Efficiency Solutions for the Life Science Industry

Eurotherm®

Optimizing Control, Operations and Regulatory Compliance

- Solutions that aid compliance to 21 CFR Part 11
- Over 50 years experience in life sciences
- From small applications to plant wide solutions

eurotherm.com/life-sciences

WATLOW®
Powered by Possibility

Maximize the Value of Your Plant

Eurotherm™ provide a range of products, engineered solutions and services throughout the world. Our expertise in Life Sciences allows us to supply solutions that suit the scale of your manufacturing requirements, while maximizing efficiency, productivity, and ultimately your return on investment.

Aiding Compliance to 21CFR part 11

- World-class measurement accuracy and precision control performance
- Tamper resistant data recording
- Batch functionality with automatic tracking and traceability
- Products designed to minimize GAMP classification time and costs

Scalable Systems and Services, Built on Application Expertise

- Delivery of engineered solutions, including: design, project management, installation and commissioning
- International engineering teams with application knowledge and automation expertise
- Proven scalable solutions enable rapid time to market from lab to pilot plant to full production
- Solutions include features that help to meet FDA 21 CFR Part 11 regulations
- A range of services offer complete life cycle support to help protect your investment, including training, calibration, consultancy, technical/engineering support and SLAs (Service Level Agreements)

Reduce Validation Efforts

Eurotherm understands the importance and complexity of validation and can reduce the cost, time and confusion of regulatory processes.

- Validation services offer efficient, cost effective compliance to regulations and GAMP guidelines
- Hundreds of successfully validated solutions globally
- Experienced, knowledgeable international teams

Case Studies

Tamper Resistant Data Recording Provides Evidence of Correct Environmental Storage

Pharmaceutical products need to be stored within a carefully controlled environment. Warehouse temperatures and humidity levels must not exceed specified limits, and details of variations must be logged in a tamper resistant format to meet FDA guidelines. Eurotherm recording solutions store data in digital tamper resistant file formats within internal memory. The data can be used to initiate alarms for fast remedial action and to review parameter deviations. Maths functions also enable automatic calculation of key values such as Mean Kinetic Temperature (MKT) for day-to-day reporting purposes.

A Cost Effective Validated Control Solution

A complete Eurotherm solution including GAMP 5 validation services was supplied for four intermediate production reactors at a new manufacturing plant. The control system included operation servers, process supervision running a redundant strategy, visual supervisor, scalable I/O and a variety of other measurement and instrumentation devices. Combined with Eurotherm validation services this solution provided bespoke, cost effective, simplified compliance to good manufacturing practice procedures.

Faster GAMP/FDA Validation Utilizing Eurotherm Validation Documentation

Eurotherm GAMP 5 (Cat.3) templates greatly reduced validation time for the IT Manager and Process Chemist of a small Life Science Laboratory. Over one week's preparation work was saved before validation of the recorder began. Total work time was reduced from an estimated 70 hours for two people, to just 20 hours for the entire system.

> *Eurotherm products are user friendly and easy to configure which helped us with our GMP requirements. We use many products across the site, including PACs (Programmable Automation Controllers), Recorders, Scalable Recorders and SCR (Silicon Controlled Rectifier) Thyristors.*

OEM Engineer

Optimize Operational Efficiency and Compliance

Eurotherm is a leading global supplier of industrial process control, measurement and data management solutions and services. Established in 1965, the business has over 50 years of knowledge and experience within the life science segment, with a proven global track record of providing pharmaceutical and biotech solutions.

Our market leading control algorithms and data management strategies add value to industrial processes by improving production efficiency and quality, while allowing data to be stored for as long as it is needed.

Eurotherm addresses many of the common problems found within the life science segment today including:

- Regulatory compliance requirements
- Accuracy, precision, and repeatability performance
- Security and traceability
- 24/7 operability

Eurotherm offers an enhanced range of products, solutions and services which contribute to a future ready pharmaceutical plant.

Power Distribution

MV/LV power with built-in safety and efficiency features.

Power & IT
- MV & LV Distribution
- Building Optimization
- Access Control & Security

Software Solutions

State-of-the art software solutions for improved production flexibility, better yield and consistent quality – leading to better business performance.

