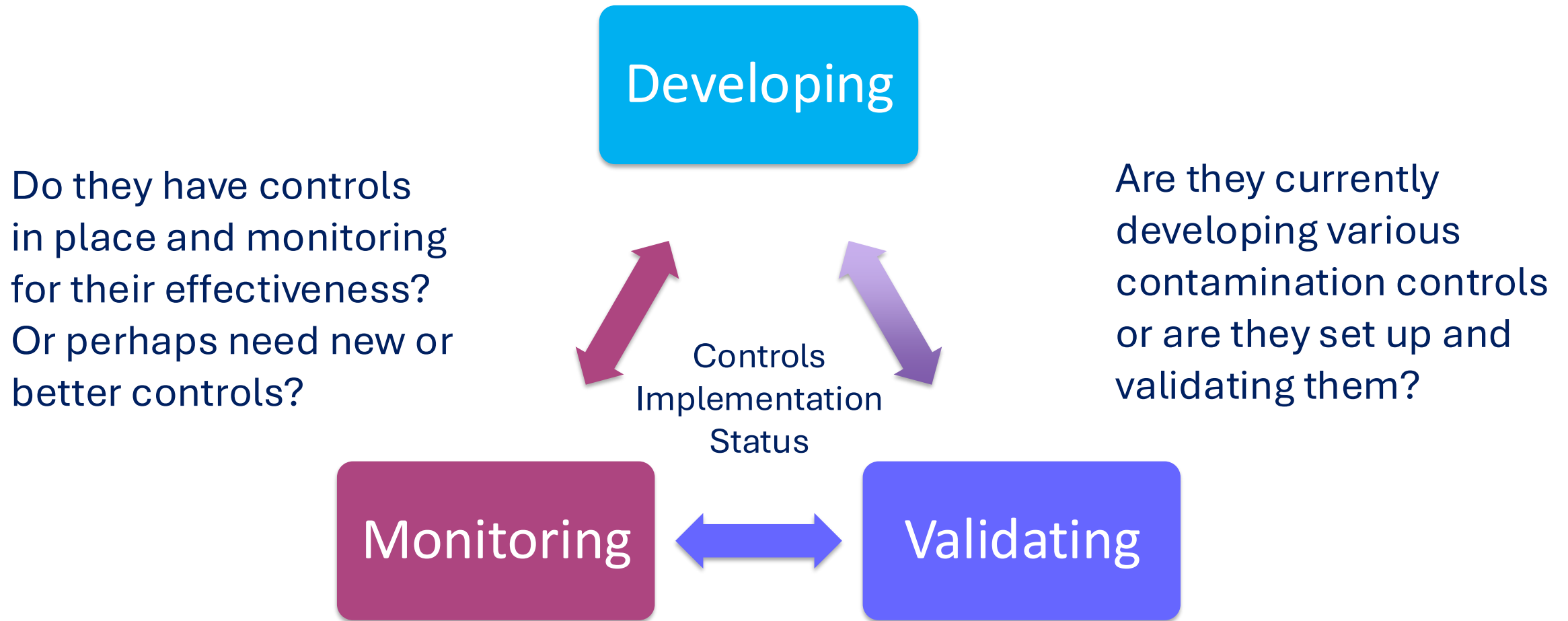
RISK-BASED:

grounded in risk principles identify, evaluate, control, review.

LEADERSHIP-OWNED:

visible in management reviews & business planning.

Important to Assess at which stage a company is at



Insights to the CCS Development Process

Process at the 30,000 foot view

High-Level Approach

Form the right team



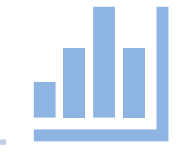
Build the Framework



Evaluate the current state



Draft and Visualize



Create a Quality Plan



Lifecycle Management



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Step 1: Forming the right team

