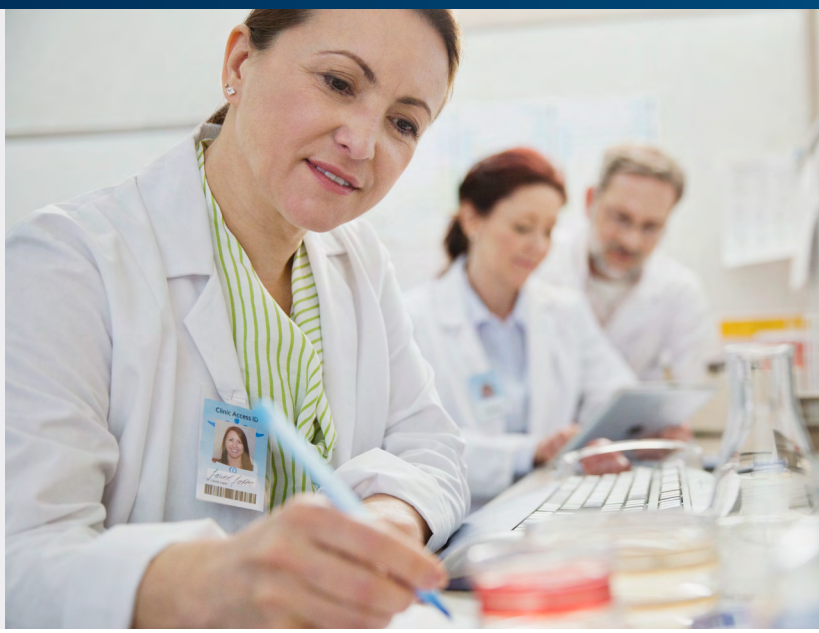
FACT SHEET

IQVIA SmartSolve® Out Of Specification Management

Ensure consistent out-of-specification lab result investigations



Your organization has a reputation to maintain for producing high-quality drugs, active pharmaceutical ingredients (APIs), excipients, and other drug components.

Yet unexpected batch failures and test result discrepancies can occur. When they do, it's your job to ensure proper investigations are performed, leading you to the root cause of the out-of-specification result. IQVIA SmartSolve® Out Of Specification Management makes your process simple, consistent, and compliant. The solution provides a closed-loop workflow to document, verify, and investigate out-of-specification test results.

Out Of Specification Management helps you:

- Demonstrate **data integrity** with consistent out-of-specification (OOS) investigations
- Identify **out-of-trend (OOT)** results through reporting and trending
- **Reduce the risk** of poor quality
- Experience the power of a **closed-loop system**
- **Integrate** with core business systems

DEMONSTRATE DATA INTEGRITY WITH CONSISTENT INVESTIGATIONS

How do you maintain your market reputation and ensure your customers know your market-released products have been manufactured exactly as designed, and with the correct potency and purity? The answer is data integrity, a critical factor for the pharmaceutical industry. Unfortunately, a trending citation for scrutiny in FDA warning letters and regulatory actions is laboratory data integrity.

A key component to any quality management system and current Good Manufacturing Practices (cGMPs) requirements is tracking out-of-specification results and investigations to support and reinforce your organization's data integrity and reputation.

"Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed."

- CGMP 21 CFR 211.192

While testing results are normally captured in a laboratory information management system (LIMS), there is often a gap for tracking OOS result investigations. Standardized best-practice workflows within Out Of Specification Management keep you in control of the OOS investigation process. Designed for compliance, the workflow mirrors the two-phase approach detailed in the FDA's guidance

document (laboratory investigation and full-scale OOS investigation). This includes a consistent process to record the investigation, drive root-cause identification, and document conclusions and follow-up.

REPORTING AND TRENDING PROVIDE A PULSE ON OOT RESULTS

Out Of Specification Management allows you to capture, investigate, escalate, and resolve product quality issues by tracking and trending your OOS lab results. As you investigate any OOS results, the intuitive, built-in reporting tools within SmartSolve keep a pulse on historical data values that may be trending away from your intended outcomes. This can help you identify potential problems sooner in your process, even if the trend has not yet triggered a corrective and preventive action (CAPA).

