CAPS® Sterile Compounding Review: Wishing You the Best Sterile Compounding Practices This Year

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At the start of each year, we don't wish friends and loved ones the minimum or even average health—*we wish them the best.*

And, although we are unable to personally greet each patient we service from our cleanrooms, we resolve to provide each one with the safest compounded medications ***by using the best sterile compounding practices***.

A top-notch cleanroom can not be built upon low-level standards. For example, meeting only a minimum number of air changes will inhibit the room's ability to counteract incoming microorganisms. If we also apply low standards to those doing the sterile compounding, the negative imbalance expands even further. Minimally trained and minimally supervised personnel can not only strain the effectiveness of airflow design, they can impair your sterile compounding program.

The minimum sterile compounding requirements contained in USP <797> are agreed upon by a committee representing various practices and risk-tolerances. This process for adopting final standards always invites compromise. The results are usually basic, generic requirements.

Developing more meaningful standards will require the involvement of individuals who are most familiar with your particular practice—the ones doing the work in your cleanroom. Why do we sometimes fail to engage cleanroom personnel? Perhaps the missing ingredients are a clear vision of the essential, and a unity of purpose.

We'd like to share four resolutions to help you add vision and unified purpose to your team's sterile compounding program.

Resolution #1 Identify the Essential Risks in the Aseptic Process and Train to Mitigate the Risks

Human operators are the greatest challenge to maintaining sterility when combining separate sterile drugs and containers into one compounded sterile preparation. Even a semi-automated process like parenteral nutrition (PN) compounding requires a human's glove to handle a barcode scanner, a human's reach to hang a source container, and a human's access to critical sites to attach a bag to a pump. Each human interaction during an aseptic process amplifies the risk of microbial contamination.

For at least a dozen years, USP <797> has required sterile compounding pharmacies to assign risk-levels to the compounded sterile preparation (CSP), based on the number of human manipulations required by the aseptic process. Soon, however, the chapter will eliminate the terms low- and medium-risk. Don't allow the change to cause you to lose sight of your most essential microbial risks. To ensure that personnel fully grasp the impact of their interactions with critical sites and sterile components, always address each type of aseptic manipulation in their training evaluations and in their media-fill tests.

Resolution #2 Aim Operational Standards Toward the Essential Sources of Bioburden

Preventing the entry of microorganisms into the cleanroom would be an ideal solution for keeping microbial contamination away from an aseptic process occurring in a hood. Unfortunately, when compounding personnel enter the room they also bring their bioburden.

A goal for any cleanroom operation is to control the shedding of human particles to prevent the spreading of human bioburden. There are two approaches for reducing the release of human particles, but one is more reliable than the other.

The first method is to minimize human motion. Reliability here will depend on the types of CSPs that are prepared. Compounding a batch of syringes, for example, only requires an operator to sit at an ISO 5 hood to perform limited, repeatable motions.

Compounding PN is anything but stationary. The near-continuous process of attaching bags, scanning barcodes and changing source containers is what keeps the compounding device in motion.

Because human activity varies, garbing, the second method for reducing the spread of human-particles, is a more reliable method for containing human bioburden. For it to be effective, the garb must be designed to act as a barrier surrounding the individual. Because personnel don't enter the cleanroom with their own personal HEPA-filters, consider adopting better-than-minimum garbing standards to keep human particles out of your program.

Resolution #3 Be Sure That Your Cleaning Process Can Keep Up with Potential Bioburden

There are two possible destinations for the human particles that escape from the individual's garb into the cleanroom air: they are either swept out of the room by the airflow, or they settle on a surface as possible bioburden until removed by cleaning and disinfection.

Some compounded formulations increase the total number of touched surfaces during an aseptic process. Making PN, for example, requires individuals to touch the surfaces of macro-nutrients, micro-nutrients, water, vitamins and trace element containers. If the cleaning program does not keep up with the bioburden, a glove can become a handy instrument for transferring contamination from a high-touch surface to a critical site.

A cleaning and disinfection program needs to do more than just meet minimum standards in USP <797>. The program must also account for challenges presented by the personnel, the workflow, the garbing, the airflow and the total number of surfaces in your cleanroom.

Resolution #4 Clear a Pathway Toward Continuous Improvement

Frequently collected sampling data—obtained with sound methods and a risk-based sample plan—will shine a light on the effectiveness of your cleaning and disinfecting program. On the other hand, poorly collected samples can produce biased results and cloud your view of the potential risks.

With air sampling, an automated instrument impartially collects a wide range of air during dynamic work conditions. It's a process that occurs over time. Surface sampling is different. It requires only a brief interaction with a smaller, fixed location. The collection process is less impartial and your impression of your cleaning program can be influenced by what you choose to sample.

Going from minimum, to good, to great sterile compounding practices also requires a look beyond the surface.

We suggest these New Year's resolutions as a way to start moving toward better standards. Continuous improvement, however, will be a process that occurs over time. It will involve wide-ranging assessments of training, performance and process. It will depend on impartial input and buy-in from the full set of individuals who work in the cleanroom. More importantly, continuous improvement will require dynamic leaders who can unify their teams and collectively establish and follow their best sterile compounding practices.

Success Requires Creative Solutions

CAPS Consulting℠ is a team of pharmacy experts who are proficient in sterile compounding. We perform USP <797>, USP <800>, and 503B outsourcing compliance tests each and every day, year round, at 22 regional 503A pharmacies and three 503B outsourcing facilities across the United States. Our consulting team is ready to share this expertise with you.

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