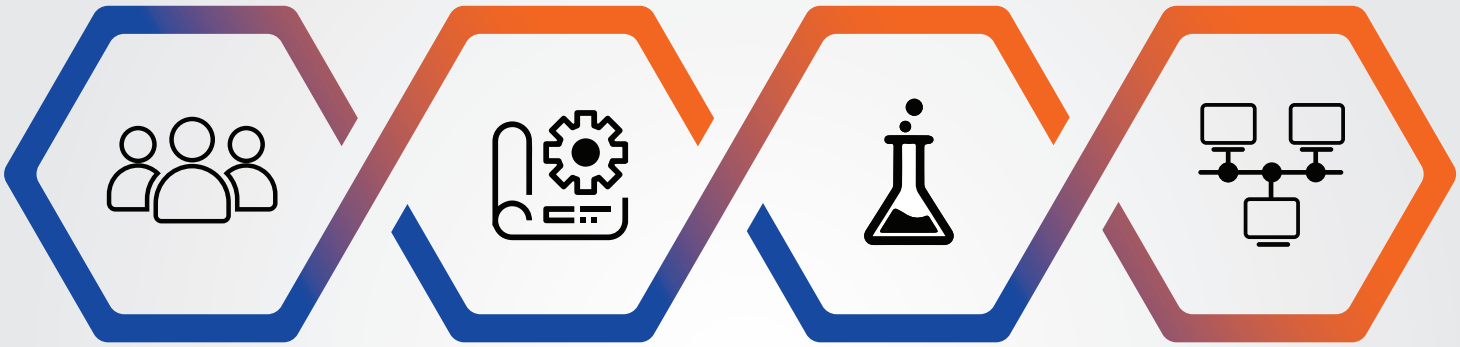
Factorytalk+

COMPUTER SYSTEM VALIDATION & DATA INTEGRITY

Recognised experts in international GMP (US FDA, PIC/s etc) and CSV methodologies with over 20+ years of experience.

Factorytalk offer a full set of activities through the systems life cycle; classification, planning, assessment, testing, verification and documentation for all the types of technology found in the Lifesciences industries. We follow and develop best practices for CSV and DI according to current GMP - DI regulatory requirements, GAMP, and incorporate latest best practice guide such as the recent GAMP Data Integrity-Key concepts.

Our wide experiences help our clients run successful projects, and we always aim to build close engagement with our customer team to enable setup their own procedures and methods to maintain GxP IT solutions thus ensuring smooth operational phase.



VALIDATE MANAGEMENT INFORMATION SYSTEM

example Information system:
- Enterprise Resource Planning (ERP)
- Manufacturing Execution (MES) & Batch Record Systems (EBR)
- Electronic Quality Management (eQMS)
- Building Management Systems (BMS)
- Warehouse Management System (WMS)

VALIDATE PRODUCTION SYSTEM

example production system/ equipment:
- Rotary Tableting Press Machine
- Blister Packing Machine
- Autoclave
- Purified Water System
- Sterile Vial filling line
- Mixing Tank
- Freeze dryer
- Process Control System

VALIDATE LAB SYSTEM

example lab system/ equipment:
- HPLC
- Chromatography Data System software

QUALIFY NETWORK INFRASTRUCTURE

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Visit our website