BellHawk® Systems Corporation
Tracking Your Inventory and Work-in-Process like a Hawk
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BellHawk Systems announces CFR 21 Part 11 Module for the BellHawk Inventory and Work-in-Process Tracking Software

BellHawk Systems www.BellHawk.com today announced the availability of a 21 CFR Part 11 compliance module. This enables the use of the BellHawk inventory and work-in process tracking software in FDA regulated pharmaceutical manufacturing and distribution applications that need to be validated to comply with FDA good manufacturing practices (GMP).

A major issue for small to mid-sized manufacturers and distributors of pharmaceutical products is that most electronic tracking systems that are compliant with CFR 21 Part 11 cost over $100,000 and in many cases can cost over $1 Million when fully deployed. These systems are typically designed for use by large Pharmaceutical manufacturers.

For the manufacturers and distributors of over-the-counter (OTC) FDA regulated products, such as skin lotions, as well as re-packers of pharmaceutical drugs, these systems are too costly and too complex to use. As a result, these manufacturers and distributors have had to rely on paper records, supplemented by Excel spreadsheets. Not only is this labor intensive but also mistake prone, often resulting in quality assurance audit problems.

Now a complete CFR 21 Part 11 compliant BellHawk inventory and work-in-process tracking system is available for as little as $540/month plus $45 per management user or shared barcode scanning device. This simple-to-use software uses a web-browser interface and so can be used with a wide range of devices. It can be installed on a Windows Server at the client's own facility or used at a secure data center in the Cloud.

BellHawk makes extensive use of barcode scanning and wireless mobile computers to track materials from receiving, through quality assurance, to production processing, to shipment to the end customer. It can handle formulas and batch records and builds a complete traceability history enabling one-step-back, one-step-forward tracking of the source of defects and the disposition of the resultant defective products.

BellHawk Systems teams with Quality Systems Integration (QSI), who can provide cGMP validation services for users of the BellHawk software. QSI can provide a complete set of BellHawk validation documentation tailored to the specific needs of each client thus speeding validation and deployment.

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