Software
- Manufacturing Execution System
- Batch Control
- Asset Management

Building Management Solutions

21 CFR Part 11 compliant BMS & EMS solutions, with the potential to integrate with process controls.

Buildings
- HVAC & Environmental Control
- Building Optimization
- Access Control & Security
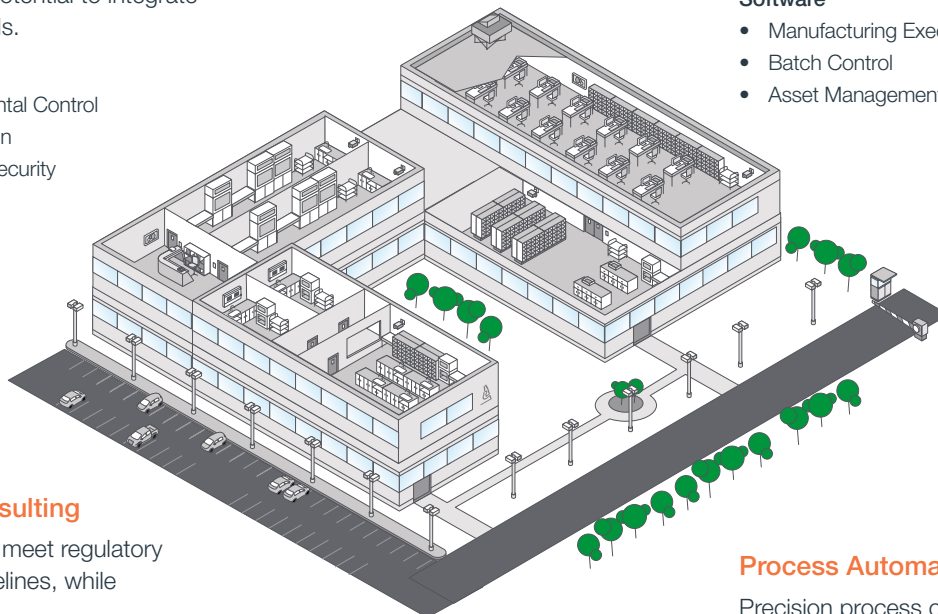
Compliance Consulting

Enabling facilities to meet regulatory standards and guidelines, while mitigating risks.

Consulting and Services
- GAMP Validation Services
- Calibration and Accreditation Services
- Compliance Programs
- Cyber Security Programs

Energy & Sustainability Services

Improving the sustainability of operations and reducing energy consumption by up to 30%.

Energy Services
- Energy Saving Power Control Products and Systems
- Reporting & Benchmarking of Carbon Emissions, Energy Usage and Costs
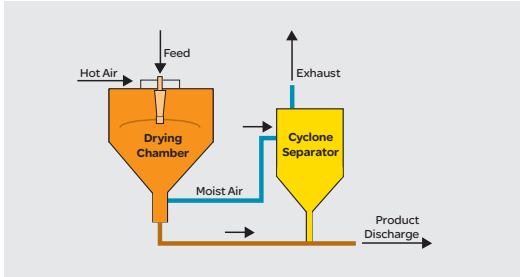
Process Automation

Precision process control and advanced data acquisition solutions that meet the stringent requirements of life science applications.

Products, Systems and Services
- Distributed/Machine Control Solutions
- Controllers, Data Recorders, PACs and PLCs
- Engineered Solutions (Design, Installation and After Sales Services)

Control and Validation Solutions for a Broad Range of Applications

Autoclaves and Sterilize-In-Place (SIP) Processes

- Precision control and monitoring
- Batch control
- Indication of pass/fail status
- Local, custom graphic displays for operator ease of use
- Tamper resistant data recording, and automatic reporting

Water Purification for Use in Pharmaceutical and Biochemical Processes

- Precise control of parameters using setpoint profile programmer
- Sequential control for sanitation/sterilization
- On-screen operator messaging
- Duty/standby pump control strategy for high availability of the pumping system
- Tamper resistant data recording for reporting

Fermentation Processes

- Precise control of temperature, pressure, pH, DO, Redox, agitation and foam parameters using setpoint programmer
- Sequential control for sanitation and sterilization
- Batch control and recipe management
- Alarm management
- Tamper resistant data recording for analysis and reporting

pH Control of Water and Other Solutions for Use in Boilers, Fermenters, CHP (Combined Heat and Power) and Water Treatment Plants

- Precise loop control and autotuning provide fast response to pH changes
- Gain scheduling provides PID sets to deal with non linear titration curves
- Optional smith predictor algorithm for tighter control of the pH level

Spray Drying Processes

- Precise loop control
- Easy to use setpoint profile programming
- Recipe management for efficient parameterization
- Sequential control for complex control strategies
- Tamper resistant data recording for analysis and reporting
- Local operator display with clear graphics

