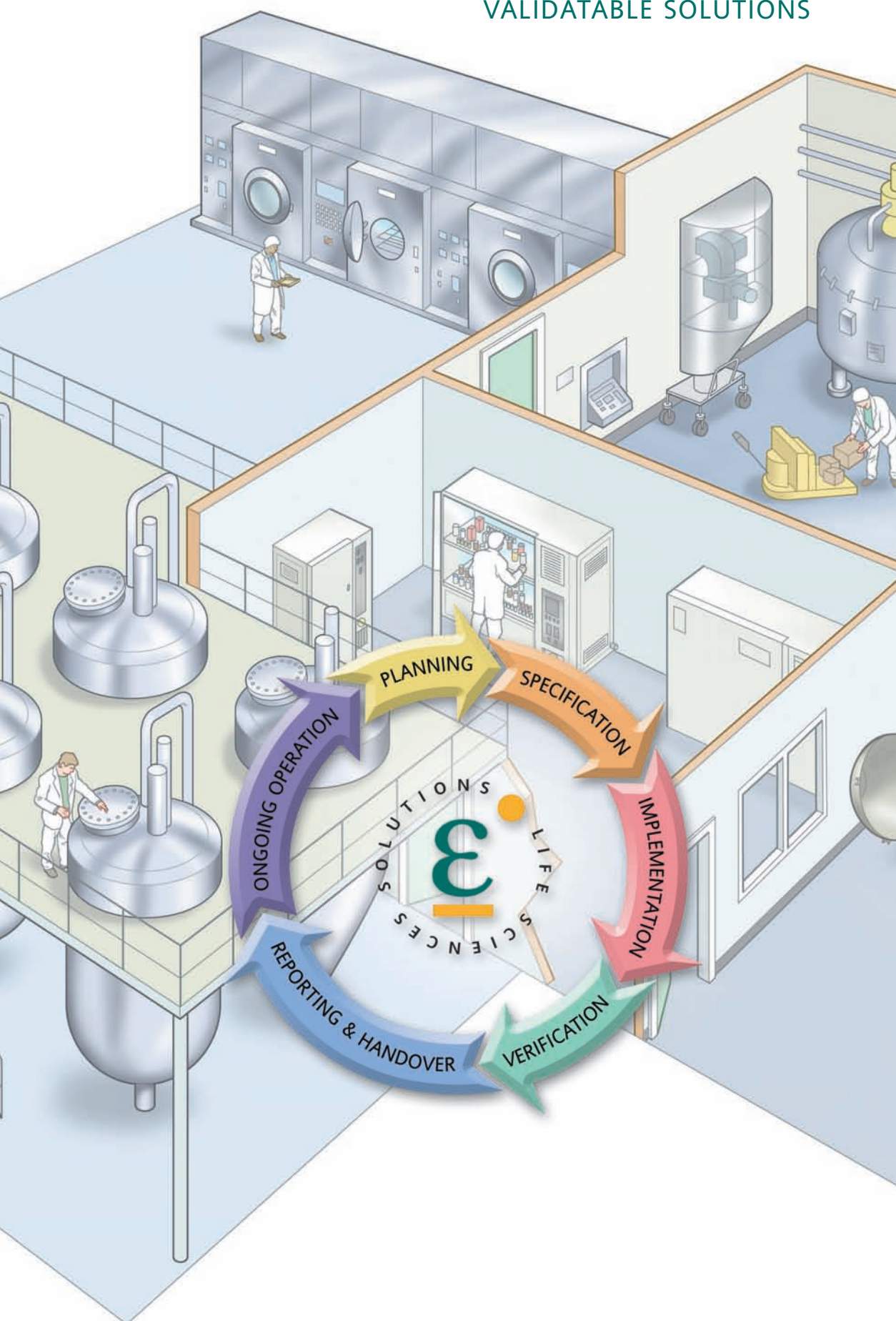


EUROTHERM® FLEXIBLE SOLUTIONS

Life Sciences

LEADING THE WAY IN
VALIDATABLE SOLUTIONS

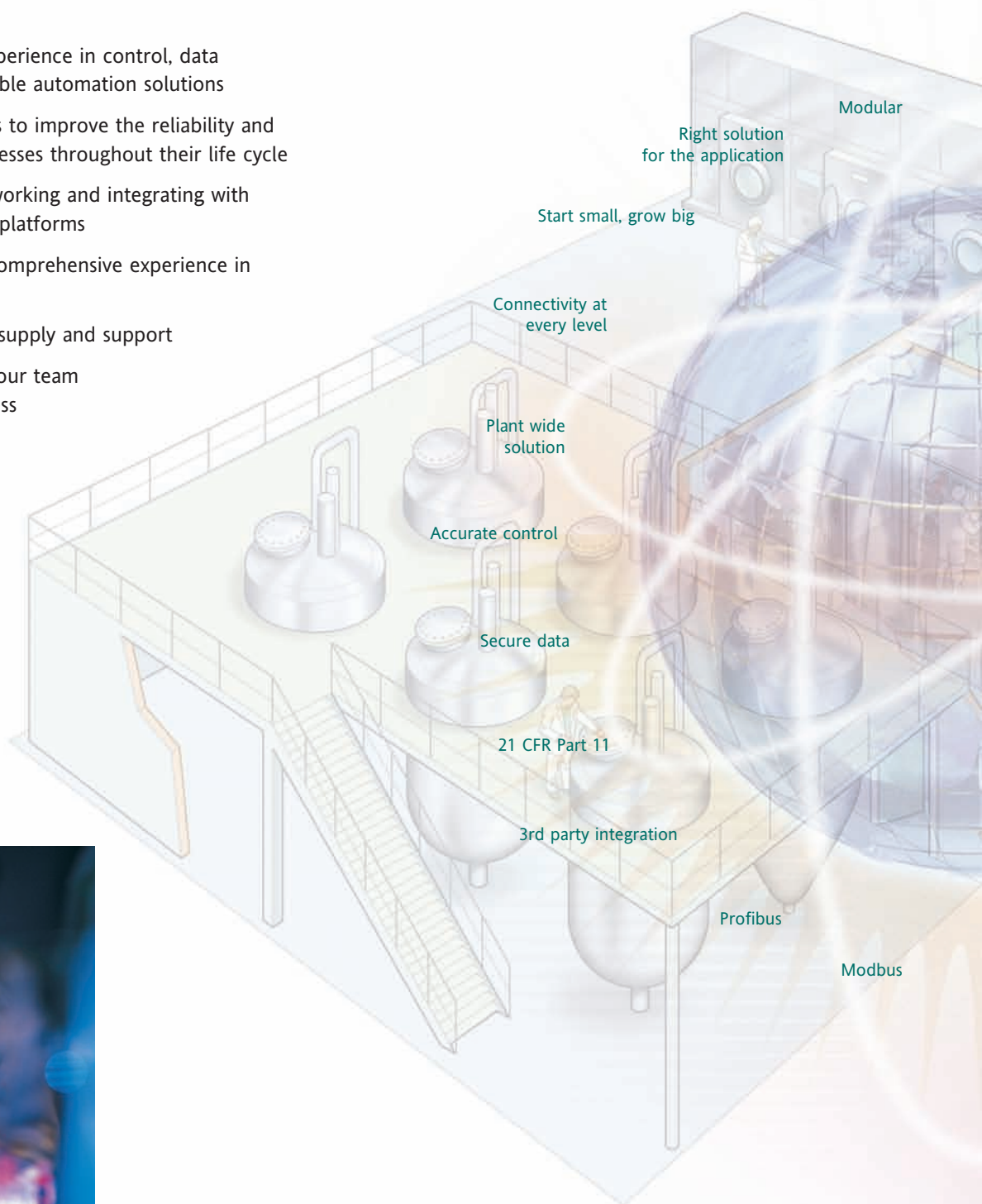


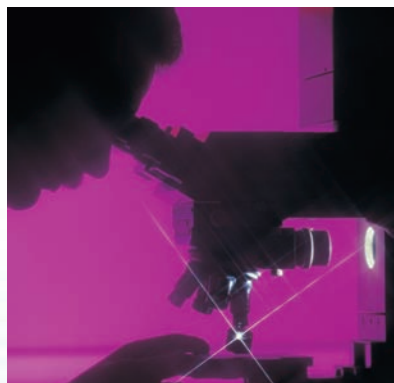
Eurotherm® - The Life Sciences Solutions Provider

Why Eurotherm?

Eurotherm is a solutions provider that specialises in improving efficiency of plant operation and compliance with regulatory bodies e.g. FDA, EMEA.

- Global expertise and experience in providing Pharmaceutical and Biotech solutions
- Proven track record in rapidly delivering solutions with optimum ROI
- More than 40 years experience in control, data management and scalable automation solutions
- Cost-effective solutions to improve the reliability and efficiency of your processes throughout their life cycle
- Proven experience in working and integrating with multiple suppliers and platforms
- Specialist teams with comprehensive experience in validating systems
- Global expertise, local supply and support
- A team to work with your team a partnership for success





