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1. Introduction

This document has been generated to define the provision of services in relation to Computerised System Validation, Data Integrity, IT Infrastructure Qualification and IT Quality and Compliance Consulting, where that service pertains to a prospective client.

Validions have worked with many regulations over many projects as part of the services we have delivered, and our services are compliant with a large body of regulations. A list of such regulations includes, but is not limited to;

1. FDA 21 CFR 11: Electronic Records, Electronic Signatures
2. FDA 21 CFR 58: Good Laboratory Practice for Nonclinical Laboratory Studies
3. FDA 21 CFR 210: Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General
4. FDA 21 CFR 211: Current Good Manufacturing Practice for Finished Pharmaceuticals
5. FDA 21 CFR 610: General Biological Products Standards
6. FDA 21 CFR 820: Quality System Regulation
7. EU GMP Annex 11: Computerised Systems
8. EU GMP Annex 15: Qualification and Validation
9. MHRA GxP Data Integrity Guidance and Definitions (March 2018)
10. FDA guide: Data Integrity and Compliance with Drug CGMP Questions and Answers Guidance for Industry (Dec 2018)
11. ISO-27001: Information Security Management System
12. ISO-13485: Quality Management System for Medical Devices
13. ISO-14971: Application of Risk Management to Medical Devices
14. Health Insurance Portability and Accountability Act (45 CFR 160; 45 CFR 162; 45 CFR 164)
15. EU Medical Device Regulation (MDR) and In vitro Diagnostic Medical Devices Regulation (IVDR)

2. Scope

The scope of this document covers the list of all services provided by Validions Ltd generally, as may, from time to time, be offered to prospective clients.

This document will be updated with further services as and when required.

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3. Abbreviations and Definitions

Item	Definition
AI	Artificial Intelligence
CDS	Chromatography Data System
CFR	Code of Federal regulations
CSA	Compute Software Assurance
CSV	Computerized System Validation or Computer System Validation
DI	Data Integrity
eDMS	Electronic Document Management System
eQMS	Electronic Quality Management System
eTMF	Electronic Trial Master File
ERP	Enterprise Resource Planning
FDA	Food and Drug Administration
GAMP	Good Automated Manufacturing Practice
GMP	Good Manufacturing Practice
HIPAA	Health Insurance Portability and Accountability Act
ISO	International Standards Organization
ISPE	International Society of Pharmaceutical Engineering
IVDR	Invitro Diagnostic Medical Devices Regulation
LIMS	Laboratory Information Management Systems
MDR	Medical Device Regulation
MHRA	Medicines and Healthcare Products Regulatory Agency
ML	Machine Learning
NLP	Natural Language Processing
QMS	Quality Management System
RAID	Risks, Assumptions or Actions, Issues, Dependencies or Decisions
VR	Virtual Reality

4. List of Services

Validions provide a range of services including Computer System Validation (CSV), Data Integrity (DI), IT Infrastructure Qualification and IT Quality Management. The following sub-sections add further detail.

4.1. Computerised System Validation (CSV)

Validions offers a fully managed Computer System Validation support service for your organisation in the procurement, development, validation and routine use of your IT systems and production/analytical equipment.

We follow the best practices described in the ISPE GAMP5 publication. We have provided the following CSV services;

1. Supplier Audits
2. CSV Audits – both internal and external
3. QMS Procedures including CSV, project governance, data governance and associated templates and risk assessments.
4. Agile / Waterfall (V-Model) methodologies
5. Full Lifecycle documentation
6. Risk-based scalable approach leveraging and utilising existing supplier documentation along with the remediation of any other identified gaps.
7. Functional Risk Assessments

4.2. Data Integrity (DI)

Validions offer bespoke DI training, DI assessments and consultations to help you effectively manage and control your data. This is summarised below.

1. DI Governance
2. Data Integrity Consulting and Risk/Gap Assessments
3. DI remediation projects

4.3. IT Infrastructure Qualification

Validions offer a wide range of IT infrastructure qualification activities to ensure IT systems remain secure and compliant. The following services are incorporated.

1. Qualification of Infrastructure including networks, Active Directory, Virtualisation environment, backup/restore solutions, data centres, network assigned storage and office 365
2. Infrastructure Assessments
3. Qualification documentation
4. Access Management Procedures

4.4. IT Quality and Compliance

Whether your IT systems or equipment requires compliance with Computer System Validation (CSV), Computer Software Assurance (CSA) or any other regulations including Data Integrity, Validions can support your regulated environment.

Validions offer a range of specialized IT Compliance and Quality services including but not limited to:

1. IT QMS policies and procedures
2. IT Quality Audits
3. IT Infrastructure Compliance and Qualification

4.5. CSV/IT Project Management

The complex nature of CSV/IT installations from projects to operation, often requires project management capabilities. Validions are able to offer these services and cover the following;

1. Project governance
2. Stakeholder management
3. Project management – turnkey management and delivery of IT systems
4. RAID logs
5. Project planning
6. Change management.

7. Incident and problem management
8. Supplier engagement and management
9. Test management

4.6. Specialist Areas

We have specialist knowledge in a range of systems including:

- Electronic Trial Master File (eTMF)
- Electronic Quality Management System (eQMS)
- Electronic Document Management Systems (eDMS)
- Laboratory Information Management Systems (LIMS)
- Chromatography Data Systems (CDS)
- Enterprise Resource Planning (ERP) Systems – warehousing, manufacturing and finance
- Serialisation systems
- EU Medical Device Regulation (MDR) and In vitro Diagnostic Medical Devices Regulation (IVDR)
- Lab and Manufacturing Equipment
- Service Now – ITIL Service management
- Backup/restore solutions
- Spreadsheet storage and control solutions
- Medical Information Systems

4.7. Training

The delivery of training can be remote based, classroom based or Virtual Reality (VR). The following subject are covered.

1. Basic GMP – Pharmaceutical regulated systems
2. Fundamentals of GAMP5
3. CSV
4. Data Integrity for users, managers / supervisors and senior executives and stakeholders

The above subjects can be delivered as standard or bespoke training presentations or VR demonstrations can be developed.

Note: VR training and demonstrations are currently in development

4.8. Software Solutions

Validions are developing a range of pharmaceutical software solutions to enhance Regulatory Compliance within the industry.

These include;

1. Auditect: Automated audit trail review software utilising AI and ML to accurately review and detect problems within your systems' audit trails.
2. Core Autonomy™ : A software platform solution that facilitates and manages regulatory compliance for pharma companies and supply chains, reducing the time spent on document bureaucracy by automating the generation of compliance documentation. It is founded on AI, ML and uses Natural Language Processing (NLP) to avoid the need for programming skills.
3. DI Risk Assessment tool : Automated DI Risk Assessment tool for site and system specific DI assessments

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"The best time to become compliant was at the start. The second-best time is now"

Gary Watkinson CEO Validions Ltd

5. Revision history

Date	Version	Revised By	Reason for Revision
28 Feb 2023	1.0	G Watkinson	This is the first issue of this document