BellHawk Compliance with CFR 21 Part 11

Introduction

This document details the compliance of the BellHawk® software with "CFR 21 Part 11" (Part 11) dated March 20, 1997 and the document "General Principles of Software Validation; Final Guidance for Industry and FDA Staff," issued January 11, 2002 by the FDA.

BellHawk is commercial off-the-shelf software (COTS) that can be customized by BellHawk Systems staff to meet specific client requirements. This document only covers the COTS version and modifications made by BellHawk Systems' staff. If a client purchases access to the source code for the software and performs their own modifications to the software then the client is responsible for ensuring that any changes that they make to the software are compliant with the above documents and also with good software development and maintenance practices.

The BellHawk software captures materials tracking and traceability data related to the manufacture, processing, and distribution of products such as food, natraceuticals, cosmetics, over-the-counter (OTC) pharmaceuticals, specialty and hazardous chemicals, and specialty materials. It is also used to track the processing of materials used in medical testing.

BellHawk captures the materials traceability data in an electronic database to facilitate:

1. Rapidly tracking back to the source of contamination or defects.
2. Rapidly tracking forward to all materials affected by a source of contamination or defect.
3. Providing a real-time view of the status of all materials, including their location, manufacturer, part number, version number, lot number, serial number (if needed), expiration date, and their quality control status (if needed).

History

The BellHawk software was originally developed using a client-server architecture in 1999 to be compliant with the requirements of the US Dept. of Defense (DoD) for tracking the manufacture and distribution of DoD related systems and components. Subsequently in 2002 changes were made to the BellHawk software to ensure compliance with Part 11 requirements, once the revised guidance was issued by the FDA.

The use of this client-server version was incorporated into Compliance with Good Manufacturing Practices (CGMP) activities by several BellHawk clients including OTC pharmaceutical users and biotechnology laboratories.

In 2009 through 2011, the BellHawk software was upgraded to V6, which uses a web-browser interface to the database rather than a thick-client interface and also provides a web-services interface for computer-to-computer interaction. These changes were all made compliant with Part 11 requirements and good software development practices.

The use of this new V6 version is now being integrated into updated CGMP activities by several BellHawk clients.

With the upgrade to V6, BellHawk Systems has been able to significantly improve data security and access control over those possible with the prior client-server version. Users are no longer able to directly access the BellHawk database. Previously, in the client-server version, database access was prevented by use of a password but now, with the web-browser interface, additional levels of security are possible.

V6 centralizes all updates to the BellHawk software onto a single server computer. In this way any updates can be tracked and controlled by the client's IT staff much more easily than when thick-client software was also required on each desktop computer.

Electronic Signatures

BellHawk supports the use of an encrypted data link between the device on which the web-browser, used to access BellHawk, is running and the Windows Server computer on which the BellHawk code is executed and through which the SQL Server database, used to record the electronic record data is accessed.

Each data collection device and external system that accesses the BellHawk software has its own encrypted login, thereby securing device access. Each employee using such a device is required to identify themselves by a means such as scanning a barcode on or reading an RFID chip embedded in their employee badge, or using a biometric identification device, whenever they record data, to identify who is recording the data. Optionally each employee can be required to have their own personal login, as well as scanning their badge into a data entry device, thus meeting the requirement for two separate forms of identification, where needed.

Optionally BellHawk can print out documents, such as batch processing records, with places for physical signatures by employees recording materials into and out of a batch processing operation, as an extra visual layer of compliance.

All data recorded in the BellHawk database is time tagged to the nearest second and identified as to who the person making the entry was.

BellHawk requires the use of a user name and password for all staff members accessing the BellHawk system. Staff members have review and electronic sign-off requirements on all data entered into the system, as appropriate to their management and supervisory role. All changes to the database records made by a staff member are recorded, with the retention of the original record and a recording of who made the changes.

All passwords are stored in the BellHawk database in non-reversible encrypted format. They can only be changed by the system's administrator, who is a trusted employee, with his or her own encrypted password. It is the responsibility of the system's administrator to ensure that appropriate password aging and control procedures are followed.

Permanence of Data Records

Data within the BellHawk database cannot be deleted through the BellHawk user interface. It can only be modified by direct access to database by the client's Information Technology (IT) staff who have such trusted privileges. It is incumbent on our clients to ensure that their IT practices related to the protection of the data in the database follow good IT practices for security and limitations on data access.

Any data record "deleted" by a user through the BellHawk user interface or the web-services interface are not physically deleted but are simply marked as deleted so as to be not visible to the user. These records can be recalled at any time for audit purposes.

All changes made to data records are logged as to who made the change and the time and date that the change is made. These data records are kept in permanent history tables.