Confidence in Validation

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

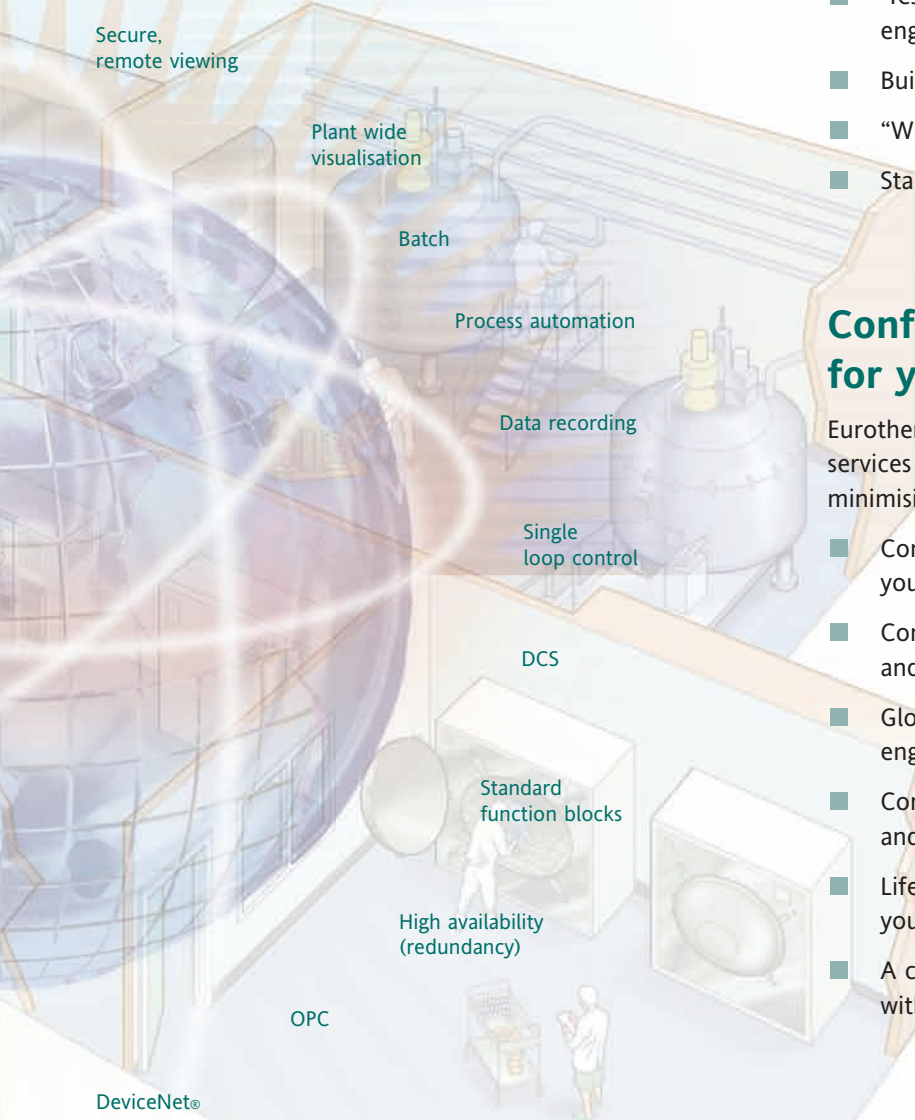
- Successful completion of validated solutions around the world
- Experienced, dedicated, specialist teams
- Active responses to latest regulatory developments e.g. PAT
- 'Test and validate once - use many times' engineering strategy
- Built-in 21 CFR Part 11 features
- "Wrap and comply" solution upgrade validation path
- Standard validation templates

Confidence in measured value for your money

Eurotherm are committed to developing products and services specifically for the Life Sciences industry continually minimising cost and maximising productivity.

- Consultancy services to ensure you get exactly what you need
- Consultancy to help you reduce validation time, costs and confusion
- Global and plant wide consistency – re-using engineering to minimise costs
- Complete life cycle support – maximising productivity and efficiency
- 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*
- *Spares management*
- *Technical support*



