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SmartNotes

Notes on compliance: Environmental Monitoring

Environmental monitoring keeps consumers safe and facilities open – but this unavoidable cost of doing business can seldom be passed on to clients.

Fortunately, there are simple, practical things pharmaceutical laboratories can do to comply with United States Pharmacopeia (USP) 1116 while keeping costs low and quality high.

What is environmental monitoring?

Environmental monitoring is the control system for maintaining operations facilities according to regulations on cleanliness. It gives an overview of surface quality, air quality, and the efficacy of sterility procedures.

Crucially, it is about avoiding contamination and keeping patients safe.

USP 1116 Microbiological Control and Monitoring of Aseptic Processing Environments covers pharmaceutical sterile products, bulk sterile drug substances, sterile intermediates, excipients, and some medical devices.

It allows for a maximum of 100 viable particulates per cubic meter within aseptic environments, which include conventional cleanrooms with unidirectional air flow (UDAF/ laminar flow), blow-fill-seal, restricted access barrier systems, and isolators.

The guideline also acknowledges that some level of microbial contamination is inevitable where human operators are present. It recommends, then, that facilities operate both total particulate and microbiological monitoring programs.

It is incredibly difficult to meet USP 1116's stringent standards without an environment that speaks to cleanliness. Once limits have been breached, rectification can be a long and expensive process: as any quality control (QC) department knows, facilities don't get compliant, they stay compliant.

Keeping bioburden loads low starts with identifying and mitigating all risks to sterility.

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What are the most common risks to sterility?

Movement

Unfortunately, every step of aseptic processing, from raw material intake to microbiological testing, introduces multiple opportunities for microbes to enter finished goods. Aseptically manufactured goods require a robust, continuous system of sampling, testing, and documenting that covers every stage of the manufacturing process and allows teams to act at the first sign of contamination.

Personnel

Qualified manufacturing and laboratory personnel are essential for maintaining the cleanliness and established system of monitoring. However, they also introduce particulates and microbes to environments, presenting a risk to the product. Validating personnel through sterile media fills helps to determine who is best suited to operate in this critical environment.

Water

Microbes proliferate in the very water that is required in the production of life-saving products. Water systems, whether purified, water for injection (WFI), reverse osmosis (RO) or tap, must be tested to determine microbiological bioburden load. They must, therefore, be included in environmental programming if facilities are to meet product release requirements.

Maintaining a facility that consistently releases quality product according to strict regulations is difficult. Yet a documented, robust environmental monitoring program can provide substantial support during an audit.

As global demand for pharmaceutical products continues to rise, the industry is increasingly on the lookout for ways to reduce the cost of this essential environmental monitoring procedure.

High volume, maximum traceability

Sometimes, the simplest solutions are often the best. This is particularly true in environmental monitoring, where innovation isn't always high tech.

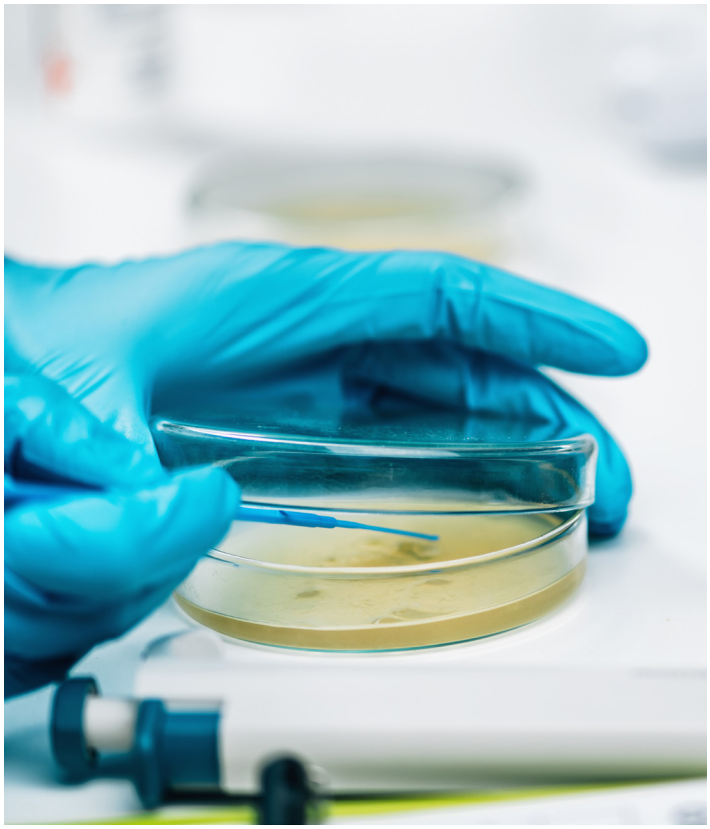
By analyzing workflows, QC departments can often uncover practical approaches to smoothing the roads to safety and compliance.

