QAlogbook™

Electronic Logbook

Are You Compliant?

21 CFR Part 211 §182

Equipment cleaning, maintenance and use log

> If equipment is dedicated to manufacture of one product, then individual equipment logs are not required, provided that lots or batches of such product follow in numerical order and are manufactured in numerical sequence. In cases where dedicated equipment is employed, the records of cleaning, maintenance and use shall be part of the batch record. The persons performing and double-checking the cleaning and maintenance shall date and sign or initial the log indicating that the work was performed. Entries in the log shall be in chronological order

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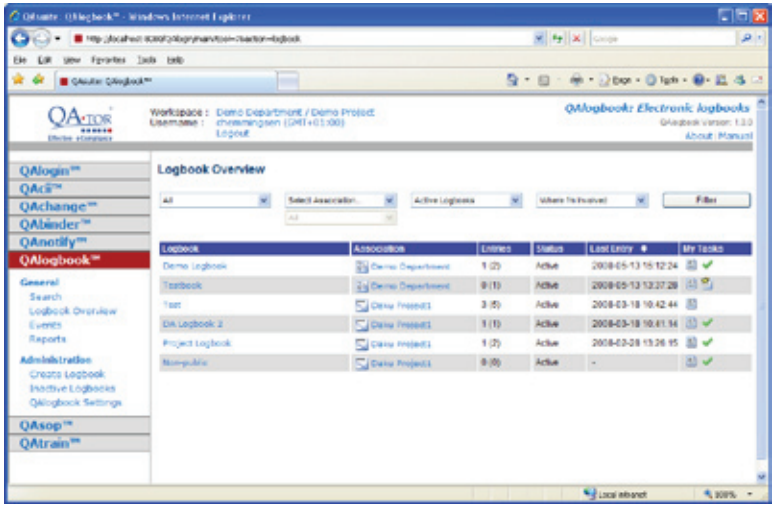
QAlogbook™

QAlogbook™ provides a simple and easy-to-use, cost and time saving tool for company wide enforcing and supporting of FDA and GxP compliance efforts in the areas of logbook registrations in all its forms.

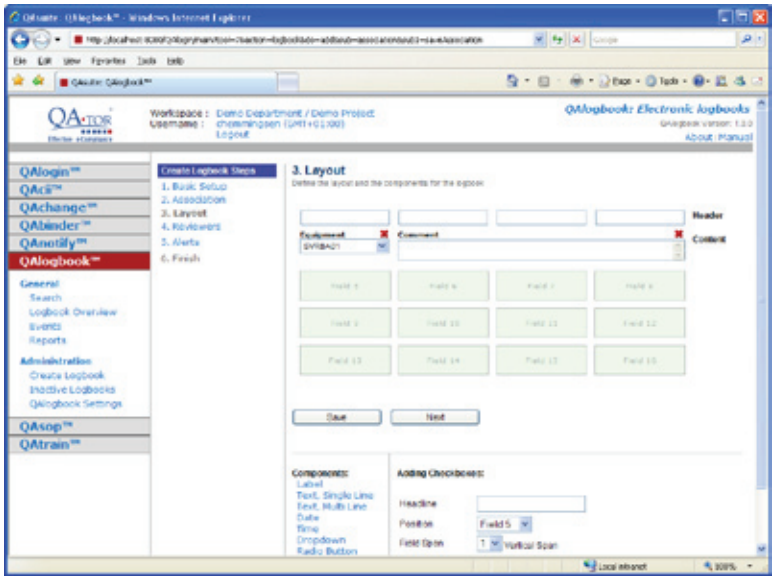
The Web-based application utilizes *true* 21 CFR part 11 compliant electronic signatures, multi-tiered privilege levels and time-stamped audit trails to ensure data integrity for legal and regulatory purposes, eliminating tampering risks that until now have forced Life Sciences to maintain handwritten documentation of equipment cleaning, maintenance and use.

QAlogbook™ provides the functionality to capture and transform logbook entries into operational intelligence making the data accessible across the organization to a wide variety of users. It replaces the myriad of paper logs, spreadsheets and disparate databases to integrate information from many different sources in one location.

The application enhances the ability of logbooks to act as a source of management information and records key site status information on environment, equipment and other issues to the resources responsible for support and maintenance. Information may be required both, on a daily basis to understand the current equipment condition, or issues and also historically to search for historical events and build up evidence of trends.



Logbooks accessible for the respective user having this privilege



Creation of the logbook layout

The electronic logbook provides the ability to search, view and report on historic equipment data for event tracking and in support of trend analysis. The logbook has a quick and intuitive method to enter data, which ensures that time spent identifying, finally writing logs and capturing operational information is minimized.

