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NO. 2, 2023

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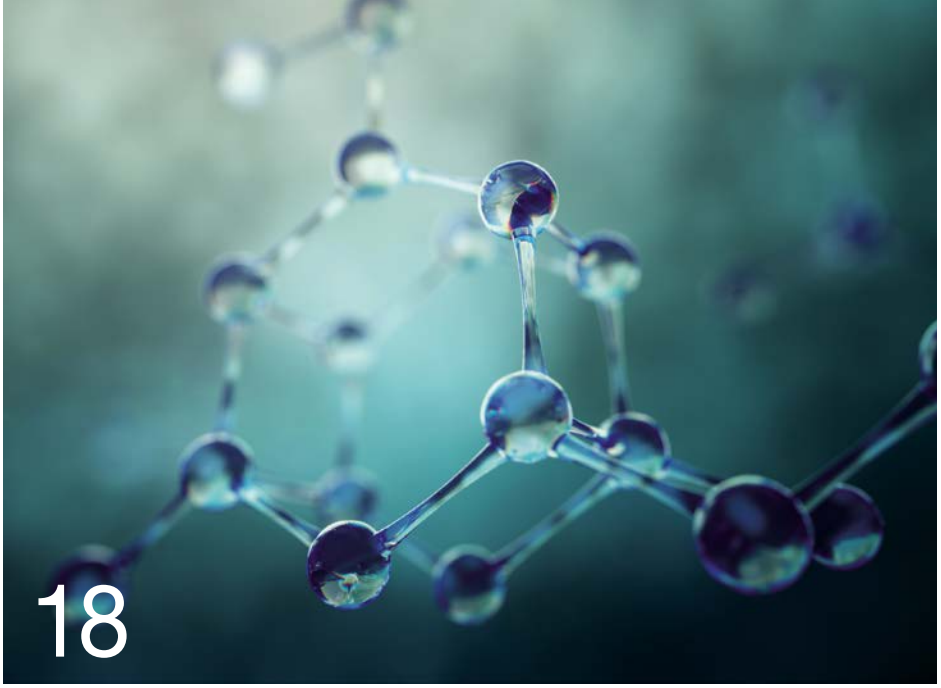

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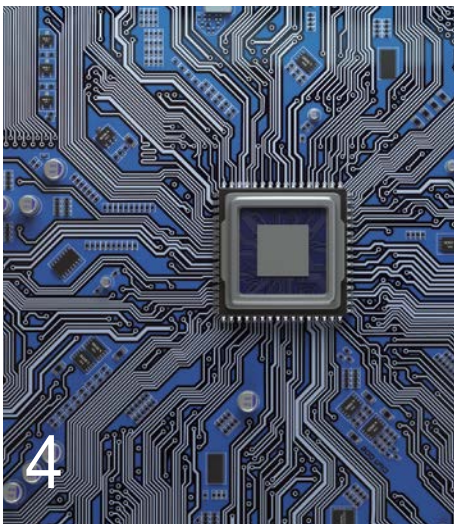

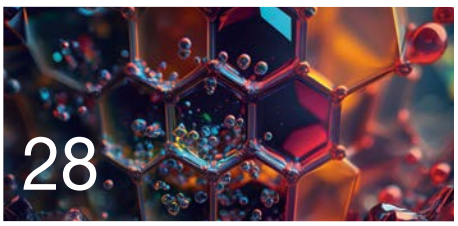

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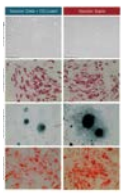

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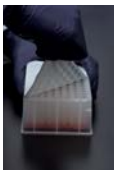

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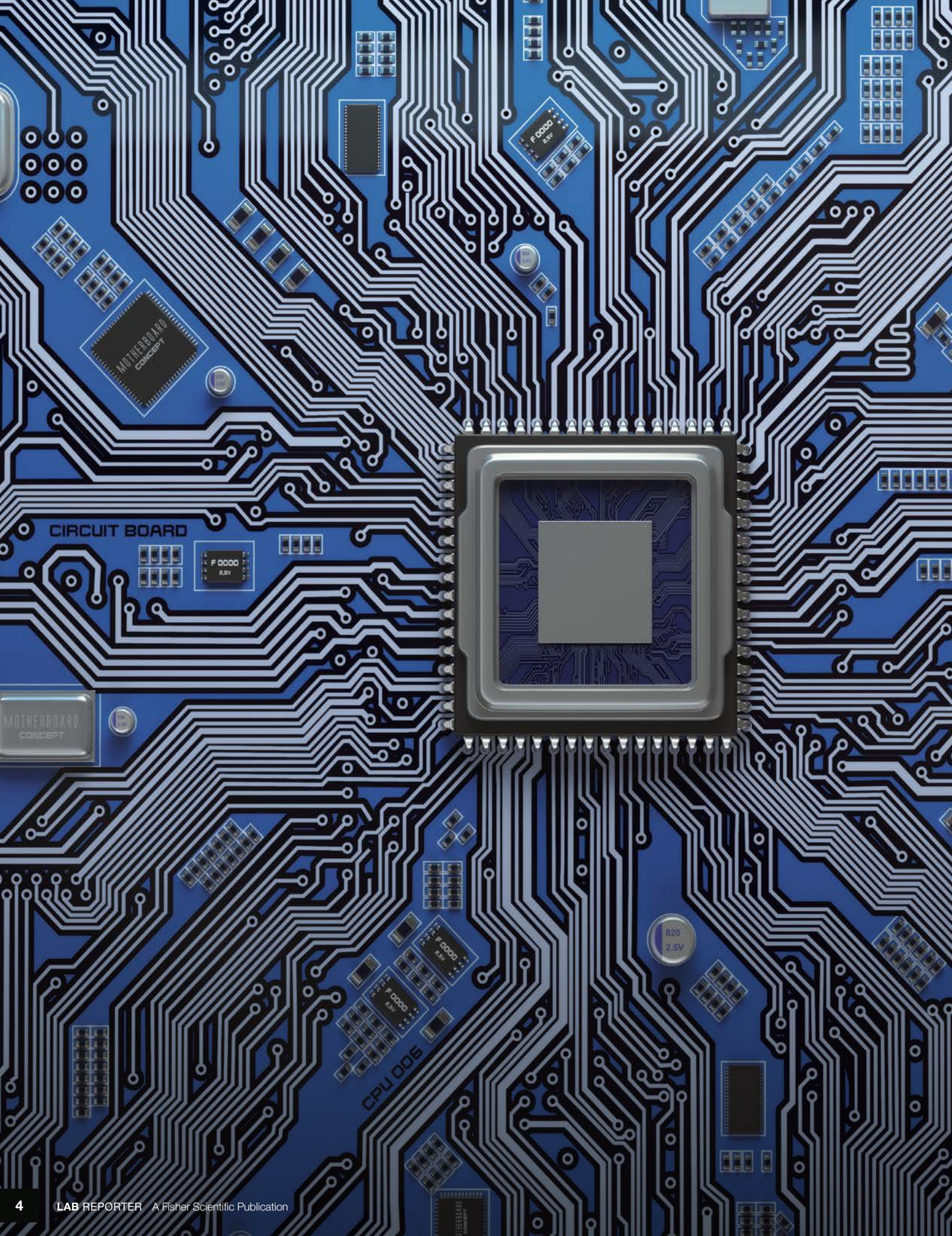
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Semiconductor Manufacturing Makes a Comeback in North America

By Mark Miller

Semiconductors—the tiny silicon chips that enable everything from smartphones to jet fighters—were invented in the United States in 1961. Yet, a White House fact sheet states that the global share of semiconductors made in the U.S. had shrunk from 37 percent in 1990 to just 12 percent in 2022.

