What makes us different?

CONFIDENCE

Knowledge, experience, and the ability to successfully tackle every project in the pharmaceutical industry.

We understand your needs by providing the best solution.

Consultancy 360°

The best option

- We accompany you throughout the project ensuring compliance with applicable regulations.
- Own multidisciplinary team of highly qualified experts.
- Cutting edge service at all levels throughout the drug life cycle:

  - **Commissioning & Qualification**
  - **Computerized Systems Validation**
  - **Data Integrity**
  - **Qualification of the Equipment & Facilities/ Process Validation**
  - **QA Services**
  - **Quality in Research & Development**
  - **Third Party Quality Audits**

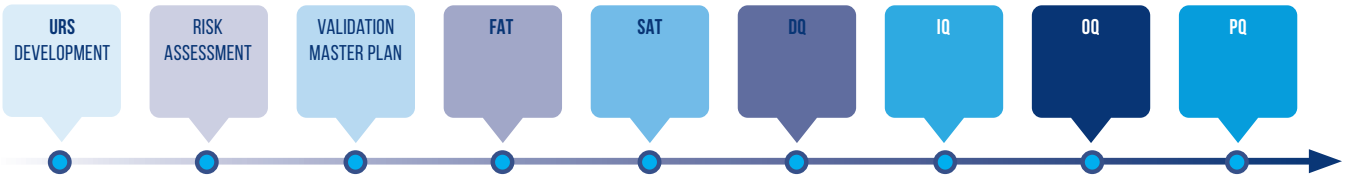
Integral vision
Credibility
Flexibility
Thoroughness
Efficiency
Expertise/Experience

Telstar®

COMMISSIONING & *QUALIFICATION OF FACILITIES AND EQUIPMENT*

Telstar advises clients in defining their qualification/verification strategy, from the traditional method to the method in accordance with ASTM E2500, analyzing intermediate options based on scientific knowledge and risk management.

Telstar develops, together with the Engineering /IT/Quality Departments and the different suppliers, all the deliverables of commissioning/Qualification/Verification.



- Qualification/Validation Project Management
- Development of the Annual Qualification/ Calibration/ Preventive Maintenance Plan
- Risk Assessment of the facilities design, cross contamination, equipment/systems, critical instrumentation, etc.
- Risk Management according to the ICH Q9 of the process requirements in order to identify those risks that require mitigation and/or control measures to reduce them, through qualification, to an acceptable level
- Commissioning/Qualification of Facilities/Equipment.
  - Air treatment systems and Clean Rooms: Architecture, Air conditioning systems (HVAC), Laminar flows, Insulators, Containment and Barrier systems, Air showers, SAS, etc.
  - Utilities: Purified water (PW), Water for injectables (WFI), Pure Steam (PS), Compressed Air and Pure Gases (Nitrogen, etc.), CIP/SIP.
  - Thermal Equipment/Installations: Autoclaves, Sterilization Tunnels, Freeze Dryers, Reactors, Freezers, Ovens, Stoves, Warehouses, Cold Chambers and Stability Chambers
  - Process and Packaging Equipment
- Re-qualification of Rooms, Equipment and Installations

As a Risk control measure, all deliverables (starting with the user requirements -URS-) are focused on product quality attributes (CQA), Critical Process Parameters (CPP), and Critical Design Elements (CDE), as well as in the regulatory aspects and the client´s own quality requirements. All tests carried out, both in the Startup (FAT/SAT/ Commissioning) and Validation, are designed to provide documentary evidence that the system complies with its intended use.

QA SERVICES

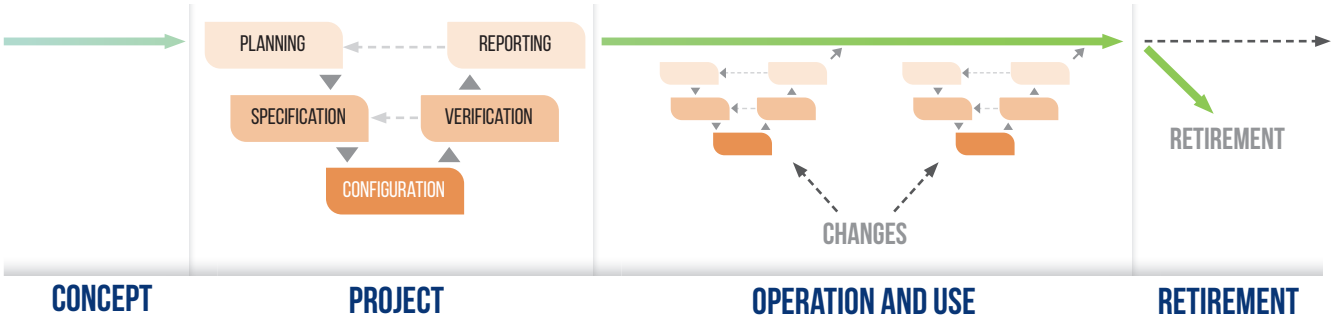
The quality assurance services provided by **Telstar** can be carried out within the company by **experts' consultants in GMP (EU/FDA)** with experience in national and international projects:

- **Continued Process Verification Protocols (CPV/OPV)**
  Telstar advises using the new requirements on process validation, defining the methodology to be followed for the implementation of a continued verification protocol (CPV or OPV) for products subsequent to regulatory requirements as well as for existing products (legacy products) validated prior to these requirements.
- Product Quality Reviews (PQR)
- Standard Operating Procedures (SOPs)
- Process Validation
- Cleaning Validation, clean equipment waiting times, dirty equipment waiting times
- Deviation management with root cause analysis and CAPA management
- Internal audits, deficiency (GAP analysis) and implementation of quality systems according to GMP (EU/FDA), GDP, ISO
- Preparation and assistance for pre-authorizations inspections (Pre- Approval Inspections, PAI)
- Regulatory Updated reports
- **Quality assessments** are another essential service that **Telstar** provides. Decisions are made based on the Risk Assessment in accordance with the ICH Q9 Guide and are integrated throughout the product life cycle.

