

Testing, qualification and support capabilities at a glance.

503A/503B Compounding · Pharmaceutical · Biotechnology · Medical Device · Health Systems

CONFIDENCE IN EVERY RESULT.

STERILITY TESTING PLATFORMS

Rapid and compendial methods under one roof, matched to each product.

RAPID · SOLID-PHASE CYTOMETRY

ScanRDI®

Laser-scanning detection of viable microorganisms captured on a membrane.

- Results in less than 4 hours
- Non-destructive testing available
- Rapid sterility validation and method suitability

BEST FOR Short-dated CSPs, urgent release, filterable products

RAPID · ATP BIOLUMINESCENCE

Celsis®

Enrichment followed by ATP bioluminescence detection of microbial growth.

- Shortened time to result vs. 14-day compendial incubation
- Accommodates a broad range of matrices
- Method suitability and validation support

BEST FOR Products not suited to membrane-based rapid methods

COMPENDIAL · GROWTH-BASED

USP <71> Traditional

Membrane filtration and direct inoculation with 14-day incubation.

- Referee method recognized by regulators
- AAMI sterility and quarterly audit testing
- B&F (bacteriostasis/fungistasis) testing

BEST FOR Complex matrices, devices and non-filterable products

Multiple products? One partner.

Portfolios rarely fit a single platform. Each product is assigned to the method that suits its matrix, volume and release timeline, so your full line is covered under one program and one point of contact.

STERILITY & MICROBIAL QUALITY

- Microbial enumeration USP <61>
- Objectionable-organism screens and method suitability USP <62> — bile-tolerant Gram-negatives, *E. coli*, *Salmonella* spp., *P. aeruginosa*, *S. aureus*, *Clostridia*, *C. albicans*
- *Burkholderia cepacia* complex testing and method suitability USP <60>
- Bioburden testing
- Antimicrobial effectiveness testing USP <51>
- Growth-promotion testing
- Autotrophic MALDI-TOF rapid identification of bacterial and fungal isolates
- MicroSEQ 16S rDNA sequencing for complex and confirmatory ID

ENDOTOXIN & PRODUCT TESTING

- Bacterial endotoxins USP <85>
- Kinetic chromogenic and cartridge-based testing
- Animal-free reagent options
- Endotoxin challenge / depyrogenation studies
- pH USP <791>

ENVIRONMENTAL MONITORING

- EM performance qualification (EMPQ)
- Routine viable air and surface monitoring
- Total particulate testing
- Personnel and gowning monitoring
- Settle plates and contact plates
- Incubation, enumeration, identification and reporting
- Program design, site selection and risk assessment
- Trending, investigations and resident-flora review
- Growth-promotion and sterility testing of media

ASEPTIC PROCESS SUPPORT

- Aseptic process simulations / media fills
- Pre-validation growth promotion
- 14-day incubation and inspection capacity
- Worst-case intervention and sampling support
- Gowning qualification and personnel monitoring
- Failure investigation and root-cause support
- Steam sterilization BI analysis, population and log reduction

WATER & CLEAN UTILITIES

- Pharmaceutical water-system qualification USP <1231>
- Routine PW and WFI monitoring
- Total organic carbon USP <643>
- Conductivity USP <645>
- pH and nitrate testing for water
- Bacterial endotoxins for water USP <85>
- Water bioburden and microbial identification
- Compressed-gas testing ISO 8573
- Clean-steam quality testing
- Washer qualification and rinse-water testing

CLEANING & DISINFECTION

- Cleaning validation and verification
- Swab and rinse recovery studies
- TOC residue and non-specific method validation
- Disinfectant efficacy studies USP <1072>
- Neutralizer effectiveness and toxicity validation
- Near-expiration / low-concentration robustness
- Clean-hold-time studies

SAMPLING KITS, ONSITE SUPPORT & EQUIPMENT RENTAL

Everything needed to collect, document and return compliant samples.

ONSITE SERVICES

Onsite sampling, scheduled pickup and project-based field support.

WATER & UTILITY KITS

TOC, endotoxin and water-sampling vials for client collection.

EM KITS

Contact plates, settle plates and supporting sampling materials.

SWAB KITS

Purpose-selected swabs for cleaning validation and EM programs.

EQUIPMENT RENTAL

Calibrated air-sampling and particle-testing equipment.

Need a specific method, matrix or turnaround?

Talk with a PlumGXP scientist to confirm platform fit, readiness and project timing.

plumgxp.com/lets-talk