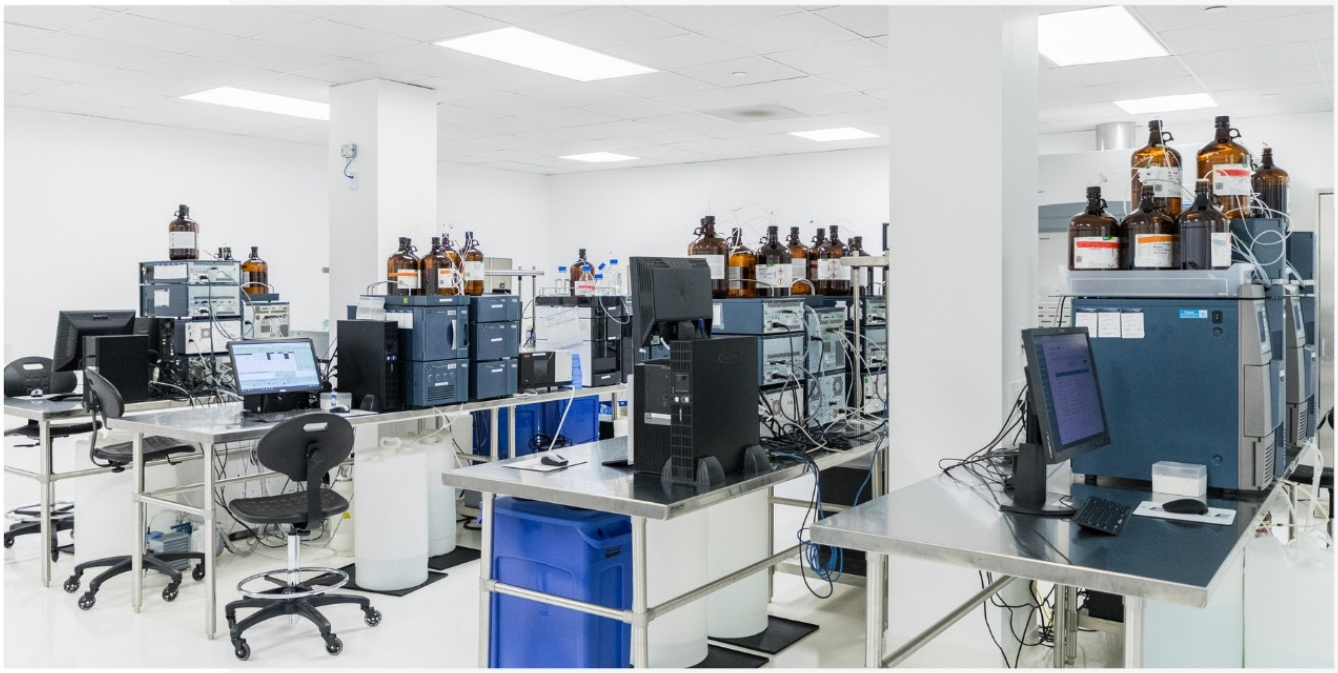
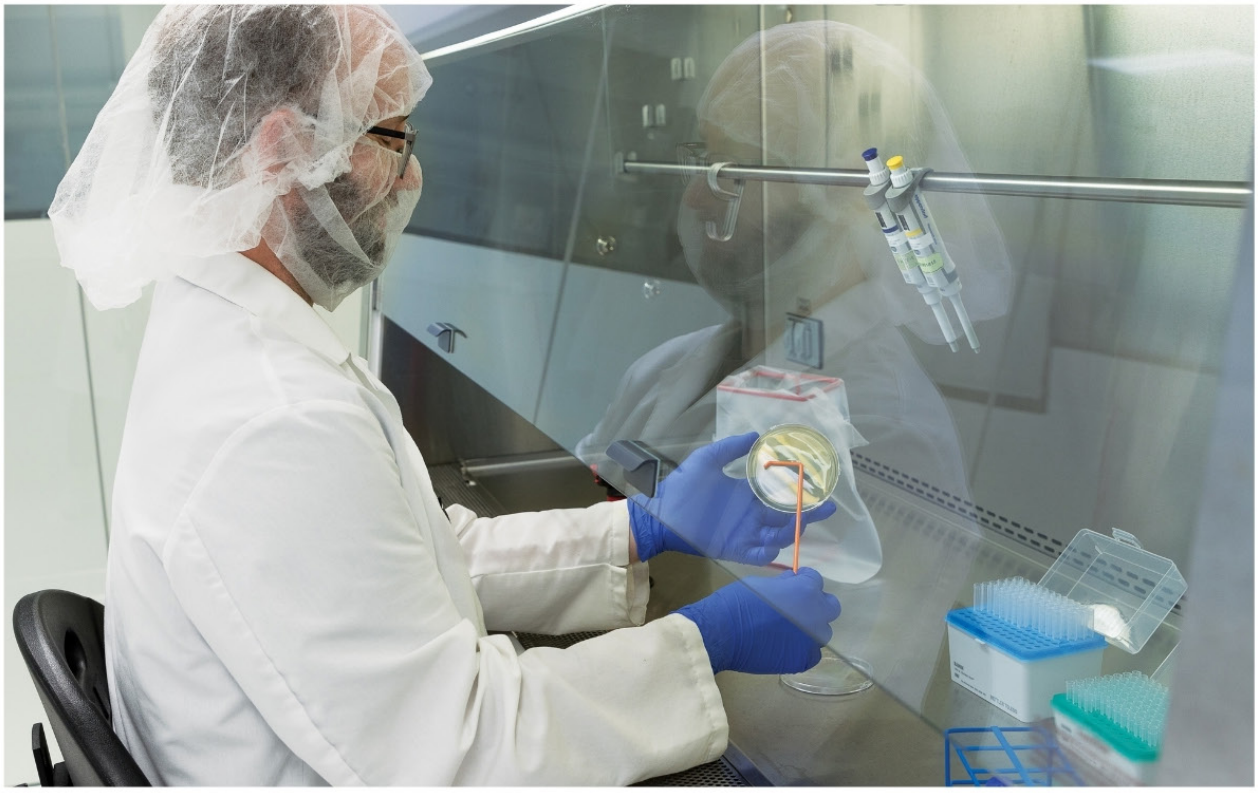
EAGLE

