Quality Decision Review

A working guide for examining the evidence behind process-control decisions

November 17, 2026 · Built on FDA warning letter 320-27-17 to USV Private Limited · The Record Behind the Decision

How to use it. Set aside about an hour with your Quality team. Bring one recent decision in which favorable test results supported a conclusion that a process was in control, or that a batch could be released. Work through the sections in order, and finish with the worksheet in section 7.

What it is not. A discussion resource. It does not determine whether your organization is compliant, it is not regulatory or legal advice, and it does not describe your organization. Applications marked *fictional* are invented for illustration.

Why this guide exists

FDA's objection was not that USV's tests failed. It was that passing sterility, endotoxin, media fill and monitoring results could not establish control of an aseptic operation whose design FDA documented as flawed. In FDA's words, "such inherent flaws cannot be validated and necessitate redesign." The firm's conclusion that the process was in a state of control rested on outcome results that did not address the design problem. That is a management question about evidence and decisions, not only a manufacturing one.

The guide turns that lesson into questions a Quality team can put to its own records. Where a statement below is FDA's, it is attributed to the letter. Everything else is ComplianceWorxs analysis.

1. Evidence to examine

Sort the evidence behind your decision into three kinds. Direct evidence observes the process. Outcome evidence samples the result. Reasoning is what connects the two to a conclusion.

EVIDENCE	KIND	WHAT IT SHOWS	WHAT TO CHECK
Airflow visualization (smoke) studies and their video	Direct	How air actually moves over open product, at interfaces and during interventions.	Whether the study conditions matched routine operation, and whether the written conclusion agrees with the footage.
Observed operator interventions	Direct	Whether first air is protected in practice and how materials move between classified areas.	How often interventions occur in routine production, and whether the observation covered them.
Equipment layout and material flow	Direct	Whether equipment, conveyors and transfer points obstruct unidirectional flow to open containers.	Whether layout changes since the last study were assessed.
Media fills and process qualification	Outcome	That the process passed under the conditions the simulation represented.	Whether known vulnerabilities were inside the simulated worst case.
Environmental monitoring	Outcome	What was recovered at the sampled locations and times.	What lies between samples, and whether locations were chosen from the airflow evidence.
Sterility, endotoxin and other release results	Outcome	The result for the units tested.	How untested units were protected. A passing result samples; it does not trace protection.
Investigations, risk assessments and disposition records	Reasoning	What was concluded and by whom.	Whether the reasoning addresses contradicting evidence or rests on supporting results alone.

> If most of the weight in your decision sits on outcome evidence, that is the first finding of this

> review.

2. Process-control assessment questions

Design

1. What direct evidence shows unidirectional airflow over open product across the critical area, including transition interfaces?
2. Where could equipment position or a conveyor interrupt that airflow, and how do we know it does not?
3. Which design weaknesses are already known, and where are they recorded?

Operation

1. Which interventions occur in routine production, and has each been observed, not only described in the procedure?
2. How is first air protected during interventions, and who verifies it?
3. How are materials moved from lower-classified areas into the critical area, and what controls that flow?

Conclusions

1. Which conclusions about process control rest mainly on outcome results rather than on evidence about design?
2. Where does a written conclusion differ from the direct evidence it cites?
3. What would we expect to see in the evidence if the process were not in control, and did we look for it?
4. Who is authorized to stop production or hold release when design concerns are open, and has that authority been used?

3. Qualification and investigation considerations

- Do the qualification and media fill designs challenge the known vulnerabilities, or the conditions under which the process is most likely to pass?
- Are smoke studies conducted under dynamic conditions, with interventions, and repeated after changes to equipment, layout or procedure?
- When a study shows a discrepancy, is there an investigation with a scope, a root cause and a documented link to the batches affected?
- Do investigations extend beyond the single result to the process, the equipment and other lots?
- Is a result invalidated only with documented scientific justification, and who approves the invalidation?
- Does each corrective action have an effectiveness check that tests the original weakness, not only completion of the action?

> FDA's letter asked USV for, among other things, smoke studies under dynamic conditions with emphasis on aseptic interventions, and a comprehensive, independent risk assessment of human interactions, equipment suitability, air quality, facility layout, and personnel and material flow. It is a useful picture of the evidence that speaks to design.

4. Unresolved-risk review prompts

Use these for any decision made while an item was open.

1. What uncertainty remained at the time of the decision, and where is it written down?
2. Was the open item assessed against this batch, this line and this period, or only in general terms?
3. Which alternatives were considered: further investigation, a hold, restricted release, interim controls?
4. Who accepted the residual risk, under what authority, and on what date?
5. Did the person who authorized the decision see the unresolved item, and how do we know?
6. What new evidence would change the decision, and who would learn of it?
7. If an investigator asked for this decision to be explained in ten minutes, which records would we hand over?