The arrival of COVID-19 brought this decline into focus. The pandemic triggered the need for devices and technology to help keep us safe and productive. The problem was—and still is—there weren't enough chips to meet the demand. That's why government, academia, and industry in North America are working together to meet this challenge, and bring the making of semiconductors back to where they began.

Team Effort

The Creating Helpful Incentives to Produce Semiconductors (CHIPS) and Science Act of 2022 provides nearly $53 billion to bolster American semiconductor research, development, and production. It was signed into law in August 2022 by President Biden and is a catalyst for the participation and cooperation of key industry stakeholders. The Canadian government is contributing, too. It has announced the Semiconductor Challenge Callout to make targeted investments of over $110 million that build on the country's strengths in semiconductor supply and development.

In the U.S., the private sector is making major investments. Samsung plans to create a $17-billion semiconductor facility near Austin, Texas and Intel is committing $20 billion to build two chip plants in Arizona, according to the report "Samsung plans to build a $17 billion chip plant in Texas" from CNBC. Taiwan Semiconductor Manufacturing (TSMC), the world's largest semiconductor maker, is also building in Arizona with two fabrication, or fab, facilities at an estimated cost of $40 billion. Micron plans to build the largest fabrication facility in U.S. history in the state of New York. It's also expanding its Boise, Idaho headquarters to compare with the size of the Pentagon, according to the article "Micron files plan for Boise expansion" from *BoiseDev*.

Academic and industry collaboration is also a key factor. The Semiconductor Research Corporation (SRC), a consortium of technology companies, academia, and government agencies announced the Joint University Microelectronics Program 2.0 (JUMP 2.0). It will support research to achieve breakthroughs in microelectronics and semiconductor development. Intel is working with Arizona State University to provide hands-on semiconductor job training and Micron has announced the Northeast University Semiconductor Network, a partnership focused on the next generation of the U.S. semiconductor workforce.

Keep It Clean

While these efforts will help bring chip-building back, it remains an expensive and risky endeavor. A publication from Intel entitled "What does it take to build a fab?" claims that chips are the most complex products in the world, requiring 1,200 multimillion-dollar tools and 1,500 pieces of equipment to produce.

Just how complex and delicate chip-making can be is illustrated by the fabrication process. It must be conducted in cleanroom facilities, where wafers are transformed into final chips. Throughout the process, the nascent chips face an array of enemies. Dust, particles, and human contamination can cause severe damage. Electrostatic discharge can lead to defects by drawing particles to the surface of the wafers. Moisture and humidity can evaporate solvents prematurely. Any of these conditions may mean the loss of some portion of the billions being spent.

Powering the Future

Given the costs and threats, what's the return? Certainly, chip-making appears profitable. The Semiconductor Industry Association (SIA) reports that sales totaled $574.1 billion in 2022, the highest annual total ever. The U.S. and Canada look to bring some of that money to North America to create jobs and economic prosperity.

But there's more at stake. Made from silicon, the second-most abundant element on Earth, semiconductors are nearly as pervasive as their essential ingredient. They power our televisions, computers, medical equipment, automobiles, and more. They connect us and help us collaborate and innovate. Investing in their future—in North America or around the globe—is an investment in our own.

Visit **fishersci.com/semiconductor** or **fishersci.ca/semiconductor** to learn about products and solutions for the semiconductor industry.

Mark Miller is a Thermo Fisher Scientific staff writer.

Navigating Annex 1 PPE Guidelines

The intricacies of the European Union Good Manufacturing Practice (GMP) for Medicinal Products for Human and Veterinary Use Annex 1 guidelines can be confusing and overwhelming. In this article, we'll explore some of the details of Annex 1 and point you to Ansell hand and body protection solutions and information to help your cleanroom meet and exceed these stringent standards. Understanding and adhering to Annex 1 PPE guidelines for sterile environments is critical to your business. Following best practices and investing in proper protective clothing can help you maintain the safety of your personnel and the safety and quality of your products.

What Is Annex 1?

Annex 1 is a legally binding part of EU GMP that provides guidelines and information relating to the manufacture of sterile medicinal products. The latest version of Annex 1 was published on August 25, 2022 and will be implemented on August 25, 2023.

What's Covered?

Annex 1 provides comprehensive guidance for the design, construction, and maintenance of facilities and equipment used to manufacture medicinal products. It also guides the production process, quality control, and documentation. Annex 1 applies to all sterile medicinal products manufactured in the EU and U.K. and to products manufactured elsewhere and exported into the EU and U.K. It applies to:

- Finished products in any size or combination
- Active substances
- Packaging materials
- Any manufacturing processes
- Any manufacturing technologies
- Any manufacturing designed to produce a sterile product
- The design and control of facilities, equipment, systems, and procedures

Contamination Risks

Contamination within controlled environments used for aseptic processing can come from raw materials, packaging, equipment, fluids, tools, processes, and—the most significant source of contamination—people. Microorganisms are continuously shed from hair, skin, eyes, and mucus membranes.[1] When people are moving around in controlled and sterile environments, they can shed up to 10 times more particles than when they are sitting or at rest.

Annex 1 Part 7.18: Activities in clean areas that are not critical to the production processes should be kept to a minimum, especially when aseptic operations are in progress.

The movement of personnel should be slow, controlled, and methodical to avoid excessive shedding of particles and organisms from over-vigorous activity. Operators performing aseptic procedures must adhere to the proper technique at all times to prevent any changes in air currents that may introduce air of lower quality into the critical zone.

The movement of personnel near or adjacent to critical zones should be restricted and the path of unidirectional (first air) airflow should remain unobstructed. A review of airflow visualization studies as part of your training program can help the team understand the issues.

Find Out More

See our ad on pages 14 and 15 of this issue of *Lab Reporter* to learn more about Ansell products that can help you meet Annex 1 guidelines, or contact our experts to find the right PPE solutions for your workplace. Visit **fishersci.com/ansell** or **fishersci.ca/ansell** to access resources such as our Annex 1 white paper and other information, including:

- Personnel: Annex 1, Part 7 Guidance on Cleanroom Garments, Protective Clothing & Donning Procedures
- The Importance of Barrier Technologies
- Ansell PPE Packaging & Sterilization: Safeguarding Cleanroom Production

You'll learn how innovative Ansell products can revolutionize your cleanroom operations while helping you comply with the latest regulatory requirements.

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1. Brandes, R. (2012, April, 12). Aseptic Processing: Qualification of Personnel. Mass & Peither AG-GMP Publishing.

Specialized Plastics for Cell Therapy Research

Cell therapy is the process of modifying and reintroducing a person's own or external donor cells to restore the function of a diseased cell or eliminate cancer cells from the human body. The cells are administered by cell injection, blood transfusion, grafting, organ transplantation, or genetic modification.

Although cell therapy practices have existed for many years, a renewed interest in research in cell therapy—especially related to wound healing—occurred during World War II. More recently, chimeric antigen receptor (CAR) expressing immune cell therapy has shown promising results as a cancer treatment.

Stem Cells: Current Status and Challenges

Because of their capacity for self-renewal, multilineage differentiation, ease of isolation, and in vitro cell culture tolerance, mesenchymal stem cells (MSCs) are a popular choice for cell therapy and regenerative medicine. MSCs have been used in bone and cartilage repair, cardiovascular disease conditions, and to repair damaged musculoskeletal tissues.[1, 2, 3] However, ongoing research is being performed to help increase the success rate of stem cell therapies by better understanding the reasons for rejection and the fate of therapeutic stem cells in the body.

To prepare the cells for injection, cell sheet grafting, or cell patch seeding, they may be cultured in vitro using fetal bovine serum (FBS) and other proteins. However, animal-sourced products can induce immune reactions in patients, so compatible xeno- and serum-free media have been developed. Since these media also lack attachment factors, MSC cultures require the addition of extra-cellular matrix (ECM) proteins, which may contain potentially immunogenic molecules.[4] Alternatively, specialized surfaces can be used for growing stem cells under serum- and ECM coating-free conditions to support the formation of intact cell sheets.

