Quality overview

ISO 13485:2016 and ISO 9001 certified - one system, two scopes

CERTIFICATION	FACILITY	LAST AUDIT	REVISION
ISO 13485:2016 / ISO 9001	**3,200 m2, Carlsbad CA**	**Customer audits supported**	**4.0**

SCOPE

The system covers design control, supplier management, manufacturing, release testing, storage and distribution of reagents for cell and gene therapy. GMP-grade and RUO-grade material are produced under the same system; the grade determines the release criteria and the documentation package, not the controls behind them.

WHAT THE SYSTEM CONTROLS

- Design control with documented inputs, outputs, verification and review
- Supplier qualification and incoming material testing
- Batch record issuance, review and release by a named QA signatory
- Equipment qualification, calibration and maintenance schedules
- Deviation, CAPA and change control with effectiveness checks
- Stability programme with defined retest intervals
- Annual product quality review and management review

DOCUMENTATION AVAILABLE TO CUSTOMERS

Document	Timing	Notes
Certificate of Analysis	With every lot	Lot-specific, signed release
Technical datasheet	On request	Catalogue specification
Safety data sheet	On request	Per product family
Quality agreement	Before first GMP order	Bilateral, signed
Audit report / site visit	On request	Under confidentiality
DMF letter of authorisation	On request	Where a file exists

AUDIT HISTORY

Customer and prospective-customer audits are supported under a confidentiality agreement. Audit reports, deviation logs and the CAPA register are made available in a secure data room rather than sent by email.

Certificates, scope statements and the current quality manual index are released after a mutual NDA. Nothing in this document constitutes a quality agreement.