Freeze Drying Machines
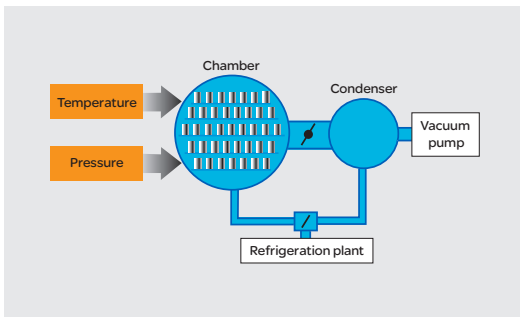
- Precise temperature control with ramping
- Sequential control of temperature, vacuum and the refrigeration plant
- Redundant strategies to help minimize scrap product in the event of a process interruption
- Alarm management and data recording for analysis and reporting

Tablet Coating Machines
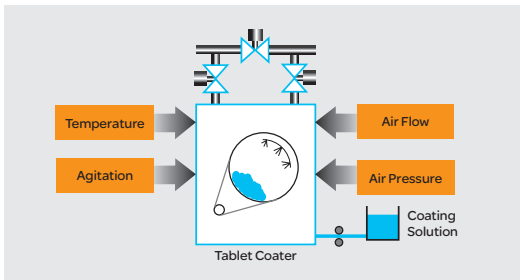
- Batch recording and recipe selection
- Precision control for repeatability in the loading, dosing, and coating environment
- Setpoint programming
- Coating system data recorded in tamper resistant files by batch, for analysis and reporting

Hydrogenation Process
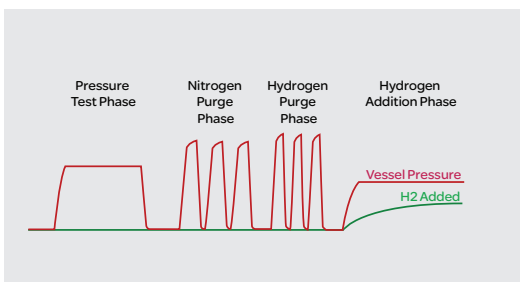
- Sequential control for vessel pressure testing, purging and hydrogen addition
- Precise control of temperature and pressure
- Process data recorded in tamper resistant format for reporting
- Local operator display with clear graphics and controlled user access

Environmental Monitoring Systems

Control and monitoring of storage and production environments are very important within the Pharmaceutical Industry. The FDA, MHRA, EMEA and other regulatory bodies require accurate measurement and storage of environmental parameters and, if the storage medium is electronic, the methods used must comply with FDA 21 CFR Part 11.

Traditional Methodology

In the past, it was common to have one system doing both the control (BMS) and monitoring (EMS) of a plant. As a result, the entire system needed to meet GMP guidelines and thus, needed to be validated. This not only increased the initial CAPEX but also increases OPEX, due to re-validation of the EMS when frequent changes need to be made to the BMS.

Current Trends

Over the last ten years however, there has been a shift to separate the BMS from the EMS as suggested by the ISPE. The immediate benefits include:

- Significant reduction in validation effort
- Changes made to the BMS do not affect the EMS
- Unscheduled stoppage of BMS does not affect EMS functionality
- Allows for independent parameter sensing if desired

Electronic Records with Auditor Options

Eurotherm Auditor and Security Manager options enable the management and recording of operator access in time-stamped tamper resistant file format. Operator activity including logins, signature details, batch stop start, alarm acknowledgements and configuration changes are logged and recorded in a historian database, providing the information required for good manufacturing practices, quality approvals and regulatory audits.
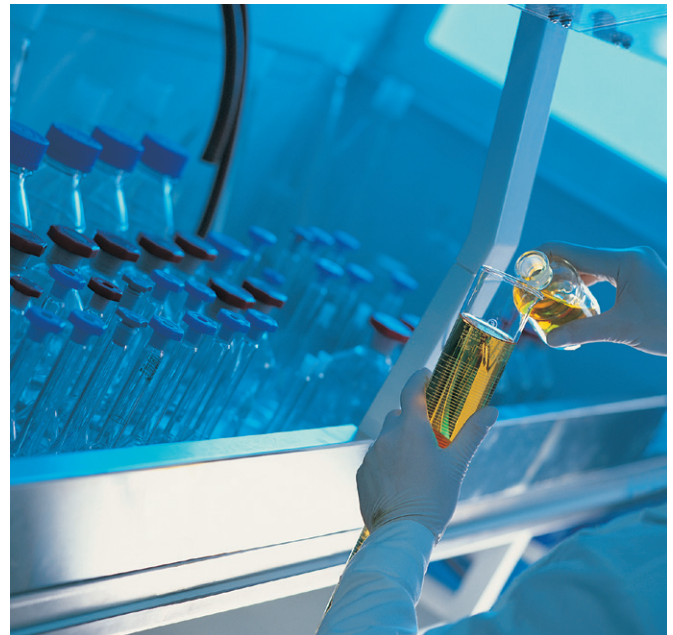
What Differentiates a Eurotherm Based EMS Solution from Others?