Nunclon Supra Surfaces

Thermo Fisher Scientific developed Nunclon Supra surfaces by exposing polystyrene to a proprietary energy source that produces a more hydrophilic surface than conventional tissue culture surface treatments. This increases cell attachment, eliminating the need to add an ECM or serum. This surface was tested by growing human MSCs derived from bone marrow, adipose tissue, and umbilical cord under serum- and coating-free conditions. Cells showed equivalent attachment and growth on uncoated Nunclon Supra surfaces when compared to a Nunclon Delta surface coated with the ECM substrate CELLstart. Additionally, MSCs grown on Nunclon Supra surfaces preserved their immuno-phenotypic profile, assessed by the positive expression of MSC-specific surface markers and negative expression hematopoietic stem cell markers. The MSCs also showed efficient trilineage differentiation to osteocytes, adipocytes, and chondrocytes (Figure 1). Taken together, MSCs can be successfully grown and differentiated on Nunclon Supra surfaces without using serum or ECM and therefore effectively used for cell therapy research.

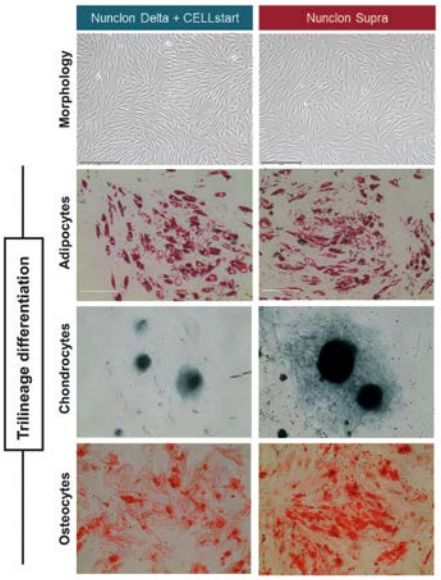

Figure 1. Nunclon Supra surfaces support MSC attachment and differentiation potential to adipocytes (Oil Red O staining), chondrocytes (Alcian Blue staining), and osteocytes (Alizarin Red staining).

Nunc UpCell Surfaces

Cell sheet tissue engineering is a scaffold-free approach to regenerating damaged tissue cells, a technique introduced in 1990. Before that, structure collagen or hydrogel were used as scaffolds to create tissue patches. Nunc UpCell dishes are grafted with a temperature-responsive polymer (poly(N-isoproplyacrylamide or PIPAAm) that allows confluent cell monolayers to be harvested as intact sheets when the temperature is reduced from 37°C to below 32°C. This avoids the need for protease treatment, which

preserves cell-cell junctions, cell surface proteins, and extracellular matrix in the sheet.

By using UpCell surfaces, 3D tissue can also be created by layering cell sheets. As shown in Figure 2, both single and stacked MSC cell sheets were fabricated using UpCell coated with vitronectin. The harvested sheets consisted of live cells (confirmed using Invitrogen LIVE/DEAD imaging) and retained expression of extracellular matrix proteins like fibronectin and collagen (Figure 3).

Cell therapy is expected to continue to make significant contributions to medicine in the coming years, many of them driven by ongoing research in these areas. The use of Nunclon Supra and UpCell surfaces to support stem cell growth and cell sheet generation should continue to support research on the next generation of MSC therapies. These tools are expected to enable scientists everywhere to more effectively culture stem cells and accelerate cell therapy research.

To learn more about Thermo Scientific Nunc specialty and core lab products or Thermo Scientific cell therapy research products, visit **fishersci.com/thermocellculture** or **fishersci.ca/thermocellculture**.

You can also visit **fishersci.com/gibco** or **fishersci.ca/gibco** to find a range of products suitable for cell therapy research applications. Contact your Fisher Scientific sales representative for more details.

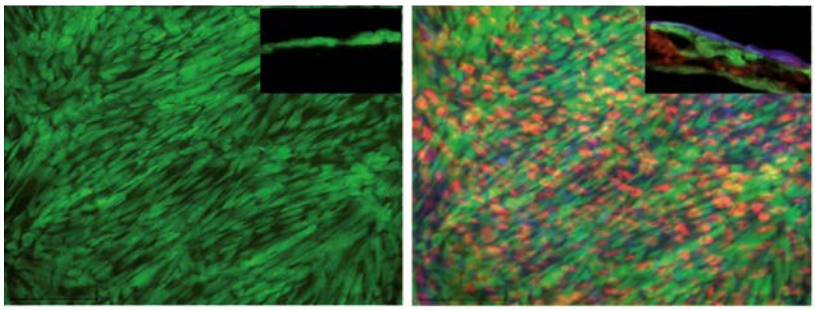

Figure 2. Single layer (left) and stacked (right) cell sheets fabricated on Nunc UpCell surfaces. Individual cell monolayers were pre-stained with CellTracker dyes for better visualization. Inset: Cross sectional view of the respective cell sheets.

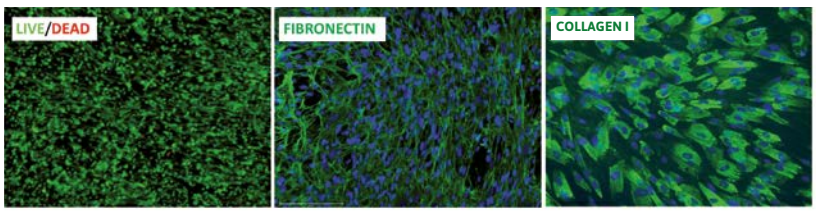

Figure 3. The cell sheets fabricated on Nunc UpCell surfaces were stained for live cell population and ECM proteins, fibronectin, and collagen I. Images were captured using the EVOS M7000 imaging system.

1. Savkovic, V. et al. (2014). Mesenchymal Stem Cells in Cartilage Regeneration. Current Stem Cell Research & Therapy, Volume 9, Issue 6. https://www.eurekaselect.com/article/61317

2. Bagno, L. et al. (2018, May 15). Mesenchymal Stem Cell-Based Therapy for Cardiovascular Disease: Progress and Challenges. Molecular Therapy. https://www.cell.com/molecular-therapy-family/molecular-therapy/fulltext/S1525-0016(18)30212-0

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Fungal Future: Exploring the Potential of Mushroom Computing

By Dani Lewis

From nutrition to medicine, mushrooms have a rich history of being used for various purposes. Most recently, fungi have caught the attention of computer scientists. Researchers have proven that, much like computers, mushrooms use networks to exchange signals and communicate.

An exciting recent advancement in this field comes from the Unconventional Computing Laboratory at the University of the West of England in Bristol, United Kingdom. Their research team announced an unprecedented discovery—a living computer powered by mushrooms.

Unconventional Innovation

Professor Andy Adamatzky founded the Unconventional Computing Laboratory in 2001 with the mission of developing computers for the next century. "We employ complex dynamics in physical, chemical, and biological media to design novel computational techniques, architectures, and working prototypes of non-linear media-based computers," explains Adamatzky on the Unconventional Computing Laboratory's website.

Adamatzky and his team conduct their research in an environment that appears to merge technology and nature. They are revolutionizing computing with wetware, combining living tissue with hardware and software. In other words, their team integrates organic matter, in this case oyster mushrooms, with electronic components.

Mushrooms were chosen as an ideal organism to experiment with because their mycelium, the fungal body, responds to environmental stimuli much like the human brain. Mycelia has the capability to transmit electrical impulses and retain memory, according to the *Popular Science* report "Inside the lab that's growing mushroom computers" by Charlotte Hu.

Unlocking Mycelium's Potential

When mushrooms are connected to the same network of mycelia underground, they can communicate with electrical signals over long distances. With this knowledge, Adamatzky and his team sought to incorporate fungal communication in a motherboard. They recorded spikes of electrical activity using microelectrodes connected to the mushrooms. In their experiments, they correlated the presence or absence of a spike to a zero or one, mimicking computer programming language.

