



# 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.

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# ABOUT EAGLE



## 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.





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# OUR SERVICE AND PRODUCT OFFERINGS

EAGLE HAS EXTENSIVE EXPERIENCE IN COMPLIANCE SOLUTIONS, TESTING, CONSULTING SERVICES, AND MORE

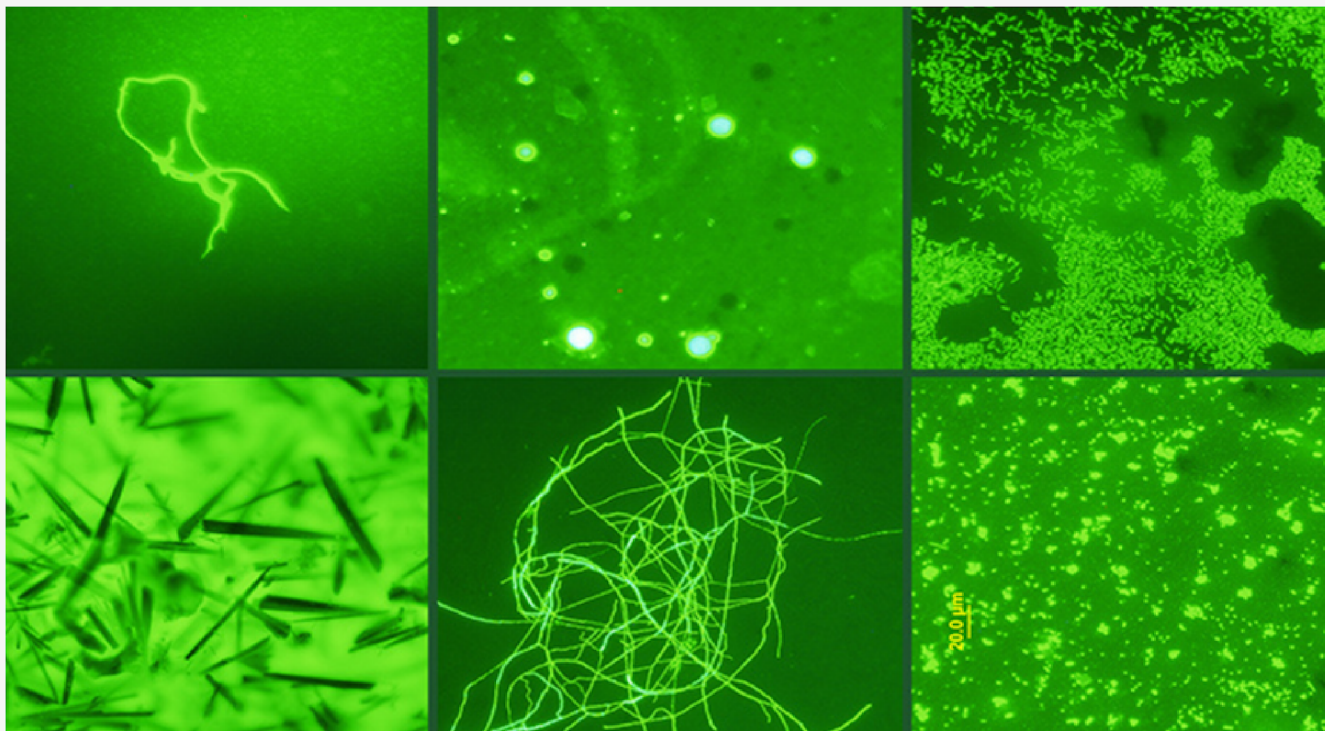


Our scientific experts excel at helping sterile and non-sterile facilities identify risks, challenges, and opportunities by suggesting and implementing cost-effective, science-based solutions. With Eagle's guidance, you will feel confident with your compliance.

