5 signs your cleaning validation program is slowing production

CLEANING VALIDATION CHECKLIST

VEOLIA

Introduction

Cleaning validation is essential to product quality, patient safety, and regulatory compliance. Yet in many pharmaceutical facilities, traditional cleaning validation workflows can create hidden operational inefficiencies.

Laboratory-based testing often introduces delays between equipment cleaning and equipment release, slowing manufacturing operations and limiting process visibility. While HPLC and other analytical techniques are common, Total Organic Carbon (TOC) testing offers a more comprehensive understanding of overall cleanliness and enables seamless transition from lab to Process Analytical Technology (PAT) with at-line or online options.

Use this checklist to assess whether your current cleaning validation program could be impacting productivity, compliance, or operational agility.

#1 You are waiting hours (or days) for cleaning validation results

Ask yourself if these scenarios apply:

- [ ] Samples must be transported to a central laboratory
- [ ] Production teams are waiting for laboratory results before equipment can be released
- [ ] Equipment remains unavailable while QC testing is completed
- [ ] Cleaning verification is creating scheduling challenges

Potential impact

Long turnaround times can delay equipment release, extend production downtime, and reduce manufacturing flexibility.

#2 Cleaning validation testing is creating laboratory bottlenecks

Ask yourself if these scenarios apply:

- [ ] QC teams manage a high volume of cleaning validation samples
- [ ] Analysts spend significant time preparing and running tests
- [ ] Laboratory workload increases during production peaks
- [ ] Additional testing requests compete with routine QC activities

Potential impact

As manufacturing demand increases, laboratory capacity can become a limiting factor for operational efficiency.

#3 Your investigation process is mostly reactive

Ask yourself if these scenarios apply:

- [ ] Contamination events are only identified after samples reach the laboratory
- [ ] Root cause investigations begin long after cleaning activities have been completed
- [ ] Trending information is limited
- [ ] Process visibility is restricted to periodic sampling

Potential impact

Delayed detection can increase investigation time, reduce process understanding, and create unnecessary operational risk.

#4 You have limited real-time visibility into cleaning performance

Ask yourself if these scenarios apply:

- [ ] Cleaning effectiveness is only confirmed after laboratory testing
- [ ] Operators have little immediate feedback during cleaning operations
- [ ] Process adjustments cannot be made in real time
- [ ] Cleaning validation is disconnected from production decision-making

Potential impact

Without timely information, opportunities for process optimization and continuous improvement may be missed.

#5 | Your facility is exploring continuous manufacturing or PAT initiatives

Ask yourself if these scenarios apply:

- [ ] Your organization is evaluating Process Analytical Technology (PAT)
- [ ] Real-Time Release Testing (RTRT) is part of future manufacturing plans
- [ ] Data integrity requirements are increasing
- [ ] Process understanding has become a strategic priority

Potential impact

Traditional laboratory-only testing approaches may not provide the level of process insight required for future manufacturing strategies.

HOW MANY BOXES DID YOU CHECK?

Your results

0-4 checks	5-9 Checks	10+ Checks
Your current cleaning validation workflow appears to be operating effectively enough for your facility's needs.	There may be opportunities to reduce laboratory workload, improve turnaround times, and increase operational flexibility.	Your cleaning validation process may be contributing to production delays, reduced equipment availability, and limited process visibility.
Continue monitoring opportunities to improve efficiency and process visibility.	Consider reviewing how cleaning validation data is collected and used throughout your facility.	Exploring at-line or online cleaning validation approaches could help improve efficiency and support future manufacturing initiatives.

Looking ahead

As pharmaceutical manufacturers continue to focus on operational excellence, data integrity, and real-time process understanding, cleaning validation is evolving beyond traditional laboratory workflows. **Modern approaches to TOC testing can help organizations:**

✓ Accelerate equipment release
✓ Improve manufacturing agility
✓ Reduce laboratory bottlenecks
✓ Strengthen process understanding
✓ Support future PAT and RTRT strategies

Download the TOC technology guide

Looking for ways to streamline your cleaning validation process? Explore our practical guide to TOC technologies to discover how modern analysis can help reduce laboratory bottlenecks, accelerate equipment release, and improve your overall testing efficiency.

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