PharmaWatch™
We watch so you don't have to

Matrix Key:

⊕   Exceeds the regulatory requirement or recommendation
√   Meets the regulatory requirement or recommendation

Compliance Matrix

		FDA (GxP, cGMP, and GLP)	FDA (CFR 21 Part 11)	FDA (HCT/Ps, CGTP)	JCAHO	VFC	AABB	State Board of Pharmacy
Alerting and Notification	Completely automated alerting	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	24 x 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	√
Monitoring	Continuous at user or agency defined sampling rate	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	Redundant backup systems	√	√	√	⊕	⊕	⊕	⊕
	User access on any internet connected device	√	√	√	⊕	⊕	⊕	⊕
Control of Process	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	⊕	⊕	⊕	⊕	⊕	⊕	⊕
Records	Retrievable from any secure internet connected device	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	Downloadable and printable in a secure, audit-ready format	√	√	√	⊕	⊕	⊕	⊕
	User defined 2+ year retention periods	√	√	√	√	√	√	√
Software	Web accessible closed system	√	√	√	√	√	√	√
	New versions validated by qualified and authorized personnel	√	√	√	√	√	√	√
	Banking level encryption	√	√	√	√	√	√	√
Hardware	Unique MAC addresses for devices	√	√	√	√	√	√	√
	Unique ID information displayed on devices	√	√	√	√	√	√	√
	Qualified via a IQ OQ PQ process supported by SOP's	√	√	√	√	√	√	√
Calibration	NIST Traceable	√	√	√	√	√	√	√
	Retrievable calibration records	√	√	√	√	√	√	√
	Calibration status displayed on device placard	√	√	√	√	√	√	√
Security and Data Protection	Encrypted web access	√	√	√	√	√	√	√
	Encrypted data storage	⊕	⊕	⊕	⊕	⊕	⊕	⊕
	System documentation controlled via use of a secure EDMS supported by proprietary SOP's	√	√	√	√	√	√	√
	Defined access levels with associated permissions	√	√	√	⊕	⊕	⊕	⊕