"We're the first lab to report about spiking activity of fungi measured by microelectrodes, and the first to develop fungal computing and fungal electronics," said Adamatzky, in the *TechSpot* article "Scientists have developed a 'living PC' made from mushrooms" by Cal Jeffrey. In their fungal computer, the mycelium acts as a conductor and replacement for electrical components like the central processing unit (CPU) or memory.

Adamatzky and his team proved that if you stimulate mycelium at two separate points, faster communication is possible because of the increase in conductivity. As this communication becomes faster and more reliable, memory can be established within the mycelium. Interestingly, brain cells form habits in a similar fashion when repeated behaviors result in a circuit of automatic activity, according to the *Scientific American* report "How the Brain Makes and Breaks Habits" by Ann M. Graybiel and Kyle S. Smith.

The Mushroom Brain

There is a widening group of researchers who are studying the fungal brain, including Professor Nicholas Money of Miami University in Oxford, Ohio. He argues a new theory that cellular consciousness resides in mushrooms. Many scientists debate what determines consciousness, but an increasing number of researchers define consciousness by an organism's awareness and reaction to its surroundings.

"Just like the animal brain, the fungal mind is aware of and responds to its environment," stated Money in the *Research Outreach* article "New theories expand cognition to fungi." In their natural habitat, mycelium can detect the presence of other organisms and react to the availability of food. To prove these theories, fungal biologists continue to study mushroom memory and conscious functioning.

What's Next?

Unconventional computing may be the future of information technology, but there's still a lot of research that needs to be done. As the current evidence stands, mushroom computers cannot compare to current technology. Even though Adamatzky and his team proved increased conductivity produces faster communication, it's not nearly the speed of traditional electronics.

"Right now, all we have are viability reports. We're just showing that it's feasible to perform computation, as well as fundamental logical and electrical circuits, using mycelium," said Adamatzky in the *Firstpost* feature "A Living PC: Scientists showcase a working demo of a PC powered by mushrooms."

As research in this field continues, there is a possibility that more advanced mushroom computers could create novel methods of information processing and analysis in the future.

Dani Lewis is a contributing writer to Lab Reporter.

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Personnel in a cleanroom are the biggest contamination risk during aseptic processing and Annex 1 Part 7 outlines the requirements needed regarding personnel numbers, behavior, skills and clothing. The implementation of a precise contamination control strategy is key to ensuring that the PPE they're wearing is suitably assessed and monitored.

All Ansell sterile PPE—gloves, clothing, goggles, RABS/Isolator gloves—has certification to prove it has been subjected to the full sterilization process and that each product within the range comes with a full validation pack, including product and quality statements and applicable comprehensive test results.

*Please check product validation pack for full test results.
**Always check your local recyclable status of packaging materials in your country.

PART 4.18–4.22 BARRIER TECHNOLOGIES

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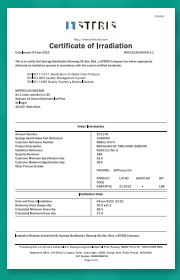
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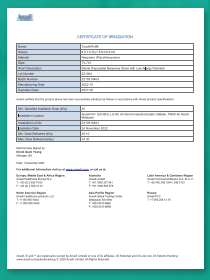
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PART 7.11 CERTIFICATION

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FEATURED ARTICLE

Persistent Pollutants

Addressing Forever Chemicals and Their Risks

By Kylie Wolfe

There's something lingering in our water and soil—and it's worth paying attention to. That something is a complex group of chemicals known as per- and polyfluoroalkyl substances (PFAS). Used since the 1950s in clothing, food packaging, cookware, and cosmetics, these substances have made their way into the environment and the human body and are now raising red flags for scientists around the world.

A Long-Lasting Pollutant

PFAS, a collection of over 5,000 synthetic organic compounds, are commonly referred to as forever chemicals because of how long they can last in the environment and our bodies. They contain a sturdy molecular backbone of fluorine and carbon, elements that form one of the strongest single bonds in chemistry, making them difficult to break down naturally.

PFAS have been around for decades in a range of industrial, commercial, and consumer goods. Many of the compounds that fit into this category provide desirable nonstick and water- and heat-resistant properties, meaning they've made their way into numerous products—so many that a complete list of products isn't known. But because they've been so widely used and don't break down easily, these substances can now be found in human and animal blood, and even in food products.

"These toxic chemicals are so pervasive and so long lasting in the environment that they've been found in food, soil, and water, even in the most remote corners of our planet," said EPA administrator Michael Regan in a news conference and as quoted by PBS NewsHour.

Many cosmetics, for example, contain forever chemicals. In a 2021 study published in *Environmental Science & Technology Letters*, Notre Dame professor Graham Peaslee and colleagues tested over 200 mascaras, lipsticks, and other beauty products and found that 52 percent of them contained high amounts of fluorine. These chemicals can not only be ingested and absorbed by the wearer but are washed down the drain and can end up in drinking water.

Effects on the Environment and Health

Due to the persistence of these pollutants, scientists are starting to study associated human health and environmental risks. Very few PFAS have been identified, but some have already been linked to infertility, cancer, and an increased risk for high blood pressure and cholesterol, thyroid disease, and kidney problems.

"We live on a planet where every component interacts," said Susie Dai, associate professor of water and bioenvironmental science at Texas A&M University, in an interview with *AgriLife Today*. "People are concerned not only about their water, but also about local crops and animals that are produced by using that same water and become part of our food supply."

> Due to the persistence of these pollutants, scientists are starting to study associated human health and environmental risks.

There are two main classifications of PFAS: short-chain and long-chain substances. The former contain fewer than six to eight carbons while the latter contain more than six to eight carbons. Studies conducted by the Centers for Disease Control and Prevention found that some PFAS can remain in the body for years—and it's the short-chain PFAS that build up and stick around.

At this stage, the health risks are unclear and there are still many questions about the long-term effects of PFAS on the body. Current studies indicate that exposure to and an accumulation of PFAS may decrease one's immune response and interfere with endocrine function.

Plans for Regulations

Over the last few decades, PFAS have been gaining attention in many countries. In the United States in 1986, California approved the Safe Drinking Water and Toxic Enforcement Act, protecting citizens and their water sources from harmful chemicals. In 2006, the Canadian government assessed the effects of perfluorooctane sulphonic acid and determined that exposure to it was not enough to negatively affect human health but that it was entering the environment at harmful levels.

In 2009, perfluorooctane sulfonate (PFOS) was listed in the Stockholm Convention on Persistent Organic Pollutants, an international treaty that aims to protect human health and the environment. Then, in 2020, the European Food Safety Authority published a report discussing the risks associated with PFAS in food. As recently as 2022, the European Commission proposed new rules for cleaner air and water, including the addition of PFAS testing.

continued from page 19

Persistent Pollutants: Addressing Forever Chemicals and Their Risks

In the U.S., some states have regulations in place to protect the public from PFAS in drinking water. The U.S. Environmental Protection Agency (EPA) recently proposed regulations to do the same on a federal level. This would mandate the testing and filtration of water systems before any water source reaches the public.

Thousands of chemicals are considered PFAS—and new regulations would regulate six of those, including perfluorooctanoic acid (PFOA) and PFOS. The cap for PFOA and PFOS would be lowered to four parts per trillion and the remaining four substances would be regulated in combination with each other. These regulations would apply to public water systems, helping to keep PFAS levels below a legally enforceable limit. The EPA requirements are intended to be in place by the end of 2023. And to further address this issue, the EPA announced a $2 billion grant program for small and disadvantaged communities.

