

# User Requirements Specification

Document ID: VDC-URS-001

Version: 1.0

System: Validated Document Control (VDC)

Deployment: AWS Serverless Demo System

Classification: Non-GxP Demonstration System

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This document is part of the VDC validation documentation set.

It demonstrates application of GxP Computer System Validation (CSV) principles including:

- Requirements definition
- Functional specification
- Traceability
- Qualification testing (IQ/OQ/PQ)
- Verification evidence
- Risk assessment
- Validation summary

This system is not a regulated production system and does not claim compliance with 21 CFR Part 11 or formal GxP requirements.

Reference Evidence:

<https://www.williamoconnellpmp.com/life-sciences/docs/iq-oq-pq/>

<https://www.williamoconnellpmp.com/life-sciences/docs/vdc-non-gxp-evidence/>