QAchange™

Electronic Change and Deviation Management

FDA Regulative, CFR Title 21 Subpart F - Production and Process Controls §211.100 - Written procedures; deviations

(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

(b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified.

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Are You Compliant?

FDA Regulative, CFR Title 21 Subpart I Laboratory Controls, §211.160 General requirements

"(a) The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified."

FDA Regulative, CFR Title 21 Subpart J Records and Reports, §211.180 General requirements

"(e) Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures shall be established and followed for such evaluations and shall include provisions for:

1. A review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch.
2. A review of complaints, recalls, returned or salvaged drug products, and investigations conducted under."

Minimize Interruptions to Production and Maximize Operational Efficiency

The Industry Challenge

Maintaining regulatory compliance and validated state in on-going pharmaceutical manufacturing may lead to avoid changes to once validated systems or documentation. However, every change in regulations or manufacturing process triggers a need to update the documentation to stay in compliance. Detailed change records for documentation of development process and process control systems are required as part of regulatory compliance requirements.

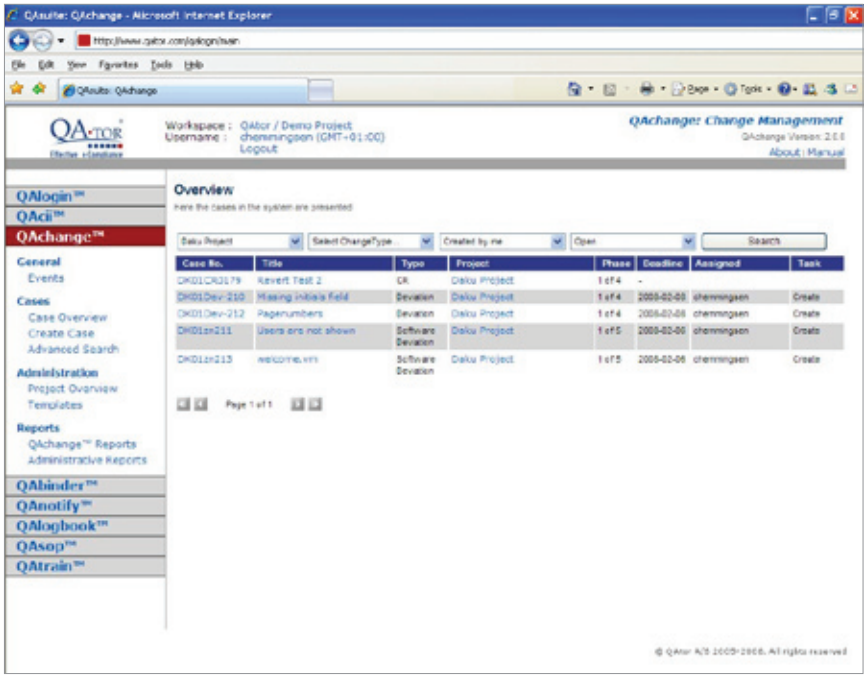
In paper based change control process another challenge is to manage priorities and focus on the most critical issues at the most appropriate time, minimizing interruptions to production and maximizing operational efficiency. It is also hard to estimate impact or risks involved in changes or how much time or resources are needed to complete change requests.

Electronic Change Control

QAchange™

QAchange™ automates the Change Control and deviation process via an intelligent Web-based interface. It supplies fully automated handling of the workflow for any given deviation or Change Control Case [CC], and through customizable templates that relates roles to specific tasks. Any template workflow defined by customer SOPs can be implemented in the system templates, all made easy accessible where needed via Web-interface.

The authorities require that you as a Life Science company have a working written change control and deviation handling procedure. But have you considered what happens in real life? Most deviations are due to various reasons not handled 100% according to the procedures. Often document signatures are made by people having the wrong roles or not participating in the according project. It is also often seen that signatures falls in a timely disorder or are delayed waiting for the correct people to sign off at a specific phase in the documents life-cycle. This is of course not happening at your company, or is it?



