



ANALYTICAL

The only cGMP, FDA-regulated laboratory exclusively designed and built to serve the container and package testing needs of the pharmaceutical, biotechnology, and medical device industries

A Comprehensive Approach to Container and Package System Qualification

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WHO WE ARE

CS Analytical is the only cGMP, FDA-regulated laboratory exclusively designed and built to serve the container and package testing needs of the pharmaceutical, biotechnology, and medical device industries. The CS Analytical Team is comprised of the world's leading experts when it comes to regulated container qualification testing. The mission of the CS Analytical team is simple: share their experience, knowledge, and commitment to regulatory compliance with each client and bring "exceeds expectations" service back to the contract lab market, which has seen a decline in consultative competency and customer satisfaction over recent years. Test services offered will cover complete USP <1207> CCI method development, validation, and analysis, as well as USP/EP/JP physical performance tests and physicochemical tests for all common or unique primary packaging components and systems.

EXPERIENCED LEADERSHIP TEAM



Brian Mulhall

25+ Years of laboratory experience and designer of first cGMP CCI Laboratory in the world that set the foundation for current USP <1207> requirements.



Brandon Zurawlow

Chief Scientific Officer with more than a decade of experience in all aspects of container qualification and USP <1207> CCI testing.



Sandra Cincotta

Director of Quality with 20+ years of contract laboratory quality system development and management. Extensive experience with container and CCI testing. 40+ FDA inspection days with no observations.

Different & Better

- **NO RUSH FEES**
- **NO QUALITY REVIEW FEES**
- **NO OOS INVESTIGATION FEES**
- **NO RAW DATA REPORTING FEE**



QUALITY EXCELLENCE

The services provided by CS Analytical are built on a foundation that adheres to a strict Current Good Manufacturing Practice (cGMP) quality system that is regulated by the FDA (Food and Drug Administration). These guidelines and regulations set minimum requirements for the methods, facilities, and controls used in manufacturing, processing, testing, and packing of a drug product and the container and packaging component used to store and deliver them.

The CS Analytical quality system is completely electronic and adheres to all 21 CFR Part 11 directives. The custom designed and built, multi-faceted system includes an Electronic Quality Management System (EQMS), an Electronic Laboratory Notebook (ELN) that enables secure digital data retention, and a Client Relationship Management (CRM) system all layered into and controlled by a Laboratory Information Management System (LIMS) that provides secure integrated connections for all workflows. This fully validated, secured, and continually backed-up system improves data integrity, limits opportunities for human error, and provides an audit trail of all functions and tasks performed with a digital date and time stamp.

cGMP Certification Statement

CS Analytical is an FDA registered analytical testing laboratory; FEI # 3017927136. Work performed for submission to the FDA is done in compliance with cGMP guidelines (21 CFR Parts 210 & 211) as applicable to a contract analytical testing laboratory.

GOOD MANUFACTURING PRACTICES

CA Analytical has implemented current Good Manufacturing Practices (cGMPs) as stated in the code of Federal Regulations. These regulations apply to the facility or controls to be used for the “Manufacture, Processing, Packing or Holding of Drugs;” Although our facility does not perform these functions and are therefore not subject to these practices, we do operate within the following sections of the regulations: 21 CFR Subpart 11; 21 CFR Subpart 210; 21 CFR Subpart 211; 21 CFR Subpart 58; 21 CFR Subpart 820.

DEBARMENT CERTIFICATION

CS Analytical has not been debarred by the FDA nor is currently involved in any debarment proceeding with the FDA. Determined by a signed and dated certification statement, no person employed by the laboratory has currently or in the past five years been convicted of any crime described in Sections 306 (a) or (b) of the Generic Drug Enforcement Act of 1992. It is written per our internal quality system that CS Analytical has not, and will not, use the services of any person debarred under Section 306 of the Generic Drug Enforcement Act of 1992.

Experts in USP <1207> Container Closure Integrity Testing

Understanding the complex inter-workings of requirements, product-package limitations, CCI test options, and broader control and risk mitigation strategies requires an experienced team. CS Analytical consists of founding members of the world's first cGMP, FDA-registered contract CCI laboratory housing all deterministic technologies as listed in USP <1207>. The resulting laboratory set standards and best practices for industry still used today, many of which are directly incorporated into USP <1207>. CS Analytical is the most trusted source for designing and implementing a comprehensive container closure integrity strategy to industry best practices that reduce organizational risk and exceed regulatory expectations.

Offering a Complete Suite of CCI Services to Include:

Method Development • Method Validation • Method Transfer

Low Temperature Studies • Capping Optimization



**HIGH VOLTAGE
LEAK PROTECTION**

HELIUM LEAK DETECTION



**LASER BASED
HEADSPACE ANALYSIS**

VACUUM DECAY



RESIDUAL SEAL FORCE

Functional Performance Testing

Functional and physical performance testing refers to the ability of the package or component to demonstrate suitability for an intended function, such as to protect from light or moisture or create an adequate seal. The ability of the component or system to adequately perform the intended function can be impacted by physical and chemical characteristics such as material composition, fit and finish, hardness, and other properties.