An Ongoing Quest for Answers

As society questions and scientists seek to understand the risks associated with these substances, EPA researchers are finding better and more efficient ways to detect and measure PFAS in the environment. This includes uncovering more information about people's exposure to these compounds, how harmful they are, and how they can be removed, managed, and disposed.

Learning more will help the EPA make informed recommendations and guidelines to protect the health of the population and the environment we live in. Although many questions remain unanswered, highlighting this concern is a step forward for science and society.

Kylie Wolfe is a Thermo Fisher Scientific staff writer.

Prepare for Your Testing Workflows

Whether you're in food manufacturing, environmental testing, or the chemicals industry, it's important to be prepared to meet future regulations and address society's concerns. Having the products needed to conduct your sampling, cold storage, and analysis steps can help you detect these substances efficiently and with ease.

Here are some of the products you can find through the Fisher Scientific channel. Visit **fishersci.com/pfas-testing** or **fishersci.ca/pfas-testing** to start shopping.

- **Sample analysis:** Find sample collection products, equipment and instruments, and consumables to test for total organic fluorine and other precursors
- **Sampling solutions:** Shop propylene sampling bottles not made from Teflon materials that are loaded with tris buffer (EPA 537.1), soil sampling containers, and more
- **Solid-phase extraction (SPE) cartridges:** Browse new solid phase extraction columns for PFAS or products for solid-liquid extraction
- **Solvents and organic standard solutions:** Find methanol, water, chromatography reagents, and more
- **Filtration:** Explore PFAS water filters
- **Chromatography:** Discover vials, columns, and other liquid chromatography and mass spectrometry essentials
- **Electrochemistry:** Monitor the pH of water samples with meters, electrodes, and other relevant products

Visit **fishersci.com/industrial-testing** or **fishersci.ca/industrial-testing** to learn more

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13-880 Series

Flow Rate	Vacuum	Pressure	Dimensions (L x W x H)	Cat. No.
20 L/min.	75 torr	15 psig	13 × 6.5 × 8.5 in.	**13-880-14**
40 L/min.	65 torr	15 psig	13 x 6.5 x 8.5 in.	**13-880-16**
20 L/min.	6 torr	15 psig	15 x 6.5 x 8.5 in.	**13-880-18**
35 L/min.	6 torr	15 psig	16 x 7 x 9 in.	**13-880-20**
35 L/min.	1.5 torr	15 psig	16 × 7 × 9 in.	**13-880-22**

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Visit **fishersci.com/dupont** or **fishersci.ca/dupont** to learn more about Tyvek IsoClean as an ideal choice for vaccine manufacturing.

Think Microplates for Sample Storage

Polypropylene microplates may be the right alternative when storage or microcentrifuge tubes won't work with your application. Microplates can be used for short- and long-term sample storage or as intermediates in sample preparation. Polypropylene's inertness and inherently low binding offers high chemical resistance and high recovery for most sample types.

Legacy of Innovation

Over 40 years of plastic manufacturing are behind Thermo Scientific Nunc storage plates. Innovations developed during this time include shared-wall technology—which increases well diameters—reduced plate height for optimized workflows, and high sterility assurance levels (SAL 10^{-6}).

Specifically selected virgin medical grade resin is used to produce today's Nunc products to help maintain your sample integrity throughout the workflow.

Economical Options

Various formats of 48-, 96-, and 384-well polypropylene MicroWell and DeepWell plates are economical and reliable sample storage options for:

- Drug discovery high-throughput screening and low-binding assays
- Molecular biology and diagnostic testing
- Drugs of abuse testing
- Sample processing for genomic applications

Sealing Formats

Thermo Scientific sample processing and storage plates are designed to work with multiple sealing formats, including thermoplastic elastomer (TPE) cap mats, adhesive seals, and heat seals. Choose sealing options that maintain the integrity of contents and let you store, retrieve, and handle your samples with confidence.

Cap Mats

Cap mats for Nunc 96-well polypropylene plates are designed to protect contents from evaporation, extraneous contamination, and cross-well contamination during storage—regardless of temperature. Choose the pierceable format for secure and repeated access. Cap mats are compatible with the Thermo Scientific SuperSealer device.

Sealing Films, Foils, and Tapes

Thermo Scientific Nunc Sealing Tapes minimize evaporation and protect samples from contamination and spilling. Adhesive seals are suitable for PCR, qPCR, fluorescence, luminescence, cell culture, and ELISA applications, and for general sample storage.

Heat Seals

Thermo Scientific Abgene Heat Seals are available in sheets and can be used with the Thermo Scientific ALPS 50 V and higher throughput devices. Rolls can provide up to 5,000 seals when used with the ALPS 3000 and ALPS 5000 sealers. Use foil, films, and tapes to secure samples in PP, PS, PE, and COC microplates for PCR, qPCR, ELISA, long-term storage, and kitting.

Storage Plate Lids

Nunc universal lids for storage and microplates are available with condensation rings, evaporation barriers, and automation-compatible features.

Contact your Fisher Scientific sales representative to learn more and select the best microplates for your sample storage needs.

Content provided by:

