## 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** 

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(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.









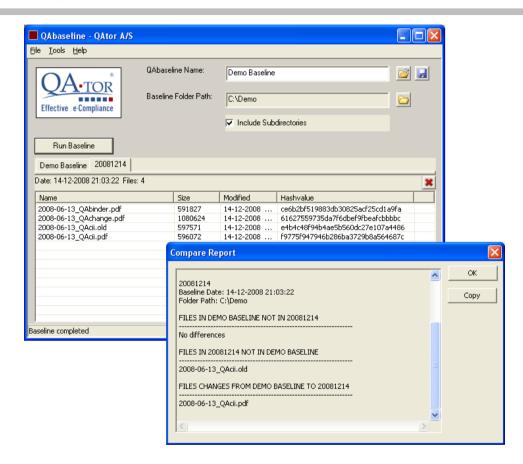




QAbaseline is a tool for creating baselines of several files in just one operation. It can compare a baseline with previous baselines and clearly identify removed, added files or modified files in a compare report.

## 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



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.