Case Overview (Change Control, Deviations, CAPA and similar cases)

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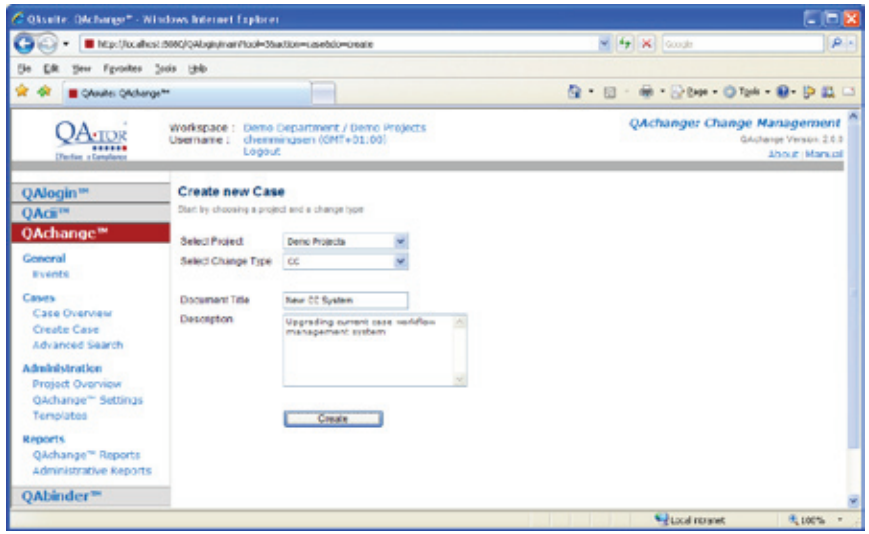

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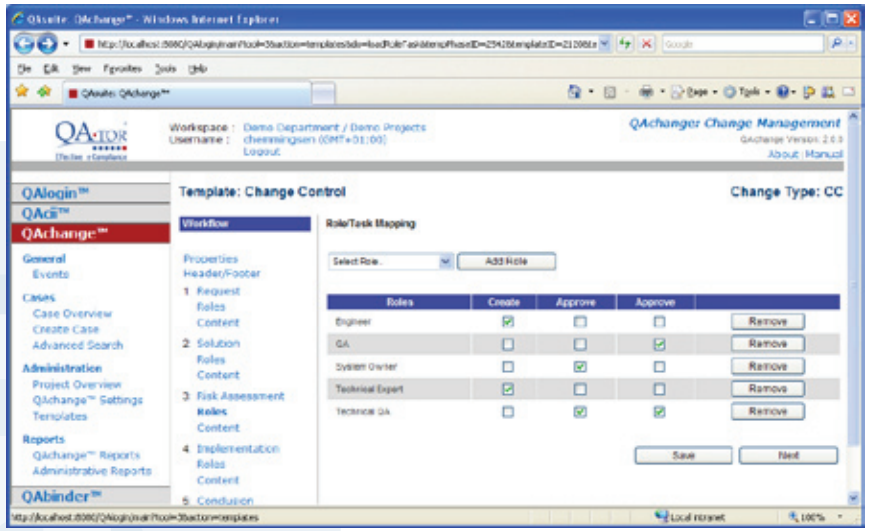


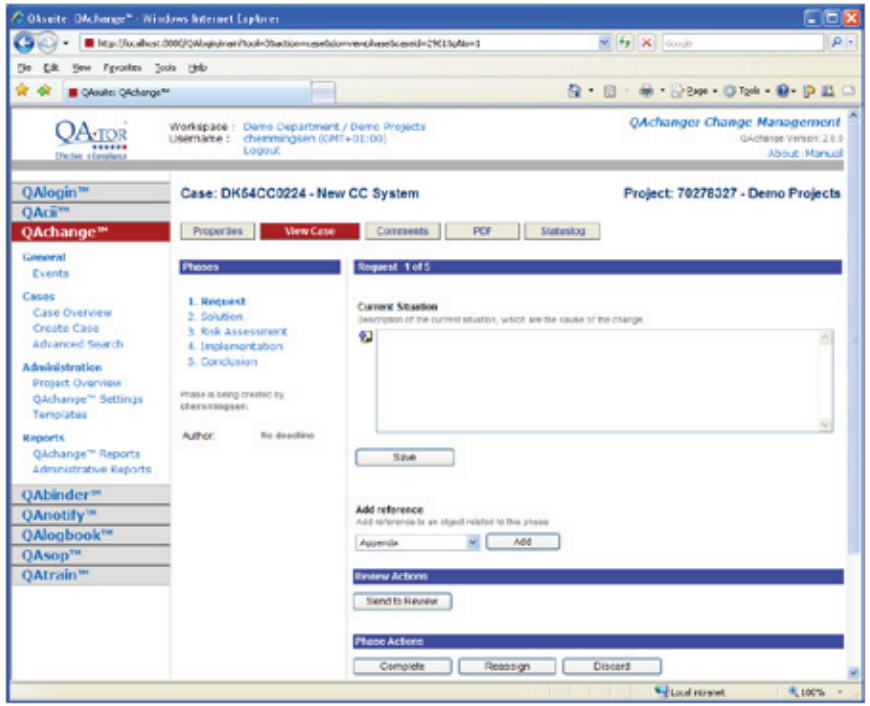
Easy design and management of templates

Solve IT!

