Banishing Bacteria From Wall To Wall

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Microbes, though invisible to the naked eye, are a huge nuisance in pharmaceutical manufacturing facilities. Contamination can cause serious issues, endangering facilities, batches and reputations.

FDA regulations provide a cleaning and sterilization roadmap for manufacturers, but companies are provided with some flexibility when it comes to the specifics. Today, new developments are giving manufacturers a wider variety of options, ranging from safer facility-wide decontamination methods to new autoclave technologies.

How have procedures and tools changed, and how can manufacturers refine standard operating procedures (SOPs) in order to more effectively clean and sterilize facilities? To find out, Pharmaceutical Processing [1] spoke with providers of cleaning and sterilization solutions.

Decontamination by Design

Floors, walls and ceilings carry more importance in sterile manufacturing processes than they do in other environments. Walls and ceilings must be designed to be easy to clean, with limited crevices which could harbor bacteria. Floors must offer the same features, while still providing enough grip to assure that operators won't slip.

Manufacturers are noticing the benefits of thinking ahead, and foresight is often beneficial when it comes to risk management. "The implementation of a good-quality risk-management policy, which incorporates all the best parts of the 'models,' e.g. HAZOP, Risk-MAPP, FMEA etc., is essential," says Alan Fisher, business development manager and contamination control specialist at Dycem USA, which offers polymer products, such as contamination control mats/flooring and non-slip products, which are designed to trap and remove particles, contamination and cross-contamination.

"The majority of contamination entering any area comes in at floor level, so introducing any method of reducing that has to be a major feature of such a risk management assessment." Fisher explains that "polymeric flooring has been established to be the most efficient and cost-effective means of stopping contamination in a number of applications within pharmaceutical manufacturing."

Proactive Procedures

Decontamination procedures help rid facilities of contaminants during every stage, whether they are going through initial startup, have experienced a contamination issue or are going through shutdown. Such procedures can also be beneficial for forward-thinking manufacturers.

“I think that many pharmaceutical companies now are recognizing that a once- or twice-a-year cleaning with decontamination has been beneficial to them to keep down any spore counts in their facilities,” explains Steve Feinstein, general manager at SixLog Corp., which provides decontamination services for the pharmaceutical market.

“When they do decontamination, they usually have had problems for fairly long periods of time.” Feinstein explains that in many cases, the company has already spent a lot of time and money trying to determine the cause.

But Feinstein says that “Typically, when you do a full facility decontamination, it knocks out the problem.” He observes that once companies go through the decontamination process and realize that it works well and results in less downtime, they often realize the benefits of being proactive. “Then they build that practice into their SOPs for shutdown periods.”

Effective Elements

The increased popularity of isolation technologies for aseptic processes is impacting current trends. According to Francesco Nigris, president at Nicos Group Inc., which offers VHP generators, washers and sterilizers for stoppers and caps, sterilizers, autoclaves, glassware washers, machine parts washers and more, this has increased the need for VHP sterilization and VHP-resistant material for equipment.

This means that pharmaceutical manufacturers will need to put forth more capital investment upfront, and it also leads to higher design and process engineering costs, says Nigris. “Hopefully this will end up in lower maintenance and operating costs.”

Equipment manufacturers must also adjust. “All suppliers need to be ready and capable of accepting the challenges of interfacing their equipment with isolators or with ALPHA BETA ports typically used in isolation techniques,” Nigris explains. “The way the product is transferred from one step of the process to the other is becoming more and more important.”

New Methods for Media

David Miles, vice president of MicroThermics Inc., which offers continuous flow thermal processors for the sterilization and pasteurization of a variety of liquid products such as fermentation media, pharmaceutical ingredients, liquid pharmaceuticals and nutraceuticals, notes an increased need for both viral inactivation and reduced heat exposure.

According to Miles, these desires have “contributed to an increased interest and demand on continuous flow thermal sterilizers and pasteurizers (HTST and aseptic processors).” Although “Continuous thermal processors have not traditionally been used in the pharmaceutical industry because of the need for guaranteed sterility,” the technology has “evolved and now generates millions of gallons of sterile products in other industries each year. As such, the pharmaceutical industry is now

adopting this type of process."

"Another issue with continuous flow thermal processing equipment traditionally has been scale (size) … However, we specialize in small-scale sterilizers and pasteurizers that work easily with high value/low volume products."

Prevention Is Better than a Cure

What's on the horizon?

Fisher believes that the increased use of contract manufacturing will shape future trends. "With the shift from in-house production to CMOs around the world, the industry itself and the regulatory authorities have found the need to re-evaluate all guidance, recommendations and regulations in respect of the control of contamination and cross-contamination in the multi-product/multi-client contract manufacturers' facilities."

Feinstein sees companies reevaluating cleaning procedures. In the past, manufacturers have "been using fairly aggressive chemicals that are very labor intensive and extremely destructive to materials." But with a decontamination system "you're able to guarantee 100 percent surface coverage ... and reduce the amount of downtime." His company is "hopeful that more pharmaceutical companies are going to recognize the value of sterilization as preventative means."

Like Feinstein, Fisher also sees proactive rather than reactive measures becoming increasingly popular, especially since the pharmaceutical industry needs to assure consumer safety at all times. "Common sense dictates that prevention is better than cure, especially where there are such high stakes at play."

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