Achieving Data Integrity In The Life Sciences Industry

Data management designed to simplify regulatory compliance and enhance trust

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WATLOW
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Data Integrity and the Life Sciences Industry

Rapid world growth, globalization, advanced technologies for Pharma 4.0 automation and data analysis trends, are emphasizing the need for high standards of data quality and integrity. Good data practices (GxP) will enrich the quality of data, enabling life science companies to make strategic decisions on batch release, based on trustable data and analytical insights.

The pharmaceutical and biotechnology industries closely regulate data production and storage to make sure that data cannot be modified without detection. Regulatory bodies such as the FDA and EMA, as well as global institutions and associations like the WHO, ISPE, PIC/S and local CDSCO, NMPA, MHRA, ANVISA, etc, emphasize the need for accurate measurement and secure storage of critical process and environmental parameters. If such storage mediums are electronic, then the methods used for controlling and monitoring of data should comply with regulations, for example FDA 21 CFR Part 11, to help ensure data integrity.

Lack of Data Integrity Could Lead To:

- Inadequate strategic data insights
- Audit warning letter
- Product scrutiny/suspension
- Import bans, forced recalls, plant shut down/ debarment
- Legal action
- Loss of reputation/public trust

Eurotherm Solutions For The Life Sciences Industry:

With specialist knowledge and experience in the life sciences industry, Eurotherm™ delivers solutions that help businesses to reduce the time and cost of regulatory compliance, throughout their manufacturing processes and supply chains. Our solutions and services help customers to efficiently manage the quality, the safety, and the authenticity of manufactured goods, through machine and process automation efficiency, high integrity data management, and an ISPE GAMP® 5 engineering approach with qualification and validation services.

Our Knowledge and Expertise Covers the Following and More:

- FDA 21 CFR Part 11
- EMA Annex 11
- Data Integrity ALCOA (+)
- ISPE GAMP® 5
- cGMP

From Simple Engineered Solutions to Plantwide Automation and Turnkey Projects

Data Management and Visualization

- Archiving strategies and storage solutions for data integrity
- Tamper resistant audit trails to aid regulatory compliance
- Dashboards and reports for simplified analysis and audits
- Security options – user management access/action control
- HMI solutions – from small panels to PC based workstations

Process Control

- Precision control strategies for process optimization
- Redundant solutions for high system availability
- Single loop or scalable modular designs to minimize capex
- Pre-developed solutions for a variety of applications

Power Control

- Energy saving control solutions for manufacturing machinery and environmental control systems such as HVAC
- Condition monitoring and notification for reducing maintenance time and costs
- Opex cost reduction through improved system design and reliability

Engineering and Services

- Project management – from specification and design to engineering, testing and installation
- Life Science ISPE GAMP® 5 engineering methodology
- Application expertise, technical support and training
- Calibration services
- Service Level Agreements and Global Alliance Agreements for improving plant efficiency and standardization

Data Integrity: ALCOA (+) Concept

Enhanced regulatory requirements demand that GxP critical records comply with the ALCOA (+) concept to maintain data integrity and quality. As a trusted advisor to the industry Eurotherm offers a range of solutions to help maintain data integrity throughout the data lifecycle.

Examples of How Eurotherm Data Management Solutions Address the Requirements of ALCOA (+) Guidelines:

Attributable
Who, when, what and why?

Risk: While sharing licenses can reduce system cost, it can violate the integrity of the metadata rendering it unattributable.

Remedy: Password protected accounts determine permission for which actions can be carried out by a user's role definition. Actions are logged within the audit trail, and the Security Manager feature can be linked to Microsoft® Active Directory for simplified and centralized user management.

Legible
Readable and permanent?

Risk: Paper records are susceptible to alterations and incorrect scaling of measured values. Tracking them can be complex.

Remedy: Process data and alarm history are digitally available in readable form for realtime and historical views via the HMI, recorder screen, Data Reviewer software, SCADA interface, data historian and reporting packages. Metadata, including audit trail information is also available for analysis, queries and periodic reviews.

Contemporaneous
At the right time?

Risk: Lack of time stamping measures can encourage backdating and exclusion of data.

