

# 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



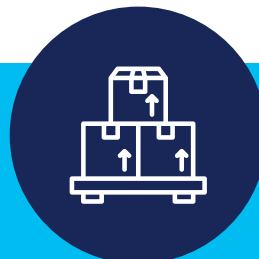
### R&D

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](mailto:lifesciences@trescal.com)

[trescal.com](http://trescal.com)

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