Life Sciences solutions to lower production costs

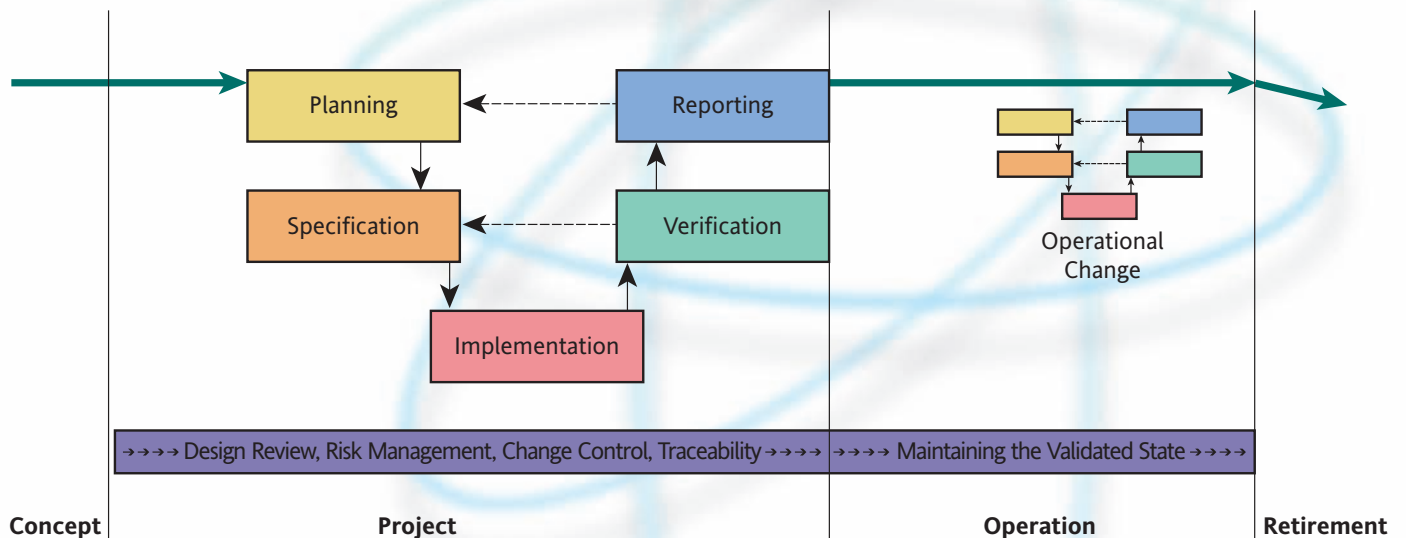
Eurotherm provide engineered solutions for plant automation throughout the world. Our hardware and software expertise can provide you with a solution to match your manufacturing requirements and maximise efficiency, productivity and ultimately your return on investment.

Eurotherm Life Sciences team can provide you with:

- Automation and application expertise and experience
- World-class accuracy of control
- World-class 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



GAMP LIFECYCLE



What does this mean to your production?

- Rapid return on investment
- Lower manufacturing costs
- Reduced labour costs and SOPs through automation
- Improved plant availability through redundancy options
- Reduced cycle times and improved asset utilisation
- Tighter tolerances to improve product quality and consistency
- Maximised efficiency and minimised production waste and interruption
- Reduced manual processes and improved data security through automatic data gathering

Full Life Cycle Support

Eurotherm use a Life Cycle Development approach based on GAMP5 to ensure consistent control and quality worldwide. This results in a reduction in validation costs and provides full control and traceability throughout the project lifecycle.

From Conception to Retirement - Why Eurotherm?

- Strategic, long-term, global partner
- A complete service. A complete solution
- Quality engineering services
- Specialist application expertise
- World-class, scalable solutions



Planning

- Feasibility studies
- Assistance with GxP risk management
- Assistance with requirements capture and formal URS creation
- Validation audits
- Formal quality planning based on GAMP5 lifecycle

Specification

- High quality documentation based on GAMP5 templates – supplier documentation can be leveraged with zero repeated effort by the end user

Implementation

- Scalable DCS solutions
- Total plant data management
- Advanced control systems
- Full range of configuration and cooling services
- Code review
- Installation and commissioning services

Verification

- Module test, integration test, factory and site acceptance test are all executed to GAMP5 guidelines and can be leveraged to reduce end user qualification effort

Reporting & Handover

- Formal quality report and handover checklist confirms fitness of the system for its intended purpose

Ongoing Operation

- Service level agreement
- Training
- Spares management
- Back-up and disaster recovery
- Periodic review assistance
- Change management services
- Assistance in decommissioning
- Data recovery

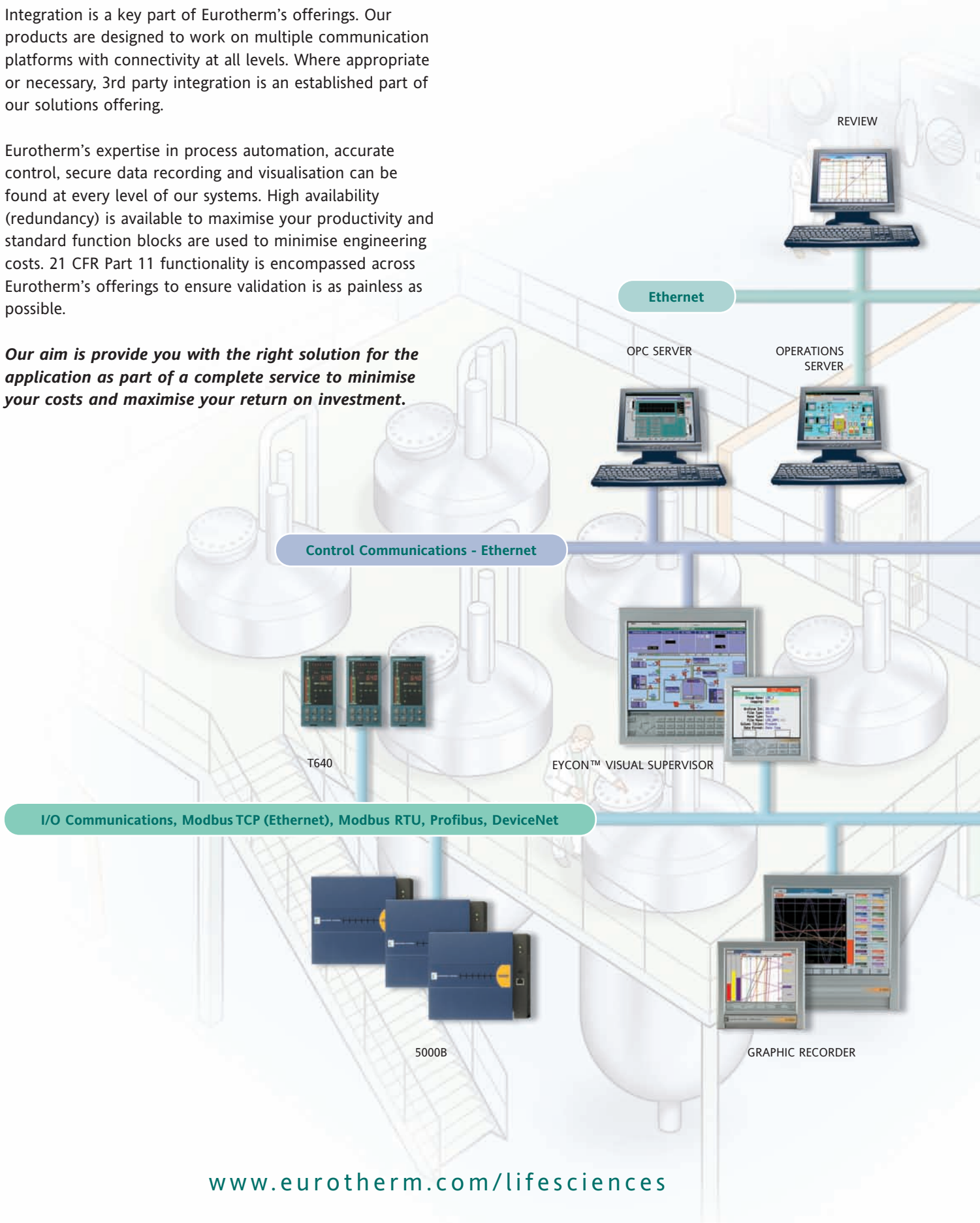
Modular, scalable solutions from lab to pilot to full production

