Expert Consultants in regulated sectors

PHARMACEUTICAL
MEDICAL DEVICE
COSMETIC
VETERINARY

CONSULTANCY
- Advice
  - GMP, GLP, GCP, validations, Data Integrity
  - Medical Devices
- Audits
  - GMP, GCP, GDP, Cloud, Medical Devices
- Assistance
  - Maintenance of validation status
  - Decommissioning etc.
- Training In Company
  - Complete training program in Barcelona / Madrid

PROJECTS
- Validation of computerised systems
- Data Integrity
  - Evaluations and implementation of policies
- Equipment qualification
- Infrastructure qualification
- Medical Devices

TRAINING

SERVICES

CONSULTANCY

PROJECTS

TRAINING

Always Meeting the Standards
We increase the maturity level of organizations
correct management of Computerized Systems and Data Integrity

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

(*) included in the validation status of TraceLink®

Source: ISPE GAMP® Guide: Records and Data Integrity
CONSULTANCY
GLP, GCP, GMP, GDP

REVIEW
regulatory compliance status of your organization

APPLICATION
IMPROVEMENT PLANS

RESOLUTION OF INCIDENTS
detected by audits / inspections

UPDATE AND APPLICATION
of NEW REGULATIONS

GLP  GCP  GMP  GMP  GDP
PreClinical  Clinical Trials  Manufacturing & Distribution
Validation of Computerized Systems
Data Integrity Assessment
Maintenance of the validation status of TraceLink®
Medical Devices
IT Services

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

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”
Validation of Computerized Systems
Data Integrity Assessment
Maintenance of the validation status of TraceLink®
Medical Devices
IT Services

A complete service to your IT department

- Services Managed to IT Qualified Infrastructure
- Documentation: Infrastructure Qualification Plans
  Process / Procedures and training
- IT infrastructure Qualification
- Hardware and software installation and configuration (time)
- Hardware and software (material)
- Backup and Restore System Validation
- Disaster Recovery Systems
- Periodic Review of IT infrastructure
- IT Pharma Consulting
- Supplier audit
- Audit of IT departments
- Time and material (specialized resources)
Some of our customers -

- Roche Diagnostics
- Esteve
- Boehringer Ingelheim
- Hartmann
- OPKO
- Grifols
- Hipra
- Kern Pharma
- Ferrer
- Lilly
- Merck
- Isdin
- Zoetis
- Mylan
- Recipharm
- Cinfara
Why working with us?

More than 20 employees

ISO 9001:2015 certified

Join Venture with phIT (CSV Experts and Ambit BST)

In-depth knowledge of regulated environments

Barcelona and Madrid delegations

ISPE Spain members AEFI & Catalonia BIO partners

Among the top 3 consultants of regulated environments in Spain

More than 100 customers
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