



# csvexperts

Always Meeting the Standards

Experts consultants in  
regulated sectors

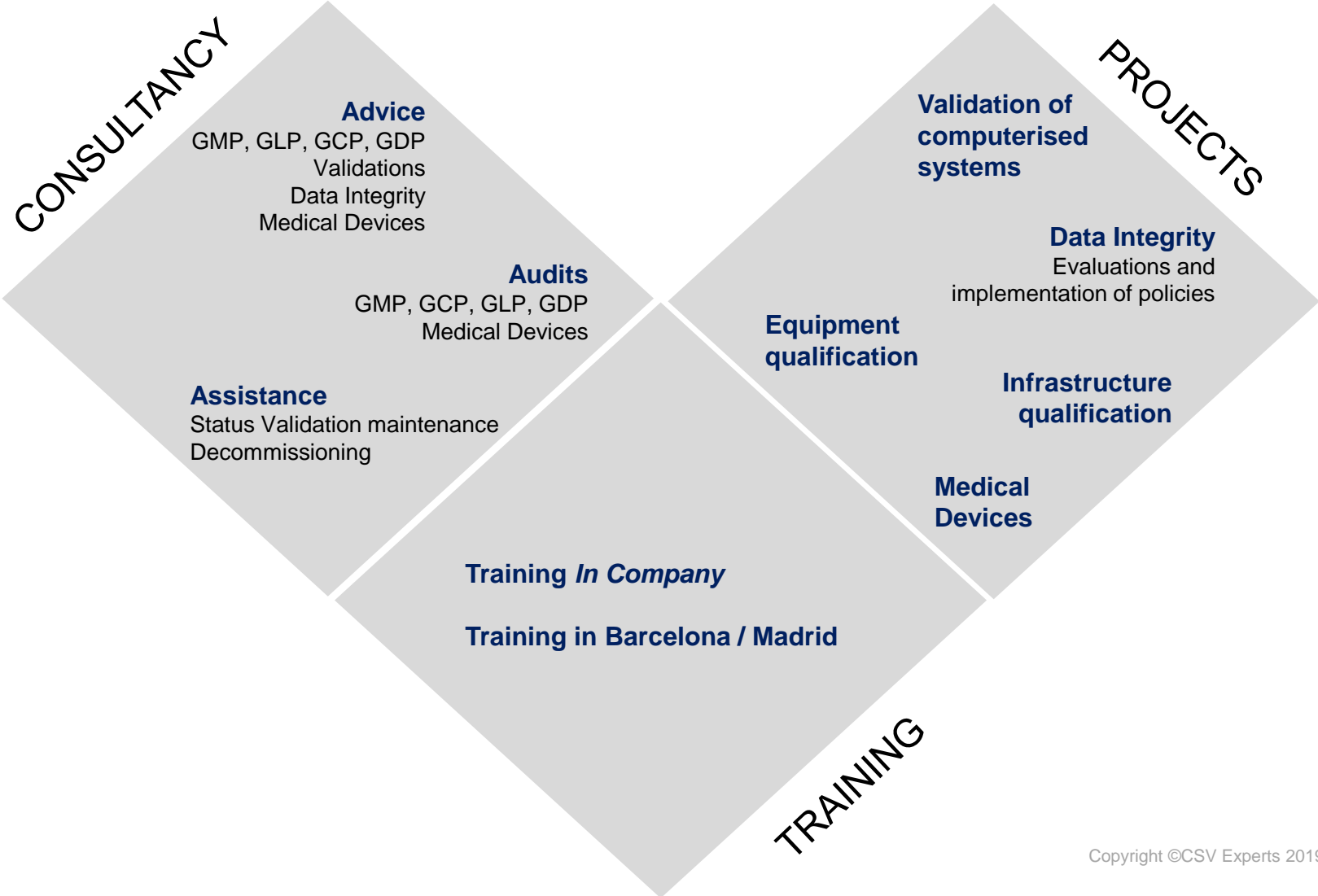


Sistema de  
Gestión  
ISO 9001:2015

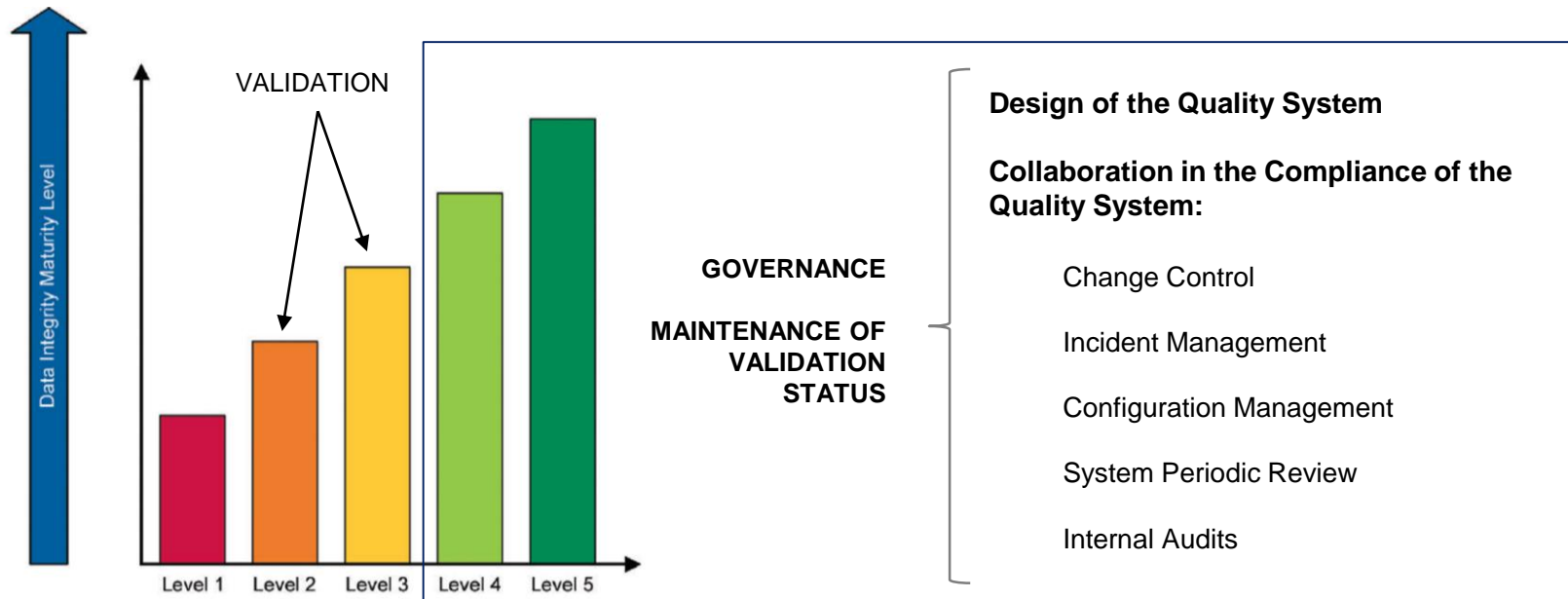
www.tuv.com  
ID 9108633814

Services

PHARMACEUTICAL  
MEDICAL DEVICE  
COSMETIC  
VETERINARY



# We increase the maturity level of organizations



Level 1	Level 2	Level 3	Level 4	Level 5
<ul style="list-style-type: none"> <li>• Undefined</li> <li>• Uncontrolled</li> <li>• Not monitored</li> <li>• No evidence</li> </ul>	<ul style="list-style-type: none"> <li>• Partially defined</li> <li>• Not formally controlled</li> <li>• Not formally monitored</li> <li>• Person dependent</li> </ul>	<ul style="list-style-type: none"> <li>• Defined policy and established processes</li> <li>• Inconsistent application</li> <li>• Inconsistent monitoring</li> </ul>	<ul style="list-style-type: none"> <li>• Defined policy and established processes</li> <li>• Routine application</li> <li>• Routine monitoring</li> </ul>	<ul style="list-style-type: none"> <li>• Defined policy and established processes</li> <li>• Proactive</li> <li>• Continuous improvement</li> </ul>

←→ Red     
 ←→ Amber     
 ←→ Green

GxP Consultancy

PHARMACEUTICAL  
MEDICAL DEVICE  
COSMETIC  
VETERINARY

**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

Services

PHARMACEUTICAL  
 MEDICAL DEVICE  
 COSMETIC  
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**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

