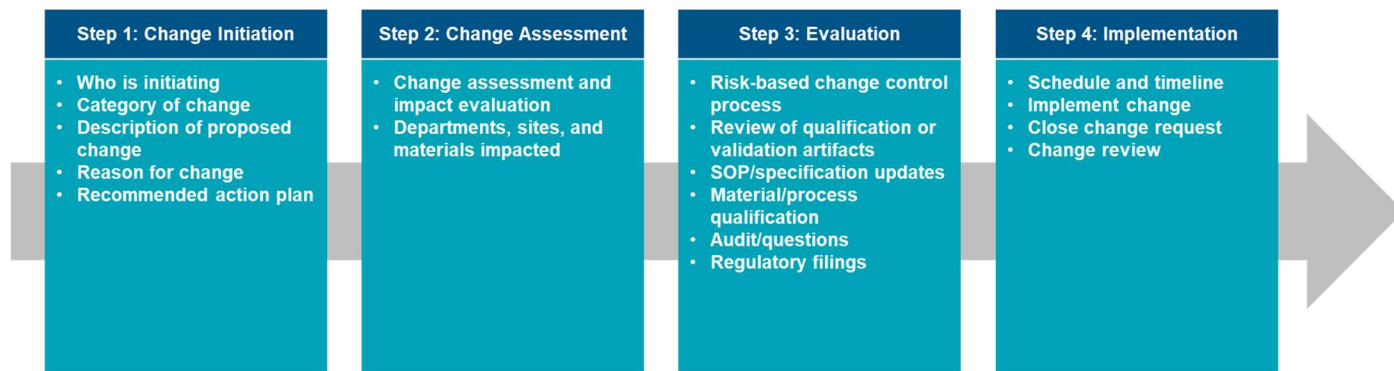# Agile Process Teams: Change Management
Streamline Supplier Change Requests and Minimize Disruptions

Evaluate, Monitor, and Approve Supplier-Initiated Changes

Managing the change control process across the supply and manufacturing network is often an ad hoc, cumbersome, and opaque activity in which critical documents and action items are exchanged via emails across pharmaceutical companies, suppliers, and contract manufacturing organizations (CMOs). The lack of a structured process and poor visibility into the status of change requests increase the risk of supply chain disruptions and poor right first-time quality. In the wake of the global pandemic, as supply chain shortages have forced suppliers to seek alternative sources of supply on short notice, lengthy change control processes are an increasing problem.

Part of the TraceLink Agile Process Teams™ suite, TraceLink Change Management™ helps companies coordinate and streamline the change control process, document management, and communications in a single workspace across all suppliers. Suppliers can submit requests and documentation, and notify all stakeholders of the reason, impact, and timing of a change control request. The application enables a collaborative process to communicate, acknowledge, iterate, and accept changes and make requests for additional information. Users can quickly understand and evaluate changes to raw materials, product contact materials, manufacturing methods, product tests, and production equipment and processes. The result is quicker change approvals, lower risk of supply chain disruptions, improved supply chain agility, and improved right first-time quality.

Step 1: Change Initiation	Step 2: Change Assessment	Step 3: Evaluation	Step 4: Implementation
• Who is initiating • Category of change • Description of proposed change • Reason for change • Recommended action plan	• Change assessment and impact evaluation • Departments, sites, and materials impacted	• Risk-based change control process • Review of qualification or validation artifacts • SOP/specification updates • Material/process qualification • Audit/questions • Regulatory filings	• Schedule and timeline • Implement change • Close change request • Change review

TraceLink Change Management Enables a Structured Process for Evaluating Supplier Change Requests

Accelerate Change Approvals and Maintain Continuity of Supply

Any supplier change, whether planned or unplanned, has the potential to interfere with production and cause disruption if the change is not thoroughly evaluated, tracked through a structured process, and approved in a timely manner. Delays in intake, evaluation, approval, and closeout can accumulate to the point of creating supply shortages and production delays. TraceLink

tracelink
NETWORK FOR GREATER GOOD

Change Management accelerates the change process by establishing a consistent, structured process for evaluating and approving supplier change requests. This way, requests and supporting documentation are not sitting in email inboxes waiting for a response. Suppliers submit changes and documentation to a secure workspace that is visible to both parties. Due dates, owners, and workflow steps are defined, and communication is streamlined. A standard process to communicate acknowledgement, acceptance, approval, or rejections of changes is established. Every stakeholder in the process has access to the latest documents and information and can collaborate with colleagues and suppliers to evaluate and close out changes. The solution offers configurable alerts and notifications as well as the ability to "follow" a critical issue for progress to completion. With a faster change control process, companies can avoid delays and deliver on-time, in-full.

Improve Supply Chain Agility

The growing level of disruptions from natural, economic, and geopolitical events over the last twenty years has highlighted the need for supply chains to be more agile. Disruptions require manufacturers to make changes to materials, equipment, and processes to adapt to changing business conditions. Thus, the ability to quickly review and approve such changes is not just a means of delivering the next order, but part of a strategy of building a more agile supply chain. By centrally managing the change control process, companies can gain a global view of their supply network, measure and monitor key performance indicators of the change process, and identify supply risks. This means you can respond to potential problems before they happen.

Safeguard the Quality and Integrity of Your Supply

In addition to accelerating the change process and improving supply chain agility, TraceLink Change Management also safeguards the integrity of your supply. Frequent supplier changes are a source of risk, particularly when done to cut costs or rushed to respond to supply chain disruptions. Change Management complements quality management systems (QMS) and R&D change management systems by providing an intercompany extension of the change control process. A structured methodology with improved access to information makes for a better review process and better decisions.

Begin the Journey to a More Agile Supply Chain

Change Management 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 Quality Review™. 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.

Contact Us

For more information about TraceLink visit TraceLink.com or call +1 (781) 914-4900

tracelink
NETWORK FOR GREATER GOOD

KEY BENEFITS

- Consistent and uniform change control process across internal and external teams
- Faster review and approval of supplier changes for improved supply chain agility
- Reduced risk of supply shortages and disruptions
- Lower operational costs from a more efficient review process
- Improved supply quality
- Elimination of manual administration, polling for status updates, and sifting through email inboxes

KEY FEATURES

- Enable suppliers and CMOs to initiate online change requests
- Assign, evaluate and track change requests through closure
- Collaborate with external partners and internal reviewers throughout the evaluation and approval process
- Track change type, material category impacted, change driver, implementation dates, and impacted sites and products
- Integrated two-way communication and document sharing with suppliers
- User roles to grant read-only and modify access to changes
- User-configurable tracking of changes by suppliers, sites, and material categories
- Extract change data for KPI analytics to monitor changes and identify supply risks
- Private and secure communication and access controls to maintain privacy