



Has Exaquantum/Batch been FDA certified?

The FDA does not actually certify software, control or information systems. Customers must validate Exaquantum/Batch as part of their overall 21 CFR Part 11 compliancy process.

Each and every Exaquantum/Batch implementation will need to be individually validated. Just because it has been validated on one plant it does not mean that it will be automatically valid at another even if the plants use exactly the same compliancy process.

To support this activity Exaquantum/Batch provides a number of features such as Strong Mandatory Authentication, Auditing and Electronic Signatures. Batch Reports are stored within an access control database and modification of these reports once created is prevented.

Exaquantum /Batch Releases Affected
All