Baxter teams with Packaging Aids to streamline the requirements for validatable medical device packaging

IS011607, Section 5, mandates that all equipment used to package sterile medical products be validated. According to Jim Sparks, senior packaging engineer for Baxter Healthcare Cardio Vascular Group (CVG) in Irvine, CA, the mandate was the driving force behind a major cooperative program that led to the development of two validatable pouch sealers from San Rafael, CA-based, Packaging Aids. Baxter CVG (now known as Edwards Life Sciences) packages a variety of medical devices, ranging from catheters to heart valves. The products are packaged in flexible pouches and trays that will undergo post-package sterilization.

Most of the products were hand-loaded into premade pouches and then sealed. "This packaging approach is very labor-intensive," Sparks explains. Most packages are sterilized using ethylene oxide or an autoclave, although some packs are gamma-sterilized. The ISO document specified the parameters of the operation that needed to be validated. In essence, "validation" means guaranteeing the repeatability and consistency of the key process parameters. At one time, medical pouch sealers called for regular calibration of certain seal process parameters, but not on a scheduled, ongoing basis. In fact, calibration might be undertaken every six months, unless the output of a particular machine became problematic. This didn't pose any safety issue, as all packages were visually inspected, and a certain number were regularly subjected to physical tests. After evaluating the mandate, Baxter's packaging research staff began a collaborative effort with Packaging Aids (a PAC Machinery company). That partnership led to the development of the Medpac and Medvac validatable impulse sealers - plus a new Model 552 Med validatable band sealer. All three machines have totally redesigned control systems that enable the user to program set points and tolerances for the key sealing parameters: time, temperature, pressure and conveyor speed. Should any of these validated parameters drift out of a predetermined range while in production, the machine shuts down and sounds an alarm. The shutdown and alarm are triggered automatically, without any operator intervention.

Packagaing Aids Model 552 Med Validatable Medical Band Sealer with UDI compliant printer.

The result was so favorable that Baxter began putting these sealers into all of its CVG plants. “The huge Puerto Rico plant was our first target, and we put in about 15 sealers there,” says Sparks. “Overall, we’ve probably purchased about 25 new machines.”

Early warning for seal integrity

In developing the sealers, the equipment wasn’t the only factor that needed consideration. Packaging material and pouch construction was also critical. “The approach is a lot like developing a capability for statistical process control,” says Mark Goldman, COO at PAC. ‘’It’s necessary to identify the primary parameters of the process and then look at how each process interrelates. Once you determine an acceptable range - and all parameters are within tolerance - you realize a dependable result.” According to Sparks, the crux of the change is how early seal problems are discovered. In the past, he says, if one key parameter started drifting out of tolerance the operator had virtually no awareness of the problem until the packages were inspected. “Sure we were inspecting,” Sparks recalls. “We performed peel tests on the seal back then. But for the machine operator, there was no way to know when the seal was falling out of spec.”

Simplified calibration

The first goal in creating the validatable sealers was to make them easier to calibrate. Sparks says most of the equipment makers rushed out with what they called “validatable sealers.” However, on close examination, there was no way to prove real validation. “For example, how can you validate a timer without using a stopwatch? Some companies told us, ‘In theory, this is how it works.’ We responded, theory is great, but we have to prove it! Only a couple of OEMs actually went back to their engineers and got them working on what we really needed: a machine with external ports for calibration instruments”. Engineering the new machine meant more than merely supplying a dependable sealer; it also required a convenient means to validate it. “Baxter has had good experience using PAC machines in the past. Our people were familiar with their machines, so PAC was one of our first choices,” Sparks points out. “Plus, the company was very receptive to our ideas about what we needed for validation.”

The validatable Medpac and Medvac impulse sealers from PAC are equipped with ports that allow Baxter to plug an electronic stopwatch directly into the machine to calibrate that machine’s timer. “Instead of using a finger to operate the stopwatch, the electronic version operates off the relay circuit. We were getting repeatability within 40 milliseconds,” Sparks claims. “This made the job of validating the equipment far easier.” The temperature-sensing thermocouple monitors the acceptable range, and delivers visual alarms at the high and low end of the range. The thermocouple improves the seal process from one that’s totally time-dependent to one that’s temperature-dependent with a time factor. “Using the thermocouple, the machine measures the heat of the sealing wire, so the ‘ramp time’ (the time required to reach sealing temperature from latent temperature) will change, depending on the temperature of the wire. What

this means is that the machine's timing doesn't start when the operator depresses the pedal. The timing starts when the thermocouple says the temperature is correct. So the thermocouple automatically adjusts for the latent temperature in the seal wire," Sparks notes. Not only does this coordinate the time and temperature conditions, but it may also result in an increase in machine output because the "ramp time" will decrease dramatically when the machine is operated at a high rate of speed. As the machine automatically adjusts for the increasingly shorter time for temperature recovery, it permits faster production.

