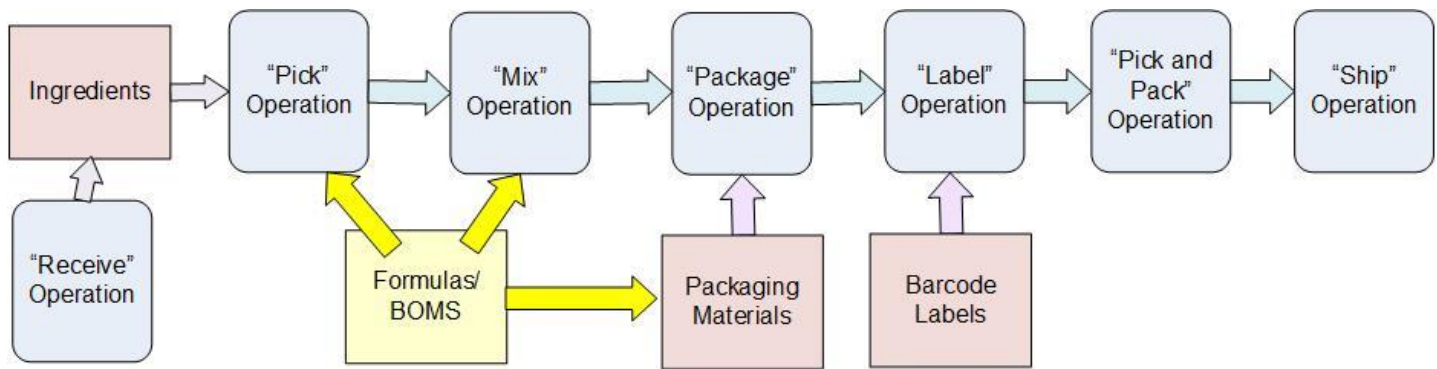## Pharmaceutical Operations Tracking & Traceability System
POTTS Bundle Data Sheet

The BellHawk Online Pharmaceutical Operations Tracking and Traceability System (POTTS) bundle provides a low-cost and easy-to-use Cloud-based solution that enables small to mid-sized organizations to comply with FDA requirements.

POTTS is suitable for use by small to mid-sized manufacturers of pharmaceutical products, such as CMOs, makers of OTC pharma products, repackagers, as well as biotechnology and specialty manufacturers of products in limited volume. With the addition of WMS, the BellHawk Online Warehouse Management (WMS) module, POTTS is also suitable for use by distributors that purchase pharmaceuticals in bulk but distribute these to their customers in small volume.

POTTS captures end-to-end materials tracking and traceability data to enable sending pedigree data to customers and data repositories by means of EDI or EPCIS data transmission.

With the addition of the BellHawk Label Printing Appliance (BLPA), within a facility, POTTS can also print out DSCSA (Drug Supply Chain Safety Act) compliant 2D barcodes for application to bottles and cartons of pharmaceutical products using automated applicators or manual application. POTTS can also print GS1 compliant barcodes on demand for application to boxes in which products are packed for shipment and shrink-wrapped pallets on which the boxes are stacked.

POTTS tracks:

1. The receipt and put-away of ingredients and other materials, tracking each container by GTIN/NSN, serial number (if applicable), lot number, expiration date and supplier.

2. Performance of quality control inspection of incoming materials.

3. The picking and usage of ingredients for mixing operations with checks to make sure that the correct ingredients are used and that all ingredients have passed quality inspection and are not past their expiration date.

4. Which ingredients by part number, serial number (if applicable), lot number and expiration date went into which mix batch.

5. Testing and quality inspection of intermediate product mixes.

6. Which mix batch and packaging materials went into each batch of finished product as well as the serial numbers of the barcodes assigned to each bottle, pack, or carton of finished product.

7. Which boxes the products were packed in and which pallets the boxes were stacked on.

8. The picking, packing, and shipment of products to customers.

POTTS is CFR 21 Part 11 Compliant and so can be validated to comply with FDA cGMP manufacturing processes. Detailed operating instruction documents are available in Word format so these can be easily modified to become the SOP documents for the specific application on which the validation is based.

POTTS manages the assignment of serial numbers to each product container to ensure that each serial number issued is unique. POTTS also tracks details about each product container related to its serial number including all details of its pedigree as well as who and when and how it was shipped and how it was packed.

Through a web portal, POTTS provides clients, and their customers, with the ability to rapidly determine if a product is counterfeit simply by scanning the 2D barcode attached to the product label. It can also show all the products, by serial number, packed into a box or pallet simply by scanning the barcodes on these containers.

POTTS is able to rapidly track back from each serial numbered product to all the ingredients that went into the product as well as who was involved in its manufacture. POTTS can also trace forward from defective ingredients or packaging materials to all the places these products were shipped.

POTTS collects all the ASN (Advanced Shipment Notice) data for each shipment, including serial numbers of the products and the nested containers in which they were packed. This data can be sent on demand using a third party Cloud-based EDI system or the EPCIS data for the shipment exported to the client's own computer either as a manually transferred file or through the BellHawk Online web services interface.

By special order, POTTS can be integrated with automated labeling and vision inspection systems in high volume production lines, with POTTS generating the serial numbers and tracking product inspection failures as well as tracking packing information.

For more information: Please contact Sales@BellHawkOnline.com or call (774) 708-9607

For more details please see www.BellHawkOnline.com.