Code	Section	Primary Owner	Secondary Owner
FAC	Facilities Design, Controls, and Maintenance	Chris Nolan	Megan Price
FAC	Air Handling, HVAC and EMPQ	Emma Roberts	Ethan Davis
FAC	Environmental Monitoring	Ryan Cooper	Kate Anderson
EQU	Equipment, Controls, Cleaning, and Maintenance	Natalie James	Jason Moore
OPS	Manufacturing Process Design	Jake Lawson	Lily Collins
OPS	Container Closure Integrity	Taylor Grant	Ben Parker
OPS	Aseptic Practices & Cleanroom Behaviors	Scarlett Hayes	Chloe West
UTI	Utilities Design, Controls, Monitoring	Michael Turner	Andrew Ross
QU	Suppliers and Vendor Controls	Jennifer Brooks	Lauren Kelly
QU	Raw Materials and Components	Daniel Reed	Ben Parker
QU	Quality Controls, In-Process and Release Testing	Zoe Carter	Emily Gray
QU	Contamination Events Management	Matthew Stone	Lucas Ward
GEN	Background, Scope, Roles & Responsibilities	Olivia Clarke	Sarah Phillips
GEN	Process and Product Families Overview	Justin Walker	Noah Taylor
GEN	Glossary, References, Revision	Rachel Bennett	Ben Parker
GEN	CCS Governance Program	Adam Scott	Lily Collins

Legend:	DOCUMENT RULES:
EQU- Equipment	list document control document number first
FAC- Facilities	if it is NOT in document control, then upload the doc
OPS- Operational	in-process documents are acceptable, so long as you
QU- Quality Unit	all folders are labeled & colored in accordance with t
UTI- Utilites	always pull the LATEST version, unless otherwise nee
GEN- General Sections	always pull the PDF or locked version of the file, no dr

- ✓ Representation from each department
- ✓ Primary & secondary owners assigned
- ✓ List out full names for accountability
- ✓ Address resource allocations/duration
- ✓ Useful color coding
- ✓ Cross-functional ownership is established

CCS Map	FAC - FDCM	FAC- AH HVAC	FAC - EM	EQU - CCM	OPS - MPD	OPS - CCI	OPS - PTQC	OPS- SFV	UTI - DCM	QU - RM & C	QU - S&VC	QU - QC	QU - CEM
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Step 2: Build the framework

Main Topic: Facilities Design, Controls, and Maintenance		Main Topic: Manufacturing Process Design		Main Topic: Personnel Training, Qualification and Controls		Main Topic: Supplier and Vendor Approval, Controls		Main Topic: Quality Controls and Finished Product Release Testing		Starting Document	Notes by	Quality
Facility	SubTopic	SubTopic	SubTopic	SubTopic	SubTopic	SubTopic	SubTopic	SubTopic	List Procedure &	n, Qualification, Work	SMF	Plan?
Manufacturing	Suppliers	Personnel	Personnel	Product Finish	Cleanroom	Process Design	Raw Materials	Equipment Overview	Description of Subtopic (as needed)			
Environment	Aseptic Control	Contractors	Microbiology	Process Validation	Contract Testing	Personnel	Component	Sanitization and Sterilization				
Pest Control	Process Validation	Contract Testing	Qualification	Personnel	Contract Testing	Personnel	Component	Sanitization and Sterilization				
Facility	Contract Testing	Qualification	Personnel	Contract Testing	Personnel	Contract Testing	Component	Sanitization and Sterilization				
Component	Personnel	Contract Testing	Qualification	Personnel	Contract Testing	Personnel	Component	Sanitization and Sterilization				
PDA	Contract Testing	Qualification	Personnel	Contract Testing	Personnel	Contract Testing	Component	Sanitization and Sterilization				
								Equipment Overview	equipment use and philosophy for reusable containers which equipment get reused, which do not, why? summary of types and classifications of processing equipment risk assessment for criticality of equipment list of small parts, changes parts, product contacting parts			
								Cleaning	cleaning program overview cleaning methods validation manual vs automated cleaning, and rationalized types of cleaning agents and their suitability water rinse for equipment and small parts			
								Component	use of water and its quality, justification risk assessments, as needed			
								Sanitization and Sterilization	which items require sanitization which items require sterilization sterilization validation, and cycle parameters			
								Storage and Flow	clean and dirty equipment separation, handling, storage and management sterile equipment management			
								Sterilization	sterilization validation, and cycle parameters handling and storage for sterilized items			

Step 3: Evaluate & Map the current state

Document Types

Validation Master Plans (VMPs): Define scope of validated systems, see what's in/out of scope for the control strategy & how the systems are effectively characterized

Risk Assessments (RAs): Identify known risks and current mitigations, look for outdated assumptions or mitigations that are not working

Standard Operating Procedures (SOPs): Operationalize controls, allow us to check for alignment with actual practice to make sure they are properly described.

