



alcami.

Pharma Storage
& Services

Commissioning, Qualification & Validation:

Intelligent Solutions



CQV Capabilities

Protect the integrity of your critical products and processes with precise solutions - accurately documented evidence that your equipment is installed correctly, operating accurately and performing reliably. Alcami can provide the crucial documentation you need to ensure the safety and reliability of your equipment.

Alcami owned equipment: the largest inventory of validation equipment in North America.

Premium thermocouples - fabricated, harnessed, and labeled in-house

Equipment calibrated and maintained by our Accredited, ISO 17025:2017 calibration lab.

Full in-depth quality assurance review and approval process for all certificates

Experienced validation team works with you to identify the best way to demonstrate sterility assurance and ensure compliance

Thoughtfully designed processes - fine tuned to save you time and reduce costs.

CQV Scope

Environmental Validation for Controlled Temperature Units

Alcami performs thorough and precise thermal distribution studies. We can also map controlled areas and equipment that requires humidity or carbon dioxide control. Depending on your user requirements, Alcami has the ability to perform empty and loaded distribution studies as well as thermal penetration studies should you need more in depth knowledge of how your product is maintaining temperature. We leverage our experience and in-depth knowledge of instrumentation and controls to recommend and implement modifications to bring your chamber into compliance. Our large team and extensive calibrated equipment inventory means no project is too large or small, and allows us to efficiently execute many mapping studies simultaneously.

We are a unique company as we not only perform qualification activities for our customers but we also perform qualification activities for our own FDA Regulated and GMP facilities, which are frequently audited and inspected.

Talk to us.

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CQV Scope

Autoclaves and Sterilizers

Our Validation team is experienced with FDA and EU regulatory standards and guidelines. We can develop protocols for installation, operation and performance qualifications, and can also perform cycle development for the sterilizer, satisfying industry requirements, including:

- EN 285, ISO 17665-1:2006
- Choice Framework for local Policy and Procedures (CFPP) 1-01 part C
- PDA Technical Report no. 1, and PDA Technical Report no. 48

Steam-in-Place Validation

Confirm the successful application of steaming procedures and ensure sterility with Alcami's Steam-In-Place (SIP) validation practices. SIP Validation helps prevent cross-contamination and deliver safe and effective products to your patients.

Manufacturing & Lab Equipment/Computer Systems

Alcami can support your company with onboarding of all GxP system types, developing and executing the following deliverables: Assessments (GxP and 21 CFR Part 11), Specifications (User, Design, Functional, Configuration), Validation Plans, Risk Assessments, Installation Qualifications, Operational Qualifications, Performance Qualifications, Traceability Matrices, Final/Summary Reports and SOPs.

Facilities & Utilities

Alcami can support your facility commissioning and qualification needs for existing or new GxP areas to include the following and more: HVAC, BMS, EMS and Utilities

Equipment

- Accumulator
- Analytical Instruments
- Autoclaves
- Cartoner
- Case Packer
- Centrifuges
- Data Acquisition Systems
- Depyrogenation Ovens
- Fill / Finish
- Generator
- Labeler
- Leak Test
- Lyophilizers
- Process Control Systems
- Shipper/Transportation Studies
- Steam Quality Testing
- Sterilizers
- Tray Unloader
- Vacuum Ovens

Steam-in-Place

- Bioreactors
- Fermentors
- Tanks
- Vessels

Controlled Temperature Units

- Controlled Rate Freezers
- Cryogenic Storage Units
- Environmental Chambers
- Freezers
- Incubators
- LN2 Chambers
- Photostability Chambers
- Ramping Chambers
- Refrigerators
- Refrigerator Truck
- Room Mapping
- Stability Chambers
- Warehouses

Enterprise Systems

- LIMS
- EDMS
- Environmental Monitoring Systems
- ERP



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Drug Product Manufacturing
Laboratory Services
Pharma Storage & Services

Charleston, SC • Wilmington, NC
RTP, NC • The Netherlands, Europe
Clinton, TN • St Louis, MO
New England • Reno, NV