TrakCel

Whitepaper

Quality at TrakCel:
FDA Title 21 CFR Part 11

The combination of emergent cell-based therapies with novel requirements to further scientific and technical progress brings new opportunities for the use of secure computerized systems.

TrakCel's technological advancement, staff training and close regulatory monitoring ensures you receive only the most up-to-date and accurate advice and support when deploying your system.

TrakCel's Closed System provides the necessary controls, validation and security to ensure product quality, safety and record integrity whilst conforming with 21 CFR Part 11.

⇒ TrakCel is a Closed System

⇒ TrakCel's approach to Validation meets the FDA General Principles of Software Validation (2002)

⇒ TrakCel's 21 CFR Part 11 compliance experts have been trained by FDA technical experts*

**Sion Wyn, team leader on the August 2003 FDA Guidance for Industry: Part 11, Electronic Records; Electronic Signatures – Scope and Application*

TrakCel is committed to assisting our customers with aligning their systems and quality practices to fully comply with all applicable tenants of 21 CFR Part 11.

This includes:

- Access Controls
- Data Export
- Device Checks
- Security
- Protection
- Training
- Data integrity
- Operational Checks
- Controls
- Audit Trail
- Authority Checks
- Documentation

> we want to ensure that our customers do not fall foul of similar pitfalls.

TrakCel monitors FDA warning letters to keep abreast of any changes in the interpretation of the regulation with the emergence of new technologies.

We want to ensure that our customers do not fall foul of similar pitfalls.

FDA Observation

"Inadequate controls over computer systems were observed. Your firm does not have security protocols, users of computer systems have administrative privileges, and laboratory raw data is not reliable.

Your firm has not exercised appropriate controls over computer or related systems to assure that changes in control records or other records are instituted only by authorized personnel."

FDA Observation

"Software used as part of production and the quality system has not been fully validated for its intended use according to an established protocol. Electronic records are used, but they do not meet requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records."

FDA Observation

"Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only be authorised personnel."

FDA Observation

"The computer system is currently enabled for any operator to delete, alter or discern test data without administrative oversight and audit tracking function."

For more information on TrakCel's commitment to quality, please see the following documentation:

- TrakCel - 21 CFR Part 11 – Regulatory Alignment
- TrakCel - Product Quality Plan
- TrakCel - Customer Project Quality Plan

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