OPTO 22

USING OPTO 22'S *groov* PRODUCTS IN 21 CFR PART 11 COMPLIANT ENVIRONMENTS

The U.S. Food and Drug Administration regulates the use of electronic records in life sciences manufacturing, including pharmaceutical and biotechnology operations, under Title 21 of the Code of Federal Regulations.

Part 11 outlines the requirements for using electronic records and electronic signatures instead of paper, including secure access, traceable operator activity, protected data storage, and the integrity of records used in regulated processes.

Opto 22's *groov* products are widely used in pharmaceutical and biotechnology facilities as secure and reliable sources of industrial data and control. When used in properly designed and validated systems, Opto 22 platforms support the electronic record, authentication, audit, and data-integrity requirements defined in 21 CFR Part 11.

Opto 22's Role in Validated Architectures

Opto 22's *groov* platforms—including *groov* EPIC, *groov* RIO, and *groov* RIO EMU—provide secure industrial connectivity, time-stamped data acquisition, and protected communication paths between process equipment and supervisory platforms such as SCADA, MES, and historians.

These capabilities provide the trusted industrial layer that supervisory systems rely on when implementing procedural and regulatory controls.

What This Means for Regulated Facilities

Opto 22 components operate within validated architectures where supervisory and enterprise systems implement the specific procedural and regulatory controls required by 21 CFR Part 11.

Authentication, audit trails, electronic signatures, and validation activities are managed in these systems according to established procedures, while Opto 22 ensures secure and trackable interaction with industrial equipment.

Key Enabling Capabilities

- Secure, authenticated communications using open industrial protocols (OPC UA, MQTT, HTTPS) with certificate-based TLS encryption supporting zero-trust cybersecurity principles
- Network-segmented architectures using modern firewall configurations and encrypted interfaces, supporting compliant isolation of regulated control systems
- Traceable and time-stamped industrial data at the point of acquisition, using authenticated NTP time-synchronization and protected communication paths
- Integration with enterprise authentication including LDAP/Active Directory and modern identity providers through supervisory platforms, enabling role-based access and secure control permissions
- Role-based authorization for control actions, ensuring that only authenticated sessions with the proper permissions can issue write commands or initiate equipment changes
- Reliable, secure delivery of audit-relevant industrial data to SCADA/MES/historian systems where electronic record retention and review take place

These capabilities allow regulated manufacturers to incorporate Opto 22's *groov* hardware into architectures that enforce the required controls for electronic records, signatures, audits, and regulatory data-integrity principles (commonly referred to as ALCOA+, meaning data must be Attributable, Legible, Contemporaneous, Original, Accurate, and also Available, Enduring, Consistent, and Complete).

Additional Reference Information

Opto 22 hardware and edge platforms integrate directly with common supervisory and enterprise systems used in regulated environments.

For more information about implementing 21 CFR Part 11 controls in SCADA and MES, refer to published guidance and technical documentation from supervisory platform providers such as Inductive Automation's Ignition Part 11 application-design white paper and Ignition Part 11 best practices.

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