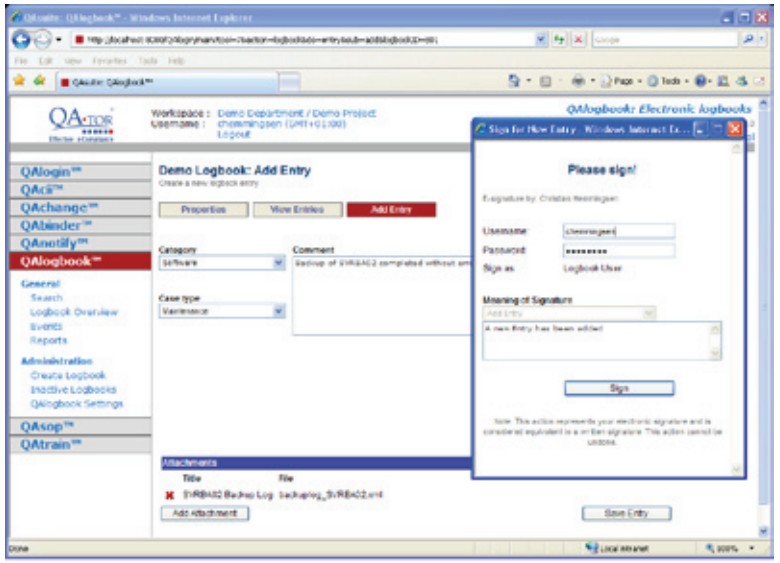
Easy logbook Configuration

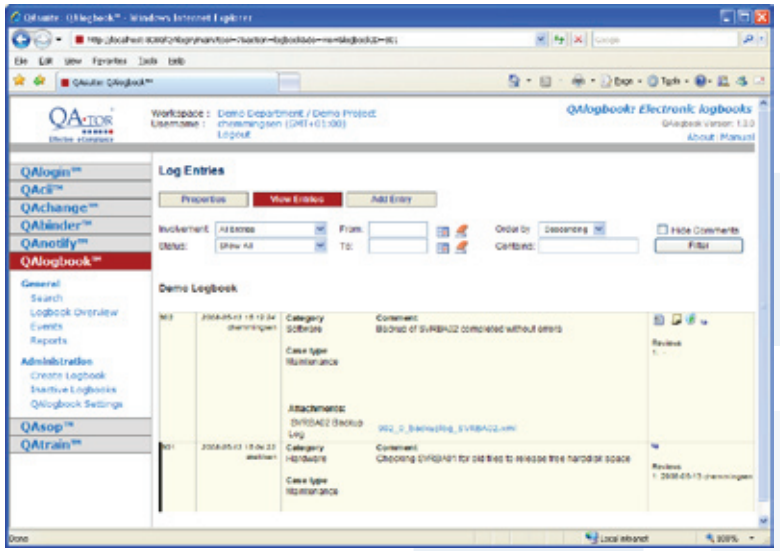
Whilst providing a mechanism for improved consistency of logs and reports in terms of format, structure and content, QAlogbook™ allows the user complete flexibility in being able to configure log entries of exactly the data needed according to instructions, including text fields, time and date, drop-downs , radio- and check-boxes.

Application Features

QAlogbook™ serves the purpose of effectively replacing traditionally paper-based logbooks. The application has important advantages compared to their paper-based counterparts:

- Web-based easy-to-use interface with Explorer type navigation and Windows style screens
- Single point of data entry
- Shared database, and Multi-site equipment control
- Intensive activity logging for security and full audit trail
- Privilege management, i.e. only viewing and accessing logbooks with right privileges





Logbook entries

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Key Benefits for Life Science Companies

- Pre-validated application (FDA/GxP). Documentation comes as part of deliverance
- Seamless integration with other QAsuite™ applications
- Configurable logbook layout, i.e. customizable forms, check boxes, drop down menus with pre-defined text, and with enforcement of required fields and the option to upload attachments
- Standardized logbook entries with real-time electronic logbook management (creating and maintaining equipment data)
- Manages electronic reviews and approval process with workflow engine
- Search ability
- Reminders and alerts, i.e. for required data review and follow-up
- Real time statistics on events performed
- One-click to create new logbook entry

System Requirements

- CLIENT: Modern Web browsers, Adobe Reader™
- SERVER: Oracle Database v11g r2

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Our Experience, Your Benefit

Focusing on Total Cost of Quality and Fast ROI

QAtor is a technology-leader in QA applications for the Life Sciences 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 and change control processes, and security features.

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.

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