Life Is On | Eurotherm by Schneider Electric

Life Science Solutions

Enabling our customers with future ready solutions for the factory of tomorrow

- Solutions meet 21 CFR Part 11 compliance
- Over 50 years of experience in Life Sciences
- From small application to plant wide monitoring solutions

eurotherm.sg/life-sciences

Reduced Validation Efforts

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

- Hundreds of successful validated solutions globally
- Global experienced, dedicated, and specialist teams
- Built-in 21CFR Part 11 features
- GAMP5, category 3 classification on our data recorders
- GAMP templates for suitable hardware

CASE STUDY

One of Eurotherm's customers performed GAMP/FDA validation on a 6000 Series recorder using Eurotherm validation CD.

The IT Manager and the Process Chemist spent 20 hours validating their system. They had nothing but good words to say about the validation documentation from Eurotherm. It saved them over a weeks work in preparation alone before they even sat down with the recorder. They estimated it would have taken over 70 hours of work for two people without the Eurotherm validation documentation.

Measured value for your money

Eurotherm is committed to developing products and services specifically for the Life Sciences industry continually minimizing cost and maximizing productivity.

- Consultancy services ensure you get exactly what you need
- Consultancy to help reduce validation time, costs and confusion
- Complete life cycle support Lifetime service level agreements to protect your investment
- A complete range of services designed to provide you with the best value from your system:
  - Installation
  - Commissioning
  - Training
  - Calibration
  - Technical support

CASE STUDY

Eurotherm Spain implemented a valuable contract to supply "Servier Laboratories Service" with a control system for controlling 4 intermediate production reactors at their new manufacturing plant. The control system includes two EurothermSuite Operation Servers, one T940 Process Supervisor (redundant strategy engine), one Eycon Visual Supervisor, twelve 2500 I/O system and Foxboro M&I. One of the key success factors for getting this order was offering a complete solution including validation services.

Lowered production costs

Eurotherm provide engineered solutions throughout the world. Our hardware and software expertise can provide you with a solution to match your manufacturing requirements and maximize efficiency, productivity and ultimately your return on investment.

- Automation and application expertise and experience
- World-class accuracy of control and secure data recording
- Delivery of proven solutions
- Scalable solutions – from lab to pilot to full production
- Rapid time to market
- Batch control with automatic tracking and traceability

CASE STUDY

Once pharmaceutical products have been manufactured, and prior to their despatch, they need to be stored within a carefully controlled storage environment. Within the warehouse, temperature and humidity levels must not exceed specified limits, and details of actual variations in these key parameters must be logged in a tamperproof format to meet FDA guidelines.

Eurotherm solutions are capable of automatically calculating Mean Kinetic Temperature (MKT). In order to permit calculation of mean kinetic temperature (MKT) for reports, each channel will have an associated daily maximum and minimum value, which is then grouped and averaged for all sensors in the warehouse. Individual sensors can be automatically removed from the MKT calculation (for example, when selected for calibration or on a fault condition) by holding the maximum and minimum channels at the last 'good' value.