**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.**

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





## BEYOND USP <71> LIMITATIONS

### SCANRDI® RAPID MICROBIAL METHOD – RESULTS IN 1 TO 2 DAYS<sup>1</sup>

#### 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

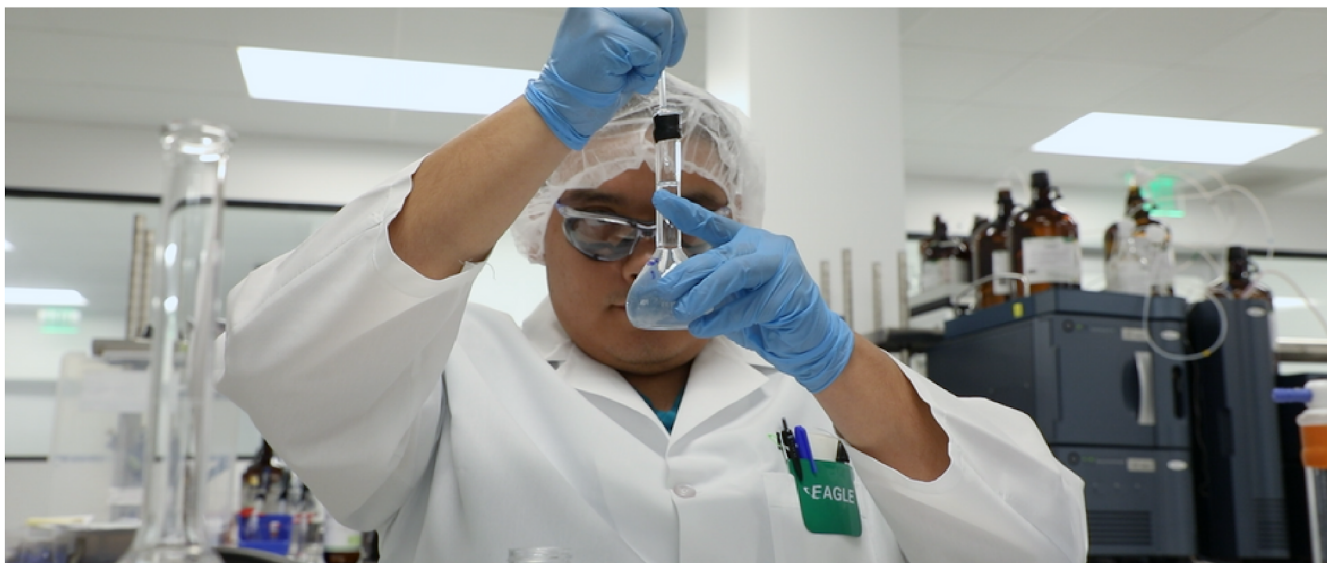
ScanRDI® rapidly detects viable microbial cells down to one microbial cell without the need for growth or cell multiplication.

#### 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.<sup>1</sup>

<sup>1</sup> 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)<sup>1</sup>

pH

Appearance (color, clarity)

Sterility (USP <71>, Rapid ScanRDI®, BacT/Alert)<sup>2</sup>

Bacterial Endotoxin Testing<sup>2</sup>

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

<sup>1</sup> Method shall be stability-indicating and validated to assign Category 3 CSP BUDs and to extend beyond the limits of USP <795>.

<sup>2</sup> Requires method suitability to maintain compliance.



# EXCELLENCE THROUGHOUT

## SERVICE OFFERINGS

### VALIDATION SERVICES

Antimicrobial Effectiveness Testing<sup>1</sup>  
Stability Indicating Method Development and Validation  
Stability Studies<sup>2</sup>  
Method Suitability  
Container-Closure Integrity Testing<sup>3</sup>  
Sterilization and Depyrogenation Cycle Validation  
Equipment Qualification  
Temperature Mapping  
Disinfectant Efficacy Testing  
Cleaning Validation  
Water Activity<sup>4</sup>

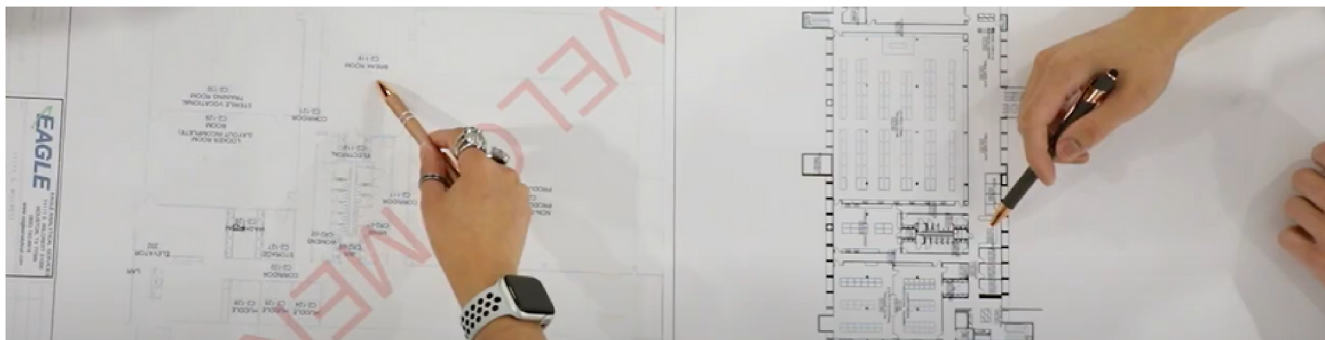
<sup>1</sup> Requires method suitability to maintain compliance.

<sup>2</sup> Must meet all release testing specifications at its intended expiration date.

<sup>3</sup> Required for each formulation in its specific container-closure system.

<sup>4</sup> Required for non-sterile liquid and semi-solid drug products.