Remedy: Process data and metadata (events, notes, messages, etc.) are automatically recorded at the time of the action against a timestamp. Recording devices can be synchronized across the system via connection to an SNTP (Simple Network Time Protocol) server.

Original
Unaltered state and 'true copy'?

Risk: Paper based records and data digitally recorded in CSV or TXT files can be easily edited and modified.

Remedy: Original process data and metadata are digitally recorded and stored in Eurotherm proprietary tamper resistant binary-checksummed file format (.UHH).

Accurate
Is it the right value/ action?

Risk: Hand written records, poorly positioned sensors and measurement drift in recording equipment can lead to data misinterpretation and inaccuracies.

Remedy: Recording digitally via high accuracy inputs, expertise in sensor positioning, and procedures to cover instrument loop calibration and validation, help to confirm that values read are representative of the actual process conditions.

(+)

Complete
Is all information available?

Risk: Values and actions recorded in different places, and communication dropouts during recording or archiving can lead to missing raw data/metadata.

Remedy: Process data and operator actions are recorded in the same data file as part of an audit trail feature. Storing data initially in the recorder device, combined with a 'Store and Forward' feature, improves data capture reliability.

Consistent
Is the sequence correct?

Risk: If not timestamped, the recording sequence and data audit trail cannot be relied upon.

Remedy: Data is recorded chronologically, with the date and time stamp in the expected sequence. Process data, alarms and events stored in the UHH files can be viewed as a trend via Data Reviewer software, where inconsistencies or missing data are evident.

Enduring
Is it securely stored for long term use?

Risk: Paper trails can get lost or disintegrate over time.

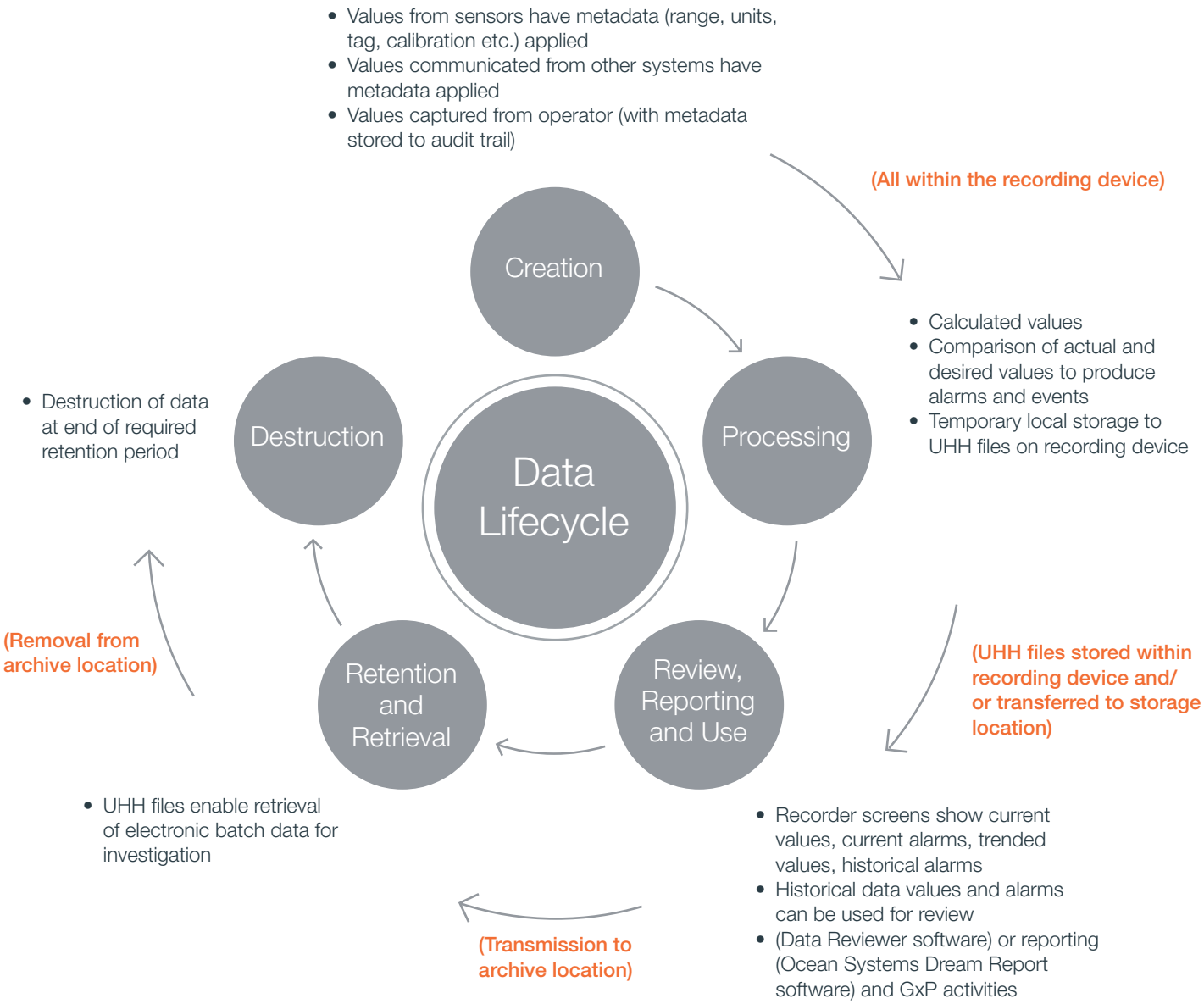
Remedy: Digitally recording data in a file format with long term compatibility retrieval support helps to ensure data is available from historian databases years after it is recorded.

