QAcii™

Electronic Configuration Management

Are You Compliant?

FDA Regulative, CFR Title 21 Subpart J

Records and Reports, §211.184 Component, drug product container, closure, and labeling records.

These records shall include the following:

"(c) An individual inventory record of each component, drug product container, and closure and, for each component, a reconciliation of the use of each lot of such component. The inventory record shall contain sufficient information to allow determination of any batch or lot of drug product associated with the use of each component, drug product container, and closure"

QA·TOR ®

Effective e·Compliance

Industry Challenge

Better, faster, and cheaper is the paradigm in the Life Sciences industry striving to improve the compliance efficiency of their new drug projects and manufacturing processes. As the industry continues to become more competitive, minimizing the costs of regulatory compliance will become one of the most important factors for future success. This has led Life Sciences organizations to re-evaluate and streamline their approach to compliance management.

Manufacturers that are the most efficient at producing the highest quality products at the lowest cost, while meeting ever-increasing number of governing regulations, will be best positioned to succeed.

The System Administrator Challenge

Successful management of components in a pharmaceutical production environment requires that you are able to prove that the components are "in control". The only way to do this is to ensure that your components are always well-documented and all changes recorded. Typically this is done by versioning Excel or Word documents, but using a database is the intelligent and time saving way to ensure full regulatory compliance. Furthermore, administrators are frequently required to create and publish baseline documents describing changes in the system since last baseline. If data are consistently structured in a database, baseline reports can be extracted in the matter of minutes.

Due to the complexity and dynamic nature of today's IT infrastructure, ensuring an effective IT system management in a GxP and true FDA 21 CFR part 11 compliant environment is a complex task. QAtor understands the need to manage all types of components such as e.g. the production IT systems and their changing configurations and relationships, which has enabled QAcii™ to do instant reporting of every change in the system as well as comprehensive statistics reporting of your overall system, based on update input from the system administrator.

How Can QAtor Help You

QAcii™, Intelligent Management of All Inventory

QAcii™ provides a simple and easy-to-use, cost and time saving tool for company wide enforcing and supporting GxP and true 21 CFR Part 11 compliance efforts in the areas of Configuration Management, Configuration Item Indexing (CII), and Baseline reports. With QAcii™ you have an easy and powerful way of monitoring all types of configurations enabling key administrators to track and manage contents throughout the entire lifecycle electronically. With QAcii™ you can be certain that all information is accurate and current.

The Web-based interface of QAcii™ uses a powerful back-end database in which it structures data and maintains information on configuration items such as e.g. software, hardware, operating system, control system, applications, libraries, raw data, as well as the relationships between them. QAcii™ ensures that a consistent inventory of assets and components is effectively managed at all times across well coordinated team members and departments.
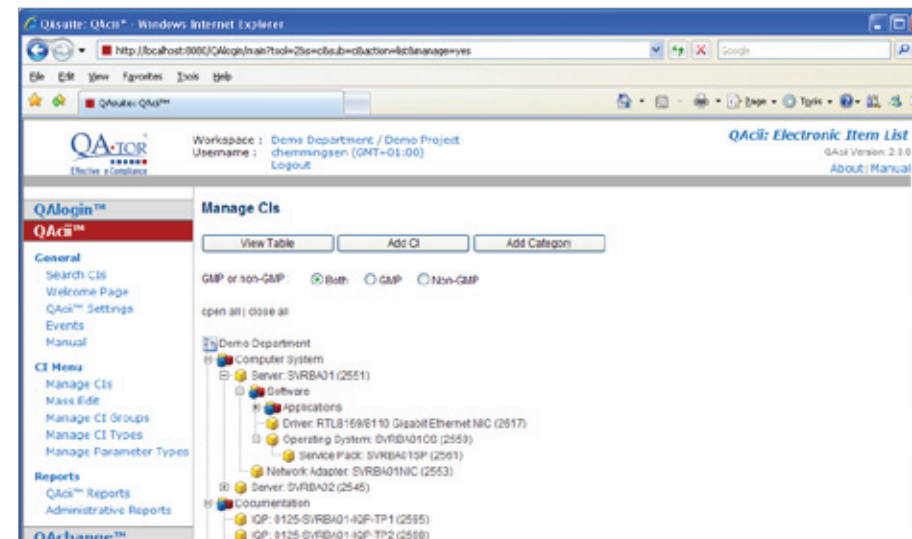

Management of Configuration Items (CI)