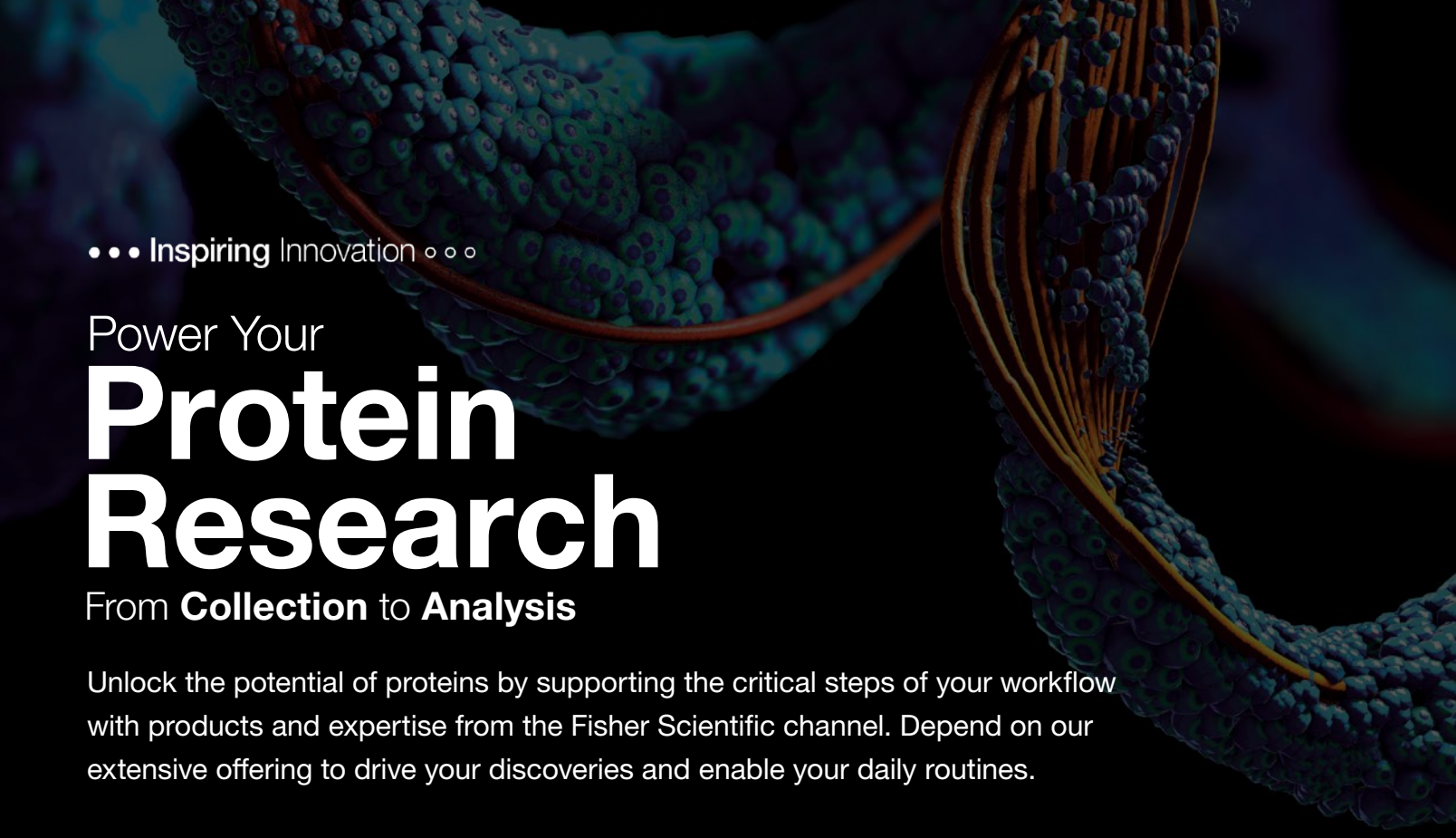
thermo scientific

Microplate Selection Considerations

Feature	Factor
Number of Wells: 48, 96, or 384	Sample volume and assay efficiency
Well Shape: Square vs. Round	Mixing requirements and sample recovery
Well Bottom: V vs. U	Use of magnetic beads and sample recovery
Plate Height: Short vs. Tall	Storage requirements and automated systems
Sterile vs. Non-Sterile	Extent of sample exposure in the workflow

Application Considerations

Feature	Factor
Equipment Compatibility	Centrifugal force, magnet style, and pipette tip size
Application-Specific Requirements	Lids, adhesive or heat seals, and cap mats
Storage Conditions	Temperature and duration



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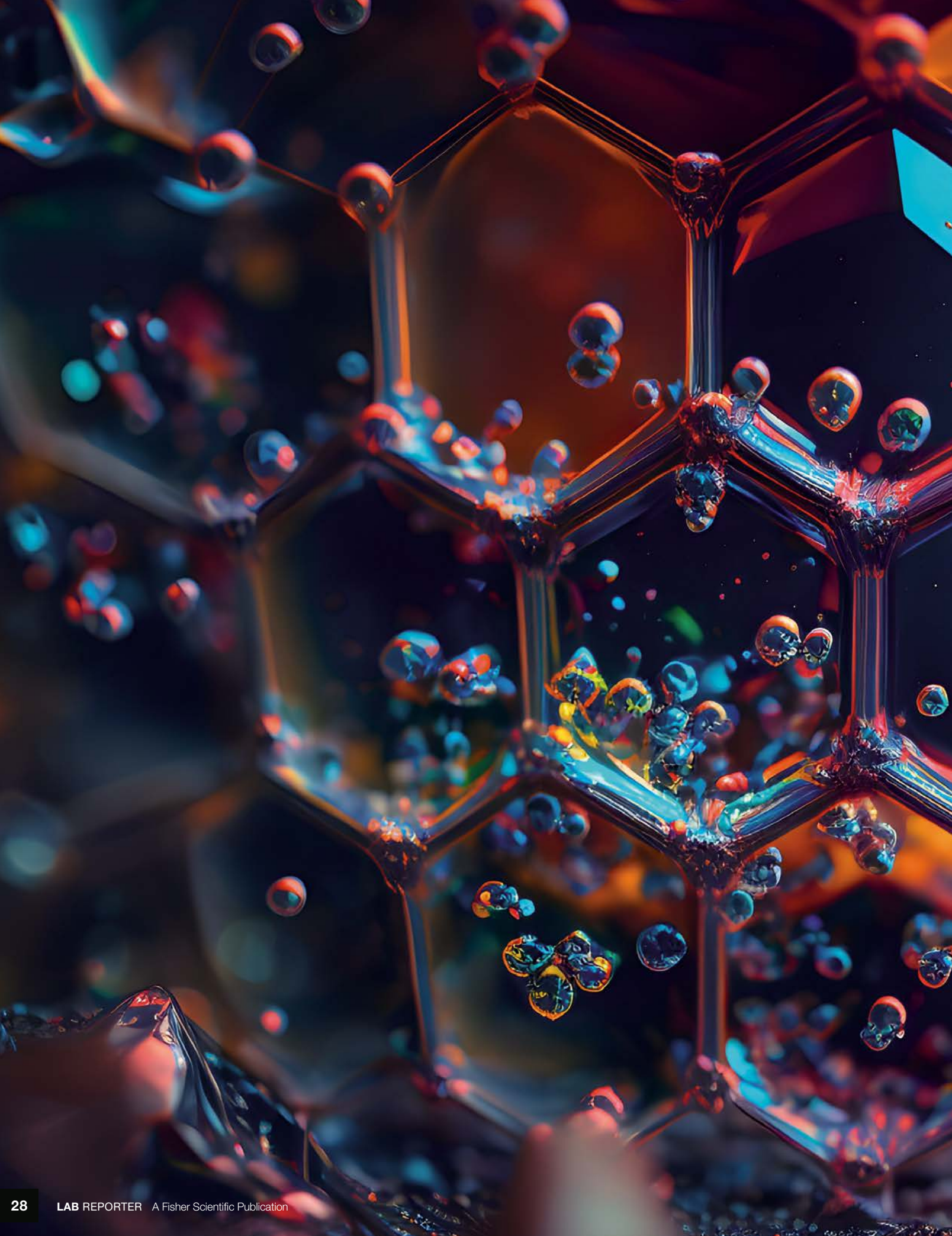

Creating an Annex 1-Compliant Contamination Control Strategy

By Gina Wynn

Controlling contamination in your facility is essential for producing pharmaceuticals that are unadulterated and safe for humans and animals. With the publication of new European Union regulations, production facilities in the United States and Canada will need to maintain compliance if they want to sell their products in EU countries.

In August 2022, the European Union Good Manufacturing Practice (GMP) for Medicinal Products for Human and Veterinary Use Annex 1 was revised. Manufacturers have until August 25, 2023, to fulfill the new minimum standards for manufacturing sterile medicinal products.

The Annex 1 revisions center around an infrastructural approach to Quality Risk Management (QRM) by establishing a detailed and extensive Contamination Control Strategy (CCS), according to the *Cleanroom Technology* article "GMP Annex 1 2022 Update Breakdown: Part 1." The restrictions involve documentation requirements, tighter control of movement between clean zones, and personnel presence.

CCS Development Overview

If you don't have a CCS in place to comply with Annex 1, you will need to establish and document a process to identify and assess risks in your facilities and define actions to prevent contamination of sterile products. This overview of what the process would involve is based on the *MedTech Intelligence* article "Contamination Control: Practical Steps to Compliance with EU GMP Annex 1" by Anna Cluet.

Designate a Team

The first step in setting up a CCS is to designate a group of individuals who will be able to uphold and enforce standards consistently across your operation on an ongoing basis. It should represent technical knowledge of different departments, including production, engineering, maintenance, quality control, microbiology, and quality assurance.

To develop a strong strategy, the team should meet weekly for one to two hours for several months to discuss areas of risk in the facility and the manufacturing process, including equipment weaknesses. When not in meetings, team members serve as liaisons to other departments to explain contamination control requirements and identify high risk areas.

Document the Policy

A formally documented contamination control policy is essential to meeting Annex 1 requirements. The document should outline how, when, and how often data will be collected and evaluated. It should cover the entire production process and will evolve over time as new data is gathered.

Additional local documents may be needed to identify critical areas to be monitored, including equipment operation, cleaning processes, and raw material storage and handling. The CCS should also define how often these documents should be updated and by whom.

Assess Risk

Individual CCS team members should perform risk assessments according to their expertise to identify critical steps that could affect product quality. In some areas, multiple experts may be needed to assess risks. Checks for water purity, for example, would need to involve representatives from engineering, microbiology, and quality assurance.