It is critical that the client's IT staff take a full backup of the database at least daily and store this backup in an off-site location from which it can be quickly retrieved in the event of need for disaster recovery.

Provided that BellHawk Systems is maintaining the copy of the client's software in its on-line version control system then, in an emergency, a database backup can be restored to another Windows Server and linked to the BellHawk software, so as to enable retrieval of critical materials traceability records.

Software Development Practices used for BellHawk

BellHawk was developed and is maintained according to good software development practices.

Version Control

The BellHawk software development staff maintains a complete on-line database of all past versions of the BellHawk V6 software using the Subversion software. This includes the standard version of BellHawk as well as special modifications made for each client. Subversion enables the BellHawk development team to track all changes made and to recover prior or alternate versions upon demand.

Each release of BellHawk is clearly shown with its version and subversion number on each user screen to aid in tracking down any issues that may arise.

Upgrades

1. All proposed changes to the software are documented in writing by a qualified system's architect (M.Sc. or Ph.D. in Computer Science plus at least 10 years experience). This document is then reviewed and approved by the originator of the request and the software development team and any needed changes made before a final specification document is issued.

2. The needed changes are then broken down into a series of tasks that can be accomplished by a single software developer. Each task is assigned to a senior software developer (with typically a Master's degree education in Computer Science and 10 years plus development

experience) who may make the changes themselves or supervise more junior people in making the changes.

3. The tasks are logged as "tickets" in an on-line status tracking system, so their status can be tracked.
4. The resultant code changes for each task are then functionally tested by the assigned senior software developer to ensure compliance with algorithmic and database access requirements.
5. The resultant code changes are then tested to by systems architect to ensure compliance with the written specifications.
6. The resultant code changes are then tested by the requestor, who may be a client.
7. If any discrepancies are found, they are logged in our on-line ticket tracking system and assigned to appropriate people to be fixed, then retesting takes place, as appropriate.

Bugs and Errors

1. Bugs or other errors are logged in our on-line ticketing system along with their priority.
2. Problems are typically investigated by a senior software developer, who will test the software or evaluate the contents of a backup database, taken as soon as possible after the incident, to determine the cause of the problem.
3. If the cause is a data entry error on behalf of the client using the software then they will be so notified and charged for the time taken to investigate the problem.
4. If the cause is system design problem then the issue will be investigated by a system's architect may issue an upgrade request and the above upgrade process will be followed.
5. If the cause is a bug in the code, then it will be coded and tested by the programmer and tested by a senior programmer.
6. The bug fix will then be tested by the client or system's architect reporting the bug.
7. The status of the problem report is tracked through our on-line ticket tracking system until it is satisfactorily resolved.

Validation and Verification Support Documentation

BellHawk Systems can provide the following documentation in support of the CGMP verification and validation (V&V) process, if needed, on an hourly rates basis for their preparation.

1. Documentation of BellHawk Systems' software life cycle development, test and maintenance process: This includes documentation for the process used to manage customizations made to the software for specific applications and our bug fixing process. A short form is provided in this document but an extended version, which may be needed for incorporation in the IP section of an overall system CGMP package, can be prepared by BellHawk Systems' staff.

2. Documentation for operation of the specific software modules used in the system, including any customizations made for the specific application. Generic versions of these documents are available at no charge on-line, and as Word documents on request. Application-specific versions, suitable for direct incorporation into the OP section of an overall system CGMP V&V document can be prepared by BellHawk Systems' staff.

3. Test scripts for the BellHawk software, with example results and description of validation methods to be used. Electronic versions suitable for incorporation into the QP section of an overall system V&V package can be created for each client specific application by BellHawk Systems' staff members.

Level of Compliance

The BellHawk software is designed to assist trained and knowledgeable personnel in collecting and maintaining one-step forward, one-step backward traceability records and rapidly recalling that data when needed. It is not intended for use as a fully automated data collection system nor does it take any action that could directly cause harm to any person or animal.

BellHawk is purely a data collection and reporting system. Its results should only be used by trained and knowledgeable personnel to assist them in their decision making processes. Such personnel must use their training and judgment in the interpretation of all reports and Excel exports produced by the BellHawk software.

Certification

To the best of our knowledge, the BellHawk software meets the requirements of CFR 21 Part 11 at this level of compliance. BellHawk Systems warrants that, if needed, it will make any changes to the BellHawk software, at no cost to clients who are current subscribers to the BellHawk Software Maintenance Plan, to ensure that BellHawk meets the requirements of CFR 21 Part 11 (March 20, 1997) to the above stated level of compliance.

Dr. Peter Green

President

BellHawk Systems Corporation

