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> This article presents a marketing strategy that is implemented using existing or new primary and secondary packaging systems.

Pharmaceutical Packaging with Brite Stock Manufacturing

by Mel Bahr

Introduction

s a business strategy, a Brite Stock packaging line might be right for your company. These lines can be beneficial for both Rx and Over the Counter (OTC) products as an economical method of production for global markets or for private branding for the big box stores. The inventories created, effectively may be used as "Just in Time" or "Make to Order," at the same time providing customized labeling and insert requirements for each market. Although this topic also could include "Processing of the Product," this article will focus on the primary packaging of the product and the subsequent secondary packaging.

Today's business trend includes the consolidation of companies which invariably result in the combining of previously competing products. By harmonizing the primary packaging, and perhaps secondary, these products can continue to be produced economically for the supply chain.

The decision to "Brite Stock" often begins as a market strategy to sell more product (increase revenue) and maintain capital expenditures by utilizing existing plant and equipment assets. The effects of product life, potential quality impact, and product mix ups are all factors that need to be evaluated. It is not the intent of this article to include regulatory or quality impact factors as this is best evaluated on a case by case basis.

Defining "Brite Stock"

The traditional concept and definition of Brite Stocking is believed to have originated from food canning product lines. Filled, unlabeled canned product is produced then stored in inventory for future can labeling and case packing. The filled cans are labeled to a manufactures specific brand or as a generic product. Variable shipping packaging such as case packs and bundling is easily accommodated. The term "Brite" is due to the storage of the unlabeled can.

Today's definition, as applied to a pharmaceutical packaging line, would include a variety of primary packages, including at least bottles, vials, ampules, blisters, and pouches. The primary packaging system will need to include a method of coding or marking the package for later verification (typically a bar code applied by a non-contact printer). The secondary packaging operation would include labeling, printing, inserts, cartons, cases, bundling, and final package labeling. This portion of the line also will need to include verification systems (bar code readers or vision systems) that are similar to those required for "Track and Trace" systems.

A deviation to the traditional "Brite Stock" is an online buffering (small accumulation) of the product between the primary and secondary packaging that allows for a change to the secondary packaging without input stoppage. See Example three below.

Advantages

This manufacturing process has the advantage of maximizing the primary packaging efficiencies by increasing utilization of equipment and labor. Using Overall Equipment Effectiveness (OEE) principles:

- Availability is increased by reducing the frequency of product and or lot/batch changeovers. Line cleanout, tweaking, and fine tuning of changeover is a major time loss of equipment uptime.
- Performance of the primary packaging equipment is increased due to the reduction in line stoppages due to downstream equipment issues.
- Performance of the secondary packaging equipment is increased as it is not dependent

on performance of the primary equipment or lack of product at the input.

• Primary and secondary packaging equipment often function best at different rates. Each piece of equipment can be fine tuned without affecting the other portion of the operation.

A typical manufacturing goal would be 100% utilization of the primary packaging equipment. Seldom does the output rate of the primary packaging equipment. Seldom does the output rate that is capable of producing 400 blisters per minute may need to be reduced in speed when inserting one blister per carton whereas if the put up is a ten pack, the cartoner will be underutilized. If this were a Brite Stock line, the thermoformer would continuously produce at an output of 400 blisters per minute 24/7 whereas the cartoner might package the product in a single shift.

Another example could be a bottling line that is producing at high speed. The secondary packaging is divided between a single bottle in a carton and bundled packs. A Brite Stock operation allows each of these outputs to happen individually or concurrently and each at their maximum speed with increased flexibility. In this situation, it makes it possible for the cartoner and bundler to be lower cost, slower speed units, neither by themselves matching the maximum output of the bottling filling and capping equipment.

The cost advantages are from the increased revenues (maintaining fixed overhead costs), reduced capital expenditures (utilizing the same facility and equipment assets), and increased efficiencies due to separation of primary and secondary packaging.

Disadvantages

These lines require a method or system to "store" the product. This may be as simple as bulk storage in a large container (filled plastic bottles), stackable products in paperboard trays (blisters and pouches), stackable plastic trays (vials and ampules), or on a pallet (glass bottles). The storage containers could be an additional cost. Securing the appropriate facilities (and its control) and space for the storage of the unlabeled productcan be a challenge. This could be partially offset by reducing the finished goods storage if a "Just in Time" process is implemented.

The addition of equipment (such as tray loaders for blisters, pouches, vials, and ampules) to automate the "storing" is a possible additional cost.

Printing, marking, or coding units will be required for later identification of the unlabeled product in secondary packaging. Refeeding of the primary package into the secondary packaging line also will be required.

Identification systems will be required to verify the product as it is entering the secondary packaging line. The identification systems will typically be bar code readers and or vision systems and will require vigorous testing and operational controls (SOPs) to be in place.