Process Maps or Flow Diagrams: Reveal critical control points and dependencies in the process, or issues throughout the facility design/vulnerabilities.

Supporting Reports (e.g., Environmental Monitoring summaries, deviation trends): Offer data to confirm whether controls are working, and how the data can feed suitability of the controls

Every function brings different documents to the table, this step *forces alignment*

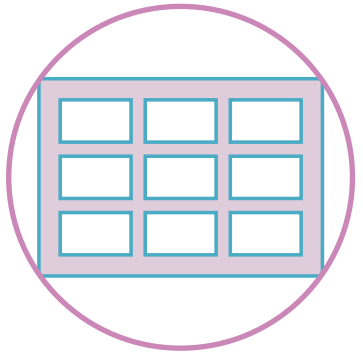
Ownership becomes *visible*, we see who maintains what, & what may be missing or overlapping

This step also helps reveal redundancy, blind spots, & potential undocumented practices



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Step 4: Draft and visualize



Translate spreadsheet data into a structured CCS document

- ✓ Organize by function, process, PQS or contamination control type



Include clear references to source documents

- ✓ Describe each control and how it's validated and monitored



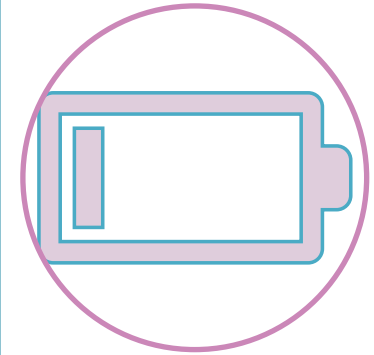
Make it traceable to the risk or quality objective it supports

- ✓ Use visuals to show interconnection between the system & the risk it measures



