CGMP COMPLIANCE SOLUTIONS FOR YOUR 503B OUTSOURCING FACILITY

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.

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 CGMP 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 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 CGMP 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 Scan RDI® sterility testing, exceptional customer service, and Eagle's variety of services, we are dedicated to being the one-stop shop for the CGMP industry.

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

COMMITTED TO QUALITY

SERVICE OFFERINGS

FINISHED DRUG PRODUCT RELEASE TESTING

Potency (API/Preservative)[1]
pH
Appearance (color, clarity)
Sterility (USP <71>, Rapid ScanRDI®, BacT/Alert)[2]
Bacterial Endotoxin Testing[2]
Particulate Matter
Microbial Examination of Nonsterile Products
Bioburden
Uniformity of Dosage Units

RAW MATERIALS AND CONSUMABLES TESTING

USP/NF Monograph Testing
Growth Promotion Testing

[1] Method shall be stability-indicating to maintain CGMP compliance.
[2] Requires method suitability to maintain CGMP compliance.

EXCELLENCE THROUGHOUT

SERVICE OFFERINGS

VALIDATION SERVICES

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

[1] Requires method suitability to maintain CGMP 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.

ATTENTION TO DETAIL

CONSULTING SERVICES, FACILITY DESIGN REVIEW AND MORE

Eagle's EagleShield consulting specializes in providing compliance and safety solutions to help facilities minimize risks. These solutions are based on scientific research, CGMP requirements, and pharmacy requirements including the most recent USP <795> and <797>) revisions. With USP's renewed focus on environmental monitoring frequencies, facility requirements, and updated information on the use of alternative technologies, personnel qualifications, garbing requirements, personnel training, 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.

Prior to starting with Eagle, our consultants have held positions at the Food and Drug Administration, pharmaceutical drug manufacturers including contract manufacturing organizations, 503B outsourcing facilities, and traditional compounding pharmacies (503A).

LET OUR EXPERIENCE WORK FOR YOU:

- CGMP 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
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

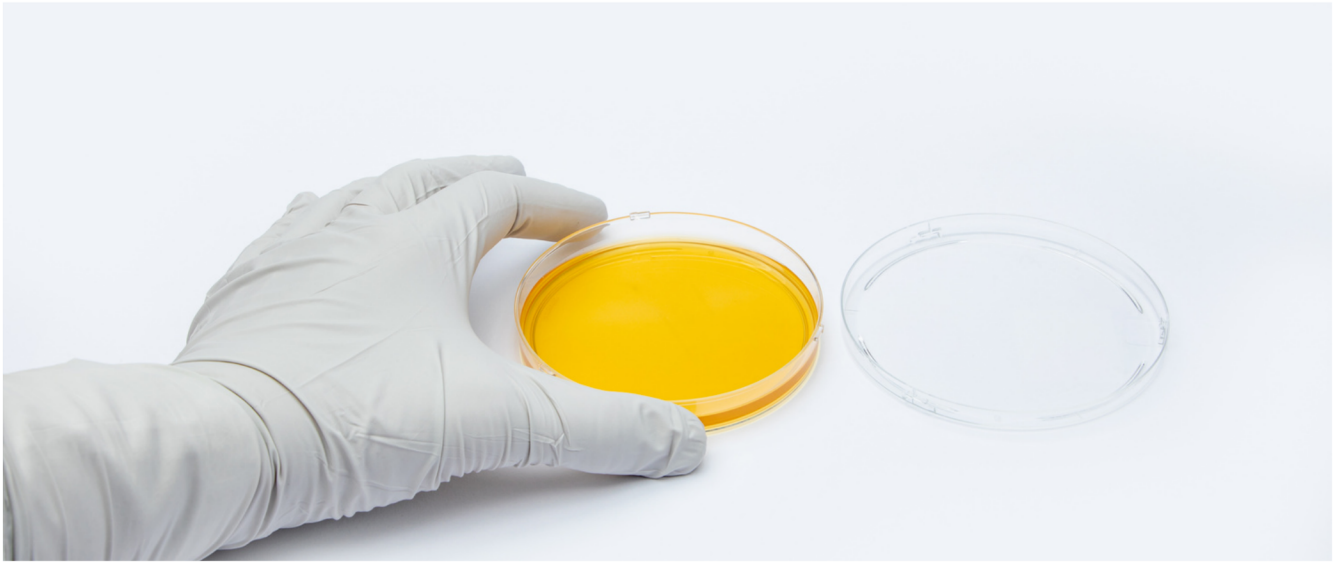
CALIBRATION

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.



ENVIRONMENTAL MONITORING SOLUTIONS

TRYPTIC SOY AGAR PLATES

Our tryptic soy agar (TSA) media plates are supplemented with neutralizers to minimize the effect of antimicrobial agents, recovering a wide array of microorganisms.

- Room Temperature Storage
- Self-Locking
- Triple Wrapped (for quicker movement through sterile ISO areas)
- Gamma Irradiated
- Growth Promotion Testing Included
- Quick and Convenient Ordering Process
- Standing Orders for Regular Shipment

65 MM TSA CONTACT PLATES

Suitable for active air, surface, and personnel monitoring.

90 MM TSA MEDIA PLATES

Suitable for air and personnel monitoring.

RELATED SEVICES

Incubation and Enumeration of Media
Microbial Identification

10 plates per pack, Minimum Order – 5 Packs.

WWW.EAGLEANALYTICAL.COM
1.800.745.8916 | INFO@EAGLEANALYTICAL.COM | 11111 S. WILCREST DR. S1000 HOUSTON, TEXAS 77099

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.

BASE KIT INCLUDES

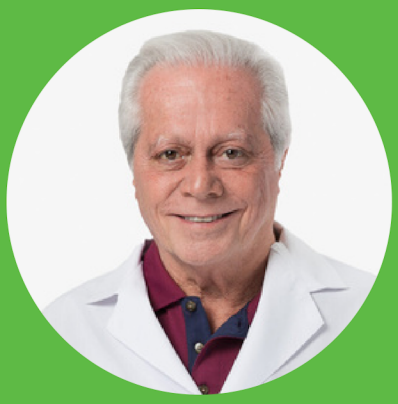
- 2 – Sample Sets (tube, swab, single-use vial of sterile water, pair of gloves in reclosable plastic bag, 10 x 10 cm (100 cm^2) template)
- 3 oz single-use cold pack
- Sampling Instructions insert
- Blank labels
- Insulated mailer

For pricing visit eagleanalytical.com/testing-services-pricing.

CONTACT US

OUR EXPERTS ARE HERE TO HELP

ROBERT BYRNE, PHD
VICE PRESIDENT OF
SCIENTIFIC AFFAIRS



ROSS CAPUTO, PHD
PRESIDENT AND
CHIEF EXECUTIVE OFFICER

DAVID HUSSONG, PHD
CHIEF TECHNICAL OFFICER

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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