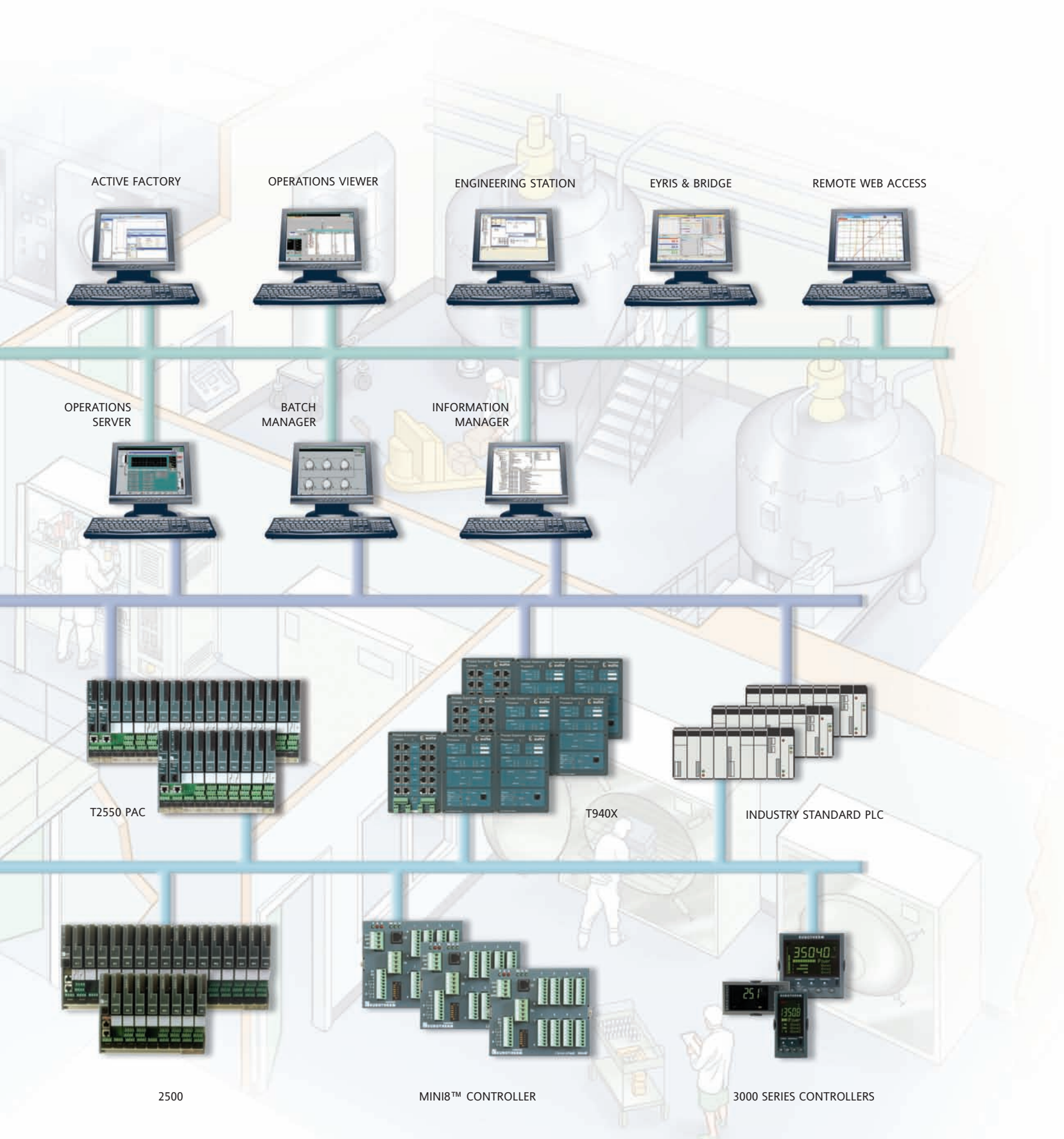
From simple loop control to information integration and plant wide DCS systems, Eurotherm can offer scalable, modular solutions to match your application and budget. As your requirements grow, new modules can be easily incorporated into your system

Integration is a key part of Eurotherm's offerings. Our products are designed to work on multiple communication platforms with connectivity at all levels. Where appropriate or necessary, 3rd party integration is an established part of our solutions offering.

Eurotherm's expertise in process automation, accurate control, secure data recording and visualisation can be found at every level of our systems. High availability (redundancy) is available to maximise your productivity and standard function blocks are used to minimise engineering costs. 21 CFR Part 11 functionality is encompassed across Eurotherm's offerings to ensure validation is as painless as possible.

Our aim is provide you with the right solution for the application as part of a complete service to minimise your costs and maximise your return on investment.





Minimising validation costs

With ever-changing global regulatory requirements for the Life Sciences Industries, it is our vision and direction to help our customers to get products to market safely and in a timely manner, while adhering to the relevant regulatory requirements.

Can Eurotherm really reduce your costs?

- To reduce costs, a real understanding of regulatory requirements is needed – we have specialist engineers dedicated to following global regulations
- Through standardisation we minimise customisation, our products have built-in features to meet regulations such as 21 CFR Part 11, PAT
- Our Life Sciences Consultants work closely with our product development teams to continuously follow and implement the latest regulatory requirements within our solutions
- Proven, standard validation templates based on GAMP5

You can be confident that Eurotherm is the right partner for your validation needs...

- Successful completion of validated systems around the world
- Involvement in major Life Sciences professional organisations e.g. ISPE, GAMP, ISA
- Customers have experienced significant reductions in validation costs by engaging Eurotherm at the beginning of a project and resolving multiple issues before manufacturing begins
- Successful audits by numerous major Pharmaceutical and Biotech companies
- All products are manufactured and tested to ISO9000 and TickIT



Wrap & Comply

It is not always necessary to replace your legacy systems to comply with current regulations...

With the “Wrap & Comply” concept we are looking at working with your current system components to minimise the validation effort. Maximising the re-use of hardware and software will enable you to “Wrap” your legacy system in a compliant architecture in order for the GxP system to “Comply” with regulatory requirements including 21 CFR Part 11.



Save time and money...

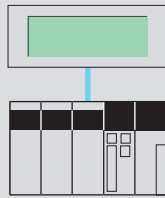
- Re-use existing hardware
- Re-use existing software
- Minimise SOPs
- Improve plant efficiency and quality
- Faster time to market
- Reduce validation

Our team of experience engineers are available to work with you and assist you to identify the non-compliant systems and take the necessary remediation action to validate them:

- **Gap Analysis** – Identify computer system validation gaps
- **Coverage Assessment** – Determine which GxP rules must be satisfied
- **Risk Assessment** – Determine and prioritise potential compliance actions
- **Mitigation/Remediation Plan** – Formulate a corrective action plan addressing the deficiencies following the rule: “Maintain as much of the existing hardware and software possible”
- **Implementation** – Implement corrective actions

Wrap and Comply: Expand, enhance, comply...