Customer Testimonial

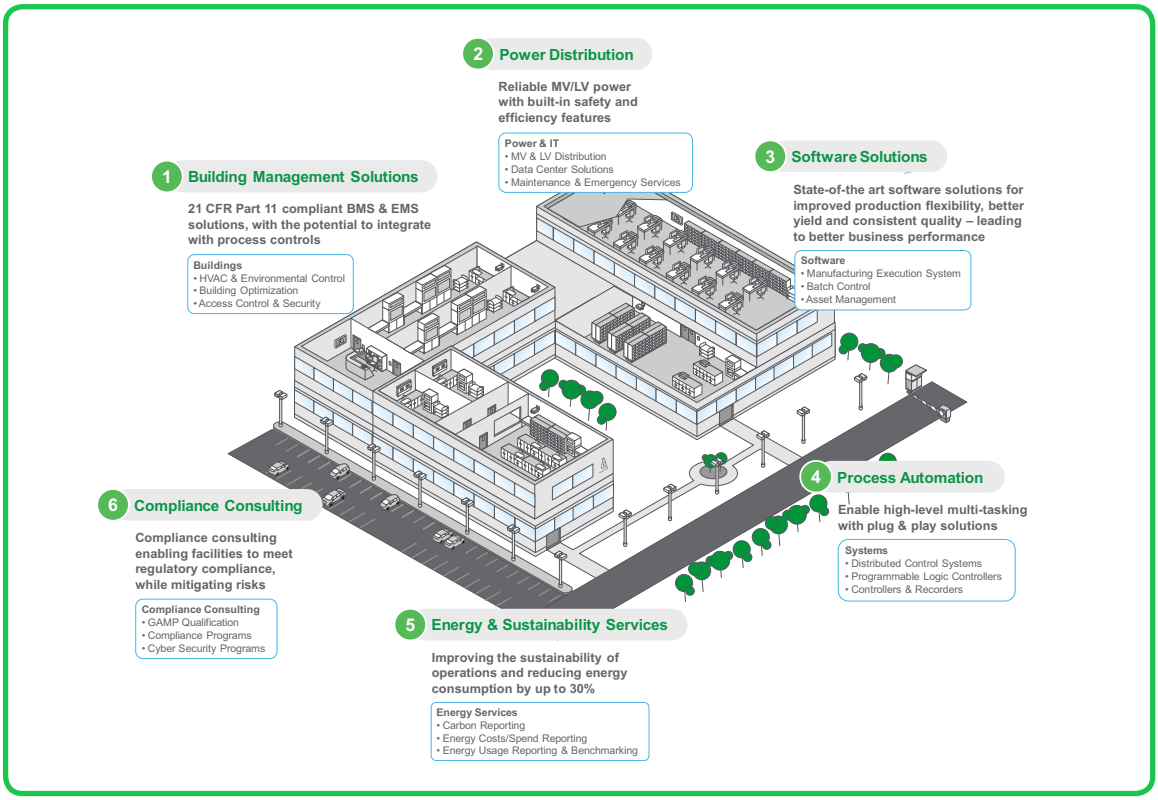
"Products are user friendly and easy to configure and they have helped us with our GMP requirements. We use many Eurotherm products across the site, including; T2750, 6000 recorders, Versadac Scalable Recorder and SCR Thyristors."

Project Manager, Multinational Indian Life Science Company

Optimise the Control and Operations of your Life Science Facility

By combining the understanding of our customers' needs with the passion of technological innovation, Schneider Electric offers an enhanced range of products & services which contribute to a true future ready pharmaceutical plant of tomorrow. Our comprehensive portfolio includes:

- Building Management Solutions – Complete Building Management Systems (BMS) and 21CFR Part 11 compliant Environmental Monitoring Systems (EMS)
- Power Distribution – Reliable MV/LV power with enhanced efficiency capability
- Software solutions – HMI and plant automation software designed to connect plants and enhance overall performance
- Process Automation – Precise process control and data acquisition products to meet the stringent requirements of various life science oriented tasks and applications
- Energy & Sustainability Services – Consulting service which can deliver up to 30% cost savings in each plant
- Compliance Consulting – Meeting regulatory compliance standards can be difficult and complex. Our expertise in compliance standards minimizes the burden.



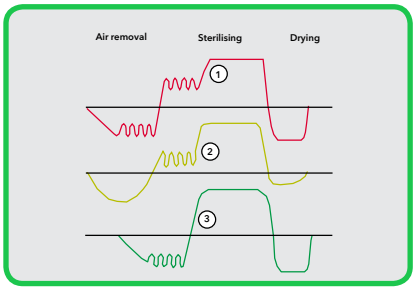
As part of the Schneider Electric business, Eurotherm is a leading global supplier of industrial and process control, measurement and data management solutions and services. Established in 1965, the Eurotherm business has over 50 years of knowledge and experience within the life science segment and have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

Our range of products contain both market-leading control algorithms and recording and data management strategies which both add value to industrial processes to improving quality and ensuring data is kept safe for as long as it is needed. Additionally, 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

Typical Life Science Application Customer needs

Sterilization Process (Autoclaves)

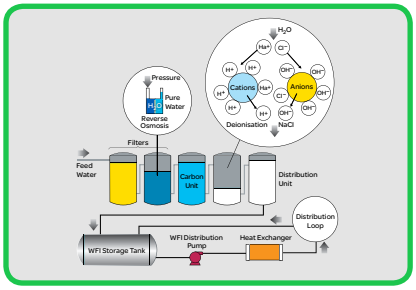


Requirements:

- Autoclave control and monitoring
- Batch control and reporting
- Pass/fail indication
- Local, custom graphic displays
- Secure data collection

Heat generated through application of high temperatures acts by disrupting membranes and denaturing proteins and nucleic acids. Transmissible agents (such as spores, bacteria and viruses) can be eliminated through sterilization.

