Reducing compliance costs in the life sciences industry

Eurotherm®

Fermentation Process Solutions

Eurotherm™ provides 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 helping to maximize efficiency, productivity, and ultimately your return on investment.

Our solutions support regulatory compliance and help create a safer world.

Compliance

We empower our customers to help maintain regulatory compliance and minimize audit costs by providing a Data Integrity layer with open IoT platforms that support the digital transformation to Pharma 4.0.

Safer world

Specialists in managing critical data and contextual metadata to efficiently manage the quality, the safety and the authenticity of the manufactured goods.

We have application expertise in:

- Control and sequencing
- Recipe management
- Batch control and reporting
- Setpoint programming
- Bespoke graphics
- Alarm management
- FDA 21 CFR Part 11 and EudraLex
- Annex 11 compliance
  - User management
  - Electronic signatures
  - Audit trail
- Data Integrity ALCOA (+) concept
- ISPE Gamp® 5 guidelines
  - Engineering qualification/validation
- System lifecycle support services

eurotherm.com/life-sciences

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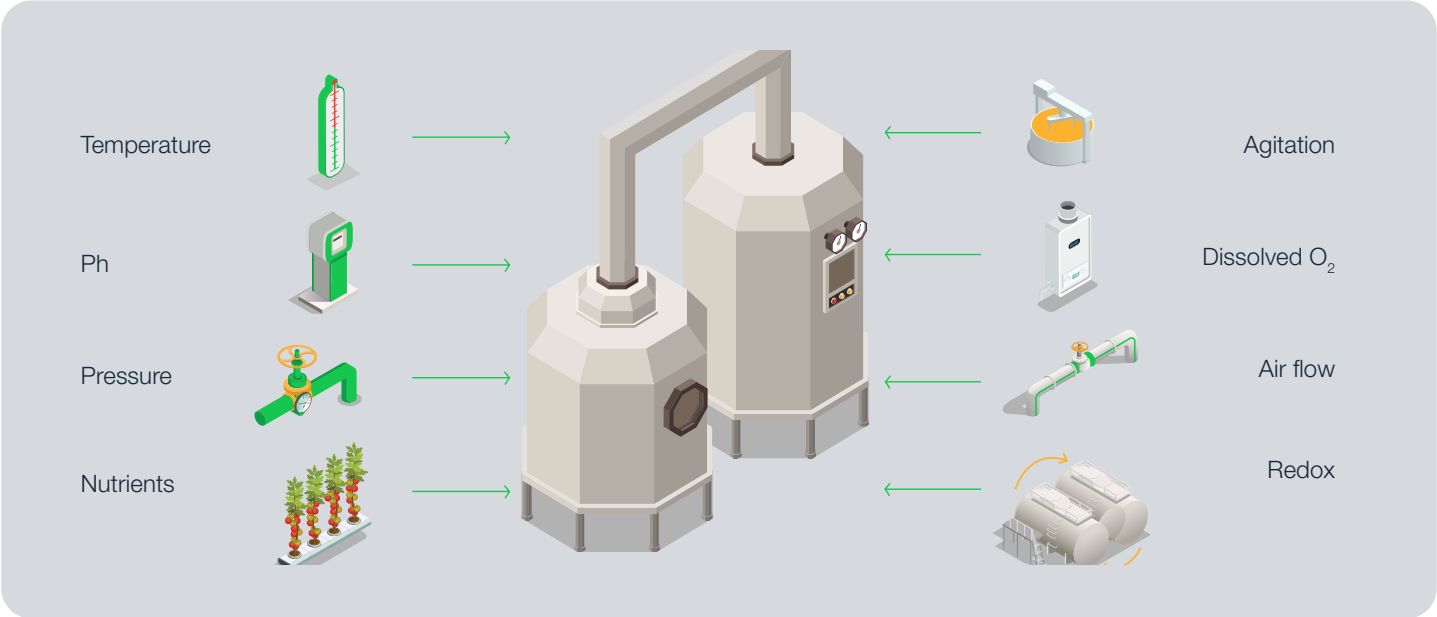
Fermentation process overview

Fermentation is widely used within the pharmaceutical, biotechnology, and food & beverage 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). The product of interest might be a bioactive metabolite, an enzyme, a vitamin, or recombinant protein. During an incubation cycle, a nutrient energy source (e.g. glucose) is added and the biomass and end product will increase as this is depleted.



Fermenter design and control

Incubation control necessitates the precise control of several parameters. Of primary importance are: Temperature, pH, DO_2 or redox, agitation, pressure, foam, and auxiliary feed.

The control of these and any other parameters is most usually carried out in fermenter vessels specifically designed for the purpose, and accommodating various working volumes depending on the yield and production requirements. Laboratory scale vessels could have a capacity of just 10 liters or less, whereas production vessels may be as large as several thousand liters. The smallest units may incorporate an electrical heater, and feedstock (e.g. nutrient and pH control agents) may be fed from flasks via peristaltic pumps. Larger vessels have an integral jacket for controlling temperature via hot or cold water and allowing indirect sterilization using injected steam. Where larger quantities of feedstock are required they may be held in separate pressurized tanks and fed in via valves arranged to work as a ‘thrust pump’. The actual fermentation process is known as the Incubation Phase and is just part of the batch cycle.