- Accurate monitoring of data with industry leading 0.1% input accuracy
- Lower validation costs due to separation from BMS, and availability of GAMP validation templates
- Our solutions are based on scalable cost effective architectures to suit the application
- Optional redundancy can include the processor, I/O, power, communications, servers and historians, offering high availability of the process
- Data recorded in a tamper resistant, high integrity format with store-and-forward functionality, offers high data reliability for regulatory auditing purposes

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We felt, right from the start of this project, that the proposed EurothermSuite Visual Supervisor solution could be ideally suited to meeting the requirements of the new life science laboratory. It provides capabilities normally inherent within considerably more expensive DCS solutions and represents a much lower-risk option than PLC/ SCADA architectures, where computer validation and 21 CFR Part 11 compliance were considered more difficult. In addition, Eurotherm demonstrated its commitment to the project by assigning highly competent project management and engineering personnel within their team. Application requirements were reflected accurately within high-quality design documentation fully compliant with GAMP requirements. The attention to detail at this stage contributed to successful code implementation and customer acceptance testing.

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OEM Engineer

Data Management, Acquisition and Control Products

Features of the Eurotherm product range include input measurement accuracy of 0.1%, precision control to help meet tight tolerances, and tamper resistant data recording that aids compliance to 21 CFR Part 11 with regard to electronic records and signatures.

Supervisory System

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

- Distributed alarm management, historical data, centralized alarm printing, etc.
- Engineered displays tailored to meet the needs of 21 CFR Part 11

T2750 Programmable Automation Controller

Provides high-performance control and recording with cost-effective redundancy options in a versatile modular system.

- Analog, logic and sequential control
- Alarm management

6000 Series and Versadac™ Recorders

6000 Series graphic recorders and Versadac scalable modular recorders offer tamper resistant data file formats, Audit Trail, Security Manager and Batch features for traceability of the process.

- Functions for calculating MKT (mean kinetic temperature) and Steam Flow
- Functions for monitoring sterilization processes
- Password controlled user access and electronic signatures provide event traceability for quality approvals and audits

Eurotherm 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

nanodac™ Recorder Controller

A compact 1/4 DIN recorder with PID control built in.

