



CS Analytical

Capabilities Overview

Company Mission

Share their experience, knowledge and commitment to regulatory compliance with each client and bring “exceeds expectations” service back to the contract lab market.



Experienced Leadership Team

Brian Mulhall & Alan Weiss – Founders Whitehouse Labs, First cGMP CCI Laboratory in the world, Set foundation for current USP <1207>.

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.

*CS Analytical Team includes world-leading experts
when it comes to regulated container qualification testing*

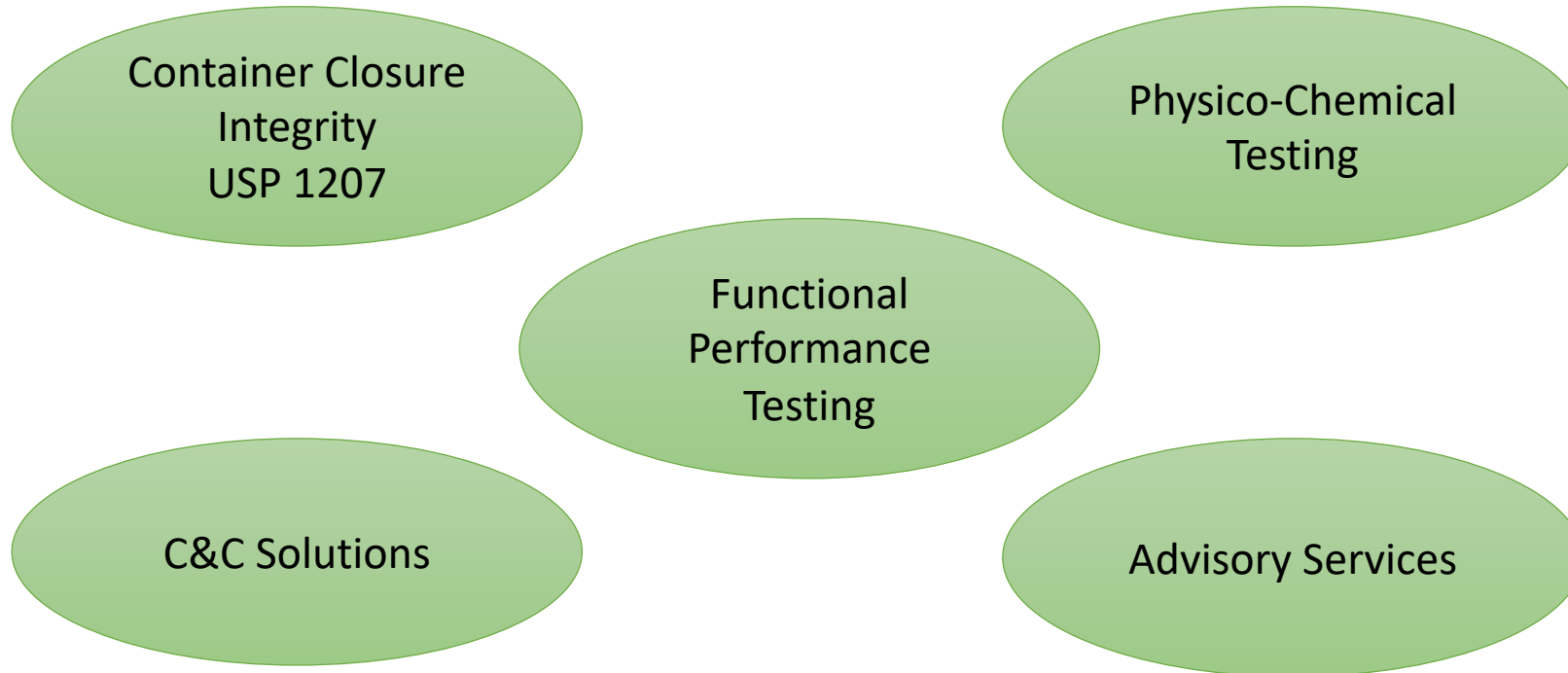
World Class cGMP Quality System

Complete 21 CFR Part 11 Validated and Compliant Quality System:

- **Qualio** – Electronic Quality Management System
- **Lab Folder** – Electronic Laboratory Notebook / Data Capture System
- **LIMS** – Custom Designed and Coded Specific to the Needs of CS Analytical
- **CRM** – Client Relationship Management System

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

Key Service Areas



A complete and comprehensive approach to container and package system qualification

Different = Better

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

A team that is dedicated to understanding the client needs specific to their product and package system and providing solutions that meet the stringent regulatory requirements that are expected in today's environment

Common Test Methods

- USP 661, USP 661.1 & USP 661.2
- USP 671 Permeation Testing (8 methods)
- USP 381 For Elastomeric Closures
- USP 660 For Glass
- Corresponding EP Methods
- Corresponding JP Methods

Common Test Methods

Complete Suite of USP <1207> CCI Services

- Laser Based Headspace
- Helium Leak Detection
- Vacuum Decay
- High Voltage

Method Development, Method Validation, Method Transfer

Common Test Methods

- Instron Method Development, Validation and Routine Analysis
- Full Suite of Dimensional Analysis Programs
- Comprehensive Capping Studies to Support USP <1207> CCI Work
- Label Adhesion and Legibility Studies
- Storage and Stability Programs
- USP <87> and USP <88> Micro Testing
- Torque Studies
- Volume and Dose Verification Studies
- ASTM & ISO Methods specific to container and package systems
- Client Developed Methods



www.csanalytical.com