



TECHNICAL FACT SHEET

Environmental monitoring for GMP facilities

Health Inspired, Quality Driven.

Supporting cleanroom readiness and GMP compliance

Pharmaceutical and biologics facilities must tightly control microbial and particulate contamination. Without a robust environmental monitoring program (EMP), there is a risk that contamination will go undetected and product quality, patient safety and supply continuity may be compromised. Facilities may also fall out of compliance with global good manufacturing practice (GMP) requirements.

When is environmental monitoring required?

Environmental monitoring is required throughout the facility life cycle and serves multiple critical functions:

- **Ensures facility readiness**
Supports commissioning, qualification and validation (CQV) of cleanrooms and manufacturing suites, demonstrating that manufacturing environments are fit for GMP manufacturing
- **Maintains regulatory compliance**
Supports alignment with global regulatory expectations, including US Food and Drug Administration (FDA) guidance, EU GMP Annex 1, ISO 14644 and USP <1116>
- **Protects product quality**
Enables early detection of microbial and particulate contamination, reducing the risk of product impact and costly deviations
- **Supports investigations and continuous improvement**
Provides data for environmental trending, root cause investigations and effective corrective and preventive action (CAPA) programs

SGS

Core components

A comprehensive environmental monitoring solution includes:

- **Cleanroom monitoring**
Viable air sampling, non-viable particle counting, surface sampling (e.g. contact plates and swabs) and personnel monitoring to assess environmental control and aseptic operator performance
- **Facility utility monitoring**
Routine microbiological evaluation of environmental utilities – including pharmaceutical water systems, compressed air and process gases – to ensure compliance with established microbial, particulate and chemical specifications

SGS environmental monitoring solutions

We provide environmental monitoring support across the full facility life cycle, including:

- **Facility start-up and qualification support**
For new or modified manufacturing facilities, we support the establishment of EMP during:
 - Commissioning and facility qualification
 - Baseline microbial monitoring
 - Performance qualification (PQ) activities

This structured approach helps demonstrate facility readiness, supports contamination control strategies and ensures preparedness for regulatory inspection and commercial manufacturing.

- **Routine EMPs**
We deliver reliable, ongoing environmental monitoring services to support sustained GMP compliance, including:

Why choose SGS

Environmental monitoring requires more than routine sampling; it demands scientific expertise, dependable data and methods aligned with global GMP expectations.

Our solutions combine microbiology expertise, accredited laboratory capabilities, and flexible service delivery with over 25 laboratories worldwide to help manufacturers establish and maintain effective environmental monitoring strategies across the facility life cycle.

We offer:

- **GMP microbiology expertise** – experienced scientists with a strong understanding of cleanroom monitoring requirements and contamination control strategies

- **Compressed gas testing (ISO 14644)**
Viable and non-viable particulate count testing:
 - Compressed air – ISO 8573, European Pharmacopoeia (EP), United States Pharmacopoeia (USP)
 - Nitrogen, oxygen and carbon dioxide – EP and USP
 - Microbial testing where required by GMP

- Cleanroom monitoring – viable air monitoring, non-viable particle monitoring, surface monitoring and personnel monitoring
- Utility monitoring – total aerobic microbial count (TAMC), total yeast and mold count (TYMC), heterotrophic plate count (HPC), coliform testing, total organic carbon (TOC), conductivity and bacterial endotoxin testing
- Environmental utilities – compressed air monitoring, dew point testing and hydrocarbon monitoring

- **Facility readiness support** – baseline monitoring and qualification support during commissioning, validation and facility start-up
- **Flexible monitoring programs** – sampling plans tailored to facility operations, product risk and regulatory expectations
- **Reliable testing and clear reporting** – accurate laboratory results, consistent turnaround times and actionable reporting to support compliance decisions

Our trusted EMP solutions provide the scientific support and laboratory capability needed to maintain effective contamination control and operate with confidence – from start-up through routine GMP manufacturing.



When you need to be sure