Simply ordering high volumes of routine supplies, for example, can cut the environmental monitoring burden significantly by reducing the number of new-batch validations.

Pharmaceutical facilities can work with thousands of plates in a single day, each one of which has the potential to introduce contamination to the manufacturing process. To mitigate this risk, each batch of plates is subject to growth promotion to ensure the media supports low level growth of fewer than 100 colony-forming units (cfu) of the challenge organisms. By acquiring the largest lot size with the longest expiry date, facilities can cut the number of batch tests required, reducing resource use without compromising on quality.

Full traceability of plates is also essential. QC teams need to know, without a shadow of a doubt, where the samples have been collected, as well as where and when potential contamination could have occurred.

Individually barcoded plates drive efficiencies by providing teams with the data they need to manage processes, investigate and rectify any breaches.



Logistical considerations

This practical approach to getting the job done transcends the laboratory.

At Thermo Fisher Scientific™, we are always working with our QC partners to find practical ways to reduce risk and boost efficiency in environmental monitoring.

We have designed special packaging that eliminates cardboard and its contamination risk, which features handles for easy transportation in facilities.

Our triple-wrapped, irradiated Thermo Scientific™ Trinity Plates take cleanroom confidence to the next level by confirming the integrity of the wrapping material and seal during VHP exposure.

We have also developed color-coded plates, meaning technicians can quickly find the media they are looking for and get on with the task in hand.

These may sound like small changes, but every second saved in staff time – and every microorganism kept out of the facility – drives down the cost of environmental monitoring and maximizes return on investment.

Simplifying quality control

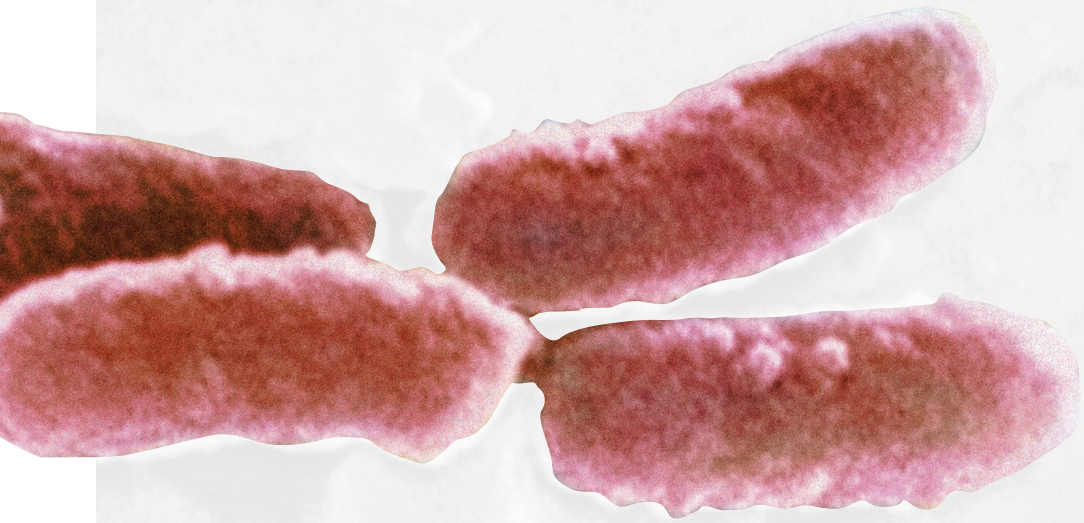
For quality control (QC) testing, we have easy-to-use Thermo Scientific™ Quanti-Cult Plus™ Quality Control Organisms, delivering <100 cfu/0.1 ml, removing the need to prepare serial dilutions of cultures manually. This significantly reduces set-up time and increases the efficiency of new media batch validation. With fully-traceable ATCC cultures, organizations can be confident in the quality of their environmental monitoring programs.