Help reviewers (internal & regulatory) quickly see how the pieces fit

- ✓ Avoid flat lists, be sure to show relationships, ownership, & lifecycle

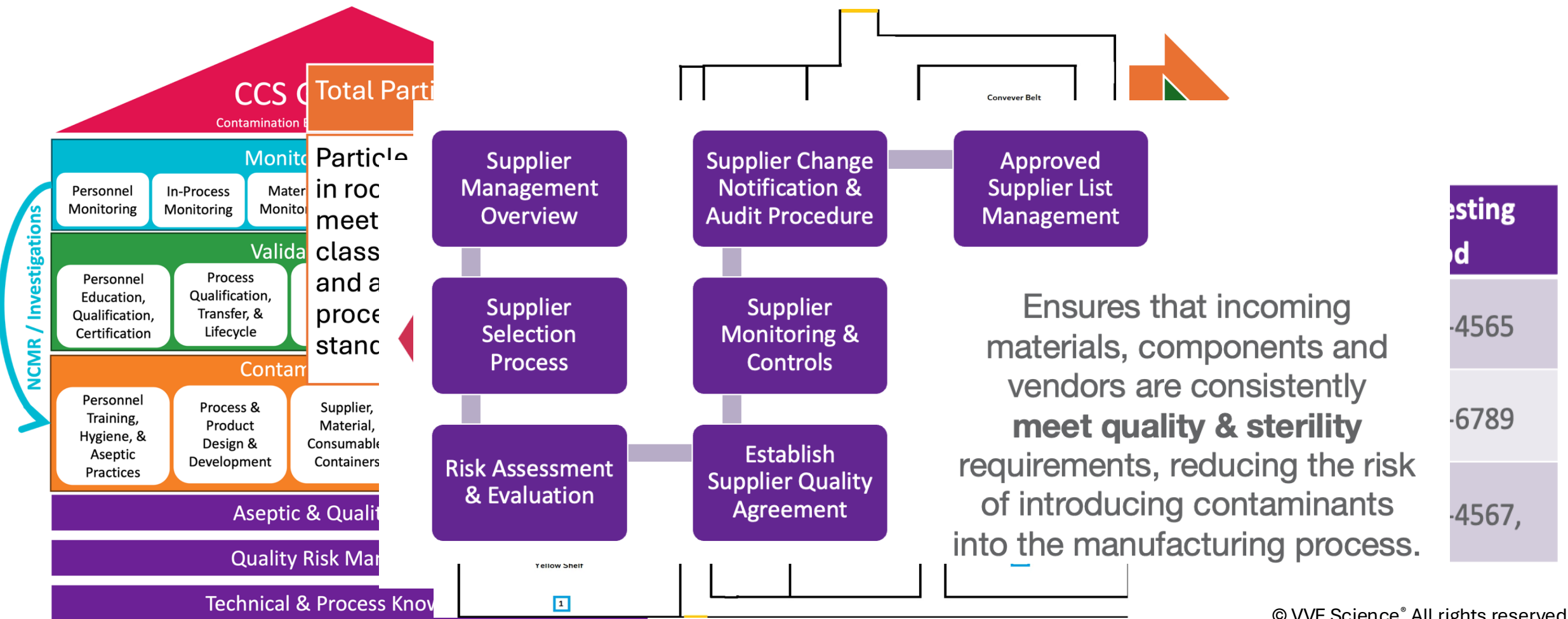


Identify potential gaps & build a Quality Plan to remediate them

- ✓ Builds trust & transparency with regulators, and shows awareness

End to End, the CCS should be ~30-50 pages depending on facility size & products scope

Visualizations must be included



Step 5: Build a Quality Plan to cover gaps

The purpose of a quality plan is to enlist the key elements of the Contamination Control Strategy that require additional design, assessment, implementation or documentation before they are considered in compliance with the regulatory standard EU Annex 1 and generate objective evidence to demonstrate compliance.

Main Topic: Facilities Design, Controls, and Maintenance					
SubTopics	Description of Subtopic (as needed)	List Procedure & Section if possible (where captured)	Supporting Document (Validation, Qualification, Work Instruction, etc.)	Notes by SME	Quality Plan?
Facility Design	drawings and maps of the facility layout requirements for surface material quality, smooth and impervious adequate workspace and movability for operators entry and exit design concept, airlocks are intentional air pressure cascades, and how they are managed access controls to buildings, and controlled spaces overview for any isolation or containment technologies powder/vacuum system overview (in Formulation) material and waste flow path and management				
Environmental Controls	requirements for differential pressure, temperature control overview for environmental controls, how they are managed areas of segregation or quarantine, and their purpose overview of any enhanced biosafety levels (BSL-1, BSL-2) temperature and humidity controls, how they are managed				
Pest Control	pest control program overview and types of controls in place monitoring, frequency and changeout of capture devices				
Facility Maintenance	physical facility cleaning and disinfection selection of disinfectants				

- ✓ There are many requirements in EU Annex 1, it may be possible that not all are met.
- ✓ In this case, if this is known or discovered during the CCS process, then it must go onto Quality Plan.
- ✓ It's possible to obtain a % complete and assess for the number of gaps.

