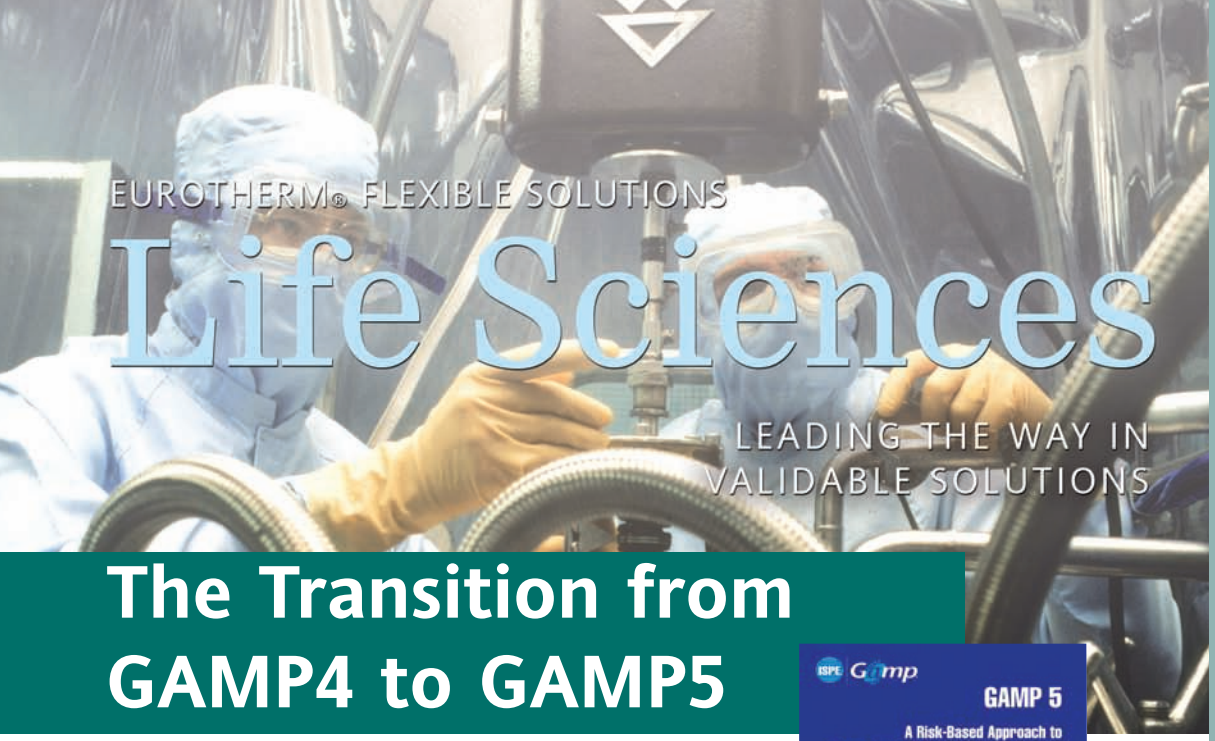


invensys®
EUROTHERM®

The Transition from GAMP4 to GAMP5

How can Eurotherm Help?

The newly launched GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems aims to focus attention on patient safety, product quality and data integrity.

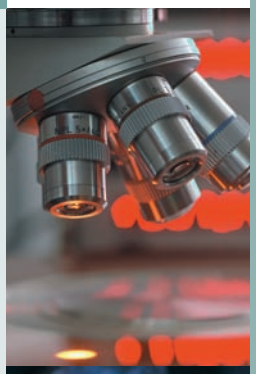
Coupled to this, the new guidance highlights the need to:

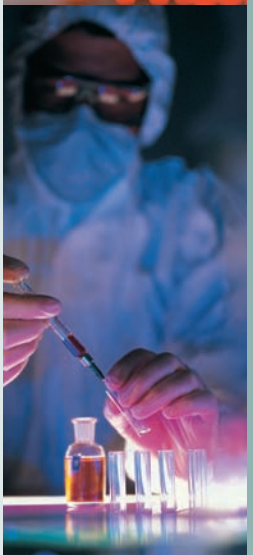
- Avoid duplication of activities (e.g. by fully integrating engineering and computer system activities so that they are only performed once)
- Leverage supplier activities to the maximum possible extent while still ensuring fitness for intended use
- Scale all lifecycle activities and associated documentation according to risk, complexity and novelty

