The Low-Down on the Pharma

A report on medical validation from PMMI's 2007 Safety and Technology Conference

"DRUGS ARE NOT LIKE CANDY," said Mel Bahr, president of MGS Machine Corp. (Maple Grove, MN) in his presentation on medical validation at PMMI's annual Safety Conference in July. He went on to explain that when you package candy, having an inexact number of pieces per package is not a serious problem. However, in the measurement of a drug, being off by one or two counts does represent a serious problem from both health and safety and product liability standpoints. How does a manufacturer avoid such dangerous discrepancies? Answer: medical validation.

Mel Bahr, past Chairman of PMMI and Chairman of MGS Machine Corporation, delivered a speech on supporting FDA, JETT and other regulatory bodies in the pharma industry.

Medical validation involves a risk assessment for pharmaceutical products – how might the product be altered by the machine packaging it? Beginning with guidelines from various regulatory bodies, then following the procedures set by recognized best practice authorities, this process is similar to a risk assessment used to determine the safety of machinery.

Both the manufactures of pharmaceutical packaging machinery and end users should be familiar with the guidelines and practices of the Food and Drug Administration (FDA), the International Society of Pharmaceutical Engineers (ISPE), the Good Automated Manufacturing Practice (GAMP) Guide and the Joint Equipment Transition Team (JETT).

Risk assessment is the primary component of medical validation. The risk assessment process (as dictated by GAMP to meet ISPE, FDA and end user requirements) involves the following ten steps: 1) Assigning the team members (with the System Owner as the process leader); 2) Preparing a system overview; 3) Developing a process map for the system (product flow, etc.); 4) Identifying the scope/boundaries of the assessment (entire system vs. specific functions); 5) Listing all documents used in the assessment; 6) Identifying controlled/monitored systems; 7) Identifying risk scenarios; 8) Documenting likely effects; 9) Evaluating and rating risks; and 10) Identifying your largest risks and prioritizing your activities accordingly – state your plan.

The user requirements and expectations from the assessments should be determined from the beginning of the engineering/purchase process. "Validation should be done up front, rather than at the last minute," Bahr says. "If a customer doesn't ask for a risk assessment or provide requirements, we do our own to get to the bottom of things prior to the design stage." When a company begins getting involved in the medical validation process, Bahr says that it is not necessary that they immediately get a validation consultant. The process can be started by the engineers already familiar with the equipment, who are ultimately aware of the user requirements for operation.

The end game of medical validation is qualification. Qualification is the act of proving and documenting that equipment or ancillary systems are properly installed, work correctly and comply with specified requirements, explained Safety Conference presenter Steve Connelly of Abbott Laboratories, (North Chicago, IL). Working through the medical validation process to achieve qualification requires a dynamic partnership between the manufacturer and the user. The benefits of the JETT approach can be seen in the equipment's 'speed to market' through a "smoother procurement process, smoother validation process and a shorter project schedule," said Bahr, adding that "project costs are also reduced for integration services, validation and re-work." Machinery that has undergone medical validation not only ensures that a safer product ends up in the hands of the consumer, but that the machinery manufacturer and end user can stand behind an international measure of quality. ■

Each year, PMMI's Safety Conference delivers information to support members' efforts to meet customer demands, including extensive risk assessment resources.

Spotlight on Kliklok-Woodman

By Laura P.T. Johnston

WITH THE HELP of the PMMI Certified Trainer Program, Kliklok Woodman has created the recipe for successful training. The Decatur, Georgia-based packaging machinery manufacturer has certified over 70 percent of their service staff, with three additional certifications in progress. Customer praise is higher than ever before and Kliklok-Woodman is equipped to serve each customer according to their individual needs. The ingredients for success lie in their partnership agreements, methodical approach and training maintenance.

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> ***—Brett Duernberger, Customer Service Manager, Kliklok-Woodman***

Prior to attending the Certified Trainer workshops, Kliklok-Woodman's primary training obstacle was being able to clearly identify customer objectives regarding training requirements. "The PMMI training definitely gives you the tools to ensure that your objectives match up with the customer's and that a 'partnership agreement' is truly established," said Brett Duernberger, customer service manager at Kliklok-Woodman. "All of our technicians that have participated in the program have taken away nothing but positive things from the workshop – the most important thing," stressed Duernberger, "is how to properly develop or solidify relationships with our customers." Once that occurs, customer objectives are understood and a training program can be laid out.

The method used by Kliklok-Woodman to develop a program has been dubbed the 'training calculator' – a tool which allows them to easily put together a customized PMMI Certified Training Program to meet the needs of their customers. According to Duernberger, "all we have to enter is the model of machinery our customer has, the number of folks they want trained and the customer location. The calculator then comes up with the investment price for the customer, the number of required classes, the duration of such classes and then the number of training manuals/aids required."

Following delivery of the training required according to the training calculator, Kliklok-Woodman follows through with their commitment to help their customers maintain the original training through the use of refresher aids and reference material. "We have also now developed an entire library of training manuals in both hard copy and media format, which ensures that the same certified training is delivered each and every time independent of which technician is doing the job," said Duernberger, adding that "this presents a huge advantage to our customers as they can rest assured that each and every training course that they invest in will certainly help them achieve better results."

As far as Duernberger is concerned, the only thing left to do is to broadcast the benefits of the PMMI Certified Trainer Program. "We here at KW certainly promote that we have PMMI Certified Trainers within our organization. We feel that this takes us to another level in what we have to offer from an after-sales support standpoint." In addition to this promotion, Duernberger added that "it would be really helpful if PMMI could get the word out to our customers that they are better off dealing with companies that have service technicians (and others) that are certified trainers."

Ultimately, Kliklok-Woodman's recipe for organized, effective training is one any manufacturer can follow – and the outcome sure is sweet. ■

PMMI's NEWEST TRAINERS

Congratulations and a warm welcome to our new PMMI Certified Trainers:

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Alfio Romano
Joe Matthews

Fowler Products
Brian Stone

MASSMAN Automation Designs
Mike Roth

Kliklok-Woodman
Donie Whitten

Ossid Corporation
Mike Summersett
Mike Ward

Septimatech Group Inc.
Michelle Wolfe