> If you don't have a CCS in place to comply with Annex 1, you will need to establish and document a process to identify and assess risks in your facilities and define actions to prevent contamination of sterile products.

The group will also need to devise control methods and establish monitoring systems that gather data about the proper functioning of equipment and processes. This data should be included in an overarching CCS document to enable comparisons over time. To comply with Annex 1, the global strategy and local activity must be re-evaluated every year to support continuous risk management.

Protect What Matters Most

By developing and maintaining a strict contamination control strategy according to the Annex 1 updates, you'll increase confidence in the quality of your output, protect your products and people, maintain your relationship with EU customers, and potentially expand your business.

To view a comprehensive assortment of contamination control products that meet the specifications and requirements of your critical environment, visit **fishersci.com/contamination-control** or **fishersci.ca/contamination-control.** To find out how we can support your production process, visit **fishersci.com/production** or **fishersci.ca/production.**

Gina Wynn is a Thermo Fisher Scientific staff writer.

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XS	700	17-900-912	3,000/Case
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L	703	17-900-915	3,000/Case
XL	704	17-900-916	2,500/Case
Typical Thickness: Palm 2.3-2.7 mil; Finger 3.9-4.7mil			

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M	502	17-900-929	1,000/Case
L	503	17-900-930	1,000/Case
XL	504	17-900-931	1,000/Case
XXL	505	17-900-932	900/Case
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XXS	1106	19-423-016	1,000/Case
XS	1100	19-423-006	1,000/Case
S	1101	19-423-007	1,000/Case
M	1102	19-423-008	1,000/Case
L	1103	19-423-009	1,000/Case
XL	1104	19-423-010	1,000/Case
XXL	1105	15-423-050	800/Case
Typical Thickness: Palm 2.3-2.7 mil; Finger 3.9-5.1mil			

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Model	Capacity	Cat. No.
FB-11201	2.75 L (0.7 gal.)	FB11201
FB-11203	5.75 L (1.5 gal.)	FB11203
FB-11206	6.9 L (1.8 gal.)	FB11205
FB-11207	12.75 L (3.3 gal.)	FB11207
FB-11209	18 L (4.75 gal.)	FB11209
FB-11211	29 L (7.3 gal.)	FB11211

Comparing Real-Time PCR and Digital PCR Technologies

Whether you are a veteran in the industry or have just received a grant for a new study, you are always evaluating your options to make sure you are using the solutions that can help you answer your important questions faster and easier.

Each lab has specific needs informing which genetic analysis technology should be used. Both real-time or quantitative PCR (qPCR) and digital PCR (dPCR) can be used to quantify nucleic acids in a sample. This is performed by amplifying a target nucleic acid sequence with a DNA polymerase enzyme. In order to decide which solution fits your project best, it's important to understand the kinds of answers each application can achieve.

qPCR

Since its development in the mid-1990s, qPCR has been a powerful and sensitive gene analysis technique used for a broad range of applications. qPCR measures PCR amplification against a reference as it occurs, unlike traditional PCR, which provides results after the reaction is complete, making it impossible to determine the starting concentration of nucleic acid. qPCR is well suited for performing quantitation of gene expression, pathogen detection, SNP genotyping, copy number variation (CNV) analysis, miRNA analysis, and viral quantitation.

With Applied Biosystems real-time PCR platforms, you get true value with excellent performance, reliability, and world-class support. The Applied Biosystems QuantStudio family of instruments enables you to obtain the results you need, connect and collaborate with colleagues, and achieve your research goals.

qPCR: Applied Biosystems QuantStudio 7 Pro Real-Time PCR System

dPCR

dPCR is a newer approach to nucleic acid detection and quantification that estimates absolute numbers of molecules using statistical methods. This is achieved by single-molecule amplification of a target across a large number of PCR replicates. dPCR is well suited for detecting rare alleles, measuring CNV, measuring viral titer, quantifying next-generation sequencing libraries, and detecting rare targets from environmental samples such as wastewater.

The Applied Biosystems QuantStudio Absolute Q Digital PCR System is a plate-based dPCR platform that helps enable all the necessary steps for dPCR to be conducted on a single instrument: compartmentalizing, thermal cycling, and data acquisition. Our dPCR workflows help improve ease of use, minimize hands-on steps, and maximize consistency, using the same qPCR workflow as QuantStudio real-time PCR systems.

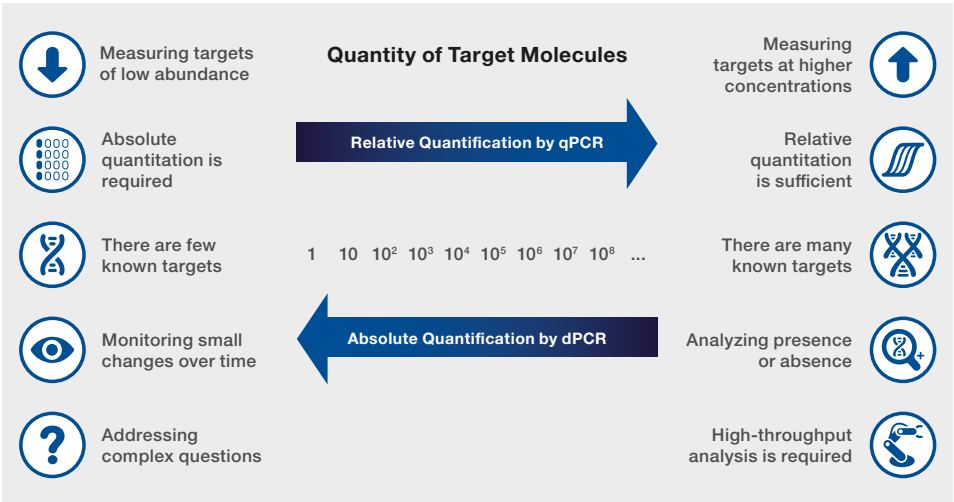
dPCR: QuantStudio Absolute Q Digital PCR System

Even with the differences between them, qPCR and dPCR are complementary technologies—both can answer the question, but the best method depends on details like sample size, data requirements, and if the researcher needs relative quantification or absolute quantification. When trying to decide which technology is best for you, here are a few things to consider:

Digital PCR vs. Real-Time PCR

	Digital PCR	Real-Time PCR
Overview	Measures the fraction of negative microreactions to determine the absolute number of copies. If you're looking for quantitative results, the fraction of negative microreactions is fit to a Poisson statistical algorithm.	Measures PCR amplification as it occurs in a bulk reaction mix. If you're looking for quantitative results, the quantity of the PCR product is directly proportional to the amount of template nucleic acid (standard curve).
Applications	• Quantification of viral load and standards • Quantification of NGS libraries • Rare-allele detection • Wastewater pathogen detection • Liquid biopsy • Quantification of adeno-associated viral vectors • Multiplex detection of multiple targets on a single molecule	• Quantitation of gene expression • Microarray verification • Quality control and assay validation • Pathogen detection • Single-nucleotide polymorphism (SNP) genotyping • Copy number variation • MicroRNA analysis • Viral quantitation • siRNA/RNAi experiments
Advantages	• No need to rely on references or standards • Desired precision can be achieved by increasing the total number of PCR replicates • More tolerant to some PCR inhibitors • Capable of analyzing complex mixtures • Provides a linear response to the number of copies present to allow small-fold changes to be detected	• Increased dynamic range of detection • No post-PCR processing • Detection is capable down to a two-fold change • Collects data in the exponential phase of PCR • An increase in reporter fluorescent signal is directly proportional to the number of amplicons generated • The cleaved probe provides a permanent record of amplification of an amplicon

Are dPCR and qPCR complementary technologies?



