COMPLIANCE SOLUTIONS FOR YOUR 503A PHARMACY

THERE WHEN YOU NEED US
Eagle is a U.S. Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA) registered A2LA ISO 17025 accredited laboratory founded in 2003 that provides analytical chemistry and microbiological testing, consultation services, and other technical services for pharmaceutical manufacturers, pharmacies, medical device companies, and other highly regulated industries, to support their compliance needs.
LET OUR EXPERIENCE WORK FOR YOU

It is our commitment to provide your organization with the tools to operate and maintain compliance in the highly regulated industry. In support of this commitment, Eagle is now home to professionals spanning the science and pharmaceutical industry, including experts in chemistry, microbiology, engineering, CGMP, quality control, and quality assurance.
Our scientific experts excel at helping sterile and non-sterile facilities identify risks, challenges, and opportunities by suggesting and implementing cost-effective, science-based solutions. With Eagle’s guidance, you will feel confident with your compliance.

In addition to laboratory testing, Eagle offers services in consulting, validation, calibration, certification, and environmental monitoring.

*With quick turnaround times, leaders in Rapid ScanRDI® sterility testing, exceptional customer service, and Eagle’s variety of services, we are dedicated to being the one-stop shop for compounding and hospital pharmacies.*
BEYOND USP <71> LIMITATIONS

SCRRANDI® RAPID MICROBIAL METHOD – RESULTS IN 1 TO 2 DAYS

WORLD’S FASTEST STERILITY TEST
Now there is a faster way to comply with USP <797> and ensure your patients are receiving quality compounds. ScanRDI® is a non-growth-based technology sensitive enough to detect a single bacterial, yeast, or mold contaminant in a matter of hours. Even spores, stressed and fastidious organisms are detected in minutes, offering an extraordinarily rapid alternative to the traditional 14-day sterility test.

ACCEPTED ALTERNATIVE
ScanRDI® is an accepted alternative to the official compendial sterility test method if validated to fulfill the requirements outlined in USP <1223> and noninferior to USP <71> testing.

DETECTS VIABLE MICROBIAL CELLS
ScanRDI® rapidly detects viable microbial cells down to one microbial cell without the need for growth or cell multiplication.

FORGOES THE EXTENDED INCUBATION PERIOD
This method forgoes the extended incubation period outlined in USP <71>, so results are ready in as little as 1 business day.¹

¹ Standard processing time is 2 business days. 1 business day turnaround time is available through our RUSH service. Please call Eagle customer care for up-to-date scheduling upon sample submission.
COMMITTED TO QUALITY

SERVICE OFFERINGS

FINISHED DRUG PRODUCT RELEASE TESTING
Potency (API/Preservative)
pH
Appearance (color, clarity)
Sterility (USP <71>, Rapid ScanRDI®, BacT/Alert)
Bacterial Endotoxin Testing
Particulate Matter
Microbial Examination of Nonsterile Products
  USP <60>
  USP <61>
  USP <62>
Bioburden
Uniformity of Dosage Units

RAW MATERIALS AND CONSUMABLES TESTING
USP/NF Monograph Testing
Growth Promotion Testing

1 Method shall be stability-indicating and validated to assign Category 3 CSP BUDs and to extend beyond the limits of USP <795>.
2 Requires method suitability to maintain compliance.
EXCELLENCE THROUGHOUT

SERVICE OFFERINGS

VALIDATION SERVICES
Antimicrobial Effectiveness Testing¹
Stability Indicating Method Development and Validation
Stability Studies²
Method Suitability
Container-Closure Integrity Testing³
Sterilization and Depyrogenation Cycle Validation
Equipment Qualification
Temperature Mapping
Disinfectant Efficacy Testing
Cleaning Validation
Water Activity⁴

¹ Requires method suitability to maintain compliance
² Must meet all release testing specifications at its intended expiration date.
³ Required for each formulation in its specific container-closure system.
⁴ Required for non-sterile liquid and semi-solid drug products.
Eagle’s consulting services specialize in providing compliance and safety solutions to help facilities minimize risks. These solutions are based on scientific research, pharmacy requirements, and industry best practices. With USP’s renewed focus on environmental monitoring frequencies, facility requirements, personnel competencies, garbing requirements, and more, it is essential for your facility to comply with local and federal regulations. Our expert guidance can help ensure your facility meets regulatory standards.

Our consultants have held positions at the Food and Drug Administration, pharmaceutical drug manufacturers including contract manufacturing organizations, 503A compounding pharmacies, and 503B outsourcing facilities.