Available
immediately?

Risk: Retrieving data from paper trails or multiple archives can be time consuming.

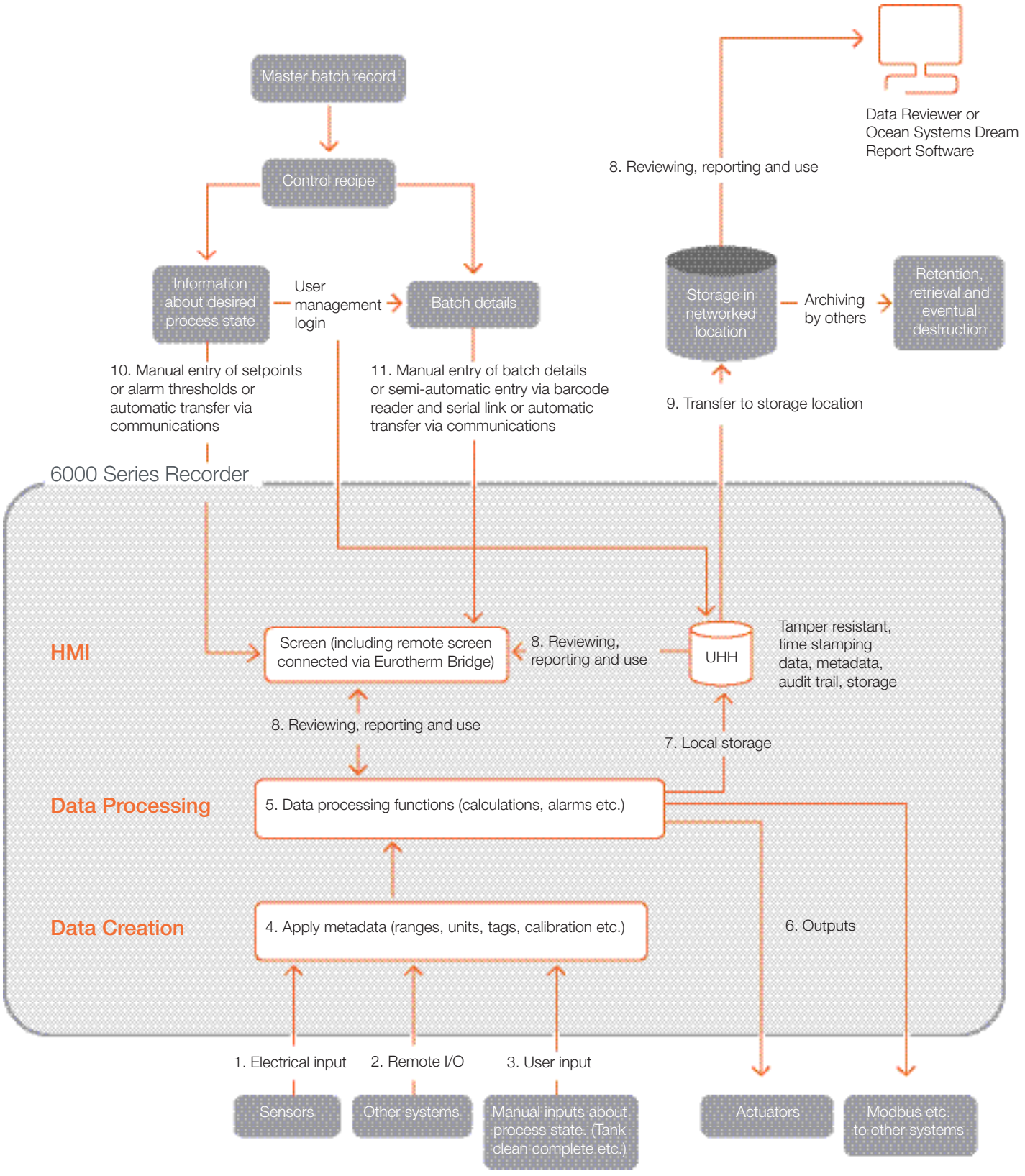
Remedy: High availability system architecture, including uninterruptible power supplies (UPS) and redundant instrumentation, servers, historians and communication networks enable fast retrieval of data. Data Reviewer software can access data quickly by batch code, recorder/group name or time/date.