Intelligent use of Information Communication Technologies

All this is unnecessary document disorder and delay. GMP is all about planning ahead and showing control. This is what QAchange™ enables you to do:

- Define your templates and workflow to be used in a project according to existing SOPs
- Relate roles to different actions or approvals in the document
- Enjoy the system managing all document management according to the pre-defined rules



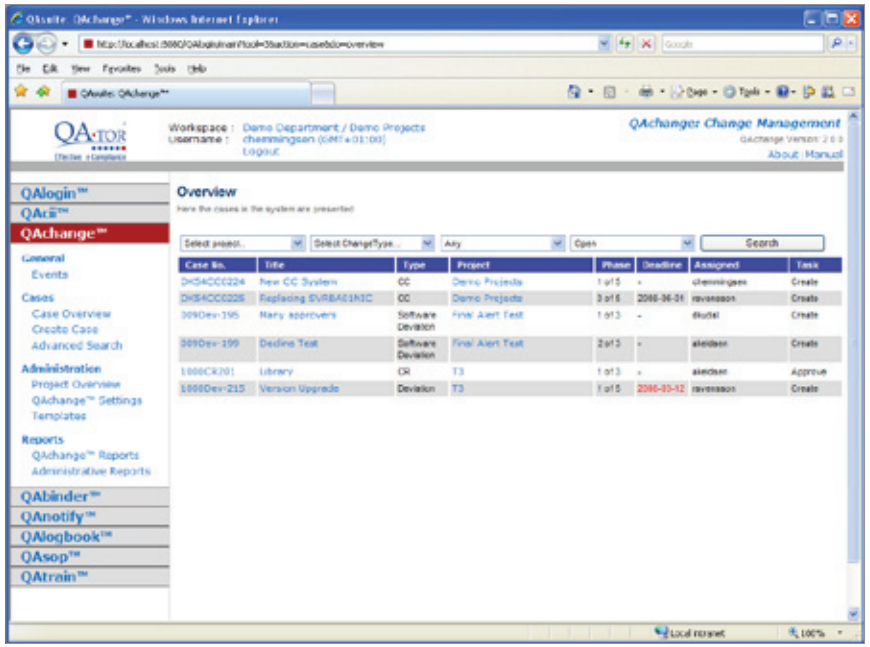
A Change Case in which a phase regarding Risk Analysis now has to be performed by the project member (respective user)

Electronic change control process ensures not only savings in time and cost but also better collaboration, visibility for management and undisputable audit trails of electronic signatures in compliance with FDA's 21 CFR Part 11. QAchange™ furthermore secures traceability in the entire process, and can interface with the other QAtor suite products.

With its focused industry templates and protocols, electronic signature functionality, change control processes, integrated workflow, and security features, the Quality Assurance suite is particularly well suited for companies that need to enforce regulatory compliance to strict quality control measures.

By providing exceptional transparency, control and overall management, the solutions enable companies to more efficiently manage compliance requirements through controlled electronic repositories, process automation, collaboration, communications, archival, and business integration capabilities in audited and tightly managed environments.

QAchange™ covers all required areas and system types including Quality, Facilities & Equipments, Materials, Production, Packaging & Labeling and Laboratory Control Systems. Other examples of areas that can be managed by using QAchange™ are changes to Supplier or contractor processes, Specifications and Established Limits or Procedure Change Requests.



Management of roles for project members

Discover quickly impact of change and lower your Total Cost of Quality while ensuring that GxP is kept at the highest level at all times.