**LET OUR EXPERIENCE WORK FOR YOU:**

- Quality Systems Development
- Cleaning Validation
- Disinfectant Efficacy Testing (DET)
- Due Diligence Analysis
- Environmental Monitoring Program Development
- Equipment Qualification
- Facility Design Review
- Gap Analysis Audit/Third-Party Audit
- Mitigation, Remediation, and Regulatory Response Services
- Process Validation
- SOP Development and Implementation
- Training
- **USP <800> Compliance**
DEDICATION TO PRECISION

CERTIFICATION, CALIBRATION AND QUALIFICATION SERVICES

CERTIFICATION
Laminar Airflow Workspaces (LAFW)
Biological Safety Cabinets (BSC)
Powder Containment Hoods (CVE)
Fume Hoods (coming soon)
Full Cleanroom Certification to <797> & CETA Standards includes:
  HEPA Filter Integrity Testing (Leak Test)
  Differential Pressure Measurement
  Air Change Per Hour Measurement and Calculation
  Non-Viable Air Sampling (Particle Counts)
  Viable Air and Surface Sampling (Environmental Monitoring)
  Static Air Visualization (Smoke) Study
  Dynamic Air Visualization (Smoke) Study with Video and Report

CALIBRATION
Balances
Temperature Sensors and Thermometers
Relative Humidity Sensors
Differential Pressure Sensors (digital and magnehelic)
Controlled Temperature Units
Pipettes (coming soon)

QUALIFICATION ¹
Installation/Operational Qualification and Performance Qualification
  Autoclave – Sterilization Cycle Validation
  Dry-Heat Oven – Depyrogenation Cycle Validation
  Incubators
  Refrigerators
  Freezers
  Stability Chambers

¹ Other equipment available upon request.
MITIGATE RISK FOR A SAFER ENVIRONMENT

ENVIRONMENTAL MONITORING SOLUTIONS

Environmental monitoring (EM) is a key element in ensuring that aseptic processing areas are maintained in an adequate state of control.

With recent USP published revisions and the current environment where potential contamination is the primary concern, it is important to meticulously test your compounding environment and to have proper procedures in place to ensure there are no unknown contaminants, which can affect the safety of your patients and ultimately the integrity of your business.

Eagle provides products and services that holistically help hospitals and pharmacies ascertain the presence or absence of viable microorganisms and chemical residue. We help facilities mitigate risk by providing compliance and safety solutions backed by science.
Eagle offers TSA plates that are ideal for the recovery of a wide range of microorganisms, including bacteria, yeast, and fungi.

Our 90 mm settle plates are suitable for active and passive air as well as gloved-fingertip sampling while our 65 mm contact plates can be utilized for active air, surface, and personnel monitoring.

Features and benefits of our TSA plates include the following:

- Supplemented with neutralizers. Lecithin and Tween 80, to inactivate disinfectants present in the environment.
- Convenient room temperature storage to eliminate the need for refrigerated storage conditions.
- Gamma-irradiation to ensure a high level of sterility and minimize the risk of false positive results.
- Self-locking mechanism to ensure the integrity of the sample during handling and transportation.
- Triple-wrapped for quicker movement through ISO-classified areas.
- Include a certificate of growth promotion from the manufacturer and a verification of growth promotion testing performed by Eagle.

Eagle also offers incubation, enumeration, and microbial identification services, complemented by on-site training from our skilled microbiologists. This equips your staff with the necessary expertise to proficiently perform enumeration of media plates, should your facility opt to incubate plates in-house.

For additional information, visit eagleanalytical.com/em.
ENVIRONMENTAL MONITORING SOLUTIONS

SURFACESHIELD WIPE SAMPLING AND CLEANING VERIFICATION KIT

The SurfaceShield Wipe Sampling and Cleaning Verification Kit is a fast, easy, and convenient method for verifying the efficacy of your cleaning program, including deactivation and decontamination. This multipurpose and affordable kit can be utilized to achieve and maintain USP <800> compliance and meet Title 21 Part 211 CFR requirements.

BASE KIT INCLUDES*

- 2 - Sample Sets (tube, Texwipe® swab, single-use vial of sterile water, pair of gloves in reclosable plastic bag, 10 x 10 cm (100 cm²) template)
- 3 oz single-use cold pack
- Sampling Instructions insert
- Blank labels
- Insulated mailer

*The base kit can be customized according to the number of sample sets required.

For pricing visit eagleanalytical.com/product/surfaceshield-wipe-sampling-cleaning-verification-kit.
Through the experience and scientific mastery of our team, we serve CGMP outsourcing facilities by testing routine samples, helping fine-tune formulations, providing feedback on techniques, and more while offering compliance solutions to meet your operational and regulatory requirements.

Visit our website or scan the QR code to learn more about our team, laboratory capabilities, or to receive an initial consultation to discuss your operation’s specific needs. We look forward to assisting you.

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