COMPUTERIZED SYSTEMS VALIDATION

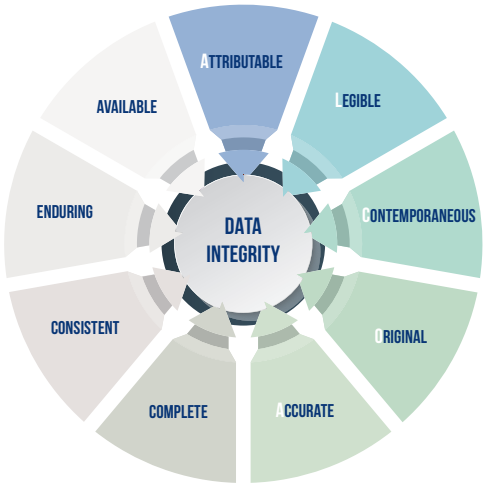
The activities offered by **Telstar** during the system life cycle are the validation of the computerized systems according to the model defined in the GAMP5 guide: Planning, Specifications, Configuration, Verification and Reporting. **Telstar's** CSV experts' consultants assist during the implementation of Computerized Systems, to ensure compliance from the design.

- Management Systems (ERP, Document Management, Quality Management, etc.)
- Process and Control System (SCADA, BMS/EMS, Process Control and Monitoring, etc.)
- Laboratory Systems and Equipment (LIMS, Chromatography Systems, Specific Equipment Laboratory).
- Warehouse Management Systems, Serialization and Aggregation Systems
- Software in Health Products (ISO EN 62304) and Software in Health environment (ISO EN 82304)
- Cloud Systems (IaaS, PaaS, SaaS) and Qualification of Infrastructure.
- Systems Implementation and Maintenance of the Validation Status:
  - Support, Design and Project Management of Implementation/Upgrade of Computerized Systems
  - Periodic Review of the Validation Status
  - Advice of implementation of SOPs and Policies for compliance of Computerized Systems
- Compliance audits of regulations 21 CFR Part 11/ Annex 11 EU GMP
- Audits on the Data Integrity Process Focused on Computer Systems and Hybrids
- Audits of Data Centers and External Systems Providers (Cloud)



DATA INTEGRITY

Telstar advises its clients to define and implement everything they need to meet data integrity requirements:



ALCOA+

- Global advice on records and data management: Focus on the data life cycle
- Development and support in the elaboration of policies and procedures (Data Governance)
- Risk Assessment on process/data flows to identify critical data and weak points of the process
- Training: personnel qualified at all levels of the organization
- Inclusion of Data Integrity in the quality management system
- Mapping/Data flows in parallel with the process flow

Data Governance

- Monitoring audits related to the data and records management process
- Implementation plans with the goal of Data Governance
- Designs of systems that guarantee data quality and integrity

| THIRD PARTY QUALITY AUDITS (TPQA):

Telstar conducts Supplier Quality Audits so that they can comply with regulatory and EU GMP/ FDA/ISO.

- Worldwide audits
- **Telstar** experts' auditors
- Local auditors in Spain, India, China, Brazil and USA
- Audit reports available
- Audit shared by different clients

TYPES OF AUDITS

- Internal audits
- Active Ingredient- API (Sterile/Non-Sterile), Intermediates and Excipients
- Packaging Material
- Medical Device
- Cosmetic Products and Nutritional Supplements
- Service Providers (Analysis Laboratories, Distributions Centers, etc.)

| QUALITY IN RESEARCH & DEVELOPMENT:

In the pre-clinic and clinic area, expert consultants and auditors offer support in the implementation of quality R&D policies, to improve their processes or those necessary to present regulatory data on efficacy and safety of the drug and its development process.

Quality management for unregulated R&D:

- Documentation and knowledge management
- Training

Good Laboratory Practices (GLP):

- Implementation of the GLP system and preparation of SOPs
- Audit of studies
- Validation of Computerized Systems
- Training in GLP
- Support as an external Quality Assurance Unit

Process evaluation and improvement:

- Data Integrity / Data Governance
- Support in the design, implementation and measures of **KPIs** in R&D

Clinical research (GCP and ISO 14155 for Medical Devices):

- Implementation of GCP system and preparation of SOPs
- Evaluation and audits of:
  - GCP Quality System and CROs
  - Providers of eCRFs
  - Phase I Units
  - Clinical Trials/Studies (TMF, laboratories and research)
  - Central and Bioanalytical Laboratories
  - Data Management and Statistics
  - Audit of IMP manufacturers (GMP for IMP)
- Validation of Computerized Systems (GCP and Pharmacovigilance)
- Training in GCP
- Support as External Quality Unit

| PERSONALIZED TRAINING PROGRAMS

Telstar offers standard and personalized training programs, combining theory and case studies. During the training course, our clients will discover what are the necessary tools to improve the results of their company. The training can be delivered via online, face to face or blending.

Main training programs

- General: GxP, FDA, QA, Risk Assessment
- Commissioning and Qualification
- Computerized System Validation
- Continued Process Verification
- Data Integrity
- Audits
- Lyophilization
- Sterilization
- Pharmaceutical Plant Design
- Containment
- Biotechnology
- Continuous Improvement

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ISO 9001: Certified Company

BR-CONSULTANCY- EN-0321

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