Step 5 cont: Build a Quality Plan to cover gaps

Category	Main Topic	Detailed Category	Full Description	Risk	EU Annex 1 section applicable	Already Known or Actively Being Worked On?	Quality plan inclusion
FAC	EM	Environmental & Particulate Monitoring	Environmental Monitoring program does not apply a <u>risk based</u> assessment, and there is no justification for the locations selected.	High	Annex 1: 2.5; 9.24–9.33	No, this is new	No, prior CAPA in place
FAC	EM	Environmental & Particulate Monitoring	Total particulate monitoring does not take place during setup of the aseptic filling process.	High	Annex 1: 9.4; 9.6–9.10; 4.3	Yes - list CAPA	Yes
FAC	FDCM	Materials & Cleaning	Cleaning of difficult-to-access areas is not fully evaluated.	High	Annex 1: 4.4–4.5; 4.34–4.38	No	Yes
FAC	FDCM	Materials & Cleaning	Disinfectant suitability is not fully demonstrated.	Medium	Annex 1: 4.34–4.38	Yes	Yes
FAC	FDCM	Materials & Cleaning	Facility mapping and their corresponding flows for material and waste are not properly documented.	Medium	Annex 1: 4.3.6	EXAMPLE ONLY	Yes
OPS	ATB	Personnel Clothing Systems	Gowning practices are not qualified.	High	Annex 1: 7.13–7.19	Yes	Yes
OPS	MPD	Materials Management and controls	There is no list of materials and how they are evaluated for appropriateness to the classified areas.	Medium	Annex 1: 4.4; 5.12	No	Yes
OPS	MPD	Intervention Classification & Traceability	Intervention classification is not consistently applied.	High	Annex 1: 9.32–9.36	No	Yes
OPS	SFV	Sterile Filtration	Not all products have the sterile filter validation.	High	Annex 1: 8.84–8.90	No	Yes
QC	FP	Finished product release testing	Data trending practices are not consistently performed.	High	Annex 1: 2.6	No	Yes
QU	RMC	Raw Materials Management	Material risk classification is not established.	High	Annex 1: 2.5	No	Yes

Step 6: Review, Maintain, and Improve the CCS

Periodic review is required: EU Annex 1 explicitly states the CCS should be updated as needed & reviewed periodically

Event-based updates are critical:

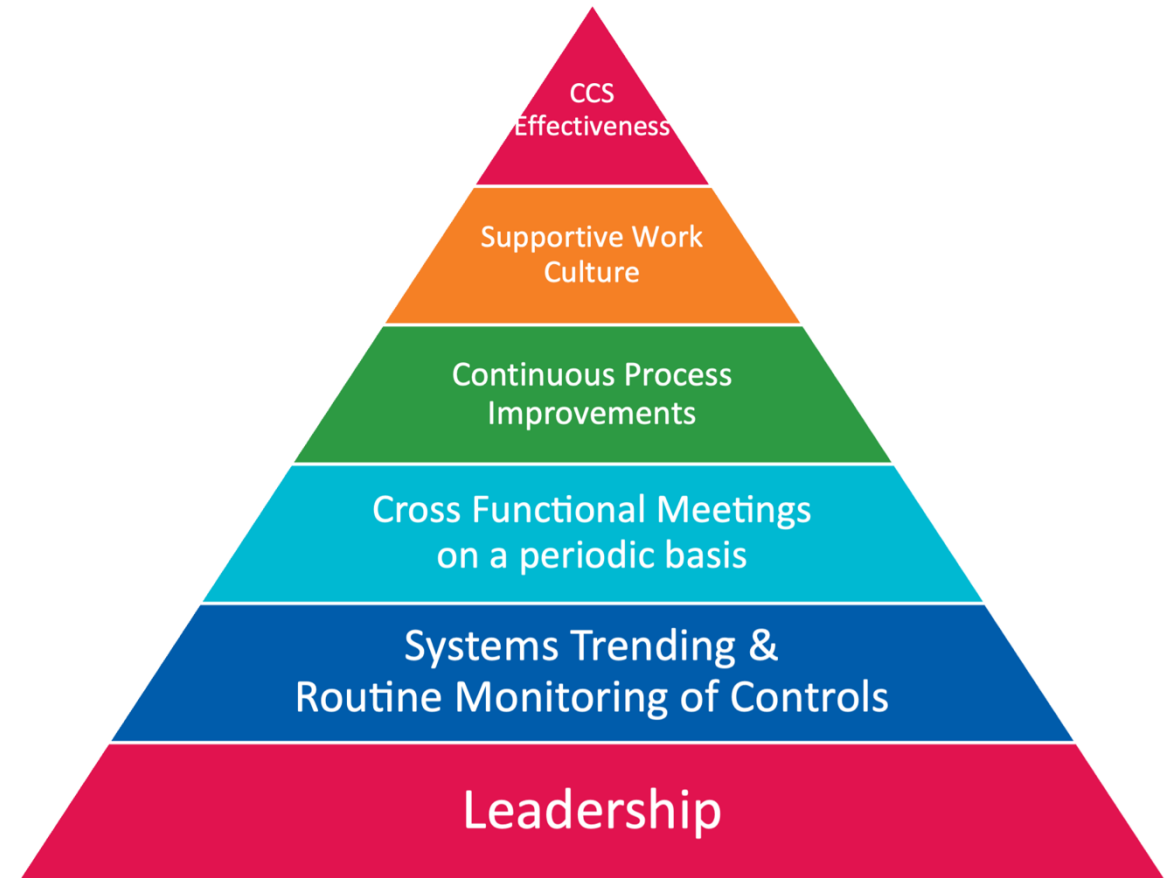
- Major process or equipment changes
- Contamination events or recurring deviations
- Trend analysis showing potential loss of control
- Introduction of new product or technology

