

Validation Support Services



Comprehensive Validation Support

The TrakCel Quality Team is your assurance for establishing and maintaining a compliant and 'audit ready' system.

TrakCel supports you through all stages of validation, with a GAMP5 aligned quality system that ensures that documentation and testing delivers a validated solution.

The TrakCel team actively supports requirements capture and provides comprehensive testing services accumulating in delivery of a validation pack for the solution. The validation pack also incorporates regulatory and GAMP5 science-based risk assessments.

This comprehensive validation pack can be leveraged by customers to achieve validation of the deployed solution with minimal impact on resources.

Benefits

- Quality system alignment
- Full test coverage of requirements
- Access to standard templates for URS and Validation.
- Expert guidance and support during the validation phases.
- A documentation set that will withstand regulatory scrutiny.
- Access to TrakCel's resources and qualified environments.
- Change control ensuring your system remains in a compliant state

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Compliant Platform

The TrakCel software platform is rigorously tested through a GAMP5 aligned software lifecycle. This ensures customer processes are configured and deployed to a stable and 'validation-ready' system.

User Requirements

The TrakCel team analyse your processes and guide you through development of a robust URS, ensuring issues of regulatory compliance with Part 11 and Annex 11 are covered.

Tested and Verified

TrakCel's in-house testing team delivers end-to-end testing and verification of all functionality and content in your TrakCel processes. All test plans and reports can be available as part of your system validation pack.

Qualified System and Infrastructure

TrakCel provides fully qualified infrastructure and system testing (IQ and OQ), along with resources to perform testing on the production environment prior to transition to a live system. Pre-production systems can also be supported for change qualification and validation.

User Acceptance

The TrakCel team can directly support you in planning and execution of User Acceptance Testing (UAT). TrakCel's expertise will ensure UAT achieves full coverage of user requirements.

Ongoing Compliance

Through integration of quality systems, change management and support processes, TrakCel will manage your system to ensure it remains in a validated state.



Validation Pack Features

- Mapping to regulatory terminology (FDA and EMA guidance)
- Project Quality Plan
- User Requirements Specification (URS)
- Design documentation
- Test Plans and Reports
- Traceability and Coverage Reports
- Evidence of infrastructure and system qualification (IQ and OQ)
- Regulatory and Risk assessments

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