TAILORED SOLUTIONS THAT SUIT YOUR NEEDS



THERE WHEN YOU NEED US

ESTABLISHED IN 2003, EAGLE IS A DEDICATED PARTNER ADDRESSING REGULATORY NEEDS IN THE PHARMACEUTICAL INDUSTRY. OVER THE YEARS, IT HAS EVOLVED INTO A PREMIER SCIENTIFIC SOLUTIONS PROVIDER, WITH A DISTINGUISHED FDA-REGISTERED CGMP TESTING/CALIBRATION LABORATORY SPANNING OVER 80,000 SQUARE FEET.



SERVICES WE OFFER

Equipped with state-of-the-art facility, cutting-edge technologies, and advanced instrumentation, Eagle delivers innovative, science-based solutions tailored to meet the unique regulatory and operational needs of our clients.

LABORATORY TESTING

CERTIFICATION
CALIBRATION
QUALIFICATION

VALIDATION SERVICES

PRODUCTS & SUPPLIES

LABORATORY SERVICES

MICROBIOLOGY TESTING

Sterility testing:

- ScanRDI® Sterility Test
- USP <73> Sterility Test using Celsis® system
- USP <72> Sterility Test using BacT/Alert® system
- Compendial USP<71> Test:
  - Membrane Filtration
  - Direct Immersion
  - Fluid path

USP <85> Bacterial Endotoxin Test (turbidimetric/ chromogenic methods)
USP <86> Bacterial Endotoxin Test
USP <51> Antimicrobial Effectiveness
USP <60> Burkholderia Cepacia Complex
USP <61> Microbial Enumeration Tests
USP <62> Tests for Specified Microorganisms
USP <788>/<789> Particulate Matter
USP <790> Visible Particulates
USP <1207> Package Integrity (CCIT)
Bioburden testing
Minimum inhibitory concentration (MIC)
Microbial identification (whole genome sequencing)