The Data Lifecycle of a Eurotherm Recorder



Data Flows – Within Recorders and Associated PC Tools

The diagram below illustrates eleven data flow paths within the data lifecycle, using the Eurotherm 6000 Series Data Recorder as an example.



Data Integrity Risk Analysis Examples – Threats and Mitigations

The following table shows potential threats related to data integrity for path 1 in the data flow diagram as an example, and how they can be mitigated based on the example of a 6000 series data recorder.

Creating Data Points Based on Electrical Signals From Sensors

Possible Threats to Data Integrity	Mitigations Through Technical Controls Within Recorder/PC Tools	Mitigations Through Procedures
Electrical noise on the physical input	• Electromagnetic compatibility standards compliance • Application of software input filters	• Good installation practices • Verification of adequate filtering during initial validation
Invalid signal (due to sensor or wiring fault)	• Provision for sensor types that can distinguish wiring faults from low range signals • Fault condition indication via alarms • Signals can be set to fail high or low	• Use of sensor types that can distinguish wiring faults from low range signals • Verification during initial validation, that alarms to indicate fault conditions are functioning correctly, and that fail high/low requirements are met
Invalid signal (due to incorrect settings on smart instruments)	• Built in calibration functionality	• Calibration of entire smart instrument measurement loop
Accidental/deliberate changes to sensor and transmitter set up/read outs		• Physical security and change control processes on sensors/transmitters (logical security on smart sensors)
Poor accuracy of measured value	• Accuracies stated in documentation for each input type • Built in calibration functionality	• Determination of required accuracy/ resolution • Calibration of entire measurement loop
Accidental/deliberate changes to the way measured value is processed	• Password-based access controls on range/calibration settings etc. • Change control processes, supported by automatic versioning and audit trail	• Use of appropriate security procedures • Change control processes on data recorder configurations • Audit trail review
Manipulation of time stamping in recorder	• Can be synchronized using SNTP • Password-based access control for clock setting	• Verification of time synchronization during initial validation • Appropriate use of access permissions

Data Management, Acquisition and Control Solutions

Environmental Monitoring Systems

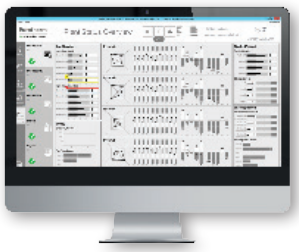
Monitoring of laboratories and manufacturing/storage environments using Eurotherm recording solutions with industry-leading input accuracy of 0.1% of reading (when subject to the necessary field calibration).

