503B Analytical Testing Obligations – SciCord Compliance Support

Category	Requirement	USP Chapter	21 CFR Citation	How SciCord Enables 503B CGMP Compliance
GOVERNING FRAMEWORK	Regulatory standards	USP <795> / <797>	21 CFR Parts 210 & 211	SciCord delivers a validated, CGMP-ready informatics platform with enforced workflows, role-based access, electronic signatures, and complete audit trails—supporting inspection readiness and standardized operations across all batches.
FINISHED PRODUCT TESTING	Identity testing	USP <795> / State boards	21 CFR 211.165(a)	SciCord manages samples from receipt to release, enforces validated methods, and captures results via structured templates or direct instrument integration—eliminating manual transcription errors and ensuring full traceability.
FINISHED PRODUCT TESTING	Potency / assay	USP <797> / State boards	21 CFR 211.165 & 211.194	SciCord provides a specifications engine (limits, rules, calculations) with automatic pass/fail, warning, and OOS flagging. Direct instrument data capture reduces transcription risk and supports review-by-exception for faster batch release.
FINISHED PRODUCT TESTING	Sterility testing	USP <797> / USP <71>	21 CFR 211.167	SciCord supports microbiology workflows including incubation tracking and structured result entry. Positive results trigger OOS investigations and block release until resolution, with full auditability.
FINISHED PRODUCT TESTING	Bacterial endotoxin (BET)	USP <85>	21 CFR 211.167	SciCord calculates endotoxin limits (K/M), captures assay data (including instrument integration), and enforces specification checks—reducing manual data entry and improving accuracy.
FINISHED PRODUCT TESTING	Particulate matter	USP <788>	21 CFR 211.167	SciCord records inspection results from manual entry or directly from instruments, enforcing acceptance criteria and minimizing transcription errors through controlled data capture.
FINISHED PRODUCT TESTING	Container-closure integrity	—	21 CFR 211.167	SciCord manages CCIT methods, sample tracking, and results, ensuring validated methods are used and data is captured in a controlled, traceable, and reviewable manner.
IN-PROCESS CONTROLS	In-process testing	USP <797>	21 CFR 211.110	SciCord captures in-process data directly within electronic batch

		(advisory)		records (eBR), including instrument-fed values where applicable, ensuring real-time, contemporaneous records and eliminating transcription gaps.
STABILITY & BUD	Stability programme	USP <795> / <797>	21 CFR 211.166	SciCord provides end-to-end stability management: protocols, sample scheduling, pull tracking, and trending. Integrated data capture and automated evaluation support OOT/OOS detection.
STABILITY & BUD	Expiry dating	USP <795> / <797>	21 CFR 211.137	SciCord links stability data to products and lots, enabling scientifically justified expiry assignment based on complete, traceable datasets.
METHOD VALIDATION	Analytical method validation	—	21 CFR 211.194(a)	SciCord manages validation protocols and datasets, capturing results directly or via instrument integration, ensuring data integrity and eliminating transcription risks during validation studies.
OOS & DEVIATIONS	OOS investigation procedure	—	21 CFR 211.192	SciCord automatically triggers OOS workflows from specification failures, with full traceability to original data (including instrument sources), supporting defensible investigations.
OOS & DEVIATIONS	Deviation & CAPA system	—	21 CFR 211.68 & 211.192	SciCord provides integrated deviation and CAPA management with structured workflows, impact assessment, and effectiveness tracking, all fully auditable and linked to originating data.
ENVIRONMENTAL MONITORING	Environmental monitoring (EM)	USP <797>	21 CFR 211.42	SciCord manages EM programs including sampling plans, locations, and trending. Data can be captured directly from monitoring systems, reducing transcription errors and enabling real-time excursion detection.
ENVIRONMENTAL MONITORING	Media fill / process simulation	USP <797>	21 CFR 211.113	SciCord tracks media fill studies and personnel qualification, ensuring structured, attributable data capture and linking outcomes to operators and processes.
CONTRACT TESTING	Contract lab use	USP <797> (advisory)	21 CFR 211.84 & 211.68	SciCord manages outsourced testing including sample tracking, result import (structured or electronic), COA management, and vendor qualification—maintaining data integrity across

				organizational boundaries.
ELECTRONIC RECORDS	21 CFR Part 11 compliance	—	21 CFR Part 11	SciCord provides secure authentication, role-based permissions, electronic signatures, and complete audit trails, ensuring compliant electronic records with full data traceability.
ELECTRONIC RECORDS	Data integrity (ALCOA+)	FDA DI Guidance	21 CFR Part 11	SciCord enforces ALCOA+ through attributable actions, timestamped entries, version control, and direct data capture from instruments—eliminating risks associated with manual transcription and spreadsheets.
ADVERSE EVENTS	Adverse event reporting	State board rules	21 CFR 310.305 & 314.81	SciCord captures adverse events, links them to products and batches, and supports controlled reporting workflows with full traceability and documentation.