Ownership must be defined: Identify who triggers CCS updates, reviews documents, and approves changes.

Review outcomes drive improvement:

Gaps found during CCS review should feed:

- Quality Plans
- CAPA systems
- Procedural updates &/or training



Looking Forward

CCS in Action: a continuous risk-control cycle

Assess Risk: Identify contamination pathways through data, design review, and process mapping.

Control Risk: Define and document control measures in the CCS: engineering, procedural, and monitoring layers of control.

Monitor Performance: Use environmental & process data to verify control effectiveness & detect early signals.

Respond & Learn: Investigate events, apply CAPAs, measure effectiveness, & feed outcomes back into the CCS in a codified way.

Review & Adapt: Management evaluates CCS performance, trends, & resourcing in periodic reviews.



Companies vary in their progress

Early CCS > Just a compliance check.
collection of documents & control lists.



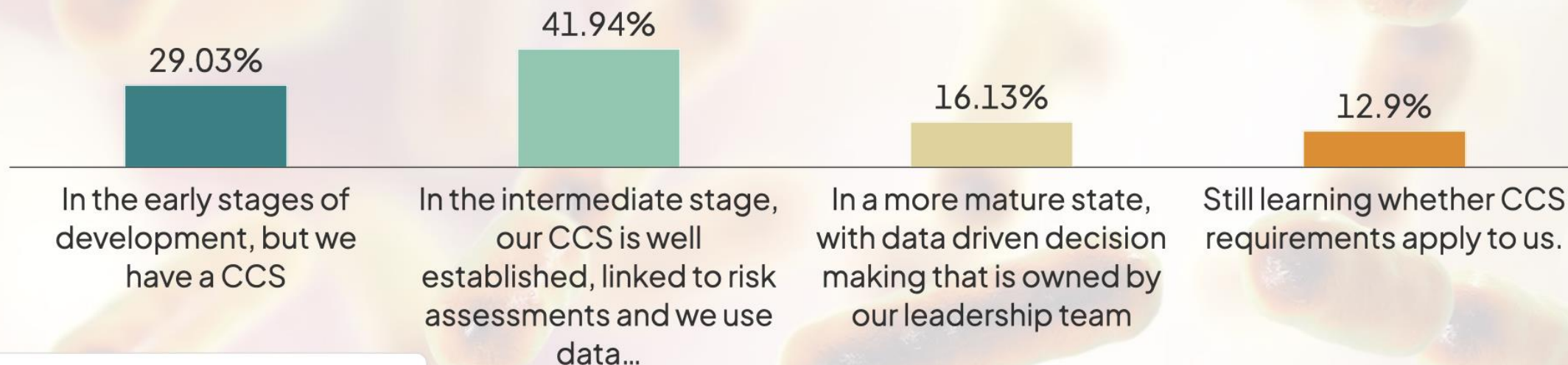
Intermediate CCS > Moves to Integration
linked to risk assessments & CAPA management.



