

ETHOS – Data Integrity Without Complexity The 21 CFR Part 11 Software Platform



In today's regulatory environment, **data integrity is no longer an IT issue; it is a compliance risk.** The FDA continues to increase scrutiny on electronic record controls, audit trails, e-signatures, and data security across sterile product, biologics, parenteral delivery systems, and device/combination product manufacturing. Gaps in these areas remain a leading cause of audit observations and warning letters, often due to incomplete traceability, uncontrolled data access, or inadequate documentation practices.

■ ETHOS protects your organization from that risk.

It provides a **holistic, validated, and secure data environment** built for deterministic and non-destructive Container Closure Integrity (CCI) test methods across the full PTI technology portfolio.

■ Work performed in ETHOS is work performed in a validated space.

Every data point generated is secure, traceable, reviewable, and compliant by design reducing the likelihood of inspection findings related to data integrity, incomplete audit trails, or insufficient Part 11 controls.

What Makes ETHOS Different

■ A Unified Platform Across All PTI Technologies

Vacuum Decay, HVLD, Helium Leak Detection, Airborne Ultrasound, and Force Decay **are all supported within one software environment.**

One training model. One validation package. One audit story.

■ Secure SQL Server Database

All data is written directly to the database at the moment of test completion; it is **never stored temporarily or available for editing.**

- Records cannot be altered or deleted
- Database checksum validates data authenticity
- Immutable master records that support strong regulatory defense
- Eliminates common audit risks such as uncontrolled local file storage or editable intermediate results

21 CFR Part 11 Compliance Built-In



- **Electronic signatures** aligned to Review and Approve workflows
- **Comprehensive audit trail** capturing all software interactions, events, and alarms
- **Recipe revision history** with full traceability to users documented with timestamps
- User access managed and controlled through existing **Windows Active Directory**
- Compliant PDF reporting and **secure record export**

■ Designed for Simplicity

Operators interact with a **clear and intuitive interface**, with minimal time spent on software tasks. **Compliance is automatic.**

■ Regulatory Confidence, Operational Clarity

ETHOS establishes the assurance that **every test result can stand up to audit or inspection without the need for additional explanation, reconstruction, or justification.**

- No manual record manipulation
- No uncontrolled data pathways
- No ambiguous or incomplete documentation trails

Your data is **qualified, defensible, and ready for regulatory review.**

ETHOS provides a validated environment where critical quality decisions are made with consistency, confidence, and full data integrity. It is the secure foundation that supports reliable operations and reduces the risk of audit findings.



Key Functional Benefits

- Secure SQL Database with tamper-detection and authenticity verification
- Password and role-based access control managed through customer Active Directory
- Searchable and sortable repository for all test results to support efficient data review
- Customizable reporting aligned to internal SOP and quality system formats
- Electronic signatures that support formal review and approval workflows
- Comprehensive audit trails for all events, alarms, user actions, and recipe changes.
- Full validation documentation package available to support qualification and regulatory readiness

The Result

Regulatory clarity, compliance assurance, and operational trust.

ETHOS establishes a controlled, validated, and inspection-ready data environment. The data supporting your product quality is protected, immutable, fully traceable, and aligned to the expectations of 21 CFR Part 11 and global regulatory agencies. This reduces the risk of audit findings and strengthens the overall defensibility of your quality system.

Your data is your defense. ETHOS keeps it secure, reliable, and regulator ready

PC Technical Requirements

- CPU: i7 12th Gen or Later
- Memory: 16 GB Ram
- Hard Drive: 256 GB SSD
- Network: Dual 1GB Ethernet Connections
- Operating System: Windows 11
- Processor: 64bit
- Monitor Resolution: min 1920 x 1080

Specifications

FUNCTION	PTI STANDALONE	PTI ETHOS
External PC Required		✓
Password protected user interface	✓	✓
Support for Windows Active Directory		✓
Multi-level access to user key functions	✓	✓
User configured test recipes for customized test methods	✓	✓
User defined pass/fail criteria	✓	✓
Minimal operator training required	✓	✓
Measurements presented in human readable form	✓	✓
Data stored at time of measurement	✓	✓
Data stored in Secure Database		✓
Full audit trail of events		✓
Full recipe history of previous revisions		✓
All events date/time stamped		✓
Secure data viewer		✓
Electronic signatures for review and approve		✓
Searchable/sortable database of all reports		✓
PDF export functionality (Audit trail and recipe report can be exported as PDF. Batch report can be exported as PDF and Excel.)		✓
Secure transfer of all data from PLC to PC		✓
Full validation package available	✓	✓
21 CFR Part 11 compliant		✓