CAAS – Compliance as A Service

In the mission to improve the quality of life, Life Science organizations need to constantly deploy technology solutions to create innovative products. Life Science companies need to ensure an effective and continuous state of technology compliance. At Infisolve, we are equipped with strong domain and technology consulting capabilities to help you achieve assured compliance.

CaaS offerings:

Our CaaS spans across all the Life Sciences industries (Medical devices, Pharmaceutical & Biotech Industries and Healthcare).

Our solutions cover the full suite of regulatory IT compliance requirements. It provides its clients:

Validation Services
- CSV Consulting/Risk Assessments
- CSV Process Implementation
- Testing Services
- Training & Audit Readiness Support
- Vendor Evaluation

Part 11 Services
- Part 11 Assessment
- Part 11 System/COTS Implementation
- Training

Platform Qualification
- Qualification of IT platforms,
- Infrastructure Qualification

Technical Writing
- Product and Process Documentation
- Policy and Procedure Writing (SOPs)
- CSV documentation
- Documentation Consulting

1.   *Fig1.Full range of offerings from Infisolve for the Life-Science and Healthcare Industry*

Validation Services

- ❖ **CSV/CFR Part 11   Consulting**
    - o Conduct risk assessment and risk mitigation
    - o Conduct CSV/ 21 CFR applicability assessment for following scenarios:
        - » Prospective Validation
        - » Retrospective Validation
        - » Revalidation
    - o Perform Gap Analysis and prepare gap analysis report

- ❖ **CSV/Part 11 Training**
    - o Identify Training Needs
    - o Prepare Customized Training Plan at various levels
    - o Prepare required training kit
    - o Facilitate and conduct Training

- ❖ **CSV/Part 11 System Compliance**
    - ❖ **Perform following activities for Prospective Scenario:**
        - o Validation Planning
        - o Conduct Requirements Definition and Traceability
        - o GxP & Part 11 assessment
        - o Design/ Development and Testing of Software
        - o Develop relevant SOPs and Validation Document Deliverables
        - o Perform User Training
        - o Execute qualifications (IQ/OQ/PQ)
        - o Summarization of Validation activities

    - ❖ **Perform following activities for / Retrospective /Revalidation Scenario:**
        - o Inspect the critical component of the computer system
        - o Perform Gap Analysis
        - o Prepare a Validation Plan
        - o Review and approve the validation documentation

> *CaaS will enable our client to ensure the 'Right-To-Operate' your IT systems and associated processes and stakeholders*
>
> **Infisolve** *transforms your systems, processes, and stakeholders into a state of always compliance.*

Consulting Services to help assess current IT compliance maturity and define a roadmap for enterprise-wide improvement.

Execute the roadmap by implementing CaaS Solution, run in collaboration with the customer.

- o Perform Impact Analysis & Prepare report suggesting changes to the system
- o Execute the IQ,OQ and PQ relevant to the critical components of the revalidation
- o Summarization of Validation activities

❖ **Bundle our Compliance services with**

- ▪ Assurance (Testing) of GxP IT Systems
- ▪ System retirement process
- ▪ Vendor evaluation

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The author is CEO and founder of Infisolve India Pvt. Ltd. He has worked for more than two decades with life-science companies and the largest ITES Company in India. Visit us at www.infisolve.in or drop a mail at info@infisolve.in