Maturely Developed CCS > Process Capability
data-driven, predictive, owned by leadership.

Poll #2

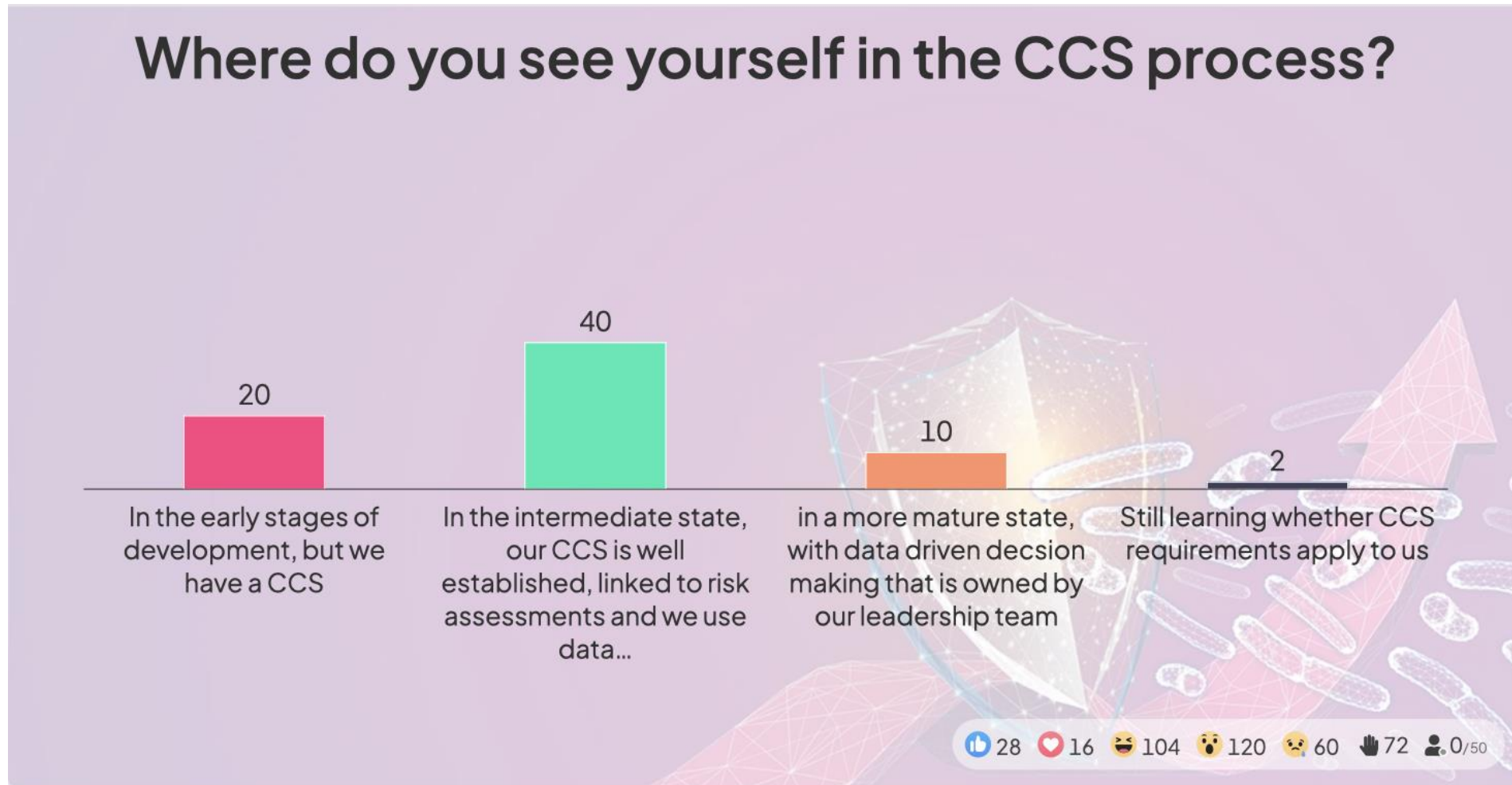
Where do you see yourself & your company in the overall CCS development process?