CHEMISTRY TESTING

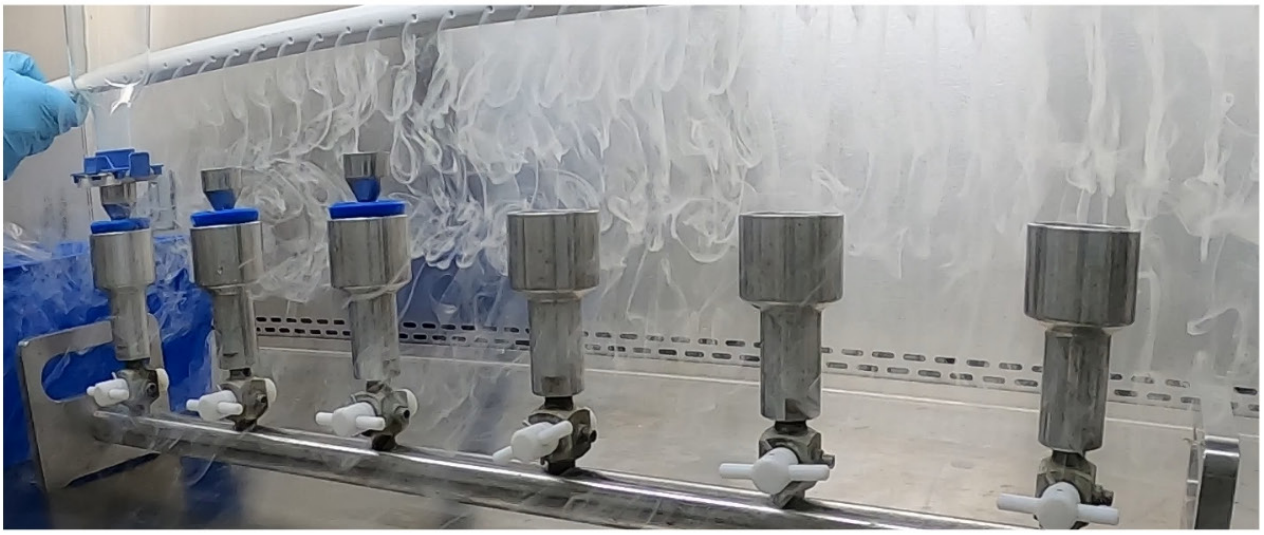
Assay and impurities testing:

- Raw materials
- Finished products testing
- Nitrosamine Impurities
- Stability studies
- Supporting IND/NDA/ANDA Products

Dissolution Testing
Peptide mapping
USP <233> Elemental Impurities
USP <467> Residual Solvents
USP <1730> Plasma Spectrochemistry
Wet chemistry testing

All testing results accessible in real time through user-friendly client portal and sample management system - EagleTrax

CALIBRATION/CERTIFICATION SERVICES



CLEANROOM

DESIGN
- CAD LAYOUT TO MEET REGULATORY REQUIREMENTS

COMMISSIONING
- COMMISSIONING SUPPORT: ENSURING CLEANROOM IS BUILT AND CERTIFIED TO SPECIFICATION

BIANNUAL CERTIFICATION
- ONGOING MONITORING AND TROUBLESHOOTING

EQUIPMENT

QUALIFICATION (IQ/OQ/PQ) – TEMPERATURE MAPPING
- REFRIGERATOR
- FREEZERS
- AUTOCLAVES
- DEPYROGENATION OVENS
- STABILITY CHAMBERS
- INCUBATORS

CALIBRATION
- BALANCES
- TEMPERATURE AND RELATIVE HUMIDITY SENSORS
- DIFFERENTIAL PRESSURE SENSORS

***Other equipment available upon request.**

CLEANROOM FACILITY

PRIMARY ENGINEERING CONTROLS (BSC, LAFW, HOTCELL)
- AIRFLOW VISUALIZATION STUDY (SMOKE STUDY)
- HEPA FILTER INTEGRITY TEST
- DOWNFLOW VELOCITY
- INFLOW VELOCITY
- VIABLE AIR AND SURFACE SAMPLING
- NONVIABLE AIR SAMPLING (PARTICULATE COUNTS)