Minimizing "clears"

The coordination of time and temperature can help to reduce or even eliminate some of the rejects caused by lock-up seals. "The previous method was time-dependent. You set a timer, and regardless of the temperature, the jaw would close and seal for a predetermined length of time and then open up. But if the seal-head temperature was building up, the residual seal temperature could be increasing as well," Sparks reports. "In essence, you would set up your machine and the first several seals would be fine. But as you continued production, depending on the operator's speed, the package seals would begin to produce "clears," continues Sparks. The term clear refers to overheating a seal in a spun-bonded material like Tyvek®, which is often chosen for its breathability. The breathability enables ethylene oxide (EtO) to enter and sterilize products in a pouch or tray. When too much heat is applied to a spun-bonded material, it melts and compresses the fibers to let light pass through - thus, explaining the name clear.

There's nothing wrong with the integrity of the clear seal, but it's a long way from being peelable. The extra heat has the effect of welding the two materials together. With an acceptable peelable seal in spun-bonded material, the color of the weave will remain white and not become clear. Understanding what's going on with equipment and packaging materials is a learning experience, according to Sparks. "Years ago, an industry standard of from one to three pounds was recommended as the ideal seal strength for a peelable heat seal. So in our lab, we'd set up our machines to produce a nice two-pound seal. We'd make a seal, inspect it closely and then test another. They tested just perfectly with no clear seals." But those results could not be completely translated onto the production floor. There, Sparks says workers are pumping out sealed pouches as fast as they can. The result soon becomes pouches with clear seals requiring extremely high effort to open them, making them unacceptable. "That's when we learned what was really happening with the equipment and began to understand that operating speed had a lot to do with seal strength," Sparks says. "The adjustability of the thermocouple allows us to operate at any speed and still know that our seal strength will stay in spec." The other key to consistency is the alarm function. The validatable sealers will alert the operator with an alarm and shut down if one or more of the seal parameters drift above or below the predetermined tolerances. "This factor alone has led us to far more consistent seals," stresses Sparks.

On the sealers developed for Baxter, each machine employs visual alarms, though sealers are also available with audible alarms as well. In addition, because Baxter often uses dissimilar materials on each side of the pouch, PAC supplied the sealers with an option to heat either or both seal jaws (bi-active sealing). This is true both for impulse and band sealers. While the impulse sealers can just shut off the seal-jaw activation when a parameter is out of tolerance, the continuous heat and conveyor of a band sealer make that impractical.

"The shut-down system developed by Packaging Aids for the validatable model 552 Med band sealers is a real stand-out feature," says Sparks. "When the alarm is triggered on these sealers, a little pneumatic gate is activated that prevents any more pouches from continuing into the seal jaws. When the problem is fixed, the gate reopens. It's a very simple device." In the past, individual operators literally had to watch readouts on the control panel closely. "Since each sealer already had an operator, this wasn't a major concern, but the monitoring was left to humans who may become distracted," says PAC's Goldman. "With the PAC sealers, we take the human element out of the equation, which eliminates another variable."

In the open position, the pneumatic gate on the band sealer automatically prevents loading of pouches when a seal parameter is out of spec. "This is probably the biggest advantage with the new sealers. They give us such tight control of the operation that we can use one machine to essentially validate the others." At the plant, engineers perform the installation and operation qualifications (IQOQs) over a few days. So, from installation to production now takes only two to three weeks once the lab has developed the testing template. Probably the most difficult part of validating equipment is identifying how you're going to do it: writing the protocol, developing the test methods," says Sparks. "By having validatable machines and the calibration tools, the IQOQ testing can be done in just a couple of days. Without all these new 'tools' on and in the machines, I can't tell you how long it would take-or even if we could do it," concludes Sparks.

Baxter CVG machine validation usually takes place in the packaging laboratory at Irvine, CA. "We did testing on an impulse sealer before the production sealers were shipped into our plant in Puerto Rico. We were able to do all the validation work here, and then we can provide a protocol 'template' so the plant in Puerto Rico can perform tests on each machine. All the engineers at the plant need to do is run relatively quick confirmation studies, and those machines can go into production. The other key to consistency is the alarm function. The new sealers will alert the operator via an alarm and shut down if one or more of the seal parameters drift beyond the tolerances that are preset. This factor alone has led us to far more consistent seals," stresses Sparks.

About PAC Machinery

PAC Machinery is a privately held company headquartered in San Rafael, California. The company manufactures equipment and materials that are used in the flexible packaging industry. Products include heat sealing equipment, vacuum sealers, automatic baggers, pre-opened bags on a roll, and shrink packaging systems. The company has had its roots in the packaging industry since the early 1950's, and now designs, manufactures and markets products through its family of companies: Packaging Aids, Vertrod, Clamco, AirPillow Products and Converting Technology. PAC Machinery is the exclusive, North American distributor for Audion bag sealers. Manufacturing facilities are located in San Rafael, CA; Berea, OH; Menomonee Falls, WI and Carrollton, TX. Contact PAC Machinery at 25 Tiburon Street, San Rafael, CA 94901. Telephone 1 (234) 222-1000.

For more information about the Packaging Aids Model 552 Med Validatable Medical Band Sealer:
http://www.pacmachinery.com/packagingaids/product/552-med-validatable-medical-band-sealer

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