OUR VIEW

Institute of Packaging Professionals

VALIDATION—
ITS IMPORTANCE IN THE PACKAGING LINE PROCESS

Robert J. Bockserman, Member
IoPP Medical Device Committee

A specific packaging operation, to be an effective means of producing a high-integrity, high-quality product, must have every segment of its line validated. This is done by performing a detailed check of every item of equipment, accessory and component on the line and comparing performance to prior written specifications and procedures.

When an extensive record is compiled and compared with the prior line process specifications, a high confidence level is created. The product will be packaged with the ultimate objective— "TO BE FREE OF DEFECTS."

The ultimate goal in reviewing and analyzing a packaging process is to strive for improvement in productivity while still maintaining a high level of product quality. By the use of packaging line validation, all procedures, equipment design, equipment placement, and equipment performance come under complete scrutiny and control.

THE TYPICAL LINE

A basic line set-up for the packaging of a pharmaceutical or medical device, where validation would be necessary, is as follows:

- unscrambling the containers
- orienting the containers
- filling of product
- capping and induction sealing
- applying the outer seal
- applying the label
- accumulating the containers
- cartoning the containers
- sealing and coding the carton

The ultimate goal in reviewing and analyzing a packaging process is to strive for improvement in productivity while still maintaining a high level of product quality.

New types of high-technology equipment have now taken the place of tedious, manual mechanisms. Some high-technology equipment follows:

- machine vision systems
- robotics
- monitoring/reporting systems
- laser printers
- barcode control
- computer-assisted manufacturing
- multi-point recorders
- material documentation control
- diagnostic computer systems
- programmable logic controllers

HIGH-TECH HURDLE

The concept of packaging line validation has become more difficult by the present high-speed manufacturing and packaging lines. The requirements of high-speed filling, labeling and container placement into cartons at 400-600 units per minute can be met only with sophisticated equipment. There is still the need to successfully detect below-specification product fill, missing or incorrect labels, incorrect label placement, missing components, and incorrect lot numbers which are only a few of the potential problems that present themselves.

Validation of the equipment is of prime importance if packaging problems are to be averted. Validating the individual equipment is the first step in the process of ultimately validating the entire packaging line. This should be undertaken under actual production conditions and for a pre-determined length of time in order to produce meaningful data.

In conclusion, effective validation of a packaging system requires the compilation of documentation. This relies on continual input data produced at pre-determined times during the packaging operation. A print-out of each position on the line is created, and it must be analyzed and carefully reviewed to determine how the data compares with the product specifications as previously set forth in the master plan. If the data shows deficiencies in the line, implementation of changes is required to bring the line into specifications.

Proper validation procedures should be looked upon as a means for continual product improvement which is required by federal agencies, industry standards and the ultimate consumer.

For more information, contact Robert J. Bockserman at Conatech Consulting Group, Inc., (314) 995-9767. Or call the Institute of Packaging Professionals (IoPP) at (703) 318-8970.