SECONDARY ENGINEERING CONTROLS
- HEPA INTEGRITY TESTING
- VIABLE AND NON-VIABLE PARTICLE TESTING
- AIR CHANGES PER HOUR (ACPH)
- DIFFERENTIAL PRESSURE TEST
- AIRFLOW PATTERN TESTING

CVE (CONTAINMENT VENTILATED ENCLOSURES)

***Cleanrooms are certified per ISO 14644 and CETA.**

COMPLIANCE THROUGH SCIENCE

EAGLE CONSULTING SERVICES

Regulatory requirements from State Boards of Pharmacy, the FDA and the DEA can be confusing and difficult to understand. That's why, in addition to science-based testing and data interpretation solutions, Eagle offers consulting services to meet your operational and regulatory needs. Our scientific experts excel at helping you define your pharmacy's challenges, risks, and opportunities, then discover and implement cost-effective, science-based solutions. With their guidance, you'll feel confident with your compliance.

The services we offer include:

- Facility Design Review — CGMP, USP <795>, USP <797>, and USP <800>
- Operational Flow Analysis and Procedural Review
- Quality Systems Development
- Gap Analysis Audit — USP or 21 CFR
- Standard Operating Procedures Development and Implementation
- Mitigation, Remediation and Regulatory Response Services

We are committed to providing you with:

- Cost-effective regulatory solutions
- Support to pharmacies and CGMP operations
- Solutions that are science-based to meet your specific needs

Our consulting team consists of industry experts dedicated to providing science-based compliance solutions.

- Pharmaceutical manufacturers, pharmacies, medical device companies, and other highly regulated industries
- Global regulatory requirements
- Inspections, remediation, and responses
- Quality systems
- Meeting with state and federal regulators

Ready to get started? Fill out the form to help us better understand your needs and initiate the process.

Consulting Services

- CGMP Quality Systems Development
- Cleaning Validation
- Disinfectant Efficacy Testing (DET) Due Diligence Analysis
- Environmental Monitoring Program Development
- Equipment Qualification
- Facility Design Review
- GAP Analysis/Third-Party Audit
- Mitigation, Remediation and Regulatory Response Services
- Process Validation
- SOP Development and Implementation Training

11111 S. Wilcrest Dr. #S1000 Houston, TX 77099 | 800.745.8916 | eagleanalytical.com/consulting-services

All pricing in U.S. Dollars and subject to change at any time.

REV-23.10.16

CLEANING VALIDATION SERVICES

ELIMINATE THE RISK OF CHEMICAL CROSS-CONTAMINATION AND ENSURE PRODUCT, PERSONNEL AND ENVIRONMENTAL SAFETY, THROUGH ADEQUATE CLEANING PROCESSES.

WHAT IS CLEANING VALIDATION?

DEMONSTRATES YOUR CLEANING PROCEDURE IS EFFICACIOUS IN CLEANING SURFACE AREAS. IT SERVES AS DOCUMENTED EVIDENCE THAT THE CLEANING PROCESSCAN BE PERFORMED RELIABLY AND REPEATEDLY TO REMOVE RESIDUES OF API, EXCIPIENTS, DEGRADATION PRODUCTS, CLEANING AGENTS AND MICROBIAL CONTAMINATION; OR DECREASE THEM TO ACCEPTABLE LEVELS.

ANALYTE-SPECIFIC METHOD DEVELOPMENT AND VALIDATION

AN ANALYTICAL METHOD WILL BE DEVELOPED AND VALIDATED FOR THE SPECIFIED ANALYTE, TYPICALLY THE ACTIVE PHARMACEUTICAL INGREDIENT (API). VALIDATION OF THE METHOD WILL INCLUDE SPECIFICITY, LINEARITY, LIMIT OF DETECTION (LOD), LIMIT OF QUANTITATION (LOQ) DETERMINATION AND ACCURACY/RECOVERY STUDIES.