# ATTENTION TO DETAIL

## CONSULTING SERVICES, FACILITY DESIGN REVIEW AND MORE

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 <sup>1</sup>

Installation/Operational Qualification and Performance Qualification

- Autoclave – Sterilization Cycle Validation

- Dry-Heat Oven – Depyrogenation Cycle Validation

- Incubators

- Refrigerators

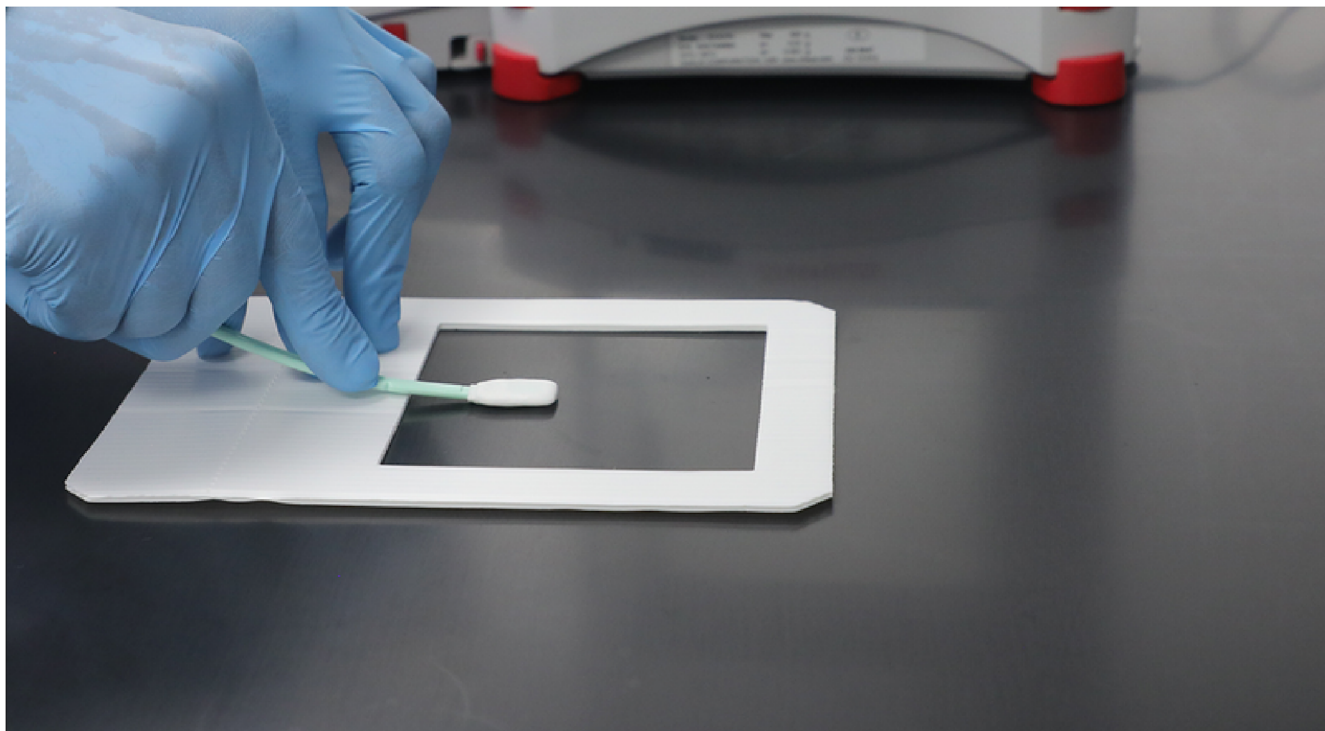
- Freezers

- Stability Chambers

<sup>1</sup> Other equipment available upon request.







*Image features a Texwipe® swab. Texwipe® is a registered trademark of the Texwipe Company, LLC [Illinois Toll Works, Inc. (ITW)].*

# MITIGATE RISK FOR A SAFER ENVIRONMENT

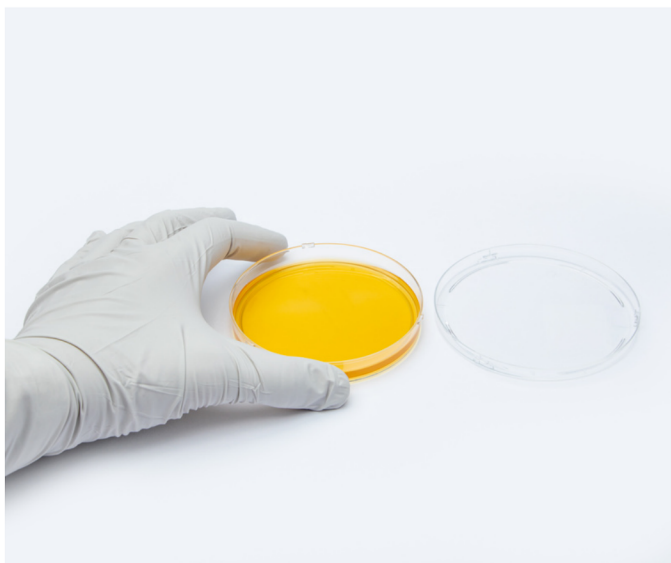
## ENVIRONMENTAL MONITORING SOLUTIONS

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.





# ENVIRONMENTAL MONITORING SOLUTIONS

**TRYPTIC SOY AGAR PLATES - 10 PLATES PER PACK, MINIMUM ORDER - 5 PACKS**

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](http://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 cm<sup>2</sup>) 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](https://eagleanalytical.com/product/surfaceshield-wipe-sampling-cleaning-verification-kit).



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# CONTACT US

OUR EXPERTS ARE HERE TO HELP



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SR. BUSINESS DEVELOPMENT SPECIALIST



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PRINCIPAL ENGINEER

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](https://www.eagleanalytical.com) 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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