Water Purification

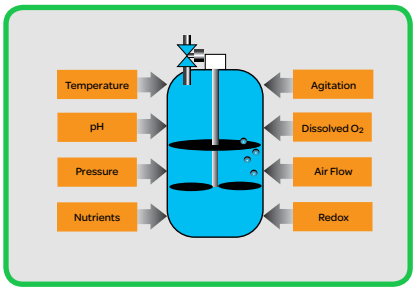


Requirements:

- Precise loop control with setpoint profile programming
- Sequential control for sanitation / sterilization
- Onscreen operator messaging
- Duty/standby pump control
- Secure data recording

Water purity is extremely important to pharmaceutical and biochemical industries. Suspended or dissolved particles, organic compounds, impurities and other contaminants prohibit the usage of tap water in laboratory applications and scientific research.

Fermentation Process

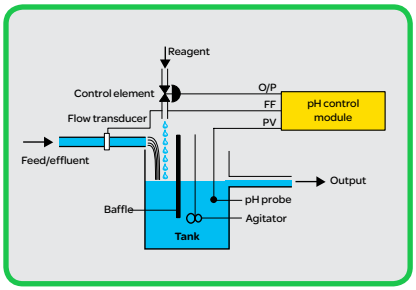


Requirements:

- Precise loop control
- Sequential control for vessel sterilization
- Recipe management with easy parameterization
- Batch control and reporting
- Setpoint programming
- Alarm management
- Secure collection of on-line data from the fermenter system or analysis

Fermentation is widely used within the Pharmaceutical and Food industries. It requires the cultivation in submerged culture of an identified microorganism (mainly bacterial) as a monoculture under defined environmental conditions. The incubation regime imposed is designed to maximize the productivity of the organism of interest by providing optimal conditions for population growth (biomass).

pH Control



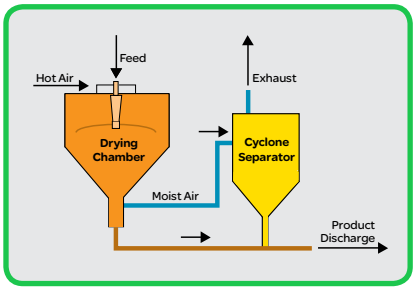
Requirements:

- Precise loop control with gain scheduling
- Smith predictor algorithm
- Non-linearity of the titration curve
- Process dead time

Process systems using water such as boilers, CHP plants and water treatment plants, or systems using any types of solution such as those in fermenters, must be designed to take into account the control of pH.

Typical Life Science Application Customer needs

Spray Drying Process

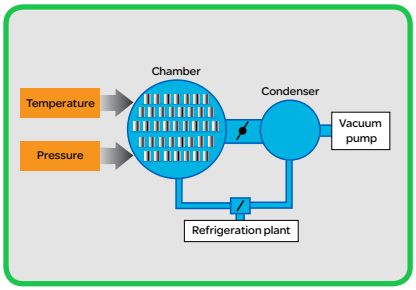


Requirements:

- Precise loop control with setpoint profile programming
- Recipe management system for easy parameterization
- Sequential control for complex control strategies
- Secure data recording for analysis and evidence
- Local operator display with clear graphics

The challenges facing both designers and users are to increase production, improve powder quality and reduce costs in the spray drying process. This requires an understanding of the process and a robust control implementation.

Freeze Drying

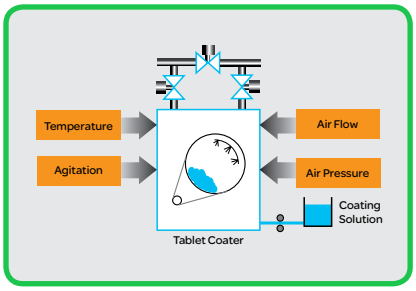


Requirements:

- Precise temperature control with ramping
- Sequential control of temperature, vacuum and the refrigeration plant – both for freeze drying and sterilization
- Safety strategies (i.e. redundancy) to minimize product damaged in the result of plant failure
- Alarm management & data recording for analysis and evidence

Freeze drying is a slow batch process used in pharmaceutical & biochemical industries to extract dry product from an aqueous solution. The product is usually in phials placed on shelves in a vacuum chamber, which is first frozen and then evacuated. The shelves are then warmed up very slowly, boiling off the liquid, whilst the chamber is continuously evacuated through a cold condenser. Once above zero degrees the chamber isolation valve is closed and a 'Pressure Rise Test' is performed to ensure the product is dry.

