Agile Process Teams: Quality Review

Accelerate Review Cycles and Ship Products Faster

Track, Review, and Approve Quality Documents with Suppliers and CMOs

Reviewing and approving quality documents with suppliers and contract manufacturing organizations (CMOs) is a cumbersome and disjointed process. Documents are circulated via email, often getting lost in inboxes, resulting in delays and confusion over a document's location and status. In addition, there is typically poor visibility between the quality and supply chain functions, with each relying on phone calls and more emails for status updates. The end result is lengthy document review times, missed commitment dates, products shipped before quality release, and products held up in quarantine.

Part of the TraceLink Agile Process Teams™ suite, TraceLink Quality Review™ provides pharmaceutical manufacturers, suppliers, and CMOs with a secure workspace to collaborate on reviews of batch records, certificates of analysis and conformance, and other quality documents that need to go through a structured review process. Quality and supplier management teams gain real-time visibility into review status, anomalies needing attention, audit trails, and key quality performance metrics for quality reviews across all sites and vendors. Team members across both organizations have dashboard views of all open and closed review processes and can immediately receive notifications when batches are released at a remote site. Quality Review does not replace your existing quality management system (QMS) nor that of your partner, but instead it streamlines the communication and collaboration on the review and approval of documents that originate in the QMS. The net result is more reliable review processes and more on time, in full (OTIF) shipments.

Expedite Approvals and Improve Product Supply

In addition to facilitating access to documents, Quality Review accelerates reviews and approvals by establishing a structured process with due dates, owners, workflow steps, and streamlined communication. Instead of documents waiting to be reviewed in someone's email inbox for days, they can be reviewed according to a schedule with accountability assigned and tracked. An integrated communication trail linking all notes, comments, and documents accelerates the process. Users can quickly check statuses, review recent activities, and see who is responsible for the next step. With the appropriate permissions, users can view the commentary captured as part of a review cycle and receive notifications when documents have been commented on or moved to the next stage in the review cycle. A dashboard summarizes which batch records are open and which have been closed, indicating batches are ready to ship.

By taking advantage of a centralized repository of up-to-date documents, users no longer waste time fumbling through emails, wondering if they have the latest document version, and trying to match lot numbers and pull together supporting quality documents. With quicker review times, they can move products from quarantine to commercial stock faster. Using a structured process and centralizing information, Quality Review customers have experienced significant reductions in batch record review cycle times (up to 75%), resulting in improved OTIF and increased right first-time metrics.

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Reduce Costs and Improve the Quality Process

Typical quality review processes are not only slow but inefficient. Review times are extended and many non-value-added tasks such as searching for and compiling information, emailing colleagues and trading partners, making phone calls, and manually compiling status reports get added to the process of approving a quality document. By streamlining the review and approval process Quality Review can reduce the amount of effort by about 20%. In addition, supply chain and commercial teams can receive instant notifications when a batch record is approved, resulting in reduced errors and faster fulfillment of customer orders.

Longer term, you can enhance your quality operations further through performance monitoring and continuous improvement. Because Quality Review provides a consistent, repeatable approach across all quality processes and sites, performance can be easily measured and compared. An integrated real-time KPI dashboard helps you monitor and improve batch record, change control, and incident reviews. Document review metrics include right first time, average iterations, and document review cycle time.

Get Started in Less than a Day with a Proven Application

Quality Review has been deployed by global pharmaceutical companies across over 90 CMOs with about 90,000 quality documents processed to date. But it's not a complex application that requires weeks or months to install, configure, and integrate. It's a SaaS application with no required integration, so you can start using it in less than a day and onboard new users in minutes. And because more than 280,000 life sciences trading partners are on the TraceLink Digital Supply Network™, many of your suppliers and CMOs are already connected. This means these partners are verified and can quickly start collaborating with you. In addition, the many CMOs already using Quality Review don't need to learn a new software system. They simply activate another manufacturer within Quality Review and start managing quality documents.

Begin the Journey to a More Agile Supply Chain

Quality Review is just one application in the Agile Process Teams suite of products for collaborating with your trading partners for a more responsive supply chain. Other applications include TraceLink Issue Tracking™ and Change Management™. Together these applications enable companies to manage and track the execution of multi-enterprise business processes in order to resolve issues and improve the delivery of medicines to patients. Start with any of these applications to collaborate with trading partners and build a more agile supply chain today.

KEY BENEFITS

- Up to 75% reduction in batch record review time
- Shorter quality review cycle times and lower operational costs
- Reduced risk of delays, shortages, and disruptions
- Increased revenues
- Improved quality and quality process performance
- Elimination of manual administration, polling for status updates, sifting through email inboxes, and laboriously compiling status reports
- Demonstration of oversight and control of information to regulators for quality review activities

KEY FEATURES

- View dashboard of all batch records pending and closed across all partners and sites
- Create a transparent, predictable, and repeatable quality review process
- Manage, track, and collaborate with vendors and internal sites
- Enable vendors to submit batch records and other quality documents
- Share documents, notes, and comments among multiple parties using a secure document repository
- Capture metrics such as right first time and document review cycle time

Contact Us

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