Quality Review Manager

- Support exception review process in a single environment

- Review process exceptions in real-time before your batch is complete

- Collect automated and manual exception information

- View exceptions easily on order-related dashboards

- Manage exception lifecycle through signature controlled resolutions

Identify, review, and resolve process exceptions to drive quality in your product release.

Introduction

Quality Review Manager is a software application designed to reduce the time and effort required to identify, review, and resolve process exceptions. Delivered as part of the Syncade manufacturing execution system (MES), this product supports a review-by-exception methodology, allowing quality and manufacturing personnel to release batches faster, resulting in a reduction in inventory and in the time required to release product to patients, while continuing to promote quality.

Quality Review Manager helps accelerate the review time associated with process exceptions by gathering exception information in one, easy to access environment. Real-time review of process exceptions allows you to investigate and resolve exceptions as they occur, even while the batch is still in process. The ability to append information related to the event in a timely manner enables more accurate investigation and faster resolutions.

Quality Review Manager provides out-of-the-box functionality for exception sources, including Syncade Workflow and DeltaV Alarms and Events. In addition, Quality Review Manager can be extended to include third party systems that

generate process-related exceptions. By tightly integrating your exception review process with your automation and manufacturing systems, you set the foundation for improved data integrity.

Quality Review Manager is designed for the life sciences industry and enables compliance with 21 CFR Part 11 and EU Annex 11 regulations.

Organize your review process with configurable exception types

Configurable exception types allow you to categorize exceptions and their resolution steps. Each exception type can be configured to automatically gather data, providing context to the exception as it occurs.

Quality Review Manager connects to exception types generated by Syncade Workflow, automatically generating exceptions when issues are detected with critical process parameters, non-standard activities (such as forced steps), or when comments are added to work instructions. Your recipes do not need to change in order to support these exceptions types. In addition, Quality Review Manager connects to the DeltaV alarms and events database. When alarms are detected that
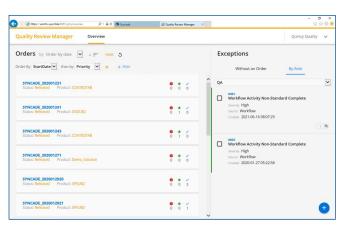
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Figure 1: Review orders and exceptions by states to prioritize your review process.

Figure 2: Review, annotate, and close exceptions for each order.

match the configured criteria, the alarm is registered as an exception. Alarms can be filtered so you can create exception types for "Controller Process Alarms." OPC tags can be monitored in a similar way using the Event Monitor plug in.

Log manual exceptions types either directly from Quality Review Manager or from Syncade Workflow. When an exception is manually logged from the Syncade Workflow environment, the system records the order associated with the exception to provide context for the exception.

Optimize quality review process with configurable resolution stages

By defining the resolution stages and signatures required by an exception type, you can categorize your response. Simple exceptions may require minimal investigation while more critical exceptions often require a more detailed and rigorous resolution process.

Quality Review Manager uses resolution stages to determine the level of investigation needed, requiring an electronic signature to move through the resolution stages. Stages must be completed in the sequence required by the exception type.

Focus review processes using exception severities

Assigning a severity to an exception type allows you to prioritize your quality review processes. Severities allow you to sort exceptions to address the most critical issues first. Easily change an exception severity after the exception is created to ensure the correct resolution stages and signatures are recorded.
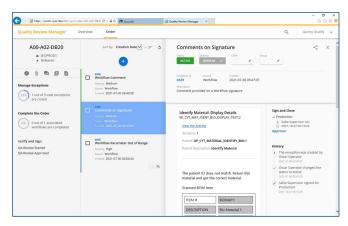
Improve product release times by streamlining review process

Once all workflows are completed and all exceptions are closed, Quality Review Manager helps you gather the signatures required to complete your manufacturing review and close the order. Orders set to auto close will move to the closed state as soon as the final review signature is collected.

HTML 5 Compatible User Interface

Quality Review Manager uses an HTML 5 user interface designed for browser agnostic systems, delivering scalability and compatibility with all current browsers and most modern mobile tablets.

Quality Review Manager displays a high-level overview of all orders and their related exceptions (see Figure 1). You can simply select an order for a more detailed review.

The detailed order view provides a view of all exceptions related to a specific order (see Figure 2). Easily add detail to an exception and move it through the relevant resolution stages to achieve final approval. Once all exceptions are reviewed and resolved, the order can complete manufacturing review and be closed.

System Prerequisites

Quality Review Manager requires the following Syncade modules.

1. Order Management to provide order information.

2. Security and Audit to provide a security model for users.

3. Document Control & Archiving to store the exception report *(Also is acceptable to use a non-Syncade document repository)*.

4. Workflow to allow exceptions to be triggered manually and automatically from workflow.

Quality Review Manager Licensing

Quality Review Manager is licensed as an add-on component to the Syncade MES. The following statements apply to the QRM license.

1. One license is required for each Syncade production server.

2. The license requires the purchase of a Guardian Support License.

3. Quality Review Manager uses the same named user license as the Syncade production server.

4. Quality Review Manager requires an Event Monitor license for connectivity to DeltaV Alarms and Events.

Ordering Information

Description	Model Number
Quality Review Manager add-on license for Electronic Batch Records	DF1218
1-Year Guardian Support for Quality Review Manager add-on license for Electronic Batch Records	DF1218-GS
An add-on task for generating exceptions from third party systems and that provides functionality to create exceptions in Quality Review Manager (QRM)	DF1218A1
1-Year Guardian Support for add-on task for generating exceptions	DF1218A1- GS
Add-on to Quality Review Manager; task for generating exceptions from third party systems	DF1218A1
1 Year Guardian Support for task add-on to Quality Review Manager	DF1218A1-GS

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