



Nonconformance Initiation

VALUE PROPOSITION

Accelerate nonconformance review and approval cycles as incidents automatically move from one stage to the next

Reduce repeat nonconformance with consistent and closed-loop investigation corrective/preventive action process

Improve communication and teamwork on quality issues across departments and functional areas

Gain enterprise-wide visibility into the status of nonconformance incidents and track related process metrics

OVERVIEW

Managing material and process nonconformance to minimize its impact on the product quality and ensuring that the cause of the nonconformance is uncovered and eliminated is one of the central functions of an organization's quality unit. Relying on stand-alone point solutions or paper-based processes to manage nonconformance is ineffective as they fail to address systemic quality problems and do not have broad enterprise reach and visibility. To successfully handle nonconformance incidents, quality managers need powerful automation and collaboration tools as review and remediation activity often spans across departments and locations.

MetricStream Nonconformance Management is a comprehensive solution that enables companies to establish and follow consistent procedures for material or processes that does not conform to desired specifications. The module supports identification, evaluation, segregation and disposition of nonconforming material as well as case investigation and tracking, possibly leading to a corrective action (CAPA). The powerful analytics and reporting capability with graphical dashboards give managers complete real-time visibility into the quality system and provide critical information for investigating nonconformance and executing corrective/preventive actions.

FEATURES AND FUNCTIONALITY

INITIATE NONCONFORMANCE

Allows initiating a nonconformance and assigns a unique case number that can be used to track the incident as it goes through various stages. Provide detailed information about the issue; categorize issue type based on pre-defined criteria and select severity level; identify the responsible department or supplier and send notifications. Correlate with past data for quick analysis and decide if containment or corrective action is needed.

REVIEW AND APPROVAL

Routes the nonconformance issue to Material Review Board (MRB) or other authorized users based on pre-configured rules for review, approval, and disposition. Procedure for rework, retesting and reevaluation can be initiated after determining quantities for return to vendor, use as is, rework and scrap. The data is applied to defects PPM metrics to enable constant monitoring of supplier performance.

REMEDIAL ACTIONS

Enables triggering automatic alerts and notifications to appropriate personnel for initiating immediate remedial action to contain the impact of the nonconformance and conduct failure investigation to identify root cause. If a corrective/preventive action (CAPA) is initiated, the case remains open till the action plan is carried out and results verified for effectiveness; manager can track the status of the case as it automatically moves from one stage to the next based on organizations quality control procedures. If appropriate, the supplier charge-back calculation and process can be started.

REPORTS AND METRICS

Provides complete real-time visibility into the nonconformance data with analytics for trend analysis. Reports for status tracking, supplier charge-backs, cost of nonconformance, supplier scorecards and PPM metrics can be readily accessed. Graphical executive dashboards and flexible reports, with drill-down capability, provide statistics and data by a variety of parameters such as production runs, plants, lots and batches.

MetricStream

DATASHEET

NONCONFORMANCE MANAGEMENT

MetricStream **Enterprise Compliance Platform** is a robust and scalable infrastructure that provides core services and capabilities leveraged by the Nonconformance Management module including:

Embedded **best practices** - such as FDA cGMPs - ready to be used out-of-the-box with the flexibility to meet specific requirements and adapt to changing business processes

Fast implementation with a workflow and collaboration engine that provides configurable forms design and creation, information flows, notifications, alerts and escalation paths

Secure **web-based** access for all users with appropriate views and tabs for initiating actions, responding to events, managing todo lists and assigned tasks, viewing reports and dashboards

Built-in **reporting** for analytics and business intelligence for statistical process control with a tool to create custom reports that can be emailed or exported into formats like MS Excel and Adobe PDF

Executive role-based **dashboards** for graphical views of information with the ability to drill down to the finest level of detail to see the underlying data

Integration with external systems to retrieve, store and deliver data; leverage XML-based adapters for connectivity to other enterprise applications

Seamless integration with **CAPA**, Document Management and other quality applications and processes



Nonconformance Dashboard

Corporate Office

2600 E. Bayshore Road
Palo Alto, CA 94303
Phone: 650-620-2900
Fax: 650-632-1953

US East Coast

3901 Roswell Rd NE
Suite 337, Marietta, Georgia 30062
Phone: 770-578-7580
Fax: 770-578-7583

Europe

Weichselmattstrasse 58
4103 Bottmingen, CH
Phone: +41 78 890 1003