The cost disadvantages are additional equipment (if storage is automated), the storage containers, unlabeled product coding (marking for identification), storage facilities, refeeding, identification, and verification of the unlabeled product entering secondary packaging.

Example One: Bottle in a Carton – *Figure 1*

The requirement is for a system that provides a liquid filled product in a bottle with the unit of sale being a carton. The market requirement is for an OTC product where the liquid product is the same for all SKUs, but the final packaging is for a variety of private and generic brands. The production speed is 250 bottles per minute.

Primary Packaging Basic Functional Equipment

- Bulk bottle unscrambler and cleaner
- Laser printer for the bottom of the bottle
- Vision system, verify printed code
- Liquid filler
- Capper
- Bulk storage container

Secondary Packaging Basic Functional Equipment

Bulk filled bottle unscrambler

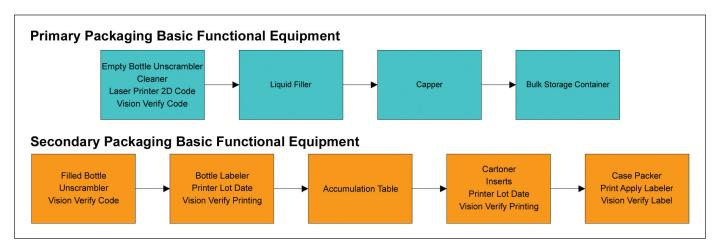


Figure 1. Example one: bottle in a carton.

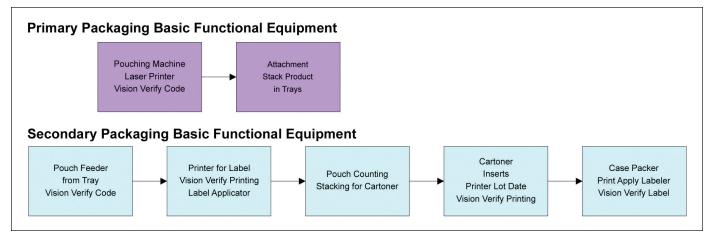


Figure 2. Example two: stackable pouches in a carton.

- Vision system, verify printed code on bottle bottom
- Bottle labeler
- Printer for bottle label
- Vision system, verify printed code
- Accumulation table (increases OEE)
- Cartoner with insert feeder
- Carton lot/date printer
- Vision system, verify printed code
- Case packer
- Print and apply labeler
- Vision system, verify printed code

Overview of Operation

- *The primary packaging* operation is to receive bulk plastic bottles, clean them, print a 2D code on the bottle bottom, verify that code (reject prior to printing), fill the bottle with a liquid, cap the bottle, and bulk store the bottles in large totes. This portion of the operation has a cycle rate of 250 BPM.
- The secondary packaging operation is to sort and orientate the filled bottles from the bulk storage containers. The 2D bar code is verified (reject prior to labeling); the label is printed with the lot/date code (and verified) prior to applying to the bottle. An accumulation table is used to increase the uptime of the system. The cartoner adds a wraparound insert as the bottle is loaded; the carton has the lot/date code printed (and verified). The cartons are arranged in a pack pattern, loaded into the case, and then the case label is printed with the lot/date code (and verified) prior to applying it to the case. The input to the labeling system runs at approximately 310 BPM (allows for planned stops for roll change) and the cartoner runs at 300 BPM. This increased speed allows for commodity changes for various SKU changes.

Example Two: Stackable Pouches in a Carton – *Figure 2*

The requirement is for a system that provides a transdermal or thin film filled pouch with the unit of delivery being a carton. The market requirement is for either an Rx or OTC product with a variety of SKUs produced based upon pouch quantity in the carton, product, and country of sale. The primary packaging production speed is 1200 pouches per minute.

Primary Packaging Basic Functional Equipment:

- Pouching machine
- Laser printer for the pouch
- Vision system, verify printed code
- Attachment to stack product into trays

Secondary Packaging Basic Functional Equipment:

- Pouch feeder from tray
- Vision system, verify printed code on pouch
- Printer for label
- Vision system, verify printed code
- Label applicator for pouch
- Pouch counter for cartoner infeed
- Cartoner with insert feeder
- Carton lot/date printer
- Vision system, verify printed code
- Case packer
- Print and apply labeler
- Vision system, verify printed code

Overview of Operation:

- The primary packaging operation is to manufacture pouches which require a number of complex roll stock feeding units. This system is very time consuming to changeover for product or format. Startup after a routine stoppage is also time consuming and wastes a substantial number of products before good useable items are produced. Once producing product, it is undesirable to stop the pouching machine. During the manufacturing process, a 2D code is printed on the pouch. The pouches are stacked into a chipboard tray that can be manually handled and stacked on a pallet. This portion of the operation has a cycle rate of 1,200 PPM. This output is used to feed several secondary operations.
- The secondary packaging operation feeds the pouches from

the trays into a labeler. The 2D bar code is verified (reject prior to labeling); the label is printed with the lot/date code (and verified) prior to applying it to the pouch. A counting system allows for a variety of put ups into cartons. The cartoner adds a wraparound insert as the pouches are loaded. The carton has the lot/date code printed (and verified). The cartons are arranged in a pack pattern, loaded into the case, and then the case label is printed with the lot/date code (and verified) prior to applying it to the case. The input to the labeling system runs at approximately 150 PPM.