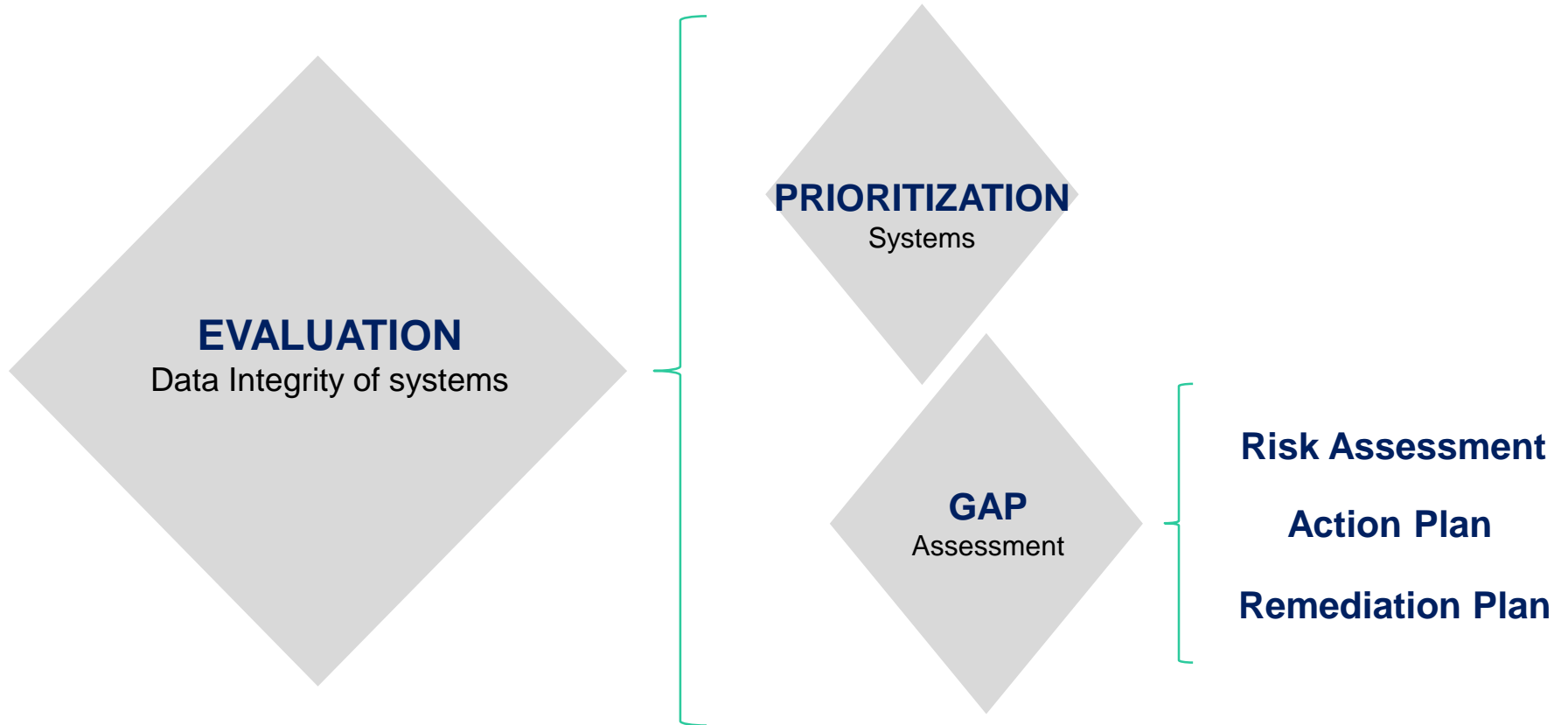
**MANTRA**  
 TraceLink

**QUALIFICATION**

**IT INFRASTRUCTURE, EQUIPMENT AND INSTALLATIONS**

# Data Integrity Assessment

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.

### ADAPTATION TO THE NEW EUROPEAN REGULATIONS - MDR AND IVDR

### TRAINING “In-Company”

### 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





**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

PHARMACEUTICAL  
MEDICAL DEVICE  
COSMETIC  
VETERINARY



**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

Some of our customers

PHARMACEUTICAL  
MEDICAL DEVICE  
COSMETIC  
VETERINARY



# Our team

PHARMACEUTICAL  
MEDICAL DEVICE  
COSMETIC  
VETERINARY



CEO



Administration



Business Development



Business Development



QA



QA



Translation



IT

## CONSULTANTS



## TECHNICIANS



# Why working with us?

PHARMACEUTICAL  
MEDICAL DEVICE  
COSMETIC  
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### Follow us