- Can lower capex and opex due to segregation of the Environmental Monitoring System (EMS) from the Building Management System (BMS)
- Can reduce capex using preset ISPE GAMP® 5 validation document templates and built in functions to meet Category 3 and Category 4 only
- Scalable cost-effective architectures to suit the application site size
- Optional redundancy can include the processor, I/O, power, communications, servers and historians, offering high availability of the process
- Store and Forward feature to help meet Data Integrity ALCOA (+) principles

SCADA Systems

Specialized features in Eurotherm Operations Server/Viewer and Eurotherm Wonderware® PAC software enhance HMI visualization software and system platform technology, aiding compliance to FDA 21 CFR Part 11.

- Distributed alarm management, historical data, centralized alarm printing, etc.
- Engineered displays tailored to meet the needs of FDA 21 CFR Part 11
- The Eurotherm product range includes input measurement accuracy of 0.1%
- Precision control to help meet tight tolerances
- Tamper resistant data/alarm/action recording and audit trail to help meet FDA 21 CFR Part 11 and Data Integrity ALCOA (+) principles
- Enhanced user management linked to Microsoft Active Directory to manage signature/approval operations
- Can reduce capex using preset ISPE GAMP® 5 validation document templates



T2750 Programmable Automation Controller

Provides high-performance control and recording with high availability options in a versatile modular format.

- Offers Distributed Control System (DCS) performance
- Analog, logic and sequential control with alarm management
- High precision control/high accuracy measurement
- Cost effective redundancy option and ‘Hot-Swap’ modules
- Local data/alarm recording option and Store and Forward feature helps to meet Data Integrity ALCOA (+) principles
- Can reduce capex using preset ISPE GAMP® 5 validation document templates and built in functions to meet Category 4 only
- Achilles Level 1 certification for communication robustness and enhanced cybersecurity

Eycon™ Visual Supervisor

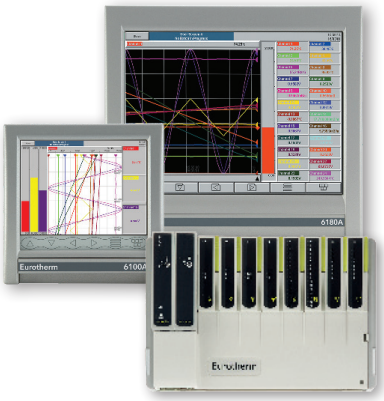
Combines Eurotherm expertise in control, data acquisition and process automation into a single process management unit.

- Continuous and sequential control with alarm management
- Built in HMI providing comprehensive functionality in one device
- User management
- Batch management and recipe capability
- Tamper resistant recording/audit trail function
- Simple to use pop-up navigation menu
- Aids compliance to FDA 21 CFR Part 11 regulation and Data Integrity ALCOA (+) principles

6000 Series and versadac™ Recorders

6000 Series graphic recorders and versadac scalable modular recorders offer tamper resistant data file formats, audit trail, user management and batch features for traceability of the process.

- Functions for calculating MKT (Mean Kinetic Temperature) and Steam Flow
- Functions for monitoring sterilization processes, including F0 calculation for parametric release
- Password-controlled user access and electronic signatures provide event traceability for quality approvals and audits aiding compliance to FDA 21 CFR
- Part 11 regulation and Data Integrity ALCOA (+) principles
- Security Manager option for centralized access control
- Can reduce capex using preset ISPE GAMP® 5 validation document templates and built in functions to meet Category 3 only
- Secure File Transfer Protocol (SFTP) client and server for enhanced cybersecurity robustness



