

# CASE STUDY

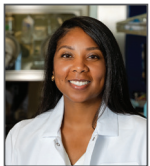
## Inside the Cleanroom: Nephron Strengthens Sterility, Comfort, and Control With Cintas



**Lou Kennedy**  
Owner  
~ Nephron  
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**Aubrey Kane**  
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### A HIGH BAR FOR SAFETY, QUALITY AND COMPLIANCE

Based in West Columbia, South Carolina, Nephron Pharmaceuticals is an FDA-approved manufacturer focused on sterile, aseptically filled medications. Serving retail pharmacies, long-term and in-home care providers, as well as hospitals and surgery centers, the company provides common generic respiratory treatments, such as liquid nebulizer medications, as well as IV drug-shortage products.

"Every one of our 750 employees is committed to bringing safe, effective, and affordable medications to patients in need," says Lou Kennedy, Nephron's owner. "And since sterility is at the center of everything we do, we have a high bar to meet in terms of FDA regulations." That's true across all departments, but critical in the cleanroom where sterile preparation takes place.

"The primary challenge for maintaining a cleanroom environment is ensuring that we have consistent and repeatable control," explains Aubrey Kane, senior director of sterility. "There are so many potential sources of contamination when it comes to a dynamic manufacturing setting like ours – and people's microbial load is always going to be the highest risk factor." That's why, she says, having the appropriate cleanroom apparel is critical to the process.

### A LAYERED DEFENSE: NEPHRON'S CLEANROOM APPAREL PROTOCOL

Before entering Nephron's cleanrooms, technicians follow a careful donning process that starts with putting on a tech suit, the first layer of protection. With this on, they can then move into a controlled environment that leads to the cleanroom. Here, they sanitize their dedicated cleanroom shoes, put them on, and place shoe covers over them. They then sanitize their hands, put on their gowns, hoods, goggles, and sterile gloves. Lastly, technicians put on a sterile coverall, sleeve covers, and booties.

### CHALLENGE: LIMITED FLEXIBILITY, INCONSISTENT FIT, AND LACK OF TRANSPARENCY

Nephron opts for reusable cleanroom apparel over disposable options and maintaining the integrity of those garments throughout their lifecycle is essential. That includes following the

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guidelines outlined in the 2022 revision of Annex 1, which requires a dedicated laundry facility and the use of qualified processes to ensure clothing is not damaged or contaminated.

From an operational standpoint, sterile manufacturers, such as Nephron, face challenges with cleanroom garments being flexible and comfortable. “Some of our people can be in the cleanroom for an extended period of time making life-saving medications for hospitals,” says Deirdre Toomer, 503B operations manager. Kennedy agrees, adding, “When you’re asking technicians to spend hours in a sterile environment, comfort isn’t a nice-to-have — it’s essential.”

This is where Nephron was running into issues with their previous supplier, explains Toomer — both with the material and the sizing. Previously, the company’s cleanroom apparel was issued in matched sets, tops and bottoms of the same size. If someone took a smaller shirt size than pant size, or vice versa, they typically went with the larger size. “We ended up having people who were literally swimming in extra fabric,” says Toomer. In some instances, they even experienced shortages. “I had one technician out of the cleanroom for about two weeks because we didn’t have access to the right-size apparel.”

Garments were made from an extremely slippery material, so sleeves and booties often slipped down and had to be adjusted. Hoods also weren’t flexible enough in their sizing to accommodate different hairstyles. If someone with long hair or a lot of hair wanted to put it up, their hoods might shift and expose a small amount of skin on the back of their necks. As a result, technicians were constantly fidgeting with tech suit tops and bottoms as well as sleeves, booties, and hoods. “Our staff doesn’t need the additional complications or distractions from apparel that doesn’t fit properly when they are working in such a critical setting,” says Kane.

It can take a long time to qualify and train people to work in the cleanroom, so retention is always important. “We’ve found that if someone is uncomfortable or needing to readjust their clothing for hours at a time, day after day, it can impact whether they want to stay in the cleanroom or move to another part of the business,” says Toomer.

Beyond these challenges, Kane says Nephron had no transparency. “We would often be billed for damaged garments, but there was no information as to what was damaged and no photographs to help us understand how the damage was occurring.”

## SOLUTION: STANDARDIZED GARMENTS, SMARTER INVENTORY, AND FULL VISIBILITY

When the potential risk of compromising contamination controls became too great, Nephron turned to Cintas, a leader in business services that provides uniform rental and cleaning, as well as a range of facility services and fire and safety products. “Cintas was already supplying our cleanroom shoes, so we were familiar with them and happy with their product and service,” says Kane.

