Experts consultants in regulated sectors
Services

CONSULTANCY

Advice
GMP, GLP, GCP, GDP
Validations
Data Integrity
Medical Devices

Audits
GMP, GCP, GLP, GDP
Medical Devices

Assistance
Status Validation maintenance
Decommissioning

PROJECTS

Validation of computerised systems

Data Integrity
Evaluations and implementation of policies

Equipment qualification

Infrastructure qualification

Medical Devices

Training In Company

Medical Devices

Training in Barcelona / Madrid

PHARMACEUTICAL
MEDICAL DEVICE
COSMETIC
VETERINARY

Always Meeting the Standards

Copyright ©CSV Experts 2019 2
We increase the maturity level of organizations

Design of the Quality System

Collaboration in the Compliance of the Quality System:
- Change Control
- Incident Management
- Configuration Management
- System Periodic Review
- Internal Audits

Source: ISPE GAMP® Guide: Records and Data Integrity
GxP Consultancy

REVIEW
Regulatory compliance status of your organization

RESOLUTION OF INCIDENTS
Detected by audits / inspections

Application
IMPROVEMENT PLANS

Update and application of
NEW REGULATIONS

GLP  GCP  GMP  GMP  GDP
PreClinical  Clinical Trials  Manufacturing & Distribution
VALIDATION OF COMPUTERIZED SYSTEMS

**ERP**  
(Management of materials and resources)

**EDMS**  
(Document management system)

**EBR / MES**  
(Electronic Batch Record / Manufacturing Execution System)

**BBDD PHARMACOVIGILANCE**

CLINICAL TRIALS
(Ecrd, TMF)

Cloud Systems / On Site

SCADA

**LIMS**  
(Laboratory Information Management System)

**LDAS**  
(Laboratory Instrumentation)

MAINTENANCE AND REMOVAL OF SYSTEMS

**CHANGE CONTROL**  
Applications - Infrastructure

**DECOMMISSIONING**  
Controlled removal of servers, PC, equipment

**MANTRA**  
TraceLink

QUALIFICATION

**IT INFRASTRUCTURE, EQUIPMENT AND INSTALLATIONS**
CSV Experts has developed an **agile evaluation and prioritization tool** in accordance with DIRA (Data Integrity Risk Assessment).
Maintenance of the Validation status of TraceLink®

ManTra Lite – What we offer?

• TraceLink® continuous validation and change assessment procedure.

• Tailor-made documentation: only critical aspects are tested.

• Added value: test scripts, execution and evidence detail are handled by the service subscriber.

• Annual subscription: includes every change released by TraceLink® during subscription period.

• One yearly payment: 2,000 €/year (at the beginning of the subscription).
Medical Devices

REGULATORY ADVICE

• Medical Device classification.
• CE marking.
• Product registration in Europe, USA – 510 (k) and other countries.
• MDSAP.
• Preliminary licence for the operation of facilities.

QUALITY SYSTEMS

• Advice and implementation for adherence to ISO 13485 and 21CFR820.

MANAGEMENT AND RISK ANALYSIS

• In accordance with ISO 14971.

VALIDATIONS

• Mobile Apps
• Software
• Manufacturing processes

ADAPTATION TO THE NEW EUROPEAN REGULATIONS - MDR AND IVDR

TRAINING “In-Company”
IT Services

A CSV Experts company

QA
- Services Managed to IT Qualified Infrastructure

PROCEDURES
- Documentation: Infrastructure Qualification Plans Process / Procedures and training

QUALIFICATION
- IT Infrastructure Qualification

INSTALLATION
- Hardware and software installation and configuration (time)

HW & SW
- Hardware and software (material)
IT Services

FULL SERVICE TO YOUR IT DEPARTMENT

- Backup and Restore System Validation
- Disaster Recovery Systems
- Periodic IT Infrastructure Reviews
- IT Pharma Consulting

- Audit to suppliers
- Audit to pharma IT departments
- Time and material (specialized resources)
- Monitoring

A CSV Experts company
Some of our customers

Roche
Diagnostics

Esteve

Boehringer Ingelheim

Hartmann

OPKO

Grifols

Hipra

Kern Pharma

Ferrer

Lilly

Merck

Isdin

Zoetis

Mylan

Recipharm

Cinfa

Goodgut
Enhancing digestive health

Normon

Uriach

Operon
Why working with us?

- More than 20 employees
- ISO 9001:2015 certified
- More than 500 projects carried out
- In-depth knowledge of regulated environments
- Barcelona and Madrid delegations
- Join Venture with phIT (CSV Experts and Ambit BST)
- ISPE Spain members
- AEFI & Catalonia BIO partners
- Among the top 3 consultants of regulated environments in Spain
- More than 150 customers