Example Three: Bulky Pouches in a Carton – *Figure 3*

The requirement is for a system that provides a pouch with a medical device in it with the unit of sale being a carton. The market requirement is for an Rx product with a variety of SKUs produced based upon pouch quantity in the carton and country of sale. All of the production of the pouching machine goes through the cartoning machine. Due to the complexity of the product and the sealing requirements of the upstream equipment, it is very undesirable to stop for SKU changes; therefore, an online accumulation system is used between the pouching and cartoning machines. SKU changes (product count and orientation in carton as well as specific country requirements) are made to the cartoner while the pouching machine is running (filling up the buffer); these changes must be made in less than 10 minutes (buffer capacity). The production speed is 200 pouches per minute.

Primary Packaging Basic Functional Equipment

- Pouching machine
- Laser printer for the pouch
- Vision system, verify printed code
- Attachment to count and stack pouches into the accumulation (buffering) system

Secondary Packaging Basic Functional Equipment

- Accumulation (buffering system) for approximately 10 minutes of pouch machine runtime
- Pouch feeder from accumulation system

- Cartoner with insert feeder and quick accurate changeover features
- Carton lot/date printer
- Vision system, verify printed code
- Case packer
- Print and apply labeler
- Vision system, verify printed code

Overview of Operation

- *The primary packaging* operation is to manufacture the pouches filled with the same medical device. A complex and critical pouch sealing is required; therefore, equipment startup is time consuming and wasteful of product. This product is also expensive to rework. Therefore, once producing product it is undesirable to stop the equipment. During the manufacturing process a 2D code is printed on the pouch. The pouches are counted and stacked into an accumulation system that is online with the cartoner. This portion of the operation has a cycle rate of 200 PPM. The output is fed to a single secondary operation.
- *The secondary packaging* operation feeds the pouches from the accumulation system into the cartoner. The cartoner adds a wraparound insert as the pouches are loaded. The carton has the lot/date code printed (and verified). The cartons are arranged in a pack pattern, loaded into the case, and then the case label is printed with the lot/date code (and verified) prior to applying it to the case. The cartoner has a cycle rate in excess of 250 PPM, which will empty the filled buffer before the next SKU change.

Summary

Applying a "Brite Stock" strategy to a pharmaceutical operation may not be as simple as the original "food canning line" defined above. Innovation and ingenuity will be required to develop the proper solution. This strategy has the potential to expand your existing products into new markets (global or private brands), continue to offer lower volume products (profitable) by harmonizing and standardizing packaging, and increase the overall efficiency of producing your product (make more product with the same equipment and labor).

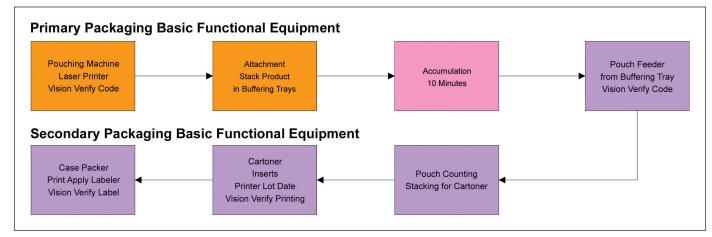


Figure 3. Example three: bulky pouches in a carton.

All of these increase revenue, which is more important than just cutting costs.



About the Author

Mel Bahr attended the University of Minnesota and began his career in designing and manufacturing of packaging machinery as an electrical engineer. He expanded his career to include engineering management and operations. He is the founder of MGS Machine Corporation. MGS has two plant manufacturing campuses in Maple Grove,

Minnesota which manufacture a variety of equipment for the secondary packaging industry. One of its main focuses is the pharmaceutical industry. He has been involved in producing more than 40,000 pieces of machinery that have been installed globally. Many of these have been complete end of line systems. He is also named on a number of patents related to equipment design. Bahr is a member of ISPE and currently serves as Chair of the Packaging Community of Practice. He also contributed to the *ISPE Good Practice Guide: Packaging, Labeling, and Warehousing Facilities.* He can be contacted by telephone: +1-763-493-8805 or email: mel. bahr@mgsmachine.com.

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