

Governance & Compliance – Pharma Market Services



Mission

Our **mission** is to supply consulting services to Customers for the compliant use of computerized systems and infrastructures.

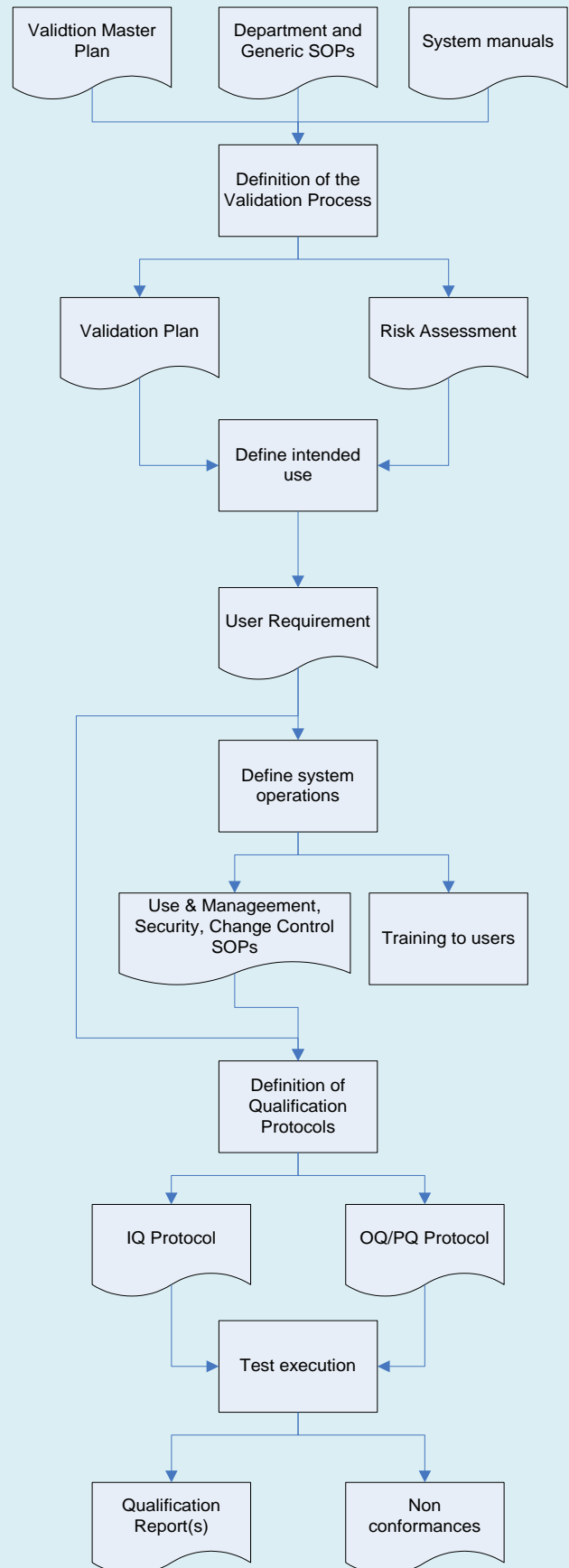
Services

- **Validation** of computerized systems including MES, laboratory and LIMS, software tools, infrastructures and management systems according to international standards and Customer's SOPs; all tasks are included: from Validation Master Plan to Qualification Reports and training on SOPs.

Validation is

Establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined

- **Periodic review** of validated computerized systems to ensure that computerized systems are still validated.



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- Compliance of computerized systems to **security** norms (21 CFR Part 11 and Annex 11) including gap analysis, update of quality system to address security requirements, management of suppliers, technical/procedural remediation and validation of solutions.
- **Test** systems: development of test benches and support to ruled use. Customisation of tools to generate documents in accordance with GxP requirements.
- **Quality management** services:
 - **Quality system** maintenance such as preparation of SOPs, selection and customisation of tools supporting Quality systems, KPI definition
 - **Change control** procedures definition and implementation
 - Support to incoming **audits** and to those ones to be carried out to suppliers
 - **Decision support** mechanisms such as lesson learned data base and knowledge management systems,
 - Management of **CAPA** and definition of relevant process
 - Management of **complaints** according to 21 CFR requirements.
- **Training** made according to customer needs. Training subjects include: 21 CFR Part 11, Annex 11, Computer Validation.

Competences

- 21 CFR Parts 11, 210, 211,
- Gamp 5,
- ICH Q7, Q10,
- Annex 11,
- ISO 9001, ISO/IEC 31010, ISO 2700x
- HAZOP, FMEA/FMECA, Root Cause Analysis



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