



Software Data Sheet BellHawk and FDA Approval

BellHawk® tracking systems can be used as part of FDA approved tracking systems in pharmaceutical and biotechnology manufacturing operations. Because BellHawk tracking and data collection systems are typically customized as they are being implemented they must be validated in their intended application.

Some of the features of BellHawk that will enable a system using BellHawk to be validated include:

- Supports Part 11 electronic signatures through the use of barcoded employee badges plus passwords. Can also be integrated with biometric devices if needed.
- Security: access to all data is controlled through user names and passwords.
- All transactions are time/date tagged and associated with person performing transaction.
- Overwriting of transactions is prevented.
- Transactions kept perpetually in the database.
- Can log all attempts to misuse system.
- Integrated from proven software modules.
- Reports of all transactions in human readable form.
- Database can be backed up while system is in use. Enables frequent regular backups.
- Can display photograph of user on screen after scanning badge for validation.
- Can be integrated with equipment to capture electronic test and analysis data.
- Supports full traceability including who worked on each process step, what equipment and materials were used, what process parameters were used and what test results were obtained.
- Supports tracking of materials both at the barcoded individual item level and at the lot container level.
- Supports tracking the quality control status of all materials and prevents use of materials that are not QC approved.
- Can be customized to only allow authorized personnel to perform certain operations for which they are trained.
- Supports tracking of work by teams of people as well as by individuals.

For more information please call 508-865-8070, see our website at www.BellHawk.com, or send Email to sales@BellHawk.com.