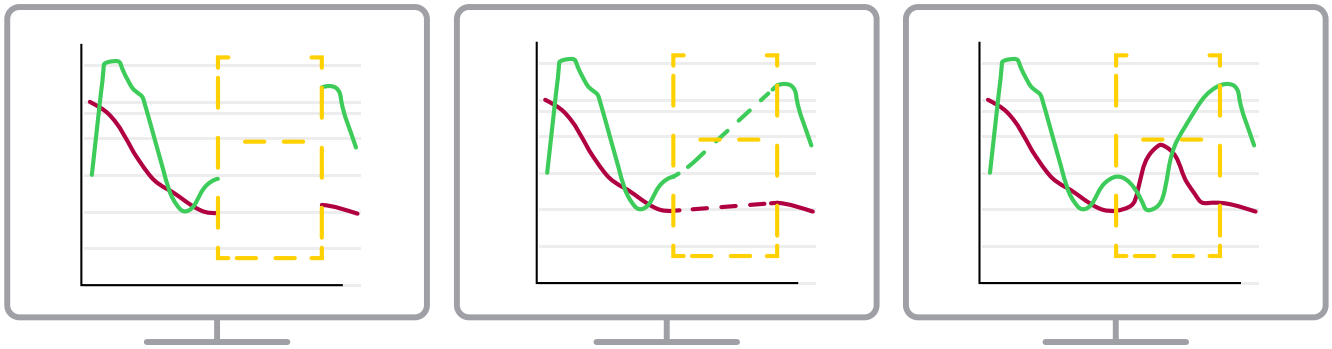
nanodac™ Recorder Controller

A compact 1/4 DIN recorder with precision PID control option.

- Digital batch recording and electronic signatures aid compliance to FDA 21 CFR Part 11 regulation and Data Integrity ALCOA (+) principles
- Can reduce capex using preset ISPE GAMP® 5 validation document templates and built in functions to meet Category 3 only
- Batch recording option
- Functions for monitoring sterilization processes
- Calculation functions for relative humidity, steam flow and mass flow
- BACnet™ Ethernet protocol for efficient integration into BMS systems
- User access features for enhanced cybersecurity robustness

Store and Forward

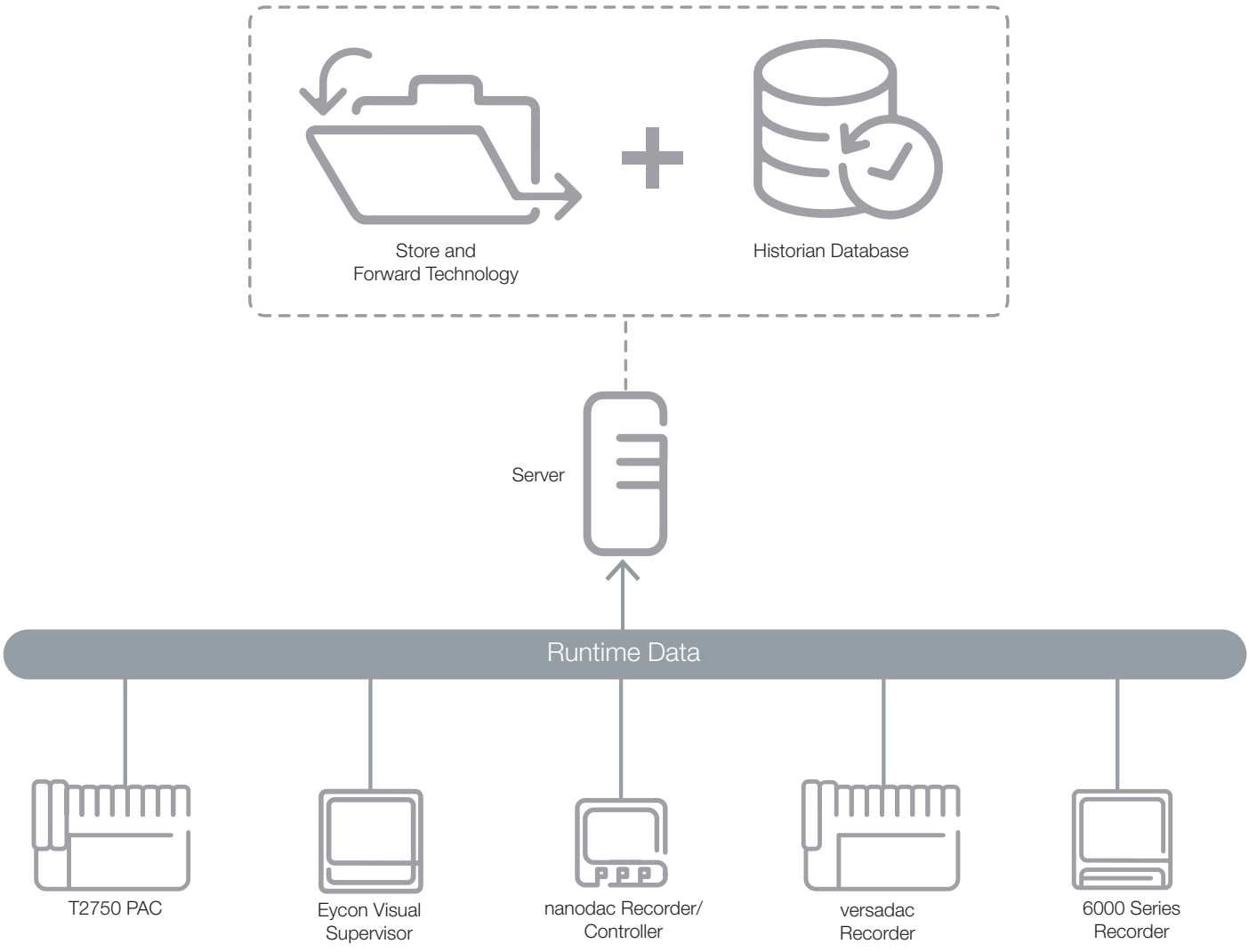
Eurotherm recording products record data at the point of measurement for archiving later, reducing the risk of data loss if the server or communications are temporarily lost. When used in harmony with a historian database, the Eurotherm Store and Forward feature aids reliability of archiving, by reconciling any missing data to storage databases when communications are resumed. This supports the ALCOA (+) data integrity concept by providing original, attributable data that is contemporaneous, consistent and complete.