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Learn more about Applied Biosystems real-time PCR and digital PCR solutions at **fishersci.com/quantstudio** or **fishersci.ca/quantstudio.**

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- Simple calibration for accurate and repeatable liquid metering and dosing
- Chemically resistant construction to tolerate even highly aggressive chemicals

Model	Metering Rate (mL/min.)	Dose Volume (mL)	Head	Diaphragm	Valves	Cat. No.
FEM1.02KT.18S	0.03 to 20	0.03 to 999	PP	PTFE-Coated	FFKM	**13-880-907**
FEM1.02FT.18S	0.03 to 20	0.03 to 999	PTFE	FFKM	FFKM	**13-880-909**
UFEM1.10KT.18S2	1 to 100	1 to 999	PP	PTFE-Coated	FFKM	**13-880-919**
UFEM1.10FT.18S2	1 to 100	1 to 999	PTFE	PTFE-Coated	FFKM	**13-880-921**

Effective Residue Removal: A Critical Step

Understanding the type of residue is important when determining which materials and detergents will be most effective. Mechanical action by personnel is needed to remove visible and sub-visible production debris, cleaning agent residues, equipment marks, and contamination. Fabrics with abrasive and absorbent properties as well as specialized detergents may be needed to perform an extra level of cleaning, without the need to scrub, in clean production areas.

A Clean Comparison

The data below shows a series of common cleanroom fabrics (ISO 5 to 9) compared to a generic 100 percent polyester fabric (control), using 70 percent IPA to remove dried surface residue (a fine white powder) from a 5,000 parts per million (ppm) sodium hypochlorite (bleach) solution.

Microfiber—a highly absorbent, slightly tufted 80 percent polyester/20 percent nylon fabric—was twice as effective as the control fabric. Microfiber with PolyMesh—a microfiber fabric with a layer of polyester braid—also removed a significant amount of the visual residue with its added scrubbing factor. NovaScrub—a durable open-pore reticulated foam—excelled at loosening the dried residue, however, more of it was visible after drying, similar to the results of the polyester control. Refer to the table for more details.

Dislodging Residue and Debris

Due to high levels of volatile organic compounds (VOCs), 70 percent IPA solutions are not practical for residue removal on large surfaces. Detergents with surfactants that dislodge residue and debris are preferred when cleaning or disinfecting.

One such cleaner is NovaClean. Filtered to 0.1 µm and containing metals and common salt ions in the parts per billion (ppb) range, it cleans surfaces without leaving significant residue.

A second comparison shows the effectiveness of NovaClean detergent compared to deionized (DI) water as solutions to remove residue of a standard quaternary disinfectant, using the same range of fabrics discussed above. Again, the slightly tufted microfiber fabric fared the best, this time leaving an impressive zero percent residue of the standard disinfectant with NovaClean as the surfactant. Several fabrics popular in aseptic areas to apply disinfectants also worked well with NovaClean to remove any disinfectant residue. Other materials—PolySorb, a textured polyester; MegaTex, a textured polyamide; and NovaPoly, a knit polyester—performed much better with NovaClean than the control. The polyester control fabric combined with DI water only removed about 50 percent of the disinfectant residue, compared to 75 percent removal when using NovaClean as the solution.

Recommendations

As you devise your plan for routine residue removal, consider the type of residue, the fabric to remove that residue, and the cleaning solution.

Tufted microfibers, such as Micronova microfiber fabric, work well at eliminating both salt and solution residues.

NovaClean detergent is superior to DI water for removing residue from quaternary amine type disinfectants. For dried salts or slurries, NovaScrub or other more abrasive fabrics are a good choice. When using NovaClean or another disinfecting detergent for residue removal, low particle-shedding fabrics like PolySorb or MegaTex may be preferred since they can also be used to apply disinfectants.

Content provided by:

Micronova®

Average Visible Residue Remaining After Wiping

Wiping Fabric	5% (v/v) Sodium Hypochlorite*	1.6% (v/v) Quaternary Ammonium Disinfectant
	70% IPA	NovaClean
Control Fabric: 100% Polyester	25%	25%
Microfiber	12.5%	0%
Microfiber with Braided Polyester	17.5%	15%
Reticulated Dry Foam	25%	25%
Textured Polyester	30%	10%
Textured Polyamide	42.5%	15%
Knit Polyester	30%	15%

Wiping Fabric	1.6% (v/v) Quaternary Ammonium Disinfectant	
	DI Water	NovaClean
Control Fabric: 100% Polyester	50%	25%**

*5,000 ppm diluted bleach **50% residue reduction using NovaClean

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How Prepared Is Your Lab for a Natural Disaster?

By Iva Fedorka

Damages caused to laboratories and scientific institutions by crises and natural disasters can directly impact your research and threaten the safety of humans and research animals.

Stories from disasters are compelling: the researcher who lost decades of work on a unique mouse lineage; a student who couldn't graduate; the young investigator whose samples were ruined by a power outage. The consequences of disasters are numerous, extensive, and have ripple effects that can often only be recognized in hindsight.

Although you can't totally prepare for disasters and emergencies, you can improve your crisis resilience by assessing assets and risks, developing communication methods, creating a plan, and improving your future responses by evaluating procedures and protocols following any event.

Document Your Assets

Know your assets and where they're located. Include facilities, equipment, instruments, and other laboratory supplies and materials, but also consider assets like people, information, and supply chains.

Asset identification can be complex, but it's essential. Maintain a complete list of current physical assets and regularly update non-static asset data like changes in employees, office locations, suppliers, and other key factors. Compile and centralize your documentation to maintain a complete picture of your laboratory that you can use to adjust your risk assessments and monitors.

Assess Your Risks

The likelihood of hurricanes, wildfires, tornadoes, and snowstorms may be seasonal or geography-based, and buildings located on flood plains will be more prone to water damage.

While making your assessments, identify risks that could be reduced:

- Can electrical systems, back-up generators, and animal facilities located in basements or flood-prone areas be relocated?
- Are storage shelves, animal cages and racks, and other equipment and instruments fastened to walls or benches?
- Are fire extinguishers, safety showers, eye washes, and other devices inspected or tested regularly?

Be proactive, not reactive when considering risk levels. Monitor equipment and instrument sensors and check messages from social media aggregators. If your location puts you at further risk, incorporate real-time alerts about earthquakes, wind speeds, flooding, storm surge, air quality, volcanic eruptions, tsunamis, and other potential events.

Establish Communication

Establish communication procedures and use technology to help create effective mass notifications to staff and key stakeholders. Telephone, email, and SMS text messages are still the most common and effective means of communication, but maintaining some system-independent devices, like battery-powered walkie-talkies, may provide a workable alternative.

Make a Plan

After you have identified your assets and risks, define standard operating procedures (SOPs) and develop a Continuity of Operations Plan (COOP) for disasters and emergencies. These protocols can help produce measured and timely responses. Although they cannot address every risk scenario, they can help mitigate operational impacts and address compliance issues. Referring to these procedures during emergency events or disasters may help you identify additional or indirect concerns that may not be immediately obvious.

Keep copies of your SOPs and disaster plans readily available in central locations so response teams and others can quickly access them.

Follow Up

After any emergency event, review and revise your processes to improve response speed and effectiveness. Regardless of the scale, type, or frequency of the event, consider how you can:

- Improve alert mechanisms
- Identify and protect the assets closest to the threat
- Communicate more effectively
- Increase collaboration for a more comprehensive response

Audit and document the decisions and time frames to understand your plan's effectiveness. Create an automated audit log of when information was received and when decisions were made. Determine best practices and add them to your SOPs for future use to improve your resilience during and in the aftermath of future crises. And adopt policies that leverage new data management and reporting technologies to identify and mitigate disruptions and safety risks.

To learn more about creating a COOP, visit **fishersci.com/lab-coop** or **fishersci.ca/lab-coop** and read the article "Plan for Unexpected Lab Interruptions" in *Lab Reporter* Issue 3, 2021.

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