

MEDTECH CSV

Compliance Through Validation



 7600606746

 www.medtechcsv.com

“MedTech CSV — Ensuring Compliance,
Quality, and Confidence in Every Validation.”

An ISO 9001:2015 Registered

OUR SERVICES



Process Control System Validation

We validate automation and control systems like PLC, SCADA, and DCS to ensure consistent performance, data integrity, and GxP compliance.

Examples:

- HVAC automation system controlling cleanroom temperature and pressure
- Autoclave or sterilizer control panel
- Water system (WFI/RO/DM) control
- Reactor and filling machine automation

Laboratory Software Validation

Our Laboratory Software Validation services ensure that all computerized systems used in laboratories operate accurately, securely, and in compliance with GxP, 21 CFR Part 11, and data integrity requirements.

We help laboratories maintain confidence in their analytical results by validating software used for data collection, processing, and reporting.



LIMS (Laboratory Information Management System)

manages sample tracking, testing, and reporting to ensure traceability and data integrity.

CDS (Chromatography Data System)

records and processes chromatographic data from HPLC/GC systems, ensuring accurate results and audit trails.

ELN (Electronic Lab Notebook)

Securely stores experimental data and observations, maintaining compliance with GxP and 21 CFR Part 11.

ENTERPRISE SOFTWARE

Our Enterprise Software Validation service ensures that large-scale business and quality management systems perform consistently, securely, and in compliance with GxP, 21 CFR Part 11, and Annex 11 regulations.

We validate workflows, user access, and electronic records to ensure data accuracy, system reliability, and audit readiness across your organization.

ERP (Enterprise Resource Planning System)

Used for production, inventory, and material management.

Validation ensures data traceability, batch integrity, and secure transaction logging for GMP operations.

QMS (Quality Management System)

Used to manage deviations, CAPA, and change control.

Validation confirms workflow accuracy, electronic signature compliance, and controlled record storage.

DMS (Document Management System)

Used for storing and controlling SOPs, protocols, and reports.

Validation ensures document version control, access permissions, and audit trail integrity.

Training Management System (TMS)

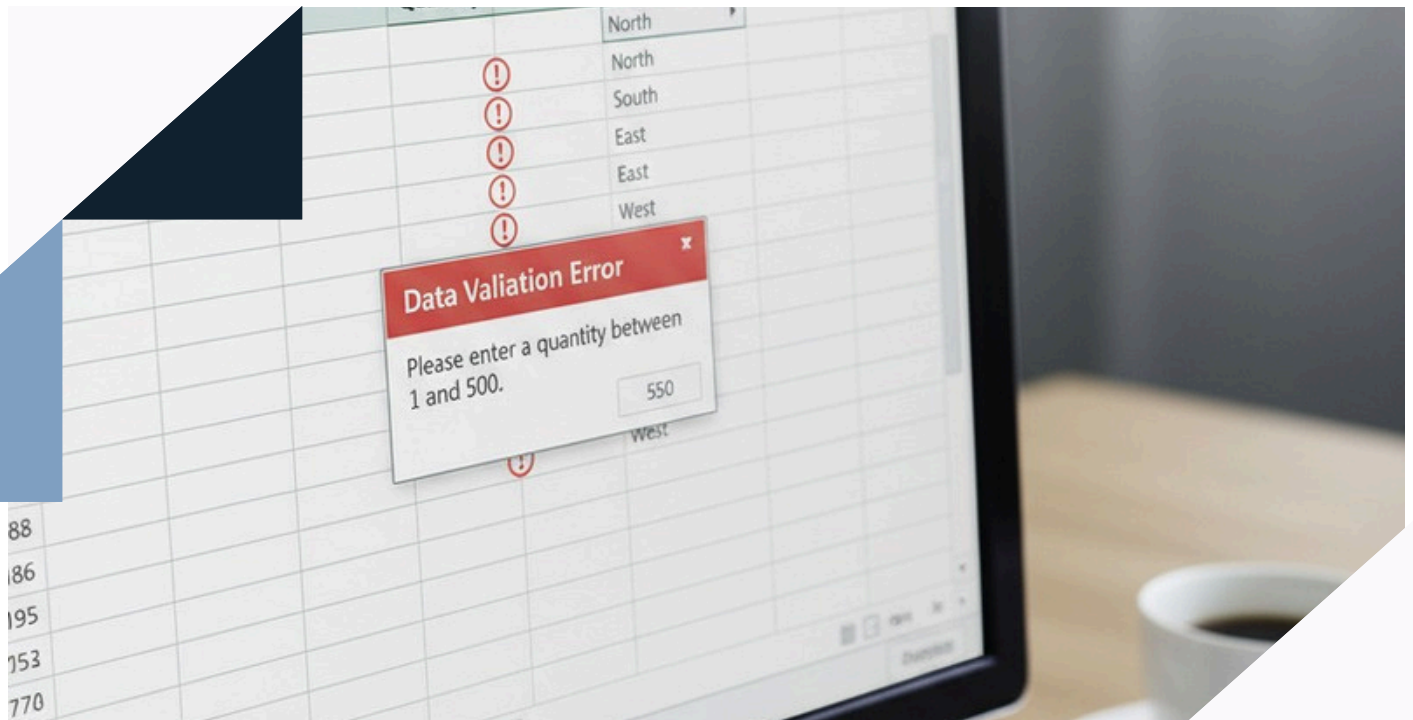
Used to track employee qualification, training schedules, and compliance status.

Validation ensures accuracy of training records, electronic approvals, and reminder functionality.



EXCEL SHEET VALIDATION

Excel sheet validation is the process of verifying that an Excel file used for critical data or calculations works accurately, consistently, and securely — especially in regulated industries like pharma or healthcare.



QC Test Result Sheet:

Used for recording assay, pH, or purity test results. Validation ensures correct calculation of averages, %RSD, and that results are automatically flagged if out of specification.

Environmental Monitoring Record Sheet:

Used to record temperature and humidity data in cleanrooms. Validation checks that data entry is within defined limits and that any abnormal readings trigger alerts or highlight automatically.

CLEANROOM VALIDATION

Ensures that controlled environments meet regulatory and quality standards for pharmaceutical and manufacturing processes. It verifies air cleanliness, temperature, humidity, and pressure conditions to maintain product integrity.



Types of HVAC & Cleanroom Tests:

1. Airflow Velocity & Pattern Test – Confirms uniform air distribution and proper laminar flow.
2. HEPA Filter Integrity Test (DOP/PAO Test) – Ensures filters are effectively trapping particulates.
3. Airborne Particle Count Test – Measures particle concentration to verify ISO class compliance.
4. Air Change Rate / ACPH Test – Validates the required air circulation per hour.
5. Temperature & Humidity Test – Checks environmental stability for product safety.
6. Differential Pressure Test – Ensures correct pressure cascade between rooms.
7. Recovery Test – Evaluates system efficiency in restoring cleanliness after disturbance.



TEMPERATURE & HUMIDITY MAPPING

Temperature and Humidity (RH) Mapping ensures uniform environmental conditions in critical storage and manufacturing areas. It identifies hot and cold spots, verifying that controlled environments meet regulatory standards for product stability and safety.



Cold Room Mapping:

Conducted to verify that temperature remains consistent (2°C–8°C) throughout the storage area. Sensors are placed at multiple points to detect hot or cold spots that may affect product quality.

Warehouse Mapping:

Performed to ensure uniform temperature and humidity control across large storage spaces. It confirms that all areas maintain acceptable environmental limits for safe product storage.