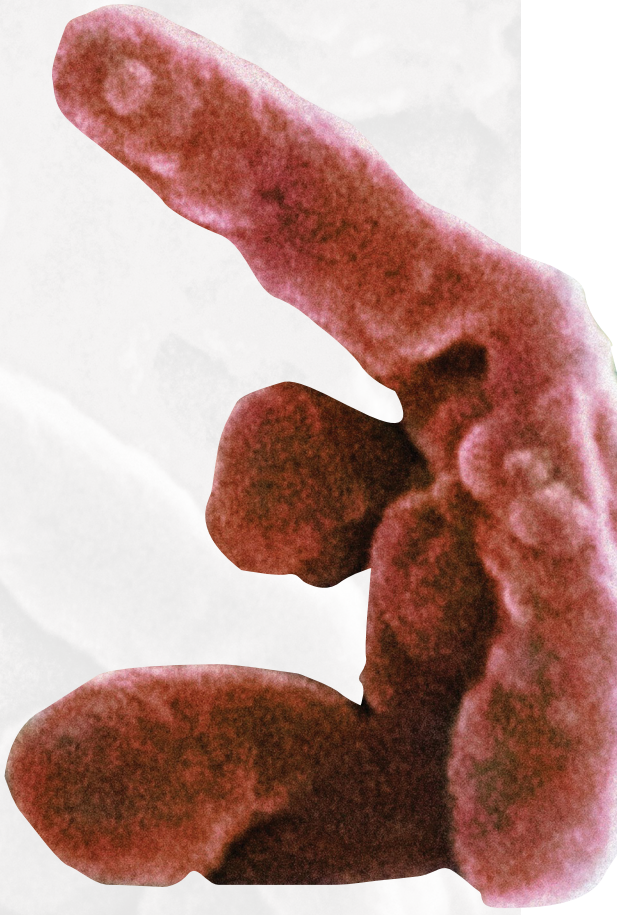
Thermo Scientific™ environmental monitoring solutions:

- Thermo Scientific Triple Wrap Sterile Pack w/VHP Indicator Tryptone Soya Agar w/Lecithin, Polysorbate 80, Sodium Thiosulphate, L-Histidine; 55mm Contact Plate; 100/pack (PO5511D)
- Thermo Scientific Triple Wrap Sterile Pack w/VHP Indicator Tryptone Soya Agar w/Lecithin, Polysorbate 80, Sodium Thiosulphate, L-Histidine; 90mm Monoplate; 100/pack (PO5501B)
- Thermo Scientific™ Remel™ Contact Sterile D/E neutralizing Agar (Irradiated); 10/pack (R111803)
- Thermo Scientific Remel Contact Sterile D/E neutralizing Agar (Irradiated) VHP resistant; 10/pack (R111823)
- Thermo Scientific Remel Settling Plate Sterile R2A; 10/pack (R111970)
- Thermo Scientific Remel Settling Plate Sterile Tryptic Soy Agar (Irradiated); 10/pack (R111870)
- Thermo Scientific Remel Settling Sterile D/E Neutralizing Agar (Irradiated) VHP resistant; 10/pack (R111833)

Quanti-Cult Plus Quality Control Organisms for growth promotion and microbial enumeration testing:

- R4717016 *Staphylococcus aureus* ATCC® 6538™ 100 tests/kit
- R4711221 *Bacillus subtilis* ATCC® 6633™ 100 tests/kit
- R4715210 *Pseudomonas aeruginosa* ATCC® 9027™ 100 tests/kit
- R4711700 *Clostridium sporogenes* ATCC® 19404™ 100 tests/kit
- R4711503 *Candida albicans* ATCC® 10231™ 100 tests/kit
- R4711100 *Aspergillus brasiliensis* ATCC® 16404™ 100 tests/kit





For more information and resource, visit
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