- 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

Historian with Store and Forward Technology

All Eurotherm recording products record data at the point of measurement for archiving later. When used in harmony with a historian database, if communications are interrupted during archiving, Eurotherm Store-and-Forward technology automatically backfills data to the historian when communications are available.
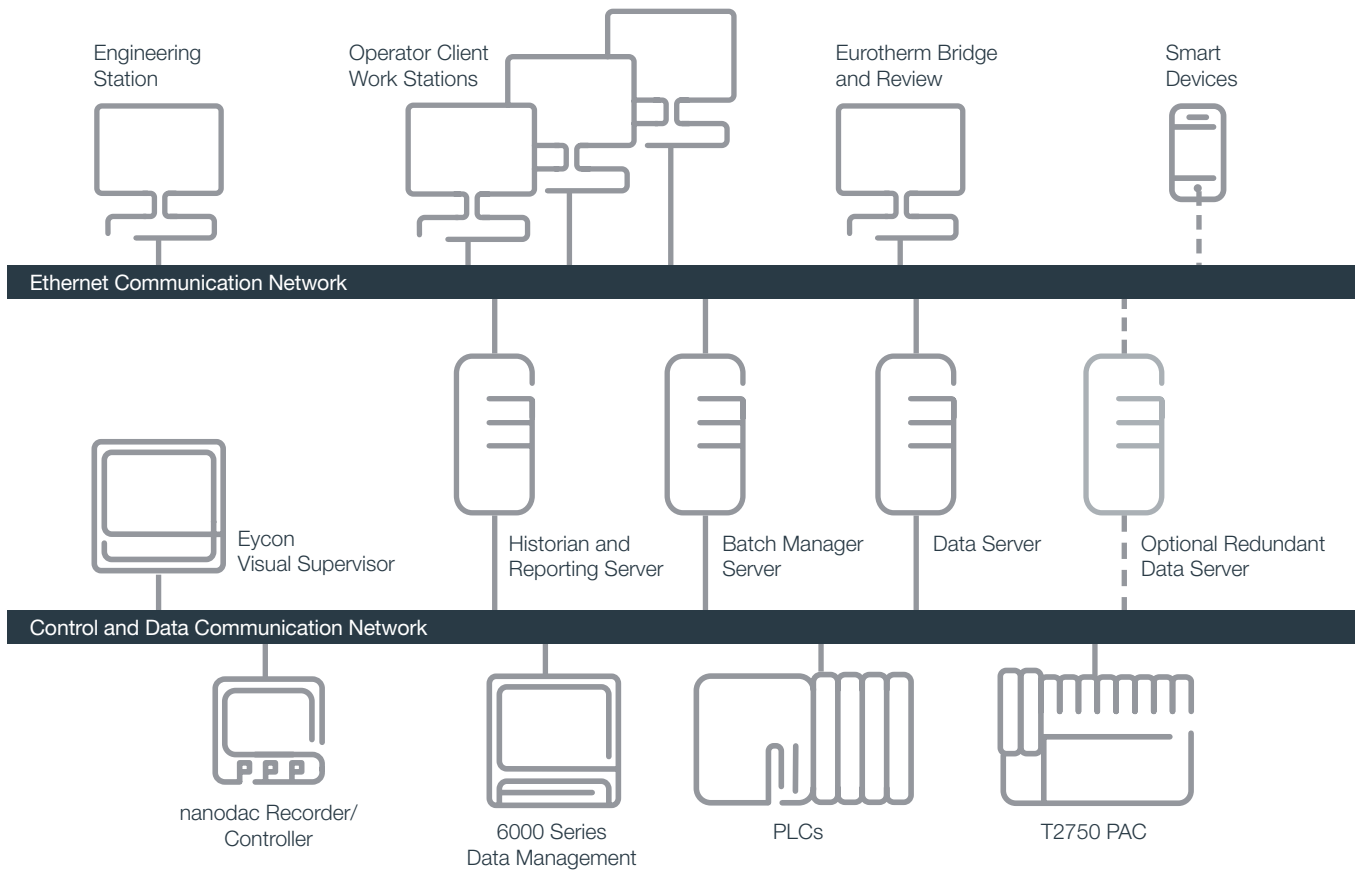
- Minimizes the risk of data loss in critical processes
- Offers fast real-time and historical data access for ERP systems
- Data volume controlled to minimize storage space

Scalable Solutions

The entry level architecture is based on Eurotherm self contained recorders. Data is recorded at the point of measurement for archiving later via removable media or to single or multiple FTP servers. Data can be easily accessed by quality personnel using Eurotherm Review software, for calculations such as Mean Kinetic Temperature (MKT).

For cost-effectiveness and expandability, the Simplex architecture is an excellent solution for warehouses, critical equipment and small production areas where a manual data recording backup system might have been considered. A mix of local recorders (nanodac, 6100, 6180, Versadac) and blind distributed I/O devices can easily be integrated on the same network with either an Eycon Visual Supervisor interface or Eurotherm Operations Server/Viewer with HMI visualization software. This architecture offers a step-by-step, automated, paperless electronic data recording system. A historian client can be added to provide sophisticated data analysis and reporting, while Eurotherm features within Operations Server/Viewer and Wonderware PAC software extend HMI visualization software and system platform functionality by simplifying validation, aiding compliance to 21CFR Part 11, and enhancing operator effectiveness.

High availability architecture including redundant instrumentation, servers, power and communication networks, as well as store and forward technology, can be implemented in critical applications where data must not be lost. This integrated scalable solution helps to meet demanding requirements, while minimizing maintenance costs and validation efforts.

Engineering Station • Operator Client Work Stations • Eurotherm Bridge and Review • Smart Devices

Ethernet Communication Network

Eycon Visual Supervisor • Historian and Reporting Server • Batch Manager Server • Data Server • Optional Redundant Data Server

Control and Data Communication Network

nanodac Recorder/Controller • 6000 Series Data Management • PLCs • T2750 PAC

Contact your local sales representative

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