COMMON FUNCTIONAL AND PHYSICAL PERFORMANCE TESTS



**USP <671>
PERMEATION TESTING**



**USP <671> / USP <660>
LIGHT TRANSMISSION**



**USP <670> DESICCANT
ADSORPTION CAPACITY**



**USP <382>
ELASTOMER FUNCTIONALITY**

With a state-of-the-art laboratory operating within a cGMP, fully electronic, Part-11 compliant quality and data management system, the team at CS Analytical is able to fulfill test requests for package components and systems to meet regulatory requirements.

Physicochemical Testing

Physicochemical tests evaluate the materials of the container component or system to ensure purity and the absence of harmful contaminants or residuals from the manufacturing process.

Common Routine Physicochemical Tests Include

- USP <661.1> Plastic Materials • USP <661.2> Plastic Containers
- USP <660> Glass • USP <381> Elastomers • EP 3.1.5 Polyethylene
 - EP 3.1.6 Polypropylene • EP 3.1.3 Polyolefins • EP 3.1.11 PVC
 - EP 3.2.1 Glass Containers • EP 3.2.9 Rubber Closures
- EP 3.1.9 Silicone Elastomer • EP 3.1.15 Polyethylene Terephthalate
 - EP 3.2.2.1 Plastic Containers • JP Section 7 Testing



Comprehensive and Complementary Services

The experienced CS Analytical offers Comprehensive and Complementary Services that include those analytical capabilities that complement the standard and required compendial test offerings to provide a comprehensive solution to a given qualification or regulatory challenge.



- USP <87> Biological Reactivity • Cold & Ultracold Testing
- Component Assembly Validation • Torque Studies • Label Adhesion • Accelerated Aging
 - Altitude Simulation • Storage & Stability • Component Dimensional Analysis
 - Dose Accuracy • Seal Strength • Break Force & Glide • ASTM Seal Integrity



Package Distribution Testing

CS Analytical is one of the unique service providers that offers Package Distribution Testing in an FDA regulated, cGMP laboratory. Testing is based upon ASTM D4169 “Performance Testing of Shipping Containers and Systems” that is designed to evaluate the ability of shipping units to withstand the distribution environment. Other ISTA test methods can also be performed.

COMMON ASTM 4169 DISTRIBUTION TEST SCHEDULES

SCHEDULE A: Handling, manual and mechanical.

SCHEDULE B: Warehouse stacking test.

SCHEDULE C: Vehicle stacking test.

SCHEDULE D: Stacked vibration.

SCHEDULE E: Vehicle vibration.

SCHEDULE F: Loose load vibration.

SCHEDULE G: Rail switching.

SCHEDULE H: Environmental hazard.

SCHEDULE I: Low pressure hazard testing.

SCHEDULE J: Concentrated impact.

The CS Analytical team understands the challenges that package distribution can present and the experienced laboratory technicians can help clients identify the most optimal approach and test program for the specific package system to ensure regulatory compliance is met.



Advisory Services

The traditional consulting model is based upon addressing the same issue for as many clients as possible. At CS Analytical, we handle things a bit differently.

CS Analytical's Advisory Services team routinely identifies regulatory challenges and trends facing our clients in the pharma, biotech, and med device industries, and builds solution-oriented packages to address them. Although a specific solution may be custom-tailored to a client's organization, product-package system, or process, the root challenge tends to be industry-wide.



Rather than charging high hourly rates as part of open-ended consulting agreements, CS Analytical Advisory Service packages are designed to capture key elements of these challenges life science companies continue to face in container closure system development and validation, but in a defined scope of service and budget.

CS ANALYTICAL ADVISORY SERVICES ENABLE CLIENTS TO GAIN INSIGHT, SAVE TIME AND CONTROL THE BUDGET



ANALYTICAL

CONTAINING QUALITY

The Only FDA Regulated Laboratory that is solely dedicated to Container and Package System testing and Qualification for the Pharmaceutical, Biotechnology and Medical Device Industries.

- Experienced “package system” Thought Leaders • State of the Art cGMP Laboratory
- cGMP Electronic Quality System • Unmatched Commitment to Client Service

***ADVISORY
SERVICES***

***PHYICO-CHEMICAL
TESTING***

***FUNCTIONAL
PERFORMANCE
TESTING***

C&C SOLUTIONS

***CONTAINER CLOSURE
INTEGRITY***

***A COMPLETE AND COMPREHENSIVE APPROACH TO
CONTAINER AND PACKAGE SYSTEM QUALIFICATION***