5. A fictional authorization example

Fictional · Fictional Decision Review / BR-042. Invented for illustration. Not an FDA finding and not a real record.

A fictional sterile injectable manufacturer completed a batch. Release testing passed. Environmental monitoring was acceptable. An airflow-study discrepancy near the filling operation remained unresolved at the time Quality authorized release.

THE RATIONALE AS WRITTEN

"All release criteria were met. No evidence of contamination was detected. Batch release approved."

- **Establishes:** test results and a signature.
- **Does not establish:** that the airflow discrepancy was reviewed, assessed against this batch, or accepted by anyone with authority to accept it.

A STRONGER VERSION (FICTIONAL)

Open item: airflow-study discrepancy AS-17 near the filling station, unresolved at the time of authorization.

Evidence reviewed: the study and video, the location and conditions of the discrepancy, release test results, environmental monitoring.

Assessment: how the discrepancy bears on this batch, and what the passing results can and cannot show about it.

Alternatives considered: hold pending repeat study; release with added monitoring; release as is. Basis for the choice.

Residual risk and conditions: stated, with who accepted it.

Authorized by: name, role, authority under the release procedure, date and time.

Passing test results do not substitute for resolving contradictory evidence. The point is not that the fictional batch should have been rejected. It is whether the authorization was scientifically justified, adequately documented, and consistent with applicable requirements.

6. Management discussion guide

TIME	STEP
5 min	Choose one recent decision where favorable results supported a conclusion of control or release.
15 min	Lay out the evidence on the page: what was direct, what was outcome, what was reasoning (section 1).
15 min	Work the assessment and unresolved-risk questions (sections 2 to 4). Note every answer that depends on memory rather than a record.
10 min	Compare the written rationale with the fictional example (section 5). What would the stronger version require here?
10 min	Agree actions: which record to complete, who owns it, by when.

Three questions for the next Quality management meeting

1. Where do we rely on acceptable test outcomes as evidence that a manufacturing process remains in control?
2. Do our qualification records directly address known vulnerabilities, or primarily document passing outcomes?
3. When contradictory evidence emerges, can we trace the investigation, risk assessment, disposition decision, and authorization?

What to take away

- The decisions where the record rests on outcome results alone.
- The records to complete, with an owner and a date for each.
- Any authority questions to settle: who can hold a release or stop production when design concerns are open.

7. Discussion worksheet

Work one decision through the worksheet in the meeting. The middle column is a completed **fictional** example (BR-042, consistent with section 5), so the team can see what a finished entry looks like. Fill the right column for your own decision. Leave a cell blank if the record cannot answer it, and treat every blank as a finding.

QUESTION	COMPLETED EXAMPLE (FICTIONAL, BR-042)	YOUR DECISION
Decision under review	Batch BR-042: authorization to release a sterile injectable batch	
Decision owner and date	Head of Quality, release authority under the site release procedure (fictional); date of authorization	
Conclusion reached	The aseptic process was in control and the batch could be released	
Direct evidence: what was observed	Airflow study AS-17: turbulence near the filling station; operator intervention observed during setup	
Outcome evidence	Release testing passed; environmental monitoring acceptable	
Contradicting or unresolved evidence	The AS-17 discrepancy was open at the time release was proposed	
How the contradiction was addressed	Repeat airflow study ordered; batch held until it was complete and reviewed	
Alternatives considered	Release as is; release with added monitoring; hold pending the repeat study. Chosen: hold, then release with added monitoring	

QUESTION	COMPLETED EXAMPLE (FICTIONAL, BR-042)	YOUR DECISION
Residual risk, and who accepted it	Low after the repeat study, with added monitoring for the next three batches; accepted by the Head of Quality	
Where each item lives in the record	Study report, risk assessment and disposition record cross-referenced from the release decision	
Gaps found, owner and date	None for this decision. For your own: which records are missing, who completes them, and by when	

> A worksheet does not make a decision defensible. It shows where the record already explains the decision, and where the explanation depends on someone's memory.

8. Sources and limitations

- FDA warning letter 320-27-17 to USV Private Limited, November 2, 2026. FDA's account at the time of issuance; some passages are redacted in the public letter and are not reconstructed here.
- FDA guidance cited in the letter: *Sterile Drug Products Produced by Aseptic Processing: Current Good Manufacturing Practice* (fda.gov/media/71026/download); ICH Q9(R1) Quality Risk Management (fda.gov/media/167721/download); ICH Q10 Pharmaceutical Quality System (fda.gov/media/71553/download).
- The full analysis: The Enforcement Record, Issue 1.

Limitations. This guide is a discussion aid. It does not assess compliance, predict inspection outcomes or guarantee any regulatory result, and it does not replace your approved procedures, your Quality Unit's judgment or qualified regulatory advice. A single warning letter does not show how common any weakness is. Fictional content is marked and is not drawn from any real company's records.

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