Incomplete data can cause a data integrity issue

This data cannot be inferred

Store and Forward reconciles the data



Historian Database

A typical historian database combines advanced data storage and compression techniques with an industry-standard query interface, offering long term access to process, alarm, and event data. It enables faster, more informed decision making and insights into operational performance.

- Minimizes the risk of data loss in critical processes
- Offers fast real-time and historical data access for Enterprise Resource Planning (ERP) systems
- Provides audit trail for periodic review
- Data volume controlled to minimize storage space
- Long-term data storage, analysis and reporting
- High availability through redundancy and disaster recovery options for improved business continuity
- Historian architecture can be hosted in the cloud

Eurotherm Data Reviewer

Eurotherm Data Reviewer is a software application designed for the viewing, analysis and printing of historical data files obtained from Eurotherm data acquisition equipment.

- Find and analyze data quickly, including by instrument group or batch
- Supports electronic signatures in accordance with FDA 21 CFR Part 11 and Data Integrity ALCOA (+) principles
- User management options for defining role based permissions
- Supports Microsoft Active Directory integration

Ocean Systems Dream Report

Ocean Data Systems (ODS) Dream Report software supplied by Eurotherm is an integrated industrial automation solution designed to extract data from multiple sources for easy creation and distribution of reports and dashboards.

- Manual and automatic Secured PDF report generation for batch and continuous processes
- Setpoint analysis, process statistics and auto-validation of processes
- User management module for defining user access rights and localizing languages
- Web portal for viewing and interacting with reports

Pharma 4.0 Ready Technology

Eurotherm control and data recording solutions are IoT ready, providing a data integrity layer within open IoT platform system architectures and aiding the digital transformation to Industry 4.0 technology.

Discover how to get more from your life science manufacturing operations at **eurotherm.com/life-sciences**

Eurotherm India Private Limited

Tamarai Tech Park, SP Plot# 16-20 & 20A
Thiru Vi Ka Industrial Estate
Inner Ring Road, Guindy,
Chennai, Tamil Nadu
600032
India
Tel: (+91 44) 42240000

www.eurotherm.com

Contact your local sales representative

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