

The Autopol Advantage for Pharma Labs

Autopol polarimeters are designed for pharmaceutical labs that must meet FDA 21 CFR Part 11 requirements for electronic records and signatures. They deliver trustworthy, traceable, and secure data with built-in 21 CFR Part 11.



- Trustworthy , Traceable , Secure Embedded software
- Built for GMP / QC / Stability / Validation labs
- Closed system architecture with audit-ready records

What Pharma Customers Care About (And What to Say)

Customer Need

Autopol Answer

Secure Access & Roles

Control who can access, change methods, and approve results.

- Multi-level user access: Operator, Reviewer, Administrator
- Automatic lockouts & password aging on failed logins or expired passwords
- Only authorized users can access or modify data
- Compliant with 21 CFR 11.10 (a)(d)(g)

Validated, GMP-Ready Platform

Systems developed and validated under quality systems.

- Software & firmware developed under GMP quality systems
- Each system ships with IQ/OQ/PQ documentation
- Performance and accuracy tested prior to shipment

Complete Audit Trails & Immutable Records

Full traceability for investigations and inspections.

- Every measurement, calibration, or change captured in a secure, time-stamped audit trail
- Audit logs can be viewed, printed, or exported as password-protected PDFs
- Original data are never deleted — records are append-only
- Results automatically saved as password-protected PDF records

Network, LIMS & Enterprise Integration

Secure, integrated data flows; no manual transcription.

- Maps to secure network drives for automatic backups
- Direct export to LIMS or SAP / enterprise systems
- Operates as a closed system – data managed within the instrument/approved network
- Data export occurs only at session completion; once saved, data are finalized and locked
- Supports TCP/IP network integration for secure printing and backups
- Enterprise data integration while maintaining full audit control

Electronic Signatures & Workflow Control

Compliant e-signatures tied to users and actions.

- 21 CFR 11 mode with secure electronic signatures, unique per user
- Each signature includes name, date/time, and meaning (e.g., review, approval)
- Signatures are embedded in the PDF and cannot be altered or removed
- Guided workflow prompts for sample ID, lot number, and method parameters
- Calibration wizards verify temperature and optical settings before measurement

Long-Term Data Retention & Support

Records stay accessible and protected for full retention period.

- Designed for long-term data retention – compliant with 21 CFR 11.10 (b)(c)
- Training, manuals, and controlled documentation provided
- Automated audit backups and complete traceability
- Supports highest global regulatory standards



Rudolph provides a validated, 21 CFR Part 11- operational solution — secure access, audit trails, electronic signatures, and documentation. Your lab defines internal policies for electronic signatures, access control, and how systems are used day-to-day. It's a shared compliance model, aligned with 21 CFR 11.10 (i-k).



Active Directory Support on PC



Using a Rudolph Polarimeter and Software with a stand alone, Lab managed PC, allows utilization of Active Directory for Centralized Management: Active Directory Provides a single point for managing users, groups, computers, and other network resources. Authentication: Verifies user identities, such as checking a username and password, to ensure they are who they claim to be. Authorization: Determines what resources a user has permission to access after their identity has been authenticated. Security policy enforcement: Allows administrators to define and enforce security settings across the network from a central location.



Frequently Asked Questions

Current process & pain points

Walk me through how you're currently measuring and documenting your [optical rotation / sample] results. Where do you see the biggest frustrations or risks in that process?



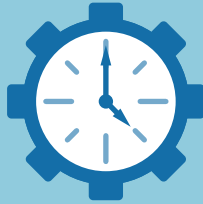
Compliance & audit risk

How do you currently handle 21 CFR Part 11 / data integrity requirements especially around user access, audit trails, and electronic records and where do you still feel exposed during an audit?



Validation & downtime

What does your validation and calibration routine look like right now how often do you run it, how long does it take, and what happens to your workflow while the instrument is unavailable?



Impact on the business

If a critical instrument failed calibration after you'd already released product, what would that mean for you in terms of investigations, rework, or batch risk?



Compliance Value Overview

Autopol polarimeters deliver full 21 CFR Part 11 support for pharmaceutical labs from secure access and validated software to unchangeable, audit-ready records and traceable electronic signatures. That means integrity, traceability, compliance, and confidence in every result.



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