Likewise, if your data shows a growing number of OOS results from a particular lab analyst, it may be a warning to review training, or the test design itself. Or, if the data shows a growing number of OOS results from materials produced on one piece of equipment, it may be time to review the maintenance and calibration schedule for the equipment. The reporting tools help guide insight and action relating to the status of OOS investigations, primary root causes, aging on open investigations, and similar OOS occurrences.

REDUCE RISK OF POOR QUALITY

When the FDA audits your business, its eyes are on key records, such as: whether your staff is properly trained; if your test procedures are properly defined; or, if there may be a design flaw allowing more results to pass than should. Keeping your eyes and attention on consistent OOS investigation results and OOT data points can help you identify gaps in your quality system so you may work toward continuous improvement. For example, are you seeing an increasing number of OOS results from a specific supplier's materials? It may be time to audit that supplier or your contract manufacturing organization (CMO).

In addition, with SmartSolve, you can define your risk tolerance for each particular failure. This allows you to configure the system to match your business practices and to ensure that each OOS result's risk is appropriately managed after its investigation.

CLOSED-LOOP QUALITY MANAGEMENT WITH SMARTSOLVE

Out Of Specification Management is designed to keep you compliant and integrate with other key quality management processes for a closed-loop quality management solution. Does the root cause of an OOS result point to a training gap? Do you need to initiate a corrective and preventive action (CAPA), Deviation or Change as a result? SmartSolve not only incorporates best practices to help you get to the root cause of your issue consistently, every time, but it also helps you manage other key quality events within a single platform.

Having a consistent, compliant process for tracking your OOS test results can keep your quality system audit-ready.

In addition, Out Of Specification Management can integrate with a LIMS to track test results and initiate the OOS record within SmartSolve. Investigations and associated root causes can be recorded and cross-reference any relevant records in the LIMS.

Having a consistent, compliant process for tracking your OOS test results can keep your quality system audit-ready. When you can prove compliance, demonstrate consistent investigations, and easily retrieve the right information from your system, you'll be prepared for an inspection.

INTEGRATE WITH CORE BUSINESS SYSTEMS

Compliance and quality data may be used in other business systems within your organization. SmartSolve provides Web Services to bidirectionally integrate key data such as products or components, test names, risk tolerance, suppliers, lot and batch numbers, sites, and departments. The ability to share data with ERP, CRM, LIMS, MES, and PLM applications reduces administration time and improves data integrity across systems.

SmartSolve — The Enterprise Quality and Compliance Management Platform

SmartSolve, IQVIA's powerful suite of quality compliance management solutions, is engineered for the life sciences. Delivered on a best-practice, compliance-ready platform, SmartSolve provides closed-loop process integration unmatched in the market. With electronic signatures, audit trails, validation packs and electronic reporting, SmartSolve gives you control and confidence. That means you can focus on progress, not problems. Opportunities, not obstacles. Whether you are ready to automate a single process or optimize your entire quality management system, SmartSolve prepares you to succeed.

FEATURES	BENEFITS
Simple OOS reporting forms	Improve data integrity by capturing OOS results in a consistent manner.
Two-phase investigation process	Maintain compliance with a process that mirrors the FDA's two-phase OOS guidance.
Phase I investigation	Reduce overall Cost of Quality by resolving investigations quickly once a root cause is determined.
Analyst and supervisor checklists	Ensure consistent, in-depth lab analysis.
Phase II investigations (LAB and MFG)	Ensure product safety with detailed investigations.
Parallel processes	Shorten OOS cycle time.
Concluding disposition	Support patient safety by allowing only those products that meet specifications into the supply chain.
Risk-based CAPA escalation	Prioritize and speed resolution of critical investigations.
Automatic notifications and escalation	Strengthen accountability by involving the right subject matter experts (including lab and manufacturing personnel) at the right time.
OOT analysis	Develop visibility into systemic issues and support continuous improvement efforts.
Integrated QMS	Streamline processes and increase efficiency through integration with CAPA, Change, and Deviation Management.
Integration with LIMS and other third-party systems	Ensure overall data integrity and reduce error.
Consumer-grade UX/UI	Increase user adoption, simplify tasks, and reduce errors and training needs through an intuitive user interface and user experience.

IQVIA TECHNOLOGIES

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