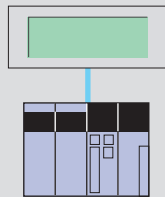
Non Compliant...



PROBLEM...

Standalone legacy system connected to a simple HMI with no security installed before 1997 (no changes or very minor changes made since).

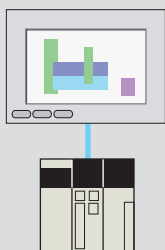
- The equipment is reliable and still supported by the original manufacturer
- There is no requirement for additional functionality
- SOPs are in place to manage change control of day to day operations and program changes. Your staff are trained in the operation and SOPs



PROBLEM...

Existing standalone legacy system connected to a simple HMI with no security. Risk analysis and/or company standards require Electronic Records and Signatures.

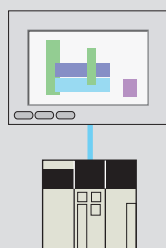
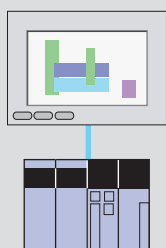
- The equipment is reliable and still supported by the original manufacturer
- There is a requirement for a small number of additional sensor inputs to increase quality and visibility of the system
- SOPs are in place to manage change control of day to day operations and program changes. Your staff are trained in the operation and SOPs



PROBLEM...

Existing standalone legacy system connected to a HMI with no security. Risk analysis and/or company standards require Electronic Records and Signatures.

- The equipment is reliable but there is reducing support from the original manufacturer
- There is a requirement for a larger expansion of the process and/or a need for additional data and implementation of PAT
- SOPs are in place to manage change control of day to day operations and program changes. Your staff are trained in the operation and SOPs



PROBLEM...

You have systems from multiple manufacturers, islands of automation and limited communication between systems. Risk analysis and/or company standards require Electronic Records and Signatures.

- The equipment is reliable but there is reducing support from the original manufacturer
- There is a requirement for a larger expansion of the process and/or a need for additional data and implementation of PAT
- SOPs are in place but there are issues managing numerous audit trails and multiple security systems
- Systems have different programming languages

...with minimum cost and effort

...Compliant

...SOLUTION

No changes are necessary. With changes made to 21 CFR Part 11 many systems are going to fall into this category. We recommend no change.

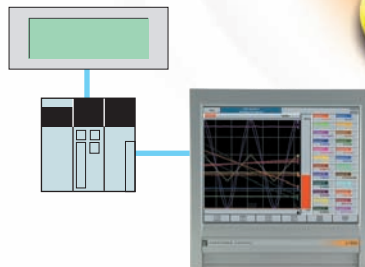


...SOLUTION

Adding a Chessell™ Graphic Recorder will provide compliant data logging by acquiring signals from new sensors.

The Eurotherm solution is:

- Cost effective
- Easy to implement and validate (configuration vs programming)

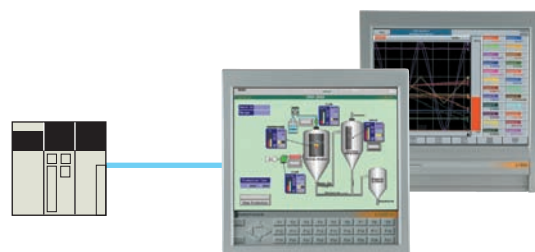


...SOLUTION

Replace the operator interface with a compliant graphic recorder and data acquisition unit or the Eycon™ Visual Supervisor.

The Eurotherm solution provides:

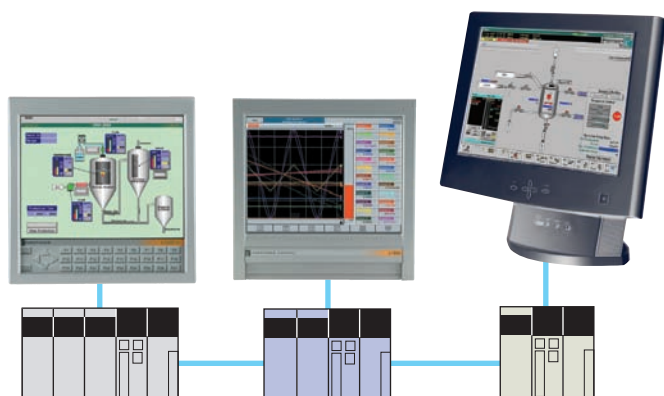
- HMI, security and control integrated all in one
- No change of control strategy (preserves validation)
- An opportunity to enhance the operator interface
- Local storage of secure process data
- Recipe, batch and set-point programming as standard



...SOLUTION

Eurotherm have a program to upgrade all of your controllers offering all of the benefits and features plus:

- One security regime (expired passwords need changing in just one place)
- One place for all audit trails (no more searching for the right one)
- Programs for all systems checked and compared with the running system



21 CFR Part 11 made easy

Eurotherm has a range of products that are designed to meet regulations such as 21 CFR Part 11. From plant wide data access security management to single, secure recorders, we can provide a solution that is right for you.

Solutions designed for ease of use and validation

- Minimise validation time and testing by using standard, built-in features to meet 21 CFR Part 11 that can be configured to your requirements
- Data recording at every level, local and plant wide
- Never lose data with cost-effective multiple recording and secure back-up
- Centralised security system allowing maintenance of user accounts and passwords from one or multiple locations
- Secure local data collection with automatic archiving across the network – truly designed to keep data safe
- Remediation solutions for legacy systems – **“Wrap & Comply”**

Electronic Records

- Secure process values and audit trails (alarms, events, operator actions, log-in/log-out, operator notes, electronic signatures)
- Protection of data through binary, compressed and check-summed records
- Accurate time stamps are ensured using automatic Time Synchronisation to a known clock source
- Provision for electronically copying data for archive
- Export facility allowing viewing of secure records in human readable form
- Store and forward
- Review and approve facility



