21 CFR Part 11 Compliance & Audit Trail Guide

Implementation Framework for Automated Pharmaceutical Control Systems

Technical Document - GentlemanPharmed Pharmaceutical Engineering Division
Category: Regulatory Compliance

Architectural blueprint for electronic signatures, secure audit trail logging, recipe version locking, user hierarchy a

SPECIFICATIONS & VALIDATION OVERVIEW:

- Contact Material: Stainless Steel AISI 316L (Mirror polished Ra <= 0.4 um)
- Non-contact Structure: Stainless Steel AISI 304 (Scotch-Brite Satin Finish)
- Automation & HMI: Siemens S7-1500 / Allen-Bradley ControlLogix PLC with 21 CFR Part 11 Audit Trail
- Documentation Package: Full DQ, IQ, OQ, PQ Protocols, 3.1 Mill Certificates, Calibration Records
- Compliance Standards: WHO-GMP, USFDA 21 CFR Part 211, EU-GMP Annex 1, ISO 9001:2015, CE

ENGINEERING SUPPORT & SERVICE CONTACTS:

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