

Offering the highest quality services by providing the knowledge and experience necessary for compliance within regulated industries, ultimately resulting in safe and healthy consumers.



Commissioning / Validation

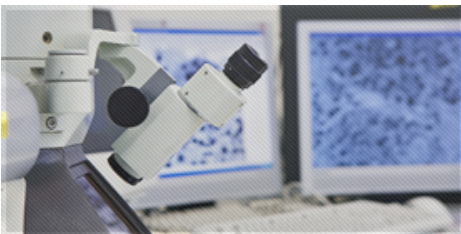
CTG has extensive experience in commissioning and validation to ensure client compliance with applicable government regulations. CTG can provide value-added commissioning / validation within your budget.

Steam Quality Testing

CTG's expert staff can provide steam quality testing in order to meet the Health Technical Memorandum (HTM-2010) and European standard EN-285. Our experts can also help in trouble shooting your steam system when failures occur.

HEPA Filter Certification

CTG provides quality, cost effective cleanroom, fume hood, and biological safety cabinet certification. See our entire list of certification and fabrication services.



MANAGEMENT TEAM:

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Overview

Compliance Technology Group, Inc., is a full-service consulting firm specializing in Commissioning/Validation, Steam Quality Testing and HEPA Filter Certification services for your pharmaceutical, biotech, medical device, and medical diagnostic cGMP/cGLP industries. Compliance Technology Group specializes in the preparation and execution of commissioning/validation documents for equipment, utilities, processes, laboratory instruments, and computerized systems..



CTG carries extensive inventory of the latest validation test equipment. This equipment is maintained and calibrated by strict and fully documented schedules. All calibrations are NIST traceable.

CTG's professional team has extensive experience in the **cGMP/cGLP and semiconductor** industries and can manage projects of any size. We can also integrate with your staff to provide temporary personnel solutions. Providing quality services at competitive pricing is what separates us from our competition. Our reputation is based on your project's success.

Compliance Technology Group is staffed with professionals of considerable experience and diverse educational disciplines. Consequently we offer a broad portfolio of services to meet your regulatory compliance needs. CTG's clients have ranged from the largest multi-national corporations to small biotechnology startups.

Commisioning / Validation

The responsibilities and jobs associated with the Commissioning and Validation efforts will be performed by staff members with the specialized knowledge of the assignment. CTG is extremely knowledgeable regarding integration of Commissioning and Validation to streamline qualification requirements. The related services we offer include:

- Compliance Support**
 - Project Management
 - Validation Strategy Development
 - Quality Program Implementation
 - Life-Cycle Planning
 - Regulatory Compliance Consultation
 - Document Control Advancement
- System/Process Auditing**
 - Hands On Support
 - Protocol Preparation
 - Protocol Execution
 - Thermal Mapping
 - Biological Indicator Studies
 - P&ID and Drawing Verification
- Testing of Sterilization Processes
 - Specification Development
 - Report Writing
 - Start Up Implementation

CTG’s experienced professional staff with extensive knowledge of the biopharmaceutical industry and the related regulatory standards are well seasoned to provide the highest level of Validation and Commissioning services to your company. Areas we provide these services include:

- Equipment**
Methods Validation
Utilities
- Cleaning Procedures and Process**
Computer System
Automated Systems
- Laboratory Instrumentation**
Facilities Related Validation
Process Validation

Biotechnology Manufacturing Related Equipment			
Scale Up	Support Services	Cell Culture	Down Stream Process
Incubators	Autoclaves	Bioreactors	Size Filtration
Table Top Reactors	Depyrogenation Ovens	Micro Filtration Skids	Viral Filtration
Wave Bioreactors	Ultrasonic Washers	Centrifuges	Column Packing Station
Bottle/ Flask Culture Set up	Parts Washers	Harvest Lines & Vessels	UF/DF Skids
DDC Units	Media & Buffer Tanks	Conditioning Vessels	Chromatography Skids
Rocker Panels	Tanks	Spin Filters	Depth & Nano-filtration
Roller Units	Transfer Lines	Aseptic Process	
Shakers	SOP Stations		
	COP Stations		

Commisioning / Validation Continued

Pharmaceuticals Process Related Equipment		
Preparation	Filling	Finishing
Mixers/ Blenders	Conveying Systems	Packaging Equipment
Lyophilizers	In-Line Washers	Bar-Code Readers
Crystallization Process Equipment	Depyrogenation Tunnels	Inspection Stations
Centrifuges	Filling Machines: Bottle / Syringe/ Vials / Ampoules	Barrier Isolators
Siliconizer-Sterilizers	Stoppering Machines	Storage Areas/ Units
Scrubbers	Capping Machines	Tracking Systems
Granulators		