A complete fermentation cycle can typically include the following steps (depending on vessel design):

- Sterilization of empty vessel and pipework using direct steam injection
- Charging with base medium
- Indirect sterilization via steam injected into the vessel jacket
- Cooling of vessel and draining of jacket
- Pre-inoculation – vessel environment under control
- Inoculation – injection of a small sample of the monoculture
- Incubation – the fermentation process itself
- Harvesting – product removed ready for extraction processes

R&D clinical trial and biotechnology environments (in which many small-scale fermenters operate) are such that it is not always possible to predict the nature of a fermentation process; either in terms of culture or incubation conditions. Production facilities must also cater to a variety of products, each having precisely defined incubation profiles

Therefore, a control system needs to provide flexibility in the way that accurate and repeatable control of the fermentation environment is achieved, and should include the following features:

- Precise loop control with setpoint profile programming
- Recipe Management System for easy parameterization
- Sequential control for vessel sterilization and more complex control strategies
- Secure collection of on-line data for analysis, archiving and reporting e.g. to support batch release
- Local operator display with clear graphics and controlled access to parameters

Eurotherm solution:

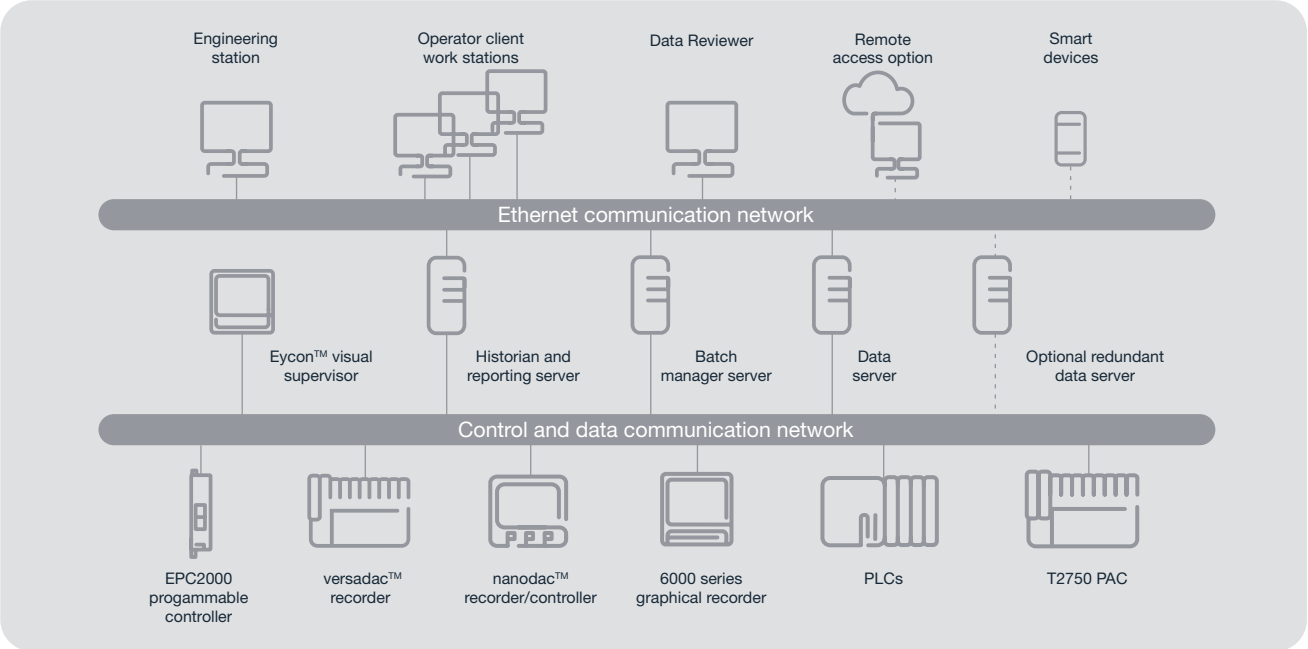
- Small/medium Distributed Control System
- Precision control strategies
- Batch/recipe management
- Digital data management
- Power control for electric heaters
- HMIs from local panels to full SCADA solutions
- High availability architecture (Redundant solutions and 'Store and Forward' feature)
- Local operator display with clear graphics and controlled access to parameters
- Data analysis
- Historian and reporting server
- Reporting

FDA 21 CFR Part 11 and EU EudraLex Annex 11 regulations compliancy

Fermentation plants are used in industries likely to require compliance with regulations and guidelines from the FDA, EMA or other applicable regulatory organizations (CDSCO, NMPA, etc.). With a long history in precision process control and high integrity data management, Eurotherm has a broad range of knowledge and expertise in life sciences, helping customers to comply with their Data Integrity related standards.

Data Integrity ALCOA (+) guidelines

Key regulatory bodies (FDA, EMA, WHO) and some advisory bodies (PIC/S, ISPE) have agreed on the Data Integrity related ALCOA (+) concept. ALCOA defines that data should be Attributable, Legible, Contemporaneous, Original and Accurate. In addition to ALCOA, guidance has gone further with ALCOA (+) to help ensure data is Complete, Consistent, Enduring, and Available. As an experienced automation supplier, well established in life science processes, Eurotherm was an early adopter of that vision and contributed to the definition and the revision of some of these guidelines.



ISPE GAMP® 5 Guide: A risk-based approach to compliant GxP computerized systems

To help secure your investment and ease future audits of your plant, Eurotherm has developed a proprietary set of Qualification/Validation documents according to the V-model from the ISPE GAMP® 5 guidelines. These proven documents, used in hundreds of audits, help to reduce risks associated with Qualification/Validation operations: helping to minimize your qualification effort and reduce your capex and opex throughout the lifetime of your installation.

Pharma 4.0 ready technology

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

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