Tablet Coating

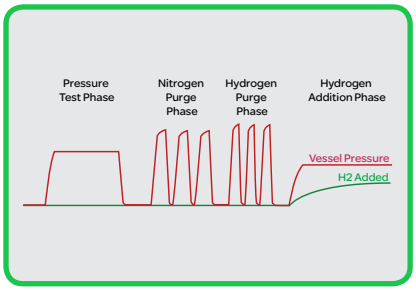


Requirements:

- Batch identification and recipe selection (film or sugar coating)
- Loading/dispensing (accurate dosing of required raw materials)
- Accurate, repeatable control of the coating environment
- Setpoint programming
- Secure collection of on-line data from the coating system for analysis and evidence

Many solid pharmaceutical dosage mediums are produced with coatings, either on the external surface of tablets, or on materials dispensed within gelatin capsules. Ideally, the tablet should release the material gradually and the drug should be available for digestion beyond the stomach. The coating can be specially formulated to regulate how fast the tablet dissolves and where the active drugs are to be absorbed into the body after ingestion.

Hydrogenation Process



Requirements:

- Sequential control for vessel pressure testing
- Purging and hydrogen addition
- Precise loop control for temperature and pressure
- Secure data collection from the hydrogenation process
- Local operator display with clear graphics and controlled access

Hydrogenation is the chemical addition of hydrogen to a hydrocarbon in the presence of a catalyst, a severe form of hydrogen treating.

Environmental Monitoring Systems

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 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 increases the initial CapEX associated with validation but will ultimately increase OpEX due to the consistent engagement with QA and validation when frequent changes to the BMS needs to be made.

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:

- Significantly reduced validation effort
- Changes made to the BMS to no affect the EMS
- Unscheduled stoppage of BMS does not affect EMS functionality
- Allows for independent parameter sensing if desired.

What differentiates an EMS solution from Eurotherm?

An EMS solution from Eurotherm ensures the following:

- Accurate monitoring of data with industry leading 0.1% input accuracy
- Reduced validation costs due to reduced scope and available GAMP templates
- Offers the most cost effective solution in part to our various architecture offerings
- Optional redundancy to include the processor, I/O, Power, and communications
- Secure and reliable data with tamper resistant, high integrity data and true store and forward functionality.

Customer Testimonial

“We felt, right from the start of this project, that the proposed EurothermSuite/Visual Supervisor solution could be ideally suited to meeting therequirements of the new LSL facility. 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 21CFR part 11 compliance were considered more difficult. In addition, Eurotherm demonstrated its commitment to the project by assigning highly competent project management and engineering ersonnel within their team. Applications 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.”

Chris Southan, Lead Control and Instrumentation Engineer at Jacobs.

Data Management, Aquisition and Control Products

Supervisory System – Operations Server/Viewer: provides a single integrated view of your system. The software enables the engineers, supervisors, managers and operators to view and communicate with the workings of your entire operation through graphical representations of your production process. The software provides a host of features including distributed alarm handling, distributed historical data, centralised alarm printing, etc.

- Aids 21 CFR Part 11 requirement
- Engineered displays tailored to meet the needs of BMS/EMS
- System wide availability of information
- Client Server architecture with master/backup servers
- Uses Wonderware InTouch

Historian – Information Manager: combines the power and flexibility of a relational database with the speed and compression of a real time historian package. The information manager is up to 300 times faster than a conventional relational database but only uses 2% of the disk space normally required by a conventional relational database.

- Aids 21 CFR Part 11 requirement
- Captures and stores all EMS data
- Realtime and historical data can be made available to enterprise
- Minimises storage space and controls volume of data
- Uses Wonderware Historian

T2750 Programmable Automation Controller: provides high-performance control and recording with cost-effective redundancy options in a versatile modular system. Capable of continuous analog, logic and sequential control that is paired with redundant 21 CFR Part 11 data recording, batch management, and true store and forward functionality at point of measurement. Aids 21 CFR Part 11 for electronic records.

- Cost effective redundancy
- Continuous and sequential control
- Hot swap I/O
- Alarm handling
- Wide range of I/O: PRT, TC, 4-20mA, 0-10V, mV, etc.
- Industry leading accuracy of 0.1% input

Eurotherm EyconTM Visual Supervisor: provide innovative, multi-function control, recording and visualisation – bringing Eurotherm's expertise in control, data acquisition and process automation into a single process management unit.

- Aids 21 CFR Part 11 requirement
- Logging with "Store & Forward"
- Accurate continuous and sequential control
- Alarm handling
- Communications including Modbus, Modbus TCP, OPC, Profibus

Recorders: adaptable functionality incorporated into the 6000A instruments will meet the most demanding of solution requirements. With their ease of use and configuration, you can be sure to maximise your return on investment.