Utilities Start-Up Validation	
Purified Water Systems (RODI, USP, WFI, Clean Steam)	HVAC
Gas Delivery Systems (Process Air, Oxygen, Nitrogen, Carbon Dioxide)	Clean-In-Place Skids
Supporting Water Systems (Chilled, Domestic)	Waste Neutralization / Biohazardous Containment Systems
Cooling Systems (Glycol, Syltherm, Oil-based)	Scrubbers
Dryer Vacuum Systems	

Computer / Automation Validation	
21 CFR Part 11	Detailed Design Specification (DDS)
Distributed Control System (DCS)	Traceability Matrix
User Requirement Specification (URS)	Computer System Validation Plan
Functional Requirement Specification (FRS)	Gap Analysis
GAMP 4 Implementation	ISA Standards (S88, S95) awareness
PLC and Microprocessor Controlled Validation	
Delta V	

Commisioning / Validation Continued

Laboratory Instrumentation

TOC Analyzers	Spectrophotometer
Moisture Analyzers	UV/IR
Densitometers	NIR
Differential Scanning Calorimeter	NMR
Elemental Analyzer	Titration
Microbial Characterization System	

Process Validation

Prospective/Concurrent/Retrospective	Clean Room Application
In-Process Monitoring	Assay Qualification
Expert Evaluation	

Method Validation

Method Selection and Development	Support Existing Methods or Generate New Protocols
Technical Consultation for: <ul style="list-style-type: none">Limits of Detection and AccuracyDetermining Acceptability of Observed Method Performance	Expert Evaluation
	Quality Requirements

Cleaning Validation

Strategic Planning and Implementation of Cleaning Programs	TOC and Swab Sampling
Generation of Protocols and Reports	Data Interpretation
Process Development and Resource Optimization	

Facility Related Validation

Surface Verification (Floor, Wall, Entrance, Filters, etc..)	Environmental Testing/ Programs
Construction Verification (Materials, Design, Safety, etc..)	Room Certification

Steam Quality Testing

CTG provides steam quality testing for the requirements of EN 285 and HTM 2010.

CTG has all necessary equipment and expertise to perform the following tests:

Compliance Support

- Non-Condensable Gases
- Dryness
- Superheat Values

CTG is also experienced in trouble shooting steam systems which fail initial steam quality testing.

Contact Compliance Technology Group to schedule testing at your facility today.

CTG HEPA Filter Certification Services

CTG has trained, experienced cleanroom specialists who can provide timely certifications and corresponding reports. We have the unique ability to adapt to tight time schedules, minimizing customer downtime.

We maintain a complete line of NIST traceable equipment to perform all certifications.

Cleanrooms	
Commissioning	Viable Testing - Airborne and Surface
Construction Project Management	Airflow Impact Assessments
HEPA Filter Repair & Replacement	Smoke Studies and Video Taping
Vaporized Hydrogen Peroxide (VHP) Fumigation	Post Construction Cleaning
Environmental Trending	Formaldehyde Fumigation
Certification in Accordance with IES-RP-CC-006.2, ISO - 14644 and Federal Standard 209 E	Temperature and Humidity Monitoring

Biosafety Cabinets / Fume Hoods / Laminar Flow Hoods	
LAF, Fume Hood, BSC Repairs	HEPA Filter Repair & Replacement
NSF 49 Testing under accreditation certified number OL10-01	Paraformaldehyde Fumigation
Required Tests:	
Downflow Velocity Profile	Inflow Velocity
Airflow Smoke Patterns	HEPA Filter Leak Scan
Cabinet Leak Test	
Optional Tests: (worker comfort)	
Lighting Intensity	Noise Level
Electrical Leakage	Electrical Ground Circuit Resistance
Electrical Polarity Vibration	

CTG HEPA Filter Certification Services

Continued

Product Representation
Veltec Associates Inc. (VAI) SMA Viable Air Sampling Equipment, Disinfectants, Disposable Cleanroom Attire

Gas Utility Qualifications
Gas Viable & Non Viable Performance Qualifications

Engineering	
Filter Selection	Modular Softwall Systems
Technical Support	SOP & Protocol Documentaion + Monitoring
Airflow Smoke Studies	Calibration Services