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↑ Get Feedback

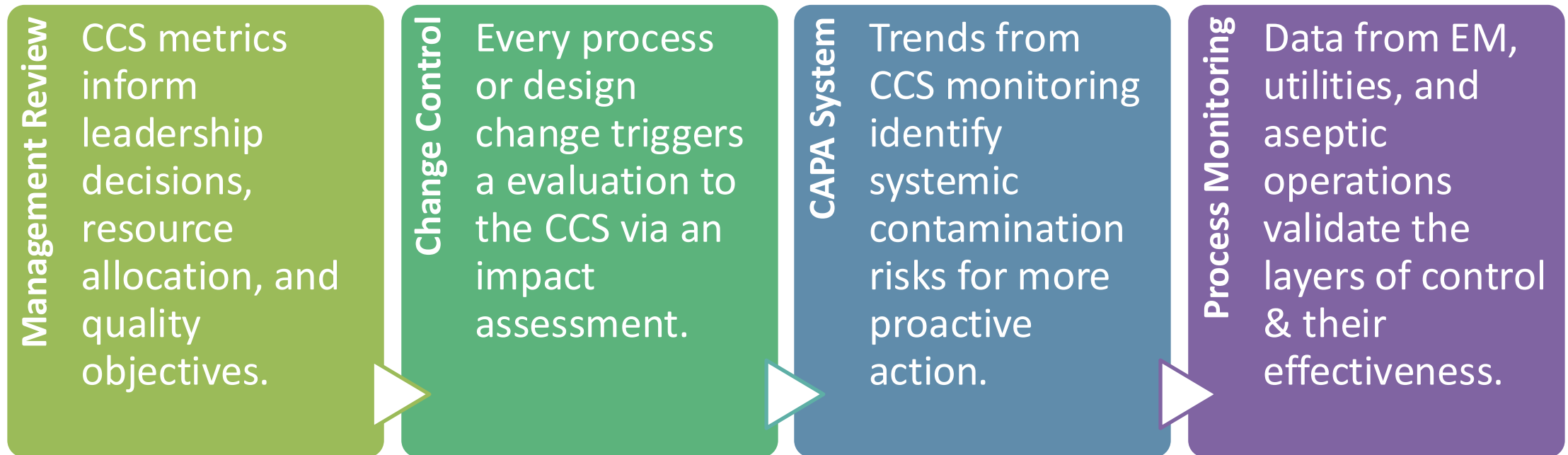
Polling Question 2 – Recent Industry Results



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How CCS Integrates with the PQS

Integrate the CCS within your Pharmaceutical Quality System



A final reflection



Contamination control isn't just a technical practice. It's not just a regulatory buzzword.

It's how an organization demonstrates awareness, accountability, and respect for what it manufactures.

It's also a measure of maturity.

References/Resources

1. *ISO 13408-1:2023 - Aseptic Processing of Health Care Products - Part 1: General Requirements. International Organization for Standardization. ISO 13408-1:2023 Aseptic Processing of Health Care Products - Part 1: General Requirements. ISO, 2023.*
2. *Pharmaceutical and Healthcare Sciences Society (PHSS). Contamination Control Strategy Guidance Explanation Document. PHSS, 2023.*
3. *Parenteral Drug Association. Technical Report No. 90: Contamination Control Strategy Development in Pharmaceutical Manufacturing. PDA, 2023*
4. *ECA Task Force on Contamination Control Strategy. How to Develop and Document a Contamination Control Strategy. Version 2.0, ECA Foundation, Dec. 2022.*
5. *European Commission. EudraLex, Volume 4: EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Annex 1 - Manufacture of Sterile Medicinal Products. European Commission, Aug. 2022.*
6. *U.S. Food and Drug Administration. Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing, Current Good Manufacturing Practice. U.S. Department of Health and Human Services, Food and Drug Administration, Sept. 2004*
7. *PDA/ANSI-03-2025 Standard Practice for Quality Risk Management of Aseptic Processes*



QUESTIONS ?

THANK YOU!

Vanessa Vasadi Figueroa
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