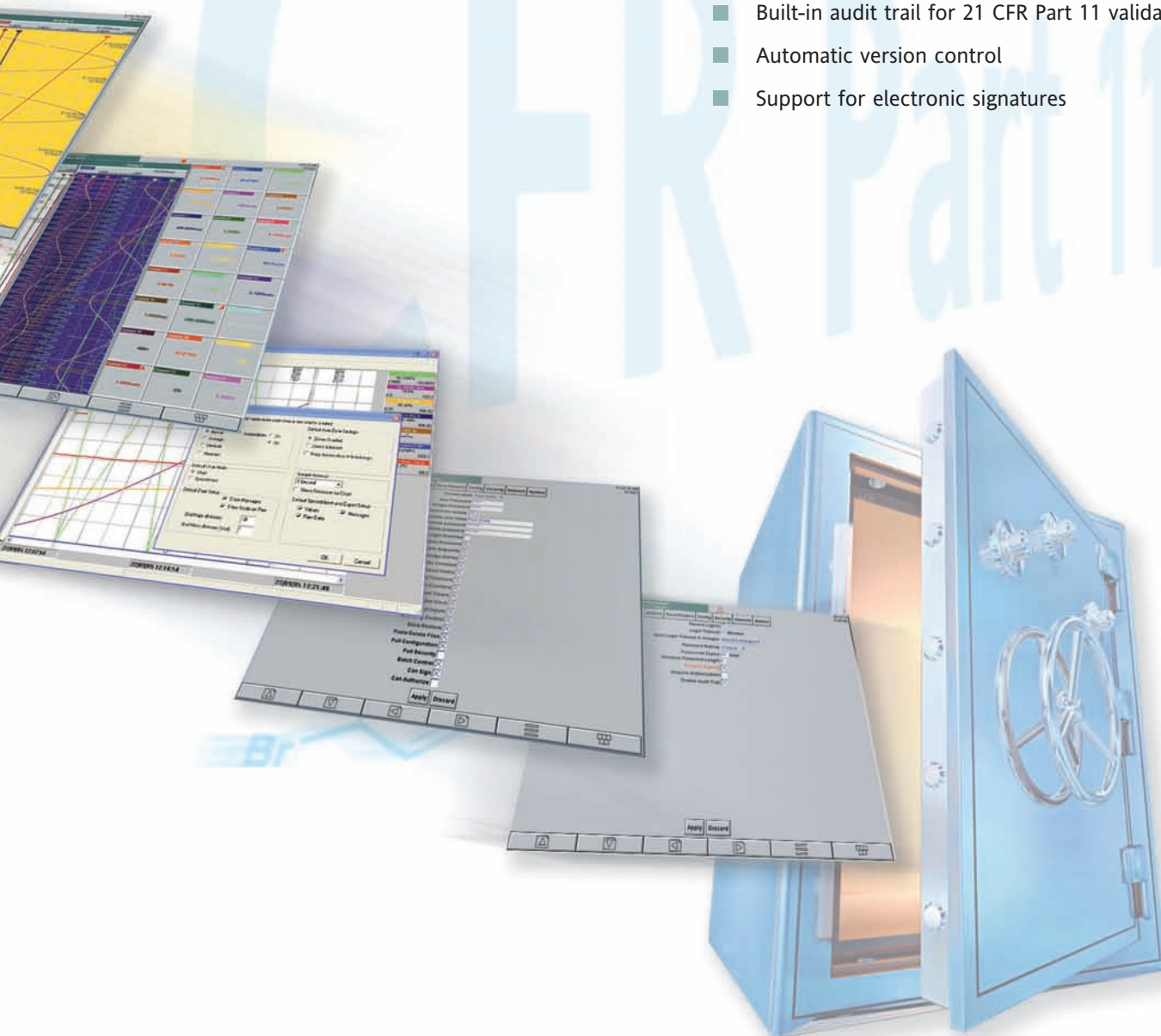
Electronic Signatures

- All user actions can be configured to require signing or require signing and authorisation
- User specific access according to authority level
- Signature element controls unique user signature, password expiry, minimum password length, automatic log-off, automatic disabling and notification of failed login attempts
- Ensuring unique users by retiring and not deleting accounts

Central Security Manager with Full Audit Trail –

Security Manager offers significant operation cost savings and ease of use by allowing maintenance of user accounts and passwords from one or multiple locations. If a user needs to change their password they can do so on a local instrument or PC and this will be automatically distributed across all systems to which they have access.

- A common security tool across multiple product ranges
- Change in one place, deploy to many
- Support for multiple security zones
- Built-in audit trail for 21 CFR Part 11 validation
- Automatic version control
- Support for electronic signatures



Strength through wide-ranging application experience

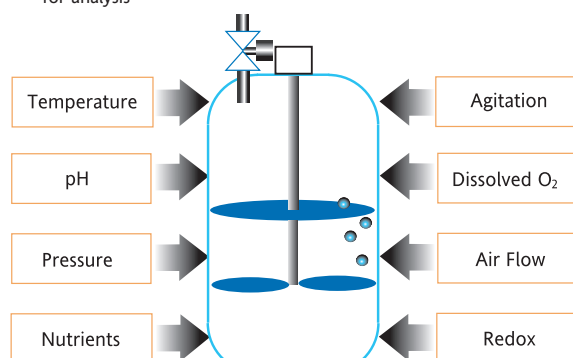
Our range of application experience could help you to increase productivity and lower costs. All of our solutions into the Life Sciences industry are flexible and scalable to suit the process exactly and have built-in 21 CFR Part 11 features.



Example applications

FERMENTATION PROCESS

- Precise loop control
- Sequential control for vessel sterilisation and more complex control strategies
- Recipe management with easy parameterisation
- Batch control and reporting
- Setpoint programming
- Alarm management
- Secure collection of on-line data from the fermenter system for analysis



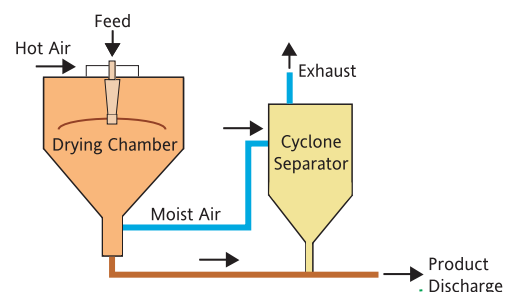
Incubation control necessitates the precise control of a number of parameters – of primary importance are:

- Temperature
- pH
- DO2
- Agitation
- Pressure
- Foam control
- Auxiliary feed

SPRAY DRYING PROCESS

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 - Eurotherm can help you to meet these challenges.

- Spray Drying phases:
- Feed preparation
- Atomisation
- Drying
- Separation of powder from moist gas
- Cooling and packaging

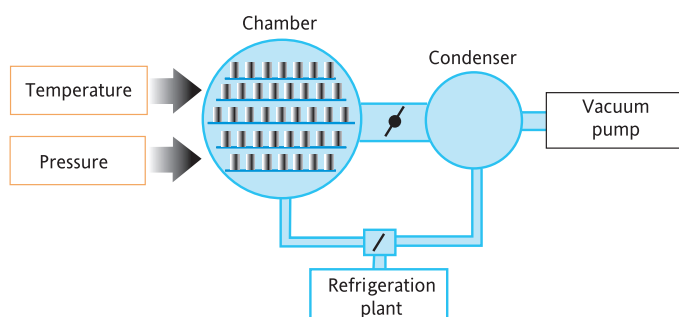


Accurate and repeatable control of the spray drying process requires a flexible control solution.