- Aids 21 CFR Part 11 requirement
- Multiple logging media
- Remote viewing with Bridge
- Maths function
- Industry leading accuracy of 0.1% input

The versadac™ scalable recorder offers a versatile solution for data recording at point of measurement. Comprehensive security and data integrity make it ideal for use in regulated industries.

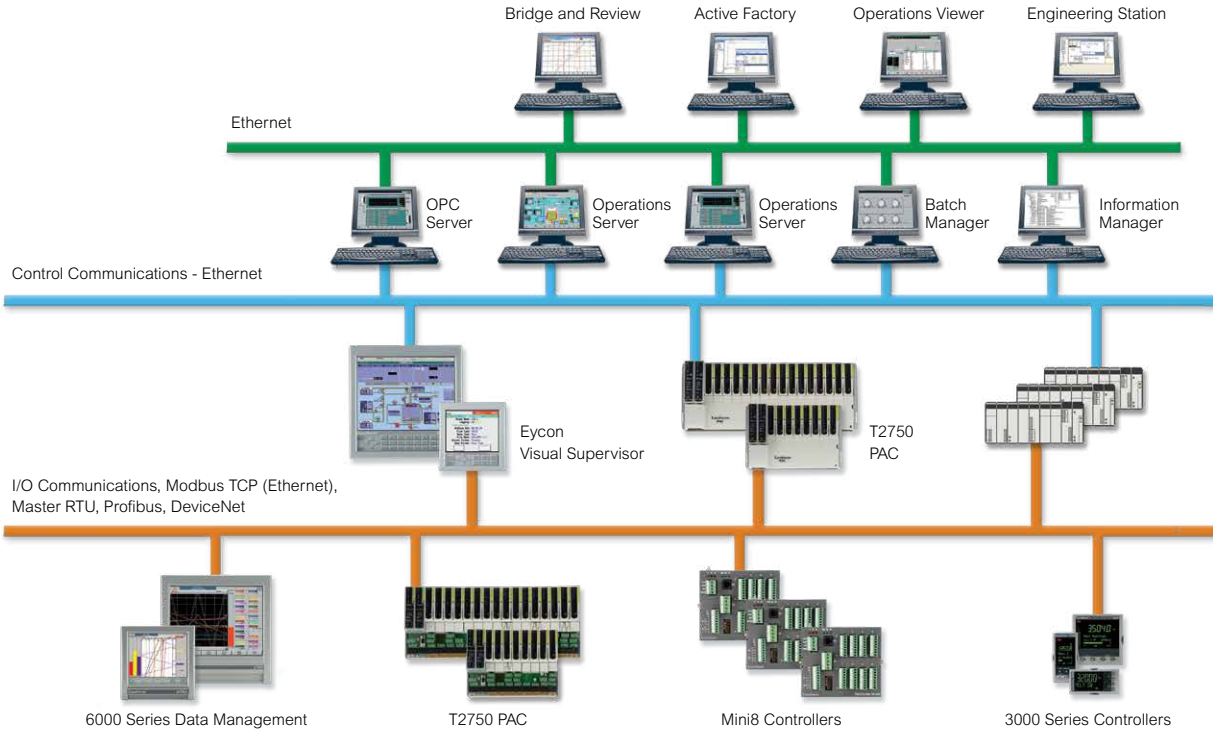
Sensors: communicate measurement and status information from the process to the control and monitoring modules of the EMS system.

Sensors supported by Eurotherm solutions include:

- Temperature
- Luminescence (light level)
- Gas Level
- HVAC healthy status
- Relative humidity
- Particle counter
- Air pressure or differential pressures
- and many others

Scalable solutions

The Entry Architecture is designed to be the starting point for systems typically with less than 150 points of I/O (and redundancy not required), Eurotherm Recorders are 21 CFR Part 11 compliant, self-contained devices. The high-quality input boards are designed for high precision, repeatability and stability and data can be easily accessed by Quality and used for complex calculations such as Mean Kinetic Temperature (MKT).



This Simplex Architecture is designed for cost-effectiveness and expandability and 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 and blind distributed I/O devices can easily be integrated on the same network with either an Eycon interface or WW InTouch® HMI. This architecture is a step-by-step, fully automatic, paperless electronic data recording, system. Historian offers the most sophisticated data analysis and reporting, while InTouch® provides operators with confidence

Redundant Architectures are used where critical data cannot be lost under any circumstances This setup takes full advantage of redundant servers for InTouch® connected to cost-effective redundant Eurotherm PAC units. One Historian Server will meet reporting requirements, with data safe thanks to Store and Forward self-healing data archiving. This integrated solution balances the need to meet demanding requirements while controlling maintenance costs and validation efforts.

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INVESTORS IN PEOPLE

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