CI Lists

The CI list is one of the most important reports in GxP compliant environments to ensure that all systems are under control. It provides a time-log listing of all systems. CI lists can be generated at several different organizational levels based on the tree structure deployed. The easy-to-use reporting tool can be configured for your company specific layout. In addition, you can check for discrepancies between asset and component information in the database and the actual assets that are active / non-active (or disabled) in the company, with no chance for missed-records.
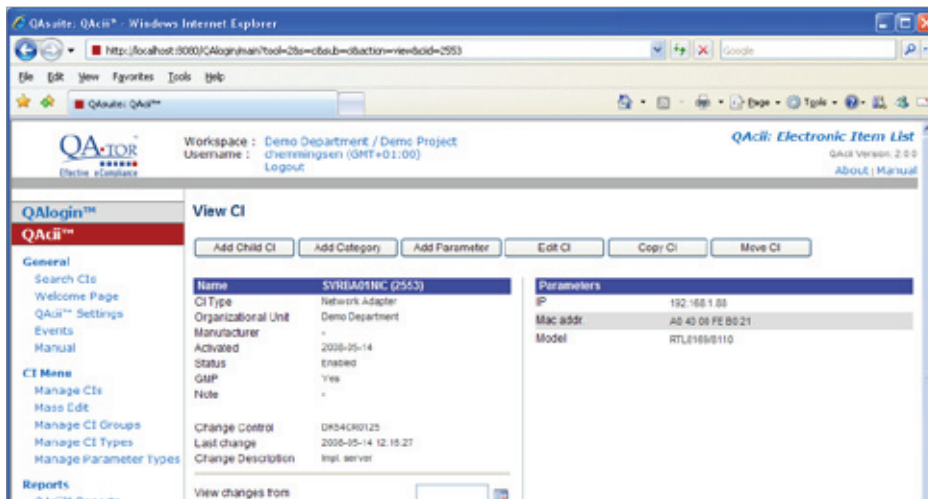

Details for a configuration item (CI)

Version Control for All Configuration Levels

The key requirement in GxP compliant environments is to track changes in system configurations. The QAcii™ uses automatic version control to ensure that every change in the controlled systems is documented according to the GxP requirements. Version number of the system is automatically updated with a reference to change control. Configuration versions are not only managed on system level but also on site and section level. By site level version control every single change to any system in the selected site can be traced. Full version history and audit trail information are available in Audit trail reports.

Examples on Standard Baseline Raport
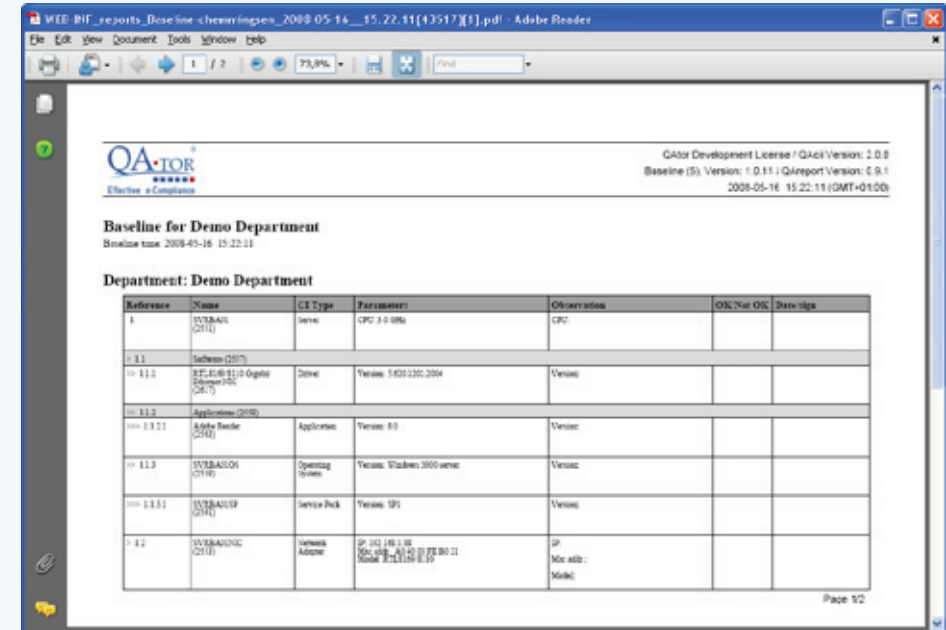
System Requirements

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

Standard Reports

Standard reports, including administrative reports for statistics and information management, are submitted with the application, including:

- Baseline
- CI list
- Change log report documenting changes in a given time period for an organizational unit (or selected items)
- Change report, e.g. tracing a Change Control number (CC) and its impacts, eventually further limited by selecting a specific time period

Further company specific reports can be made on request.

Application Features

- Web-based easy-to-use interface with Explorer Type Navigation and Windows Style Screens
- Single Point of Data Entry
- Shared Database, Multi-site enterprise control
- Electronic CI lists for inventory assets
- Automatic version management for Sites, Sections and Systems
- Search and retrieve functionalities
- Intensive activity logging for security and full audit trail
- Configuration management of all types of inventory components
- Pre-defined reports easy to customize with portable PDF file export: Baseline, CI list and Audit-trail

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 product annual review as assets can be classified as critical / non-critical and thus reviewed accordingly
- Always up-to-date CI lists to track status and changes
- Ensures full control and audit trails
- Improves quality, adds transparency and address regulatory concerns
- Improved control translates into more profit
- XML standard-interface secures a fast migration of existing component and inventory data

At Your Fingertips - World Wide Inquiries

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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 man-agement framework, which includes standard templates and protocols, electronic signature functionality, configuration management and change control processes, and security features in order to reduce Total Cost of Quality.

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