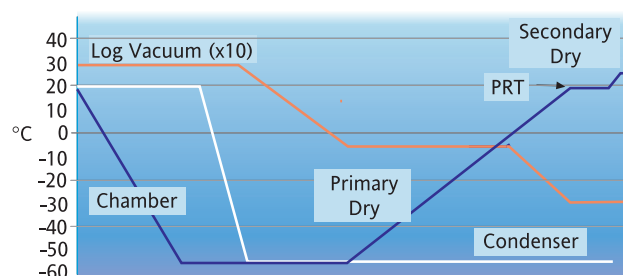
- Precise loop control with setpoint profile programming
- Recipe management system for easy parameterisation
- Sequential control for complex control strategies
- Secure data recording for analysis and evidence
- Local operator display with clear graphics and controlled parameter access

FREEZE DRYING

- Precise temperature control with ramping
- Sequential control of temperature, vacuum and the refrigeration plant – both for freeze drying and sterilisation



- Safety strategies to ensure product is not damaged as a result of plant failure
- Data recording for analysis and evidence



ENVIRONMENTAL AND STABILITY CHAMBER MONITORING AND CONTROL

- Multiple room monitoring with local logging capability
- Mean Kinetic Temperature calculation
- Selectable stability testing period
- Selectable sampling frequency
- Sophisticated alarm functionality
- Accurate continuous and sequential control
- Report generation
- SMS or email alerts triggered by alarms or events

$$T_k = \frac{\frac{-\Delta H}{R}}{\ln \left[\frac{e^{\frac{-\Delta H}{RT_1}} + \dots + e^{\frac{-\Delta H}{RT_n}}}{n} \right]}$$

T_k being the mean kinetic temperature in Kelvin
 ΔH is the heat activation in kJoule per mole
 R is the universal gas constant in kJoule per mole per Kelvin
 T_1 and T_n are the temperature samples for periods 1 and n, respectively
 n is the total number of periods in the calculation

STERILISATION PROCESS

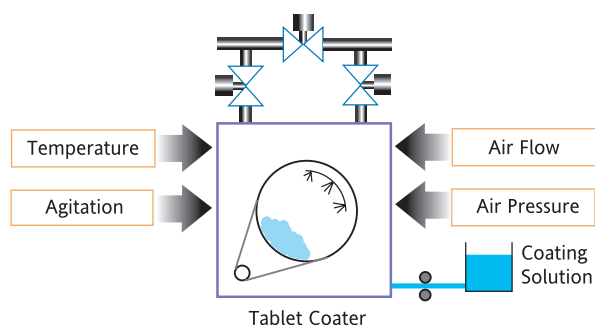
- Autoclave control and monitoring
- Batch control and reporting
- Pass/fail indication
- Local, custom graphic displays
- Secure data collection

MIXER/BLENDER CONTROL

- Precise loop control with setpoint profile programming
- Recipe management system
- Sequential control
- Secure data recording for analysis and evidence
- Local operator displays with custom graphics to best suit the process

TABLET COATING

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



WATER PURIFICATION

There are a number of methods commonly used to purify water. Their effectiveness is linked to the type of contaminant being treated and the type of application the water will be used for:

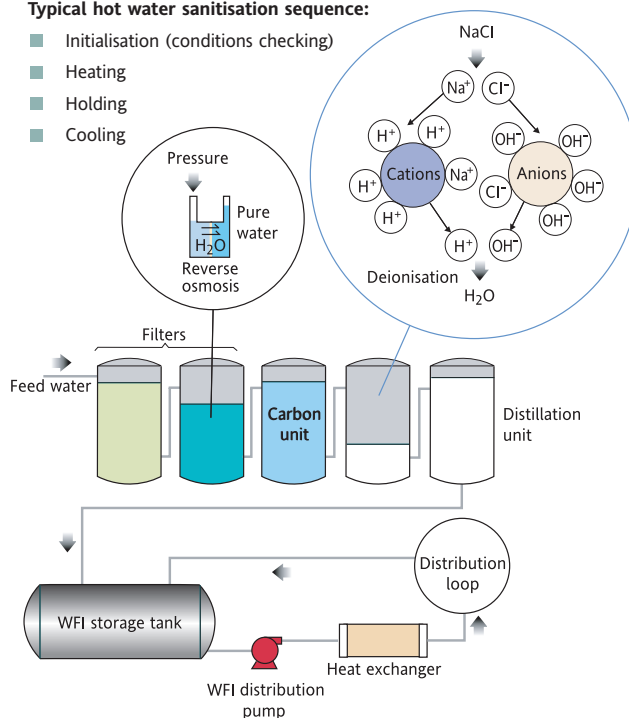
- Filtration
- Distillation
- Activated carbon adsorption
- Deionisation (ion exchange)

Hot Water Sanitisation

Sanitisation of water purification equipment with hot water is achieved via an appropriate combination of exposure time and temperature.

Typical hot water sanitisation sequence:

- Initialisation (conditions checking)
- Heating
- Holding
- Cooling

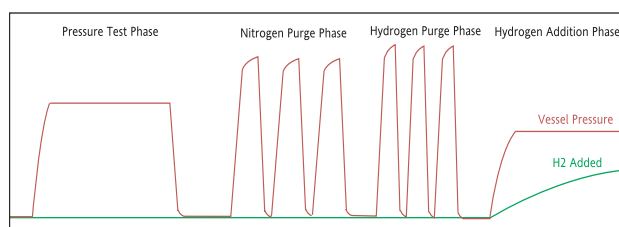


Flexible, accurate and repeatable control:

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

HYDROGENATION PROCESS

- 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



Eurotherm products: The most complete set of products for Life Sciences solutions from a single supplier

DCS Operations Viewer and Server

Enhances the view of your plant - meeting the diverse needs of operations, maintenance and plant management. The simple to use display structure provides data to users in a fast and meaningful way.

- Meets requirement for 21 CFR Part 11
- Client/server architecture with master/backup servers
- Defined display structure
- Trending
- Sophisticated alarm functionality
- Batch manager to ISA-S88
- Single global database
- Time Synchronisation



Information Manager

The Information Manager combines the power and flexibility of a relational database with the speed and compression of a real time historian package.

- Capture and stores all plant data
- Real-time and historical plant information accessible to the entire organisation
- Embedded Microsoft SQL Server provides standard access via SQL queries
- Based on Wonderware's IndustrialSQL Server™ real-time plant historian
- 21 CFR Part 11 Validatable
- Client Server architecture



Advanced DCS Controller Range

Eurotherm T Series configurable controllers offer the strategy elements of DCS systems capable of continuous analogue, logic and sequential control. They may be used stand alone or as building blocks for larger systems.

- Distributed control units
- Full function continuous and sequential control
- Optional redundancy with bumpless transfer and live replacement
- Unit supervisor concept in line with ISA-S88 Batch Model Control
- Peer-to-peer communication
- Support for Modbus network master and slave
- Support for Profibus network master





Eycon™ Visual Supervisor

The Eycon Visual Supervisor is a multi-function controller with data logging and integrated display – providing all of the features required to control and monitor processes. It can be used as a stand-alone or as a building block within a larger system.

- Meets requirement of 21 CFR Part 11 for Electronic Records and Electronic Signatures
- Batch manager to ISA-S88 with batch log
- Recipe and setpoint programmer
- Accurate continuous and sequential control
- Support for Modbus and Profibus networks
- Barcode reader & printer support
- Time Synchronisation
- Support for USB

Discrete Controller Range

With over 15 models, the 2000 and 3000 Series controllers and indicators are available from a single loop controller for small applications to multi-loop controllers with logic capability for more complex applications.