USP <643> TOTAL ORGANIC CARBON (TOC) MEASUREMENT

TOC MEASUREMENT IS A NONSPECIFIC TECHNIQUE THAT EVALUATES THE OVERALL EFFECTIVENESS OF THE CLEANING PROCESS. IT IS IDEAL FOR DETECTINGALL CARBON-CONTAINING COMPOUNDS INCLUDING THE APIS, EXCIPIENTS AND CLEAN- ING AGENTS.

USP <61> MICROBIAL ENUMERATION TESTS

MICROBIAL ENUMERATION TESTING (BIOBURDEN TESTING) PROVIDES A QUANTITATIVE MEASUREMENT OF THE MICROBIAL SURFACE TO EVALUATE THE EFFECTIVENESS OF THE CLEANING PROCESS IN REDUCING MICROBIAL CONTAMINATION.

CHOOSE EAGLE!

WE ARE A LABORATORY THAT OFFERS CUSTOMIZED SOLUTIONS, PRIORITIZING EXCELLENTCLIENT CARE AND QUICK TURNAROUND TIMES. WE WORK WITH MOST DISINFECTANTS, SURFACES AND MICROORGANISMS; ALSO, OUR TESTING METHODS FOLLOW REGULATORY REQUIREMENTS.

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DISINFECTANT EFFICACY STUDIES SERVICE

TO ENSURE COMPLIANCE WITH CGMP (CURRENT GOOD MANUFACTURING PRACTICES), EU GMP ANNEX 1 AND USP <1072> DISINFECTANTS AND ANTISEPTICS.

HOW DOES IT WORK?

DISINFECTANT EFFICACY TESTING IS EXECUTED USING A SUR- FACE CHALLENGE METHOD THAT BEST MIMICS NORMAL DAILY CONDITIONS FOLLOWING THE FACILITY'S CLEANING SOP (CON- TACT TIME, SURFACE TYPE, DILUTION, AND METHOD OF APPLICATION). SELECTED MICROORGANISMS ARE APPLIED ONTO A 2X2 COUPON OF A SELECTEDSURFACE TYPE AND SUBJECTED TO ASELECTED DISINFECTANT FOR A SELECTEDDWELL PERIOD. THE COUPON WILL THEN BE ENUMERATED AND CHECKED FOR A PROPER LOG REDUCTION.

SUBMISSION REQUIREMENTS

1. SELECT YOUR CHEMICAL AGENT
2. SPECIFY ASSOCIATED CONTACT TIME
3. SELECT YOUR TEST MICROORGANISMS (PER USP <1072>, ENVIRONMENTAL ISOLATES OR BOTH)
4. SPECIFY YOUR FACILITY SURFACES AND PROVIDE 2X2 COUPONS

CUSTOMIZABILITY

TAILOR YOUR DISINFECTANTS BASED ON YOUR SPECIFIC ENVIRONMENTAL MONITORING DATA AND QUALIFY YOUR CUSTOMIZED CLEANING PROGRAM.

TURNAROUND TIME

AS FAST AS 1 MONTH.

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START YOUR JOURNEY WITH US,

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PRODUCTS

ENVIRONMENTAL MONITORING 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 - for active air, surface, and personnel monitoring
90 mm TSA Media Plates - for air and personnel monitoring

RELATED SERVICES

- Incubation and Enumeration of Media
- Microbial Identification
- Temperature Mapping
- Recovery Studies
- Qualification of the Incubation
- Process Control Charts

ORDER YOUR PLATES NOW!

CONTACT US

OUR EXPERTS ARE HERE TO HELP

Our consulting experts at Eagle bring experience from various areas in the pharmaceutical industry, including drug manufacturers, contract manufacturing organizations (CMO/CDMO), 503B outsourcing facilities, traditional compounding pharmacies (503A) and various state and federal regulatory agencies.

EAGLE

SCIENCE-BASED SOLUTIONS

Through the experience and scientific mastery of our team, we provide science-based solutions helping customers to operate efficiently and stay compliant with regulatory requirements and standards.

Visit our website 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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