While ensuring compliance with Annex 1 guidelines and addressing immediate fit and inventory challenges were critical, Nephron was also looking for a partner who would support continuous improvement. Cintas delivered on all fronts.

When Nephron conducted an audit of the Cintas facilities as part of its supplier qualification program, Kane says they saw firsthand the procedures and standards in place. This includes a validated laundry and packaging process, as well as cleanroom certifications for the area where apparel is folded before it’s packaged. “Having the confidence in their compliance, which helps us stay compliant, is everything to us,” says Kane.

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In terms of the apparel, what they noticed right away — particularly about the tech suits — was the fabric used, which is probably the most critical factor for comfort. Not only was it made of a low-particle shedding material, but it was also incredibly breathable. The game-changer, however, was the vending process. “There's complete flexibility,” says Kane. “There are over 1,000 individual tops and bottoms in the vending machine and employees check out whatever size top and whatever size bottom they need for that day.” That means employees can easily change sizes day to day if needed.

The vending system also gives Nephron an audit trail of inventory for complete transparency. “If a garment is damaged, we know Cintas will provide us with photographs and other specifics like what shipment the apparel came from, what the size and what the lot number was,” says Kane. This helps the company narrow down when and how the damage occurred, and they can fine-tune processes to avoid future issues.

That flexibility extends beyond sizing to the Cintas customer service approach. Nephron's contracted delivery day is Thursday. Of course, in the U.S., Thanksgiving falls on a Thursday every year. “We were concerned we might be faced with a shortage of cleanroom apparel if we missed a delivery,” says Kane. When she reached out to Cintas, they immediately moved their regular delivery up so they wouldn't have to wait two weeks for new garments. As a result, there were no interruptions or disruptions in cleanroom apparel inventory.

In another instance, Nephron needed to adjust the allocation of garments by size. “Usually, when you enter into an agreement as we have with Cintas, you commit to certain sizes and quantities for a set period of time — whether six months or a year,” says Kane. “They let us make the change even though, contractually, they didn't have to.” In both examples, she adds, Cintas understood and immediately met Nephron's need. “Cintas really goes above and beyond to make sure they're meeting the needs of their customers. I think that's what really sets them apart from many vendors.”

## RESULT: A LONG-TERM PARTNERSHIP BUILT ON RELIABILITY AND RESULTS

With Cintas as a partner, Nephron knows it can count on the durability, performance, and fit of their cleanroom apparel. “I love that the product from Cintas is the same every time,” says Toomer. For technicians working long hours in a highly controlled environment, that consistency matters. “Not just the material for comfort, which is really fabulous, but the ability to mix and match sizes,” she adds. “Now our techs don't have to worry about how their tech suits fit. They only worry about their aseptic technique in the cleanroom.”

That reliability has delivered a measurable impact. In the first year alone, Kane says Nephron saved approximately \$600,000 by transitioning to Cintas reusable cleanroom apparel. “Our plan is to onboard new products such as lab coats, sterile sleeves, and reusable sterile goggles,” says Kane. With this, the company estimates it will see \$2.4 million in cost savings over a five-year period.

Just as important, Kane adds, is knowing that Nephron has a partner that takes compliance as seriously as they do and responds quickly as needs change. “It feels seamless,” she says. “They understand what's at stake for us and consistently go the extra mile.” For Toomer, that support makes a clear difference on the manufacturing floor. “Cintas allows us to focus on producing reliable, safe medications for patients,” she says. “That's what matters most.”

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## CLEANROOM RESOURCES

Gowning Service to Help Keep Your  
Controlled Environment

**Ready for the Workday®**

### PROTECT YOUR PEOPLE. PROTECT YOUR PROCESS.

When you need Cleanroom garments — and the peace of mind that comes with them — Cintas delivers. With strategic ISO 5 Cleanrooms across the U.S., we support a diverse range of industries.



#### COVERALLS

Get the right coverall for your specific controlled environment needs.



#### FROCKS, ESD LAB COATS & SPECIALTY GARMENTS

Many options to keep your employees in the cleanroom **Ready™**.



#### BOOTS AND SHOE COVERS

The right footwear for your controlled environment.



#### GOGGLES

Protective eyewear for your team. Gamma sterilization compatible.



#### MOPS

Innovative cleaning solutions at your fingertips.



#### WIPES

Cleanroom cleaning wipes delivered with your gowning.



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