

CAPABILITY	FDA GxP · cGMP · GLP	FDA CFR 21 · Part 11	FDA HCT/Ps · CGTP	JCAHO	VFC	AABB	State Bd. Pharmacy
ALERTING & NOTIFICATION							
Completely automated alerting	+	+	+	+	+	+	+
24 × 7 alerting — always on, always ready	+	+	+	+	+	+	+
Notifications via email, SMS text, and/or phone	+	+	+	+	+	+	+
User alerts	+	+	+	+	+	+	+
Algorithm for elimination of false positives	+	+	+	+	+	+	+
Twice daily check-in ("Documented Eyes")	n/a	n/a	n/a	n/a	+	n/a	✓
Continuous at user or agency defined sampling rate	+	+	+	+	+	+	+
CONTROL OF PROCESS							
Redundant backup systems	✓	✓	✓	+	+	+	+
User access on any internet connected device	✓	✓	✓	+	+	+	+
MONITORING							
Temperature	✓	✓	✓	✓	✓	✓	✓
Humidity	✓	✓	✓	✓	✓	✓	✓
Light	✓	✓	✓	✓	n/a	n/a	✓
Pressure differential	✓	✓	✓	✓	n/a	✓	✓
Voltage	✓	✓	✓	✓	✓	✓	✓
Network connection	✓	✓	✓	✓	✓	✓	✓
Backup systems status	✓	✓	✓	✓	✓	✓	✓
REPORTING							
Health agency audit-ready reports and charts	✓	✓	✓	+	+	+	+
Administrative reports (alerting, response times)	✓	✓	✓	+	+	+	+
Fully auditable database with corrective action reporting	+	+	+	+	+	+	+
Retrievable from any secure internet connected device	+	+	+	+	+	+	+
Downloadable and printable in a secure, audit-ready format	✓	✓	✓	+	+	+	+
RECORDS							
User defined 2+ year retention periods	✓	✓	✓	✓	✓	✓	✓
Web accessible closed system	✓	✓	✓	✓	✓	✓	✓
SOFTWARE							
New versions validated by qualified and authorized personnel	✓	✓	✓	✓	✓	✓	✓
Banking level encryption	✓	✓	✓	✓	✓	✓	✓
HARDWARE							
Unique MAC addresses for devices	✓	✓	✓	✓	✓	✓	✓
Unique ID information displayed on devices	✓	✓	✓	✓	✓	✓	✓
CALIBRATION							
Qualified via an IQ / OQ / PQ process supported by SOPs	✓	✓	✓	✓	✓	✓	✓
NIST traceable	✓	✓	✓	✓	✓	✓	✓
Retrievable calibration records	✓	✓	✓	✓	✓	✓	✓
Calibration status displayed on device placard	✓	✓	✓	✓	✓	✓	✓
SECURITY & DATA PROTECTION							
Encrypted web access	✓	✓	✓	✓	✓	✓	✓
Encrypted data storage	+	+	+	+	+	+	+
System documentation controlled via a secure EDMS supported by proprietary SOPs	✓	✓	✓	✓	✓	✓	✓
Defined access levels with associated permissions	✓	✓	✓	+	+	+	+