

QAbinder™

Electronic Storage of Documentation

Ever Thought About What 'Readily Available' Means?

FDA Regulative, CFR Title 21 Subpart A

General Provisions §11.1 Scope

(e) Computer systems (including hardware and software), controls, and attendant documentation maintained under this part shall be readily available for, and subject to, FDA inspection



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

(c) "All records required under this part, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by computer or other electronic means shall be considered as meeting the requirements of this paragraph."

Maintaining the Exact Data

Have you ever tried having a document referring to a specific version of a Standard Operating Procedure or another document? Sure you have! Does your company have a system for storing documents? You bet - and it works just nicely!

It properly does, but when inspection shows up, you will most likely find that your current systems will present the most recent versions of your documents. Then make an on-line inquiry in your system for an immediate 3 versions old document. Did you fulfill the requirement 'Readily available'?

The User Challenge

For anybody who ever tried this, it is obvious that this is not the most wishful situation. Consider the advantage of being capable of referring to the exact information, stored in a virtual binder, readily available with a few pushes on the buttons. QAbinder™ stores the documentation referenced from other documentation.



Application Features

- Web-based easy-to-use interface with Explorer Type Navigation and Windows Style Screens
- Single Database, Multi-site enterprise control
- Intensive activity logging for security and full audit trail
- Easy customization able

System Requirements

- CLIENT: Microsoft Internet Explorer v6.0™ and higher, Adobe Reader™
- SERVER: Oracle Database v10G or higher

Virtual Binders

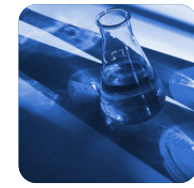
Organized as Nicely as Physical Binders, But Readily Available via a Web-Interface

QAbinder™ provides everything you ever wanted from physical binders - just electronically. QAbinder™ stores all types of electronic data in virtual binders, with binder backs, index pages and search and storage information. All binders are thus fully searchable, and it is possible to print physical binders from the respective virtual ones. Furthermore, the access to information in the binders are subject to a full 21 CFR Part 11 compliant audit trail, so that it can be found who and when data was submitted to the system, and data are disabled rather than deleted from the system, so that no information is ever lost.

It is possible to directly link to the information inside QAbinder™ via the unique IDs of the contained data, and QAbinder™ works as data storage for other QAtor applications. The virtual binders are stored neatly on shelves in cabinets, just as you could find data stored in the physical world. QAbinder™ also implements restricted binders that allow only a limited amount of people to access specific binders and their contained data.

Binders can be stored in projects, which are groups of related binders, and QAbinder™ supplies a number of pre-defined reports for easy overview of system contents. Data inserted in binders can be “signed off” if required, and notes can be added to each document attachment. If documents are transferred from physical documents via a scanner interface, the system can furthermore contain references to the physical location of the original documents (handy for inspections, and this is a regulatory requirement).

The system comes fully validated with template documents for roll out, and template procedures for system use.



Our Experience, Your Benefit Focusing on Total Cost of Quality and Fast ROI

QAator 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 and change control processes, and security features in order to reduce Total Cost of Quality.

Investment ROI within 12 Months Calculate the ROI of Your Investment

Using the QAator 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 documents 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 may be achieved by your company through successfully implementations, you can easy 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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