- One to multi PID loops
- Maths functions
- Logic functions
- Automatic PID tuning
- Support for Profibus, Modbus, DeviceNet networks
- Lockout front panel keys for use with 21 CFR Part 11 operator display
- Switchover of inputs upon failure



Eurotherm products: The most complete set of products for Life Sciences solutions from a single supplier

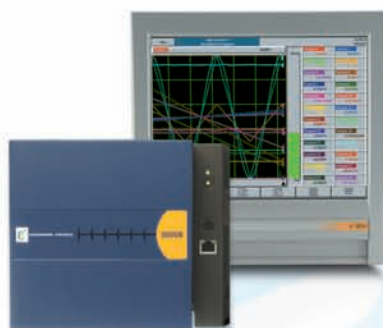
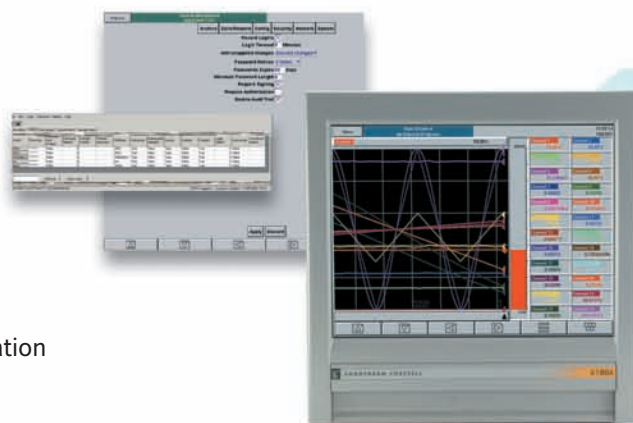
Data Management

Eurotherm provides a complete range of products from strip and circular paper chart recorders to graphic recorders to networked, plant wide Data Management solutions.

Electronic Data Recording

Products are designed to acquire process data and then to display, transfer and manage that data using secure yet flexible means to meet varying user needs.

- Meets requirements of 21 CFR Part 11 for Electronic Records and Electronic Signatures
- Multi-batch recording
- Range of Ethernet protocols available
- Standard networking via Ethernet
- Maths capability including Mean Kinetic Temperature calculation, F0 calculation for sterilisation
- Remote viewing via Bridge software
- Time Synchronisation
- Offline data viewing via Review software
- Report generation
- Direct printer output
- Support for Email/SMS notification
- Web visualisation

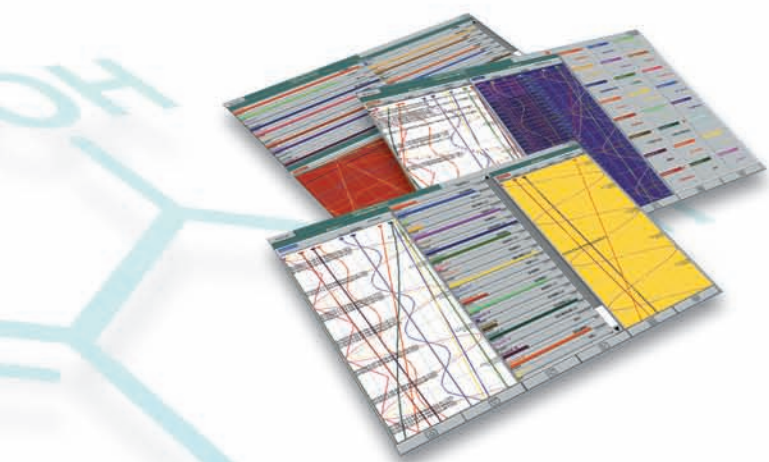


Paper Recorders

Eurotherm offers a versatile range of strip and circular chart recorders. The 4000 Series is a 100mm strip and the 392/394 in 10" circular chart size.

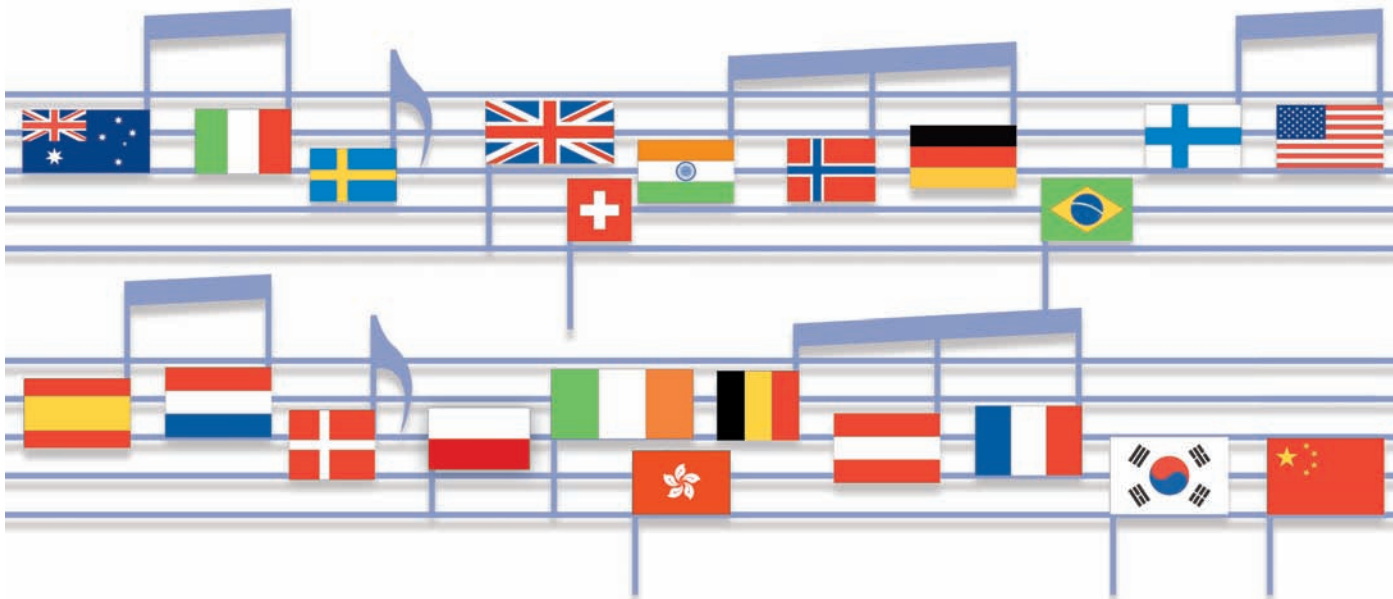
These ranges of paper chart recorders offer a wide range of features that include: annotation, custom messages, powerful maths pack and local archiving to PC card.

- Up to 48 universal inputs
- Remote chart control
- Analogue retransmission
- Maths pack including F0 calculation for sterilisation
- Offline data viewing via Review software
- Online configuration
- Serial communications
- Pen offset compensation



Eurotherm: International sales and service

Understanding and providing local support is a key part of Eurotherm business. Complementing worldwide Eurotherm offices are a whole range of partners and a comprehensive technical support team, to ensure you get a service you will want to go back to.



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