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

Trescal for Life Sciences

Trescal
/ LIFE SCIENCES /

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

- Computer system validation
- Computerized systems
- IT infrastructure
- Facilities & utilities (e.g. HVAC, water for pharmaceutical use, gas systems, sanitation, drainage systems, plumbing)
- Cold chain management
- Transport
- Cleaning process management
- Production and packaging processes
- Analytical methods

GxP, QUALITY & REGULATORY CONSULTING

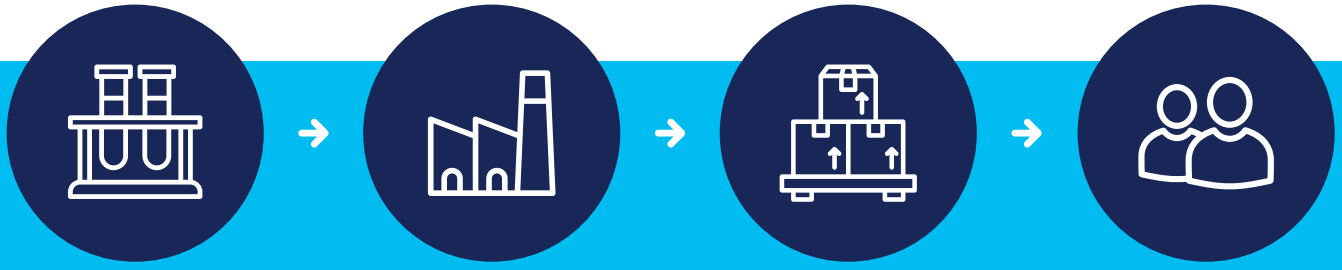
- Development and optimization of GxP quality systems
- Manufacturing process & facility transfers
- Pharmacovigilance quality system
- Quality risk management
- Data integrity and governance
- Audits (internal, supplier)
- Regulatory documentation
- Serialization / traceability
- Transition CSV to CSA (FDA)
- CPV and PQR reporting
- Computerized systems and electronic data in clinical trials
- Medical devices & software

QUALIFICATION OF EQUIPMENT & INSTALLATIONS

- 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

CALIBRATION OF MEASURING INSTRUMENTS

- Process and laboratory instrumentation
- Multiple variables
- Tablet quality control equipment
- Calibration services on-site or in-house via pick-up and 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

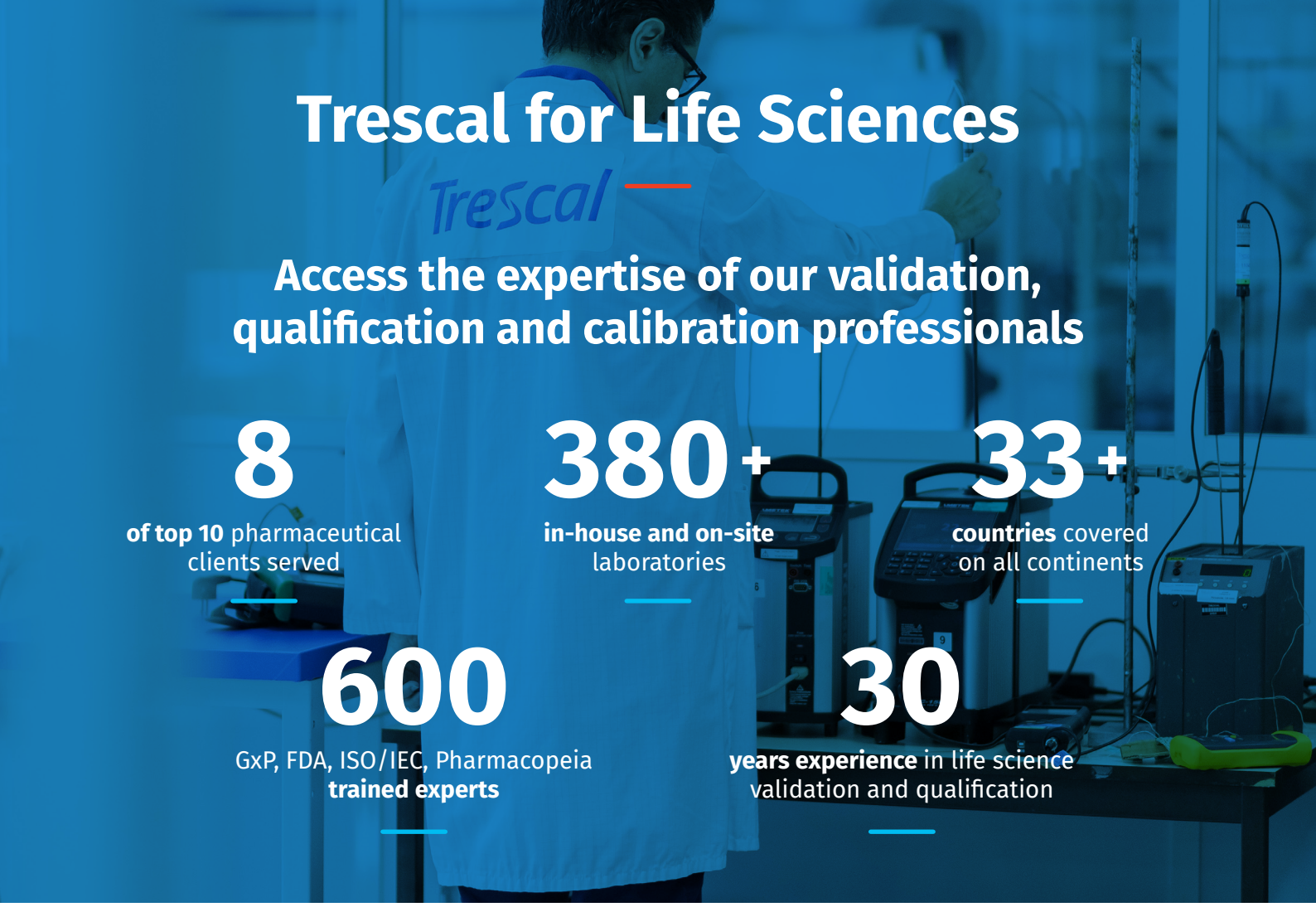
Experienced Consultant Team in Qualification/ Validation Engagements:

- 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. **Create** validation package (RA, IQ-OQ-PQ test plan)
4. **Review** risks
5. **Review** IQ-OQ-PQ test plan
6. **Execute** tests
7. **Produce** test report
8. **Deliver** final report

50% of the project in-house and **50%** on-site but 100% flexible



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

33+
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.com

Trescal
| CALIBRATION SOLUTIONS TO IMPROVE YOUR PERFORMANCE |