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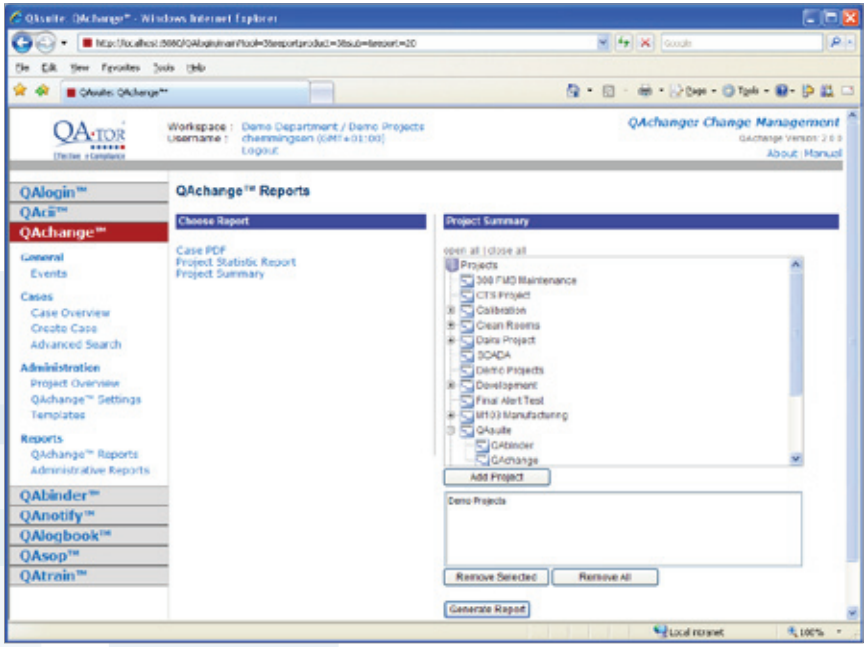
Impact of Change Traceability

Management of not only individual documents, but also information inside and across documents and processes is becoming ever-increasingly important. In Change Control process the challenge is to understand impact of change early in the process to avoid unnecessary and costly changes.
QAchange™ is specifically designed to help in creating, linking and tracking compliance information inside and across any document or protocol. At the same time compliance with FDA and GxP regulations governing pharmaceutical manufacturing is always ensured and your company can be confident of covering all requirements whenever inspected.



QAchange™ Reports

Standard reports, including administrative reports for statistics and information management, are submitted with the application. Further company specific reports can be made on request.

Application Features

- Role-based workflow
- Web-based easy-to-use interface with Explorer Type Navigation and Windows Style Screens
- Single Point of user-login by using the QAlogin™ application. This application can be configured to interface with the company's existing login procedures
- Shared Database, Multi-site enterprise control
- Provides Electronic Change Control List and Change Request process
- Easy to use electronic Change Request form with enforcement of required fields
- Manages electronic reviews and approval process with workflow engine

Key Benefits for Life Science Companies

- Pre-validated application (FDA/GxP). Documentation comes as part of deliverance
- Seamless integration with other QAsuite™ applications
- Easy and fast to fill in electronic change request form
- Always up-to-date Change Control List to track change request status and priorities
- Faster review and approval process for Change Requests
- Ensures full control and audit trail over GxP compliant change control
- Improves quality, adds transparency and address regulatory concerns
- Enforced QA approved workflow
- Lean QA

System Requirements

- CLIENTS: Modern web browsers, Adobe Reader™
- SERVER: Oracle Database 11g r2

QAchange™, and QAcii™ Configuration Management

Change Control process is closely related to the Configuration Management so naturally QAcii™ as configuration management application can be used seamlessly together with QAchange™. When changes are proposed it is also necessary to evaluate impact of changes to the existing configuration.
Generally any change to systems under configuration management will require a change request. These change requests can be managed by QAchange™ and linked directly to systems or configuration items listed in QAcii™ application.

Investment ROI within 12 Months

Calculate the ROI of Your Investment

Using the QAtor applications, you will enhance Quality Assurance quality and cost reduce significantly thus overall reducing your Total Cost of Quality, i.e.:

- No lost documents or missing signatures
- Improved regulatory FDA compliance
- 25-60% less paperwork overall in Quality Assurance
- 30-50% fewer document changes, signatures, and initials
- 20-30% fewer man-hours spent on Quality Assurance documentation
- 50-60% reduction in time spend on investigations and deviations analysis

When implementing our solutions and methodology, ROI will be less than 12 months. Calculate your ROI when implementing our solutions and methodology and evaluate the potential benefits that will be achieved by your company through successfully implementations, you can easily and conveniently make an inquiry to our World Wide contact center and get a confidential discussion with one of our senior consultants.

Our Experience, Your Benefit

Focusing on Total Cost of Quality and Fast ROI

QAtor is an industry-leader in QA applications for the Life Science industry. This FDA-regulated industry benefits from a fully Web-based, validated compliance management framework, which includes standard templates and protocols, electronic signature functionality, configuration management, change control processes, and security features in order to reduce Total Cost of Quality.

At Your Fingertips

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