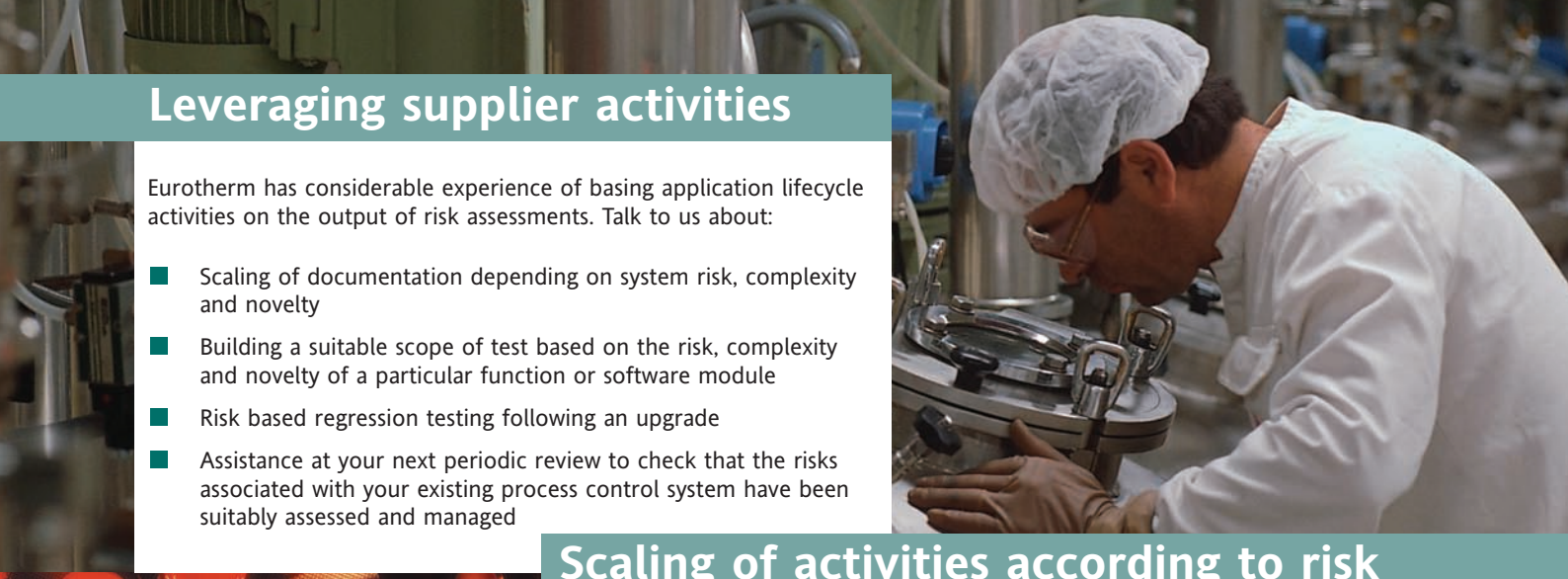
Avoiding duplication of activities

Eurotherm has many years experience managing control system integration projects; working with numerous pharmaceutical end users to develop streamlined approaches to validation. Within the application lifecycle Eurotherm can offer:

- Well-developed documentation templates including traceability from user requirements through to design and verification activities
- Configuration and documentation management with full traceability of changes back to the source (whether that is a customer request, a code review action or a test incident)
- Careful test planning to avoid duplication between module, factory and site tests but still ensure appropriate coverage
- Test specifications written to integrate with your IQ/OQ so that effort is not wasted duplicating activities for control system, process equipment and the process itself
- Support for ongoing operation including service level agreements, helpdesk, bonded spares, support for installing patches or upgrades







Leveraging supplier activities

Eurotherm has considerable experience of basing application lifecycle activities on the output of risk assessments. Talk to us about:

- Scaling of documentation depending on system risk, complexity and novelty
- Building a suitable scope of test based on the risk, complexity and novelty of a particular function or software module
- Risk based regression testing following an upgrade
- Assistance at your next periodic review to check that the risks associated with your existing process control system have been suitably assessed and managed

Scaling of activities according to risk

Eurotherm recognises the need to support end users in their desire to leverage supplier activities:

- Auditors from pharmaceutical end users are always welcome
- All Eurotherm products are developed under a mature quality system (ISO9001:2000, TickIT) which has been complimented by many end users during supplier audit
- Validation is supported throughout the product lifecycle, with full documentation and testing of upgrades prior to release and comprehensive release notes made available to end users
- Many functions are incorporated as standard for ease of validation – requiring only parameterisation by the end user

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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