

Trescal for Life Sciences

Meet standards,
GxP guidelines and
regulatory compliance
to be audit-ready



Trescal

| CALIBRATION SOLUTIONS TO IMPROVE YOUR PERFORMANCE |

Your single service solution to ensure compliance

You need to trust that all of your GxP systems, processes, software, equipment and facilities meet quality requirements so that you can focus on your core business.
We provide documented evidence that you meet internal standards, GxP guidelines and regulatory compliance.

VALIDATION OF PROCESSES & SYSTEMS

GxP, QUALITY & REGULATORY CONSULTING



QUALIFICATION OF EQUIPMENT & INSTALLATIONS

CALIBRATION OF MEASURING INSTRUMENTS

- Validation Master Plan (VMP)
- Validation plan (VP)
- Writing user requirement specifications (URS)
- Risk assessment (RA)
- Design Qualification and Design Review (DQ)
- User Traceability Matrix (UTM)
- Factory/Site Acceptance Test (FAT / SAT)
- Validation of the installation, operation and process (IQ-OQ-PQ)
- Preparation of operational standard procedures (SOP)

- Development and optimization of quality systems
- GxP
- Pharmacovigilance quality system
- Quality risk management
- Data integrity
- Audits (internal, suppliers)
- Technical-regulatory documentation
- Software validation
- Serialization / traceability
- Transition CSV to CSA (FDA)
- Continued Process Verification (CPV) reporting
- Product Quality Review (PQR) reporting

- Equipment: autoclaves, incubators, refrigerators, freezers, water baths, ovens, etc.
- Installations: clean rooms, thermal control storage, sterilization and depyrogenation, production, conditioning and analysis equipment
- Pharmaceutical services: air conditioning; water, steam and gases; computer systems for document management, process and facility conditions

- Process and laboratory instrumentation
- Multiple variables
- Tablet quality control equipment
- Calibration services on-site or in-house via pick-up or delivery service
- Optimization of your calibration plan
- Maintenance and repair



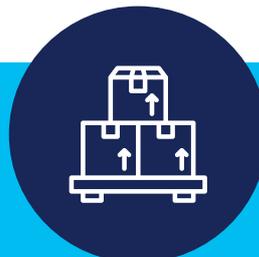
R&D

Research & development



Manufacturing

Manufacturing plants



Distribution

Logistic providers, Transport companies, Wholesale distributors, Warehouses



Dispensing

Pharmacies, Hospitals

Our roadmap to quality and regulatory mastery

GXP

We meet **GxP standards**. Our systems are validated and our equipment qualified. We pass periodic pharma audits every year

ISO

Our Quality Management System is **ISO/IEC 17025** accredited, Reg. ISO 9001

SOP compliant

We follow **our SOPs** or your specific requirements

SI

All calibrations are traceable to **SI**

QA review

All certifications are **QA reviewed** for accuracy



Regulatory calibration certificates available online

We manage your projects from planning to implementation

Experienced Consultant Team in Qualification/Validation Engagements:

- Process-oriented methodology
- Regulatory agency inspection planning
- Risk assessment
- GxP compliance services
- Warning letter remediation
- Good documentation practices

We work with your teams to tailor compliance projects to your needs:

- 1 — **Compile** information
- 2 — **Revise** requirements, functionalities, use cases
- 3 — **Determine** KPIs
- 4 — **Create** validation package (RA, IQ-OQ-PQ test plan)
- 5 — **Review** risks
- 6 — **Review** IQ-OQ-PQ test plan
- 7 — **Execute** tests
- 8 — **Produce** test report
- 9 — **Deliver** final report
- 10 — **Measure** KPIs



50%

of the project in-house and

50%

on-site but 100% flexible

Trescal for Life Sciences

Trescal

Access the expertise of our validation, qualification and calibration professionals

8

of top 10 pharmaceutical clients served

380+

in-house and on-site laboratories

30+

countries covered on all continents

600

GxP, FDA, ISO/IEC, Pharmacopeia trained experts

30

years experience in life science validation and qualification

Choose the world leader in life science services for proven results



Single source solution includes validation, qualification, calibration and GxP consulting



Regulatory compliance with ISO/IEC 9001 & 17025, FDA 21 CFR Part 11 and 780 other local regulations



Our large network allows us to easily transfer equipment in case of contingencies



Capital expenditure mobilized by Trescal to address your needs

Want to know more?
Email us at: lifesciences@trescal.com

Trescal for Life Sciences

Access the expertise of our validation, qualification and calibration professionals

8

of top 10 pharmaceutical clients served

+380

in-house and on-site laboratories

26

Trescal countries covered on all continents

600

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