

QAbaseline™

Electronic File modification Tracker

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:

FDA

”

(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.

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QAbaseline is a tool for creating baselines of several files in just one operation. It can compare a baseline with previous baselines and clearly identify removed, added files or modified files in a compare report.

QAbaseline key facts

- Easy to perform, manage and compare baselines on files
- Save baselines in a single file making it easier to manage
- Save settings for baselines to perform them again and again
- No installation required, runs from supplied USB key
- Baseline data will be saved on USB key so target machine is not altered
- Easy and simple user interface
- Can run on 640x480

The screenshot shows the QAbaseline - QAtor A/S application window. The main window has a menu bar (File, Tools, Help) and a toolbar. The main area contains a logo, a 'QAbaseline Name' field (Demo Baseline), a 'Baseline Folder Path' field (C:\Demo), and a checked 'Include Subdirectories' checkbox. A 'Run Baseline' button is present. Below this, a table shows the results of a baseline run:

Name	Size	Modified	Hashvalue
2008-06-13_QAbinder.pdf	591827	14-12-2008 ...	ce6b2bf519883db30825acf25cd1a9fa
2008-06-13_QAchange.pdf	1080624	14-12-2008 ...	61627559735da7f6dbef9fbaefcbbbbc
2008-06-13_QAcii.old	597571	14-12-2008 ...	e4b4c48f94b4ae5b560dc27e107a4486
2008-06-13_QAcii.pdf	596072	14-12-2008 ...	f9775f947946b286ba3729b8a564687c

A 'Compare Report' window is overlaid on the main window, showing the following details:

20081214
Baseline Date: 14-12-2008 21:03:22
Folder Path: C:\Demo

FILES IN DEMO BASELINE NOT IN 20081214
No differences

FILES IN 20081214 NOT IN DEMO BASELINE
2008-06-13_QAcii.old

FILES CHANGES FROM DEMO BASELINE TO 20081214
2008-06-13_QAcii.pdf

QAbaseline is a tool developed and validated by QAtor for keeping track of large numbers of files and easily identify differences over time using a well-defined mathematical algorithm (HASH function) which converts a large, possibly variable-sized amount of data, into a single number.