Functional Requirements Specification

Document ID: VDC-FRS-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/