Based in the North West of the UK, CSVuk provide Computer Systems Validation (CSV) Services to the primary and secondary pharmaceutical industries in the UK and Europe, which are regulated by the Food and Drug Administration (FDA) and the Medicines and Healthcare products Regulatory Agency (MHRA).

We have a proven history of providing high quality, cost effective validation solutions to meet our customer needs in the biotechnology, active pharmaceutical ingredient (API) and medical device industries; with a range of experience through project management, engineering design, risk assessment, and validation (prospective and retrospective).

We frequently undertake assignments to complete prospective and retrospective computer systems validation of manufacturing and laboratory equipment, perform GMP audits of existing computer systems, risk assess new and existing computer systems, and review/enhance CSV policy in line with current regulations and regulatory guidance. We also give added value by managing technical fixes, provide technical detail for inclusion in Operation and Maintenance (O&M) manuals and Standard Operating Procedures (SOPs), and offer technical support to production departments whilst operators are being trained.

Our associations with similar CSV Consultancies and Engineering Services companies in the UK and Europe enables us to provide single consultants and teams of consultants on short-term and long-term assignments at competitive market rates.

Computer Systems Validation Services:

- CSV Site Validation Master Plans and Summary Reports.
- Validation Plans and Summary Reports.
- Validation Gap Analysis Reports.
- Validation Position Papers.
- High level risk assessment of Computer Systems.
- Management of Computer Systems Inventories.
- Categorisation of hardware and software according to GAMP 5.
- Electronic Record; Electronic Signature assessments, remediation plans, protocols and reports.
- 21 CFR part 11 interpretation.
- High level Risk Assessments (for prioritisation of validation activities).

- Functional Risk Assessment of systems (providing rationale for content of validation protocols).
- Design Qualification (DQ) protocols.
- Installation Qualification (IQ) protocols.
- Operational Qualification (OQ) protocols.
- Performance Qualification (PQ) protocols.
- Validation Execution and Reporting.
- Equipment Qualification (combined IQ/OQ) protocols and reports.

Computer Systems Validation Policy Services:

- Computer Systems Validation site policy procedures.
- Computer Systems Validation Gap Analysis Reports.
- Computer Systems Inventory management procedures.
- Risk Assessment procedures.
- Configuration Management procedures.
- Backup, Restoration and electronic housekeeping procedures.
- Security Access procedures.
- Disaster Recovey procedures.
- Time synchronisation procedures.
- Control of Suppliers procedures.
- Network management procedures.
- Computer Systems Validation training packages.
- Record retention policies.

Engineering Services:

- Quality Plan generation.
- User Requirements Specification (URS) generation.
- Functional Specification (FS) generation.
- Requirements Traceability Matrix (RTM) generation.
- GMP review and Impact Analysis of equipment and processes.
- Design Reviews.
- Test Planning.
- Factory Acceptance Test (FAT) specification and execution.
- Site Acceptance Test (SAT) specification and execution.
- Installation and Commissioning specification generation.
- Equipment maintenance methods for SOPs.
- Computer System operation and administration methods for SOPs.
- Configuration Management of site Computer Systems.
- Change Control of site Computer Systems.

- Backup/archive strategy of site Computer Systems.
- User, Maintenance, and Administrator level Training on site Computer Systems.
- Security/Access control of site Computer Systems.
- Lockdown of standalone PC systems.
- Programming Microsoft Excel VBA macros for computer systems validation of spreadsheets.
- Retrospective technical specification/system overview generation.
- Alarm Management.

Quality Management System Review:

- Supplier Assessments/Audits.
- Configuration Management.
- Source Code Reviews.
- Implementation Lifecycle.
- Design Reviews.
- Software testing.
- Hardware testing.
- Security of Data and Systems.

Equipment and Systems:

- Usifroid Freeze Driers.
- Getinge and Fedegari Autoclaves.
- Fedegari Vapourised Hydrogen Peroxide (VHP) Hatches.
- Automated packaging and overprinting systems.
- Bausch and Strobel and IMA powder handling and automated filling and assembly machines.
- Automated sterilizers, vial washers, sterilizing tunnels (Bausch and Strobel, Bosch, IMA).

- Packaging Vision Systems.
- Automated Test Robots (medical devices).
- Laboratory Equipment (HPLC, GC, CDS, UV, FTIR, LIMS).
- iFix and Wonderware InTouch Supervisory, Control and Data Aquisition (SCADA) systems.
- Distributed Control Systems (DCS) (APACS, Fisher Rosemount PRoVOX, Emerson DeltaV, Siemens PCS7, Bailey INFI 90).
- Programmable Logic Controller (PLC) systems (Siemens, Omron, Rockwell, Schneider).

- Purified Water generation and distribution systems.
- Pure Steam generation systems.

- Water For Injection (WFI) Still and distribution systems.
- Laboratory calculation spreadsheets (Excel).
- Batch control systems (Wonderware InBatch, Fisher Rosemount PRoVOX, Emerson DeltaV, Siemens PCS7).
- Continuous control systems.
- Building Management Systems (BMS) including Heating, Ventilation and Air Conditioning (HVAC) Systems.
- Oracle E-Business Suite ERP.
- Paperless Chart Recorders.
- Emergency Shutdown (ESD) Systems (Serck, Rotork, DeltaV SIS).

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