white paper

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21 CFR Part 11 Remediation Strategies From Eurotherm

The information below indicates the various ways to achieve compliance with 21 CFR Part 11. The difference between the options is one of complexity and cost. A range of remediation strategies is described, including a new option, option 4, which has generated a great deal of interest for its relative simplicity and significant reduction in cost.

Background

The requirements of 21 CFR Part 11 demand compliance to certain regulations when using Electronic Records as the primary source of data for the pharmaceutical industry. In brief, the requirement is for secure, tamper proof data, which can also be created in a standard format such as an .xls or .pdf file.

Electronic Signatures also have a number of specific requirements such as minimum number of characters, password expiry, unique name/password combinations and the option for a second signature to permit access. The creation of an audit trail of all data and events, etc., is a fundamental part of this regulation.

This is the requirement, so what are the implications?

New systems being put into place today should be designed with 21 CFR Part 11 in mind, as the trend is to use Electronic Records. These systems tend to use software running on computer systems to meet the regulation.

This regulation does not only apply to new systems, however. The majority of existing control systems will also need to meet this regulation at some time in the future. It is this requirement that is often a daunting prospect.
The cost implications of achieving compliance of existing systems are very severe, not just relating to the replacement of hardware and subsequent software programming but also in the re-validation costs, which often dwarf the hardware costs.

A leader of a remediation team at a major pharmaceutical company commented: “The task of remediation is difficult enough without the problem of new equipment arriving without this compliance, or worse, without the ability for it to be made compliant.”

This establishment of remediation teams from multiple disciplines within the organization is a common occurrence. They all struggle with how to achieve 21 CFR Part 11 compliance and how much can be done in what timeframe with the budget allocated.

As a supplier we see this common theme. The information below describes the various options and the solutions Eurotherm is able to offer to enable the pharmaceutical industry to achieve compliance with the 21 CFR Part 11 regulation.

**Remediation Options**

So, what are the options? There are in fact a variety of options, all of which involve hardware, software, programming, changing SOPs and validation. Some remediation options are indicated below. The difference is in the complexity and cost of implementation.

**Option 1: Replace the existing control system**

You can replace the existing system with a new system with 21 CFR Part 11 compliant features. This has the obvious drawbacks of not only the cost of the hardware and software programming but also the cost of validating the new system. This is not a popular option for most companies.
Option 2: Add compliant computer data acquisition to the existing control system

One way to do this is to add a computer SCADA system such as WonderWare, which has the 21 CFR Part 11 features, and communicate to the control system. This solution has a lot of features but is generally relatively high in cost as there is the cost of the software and then the generally much higher cost of the programming of the SCADA system. In many cases the operator interface has now become more complicated.

Option 3: Add a compliant Eurotherm Chessell data logging unit to the existing control system

Process data and events are logged by the Chessell 5000 Series. This range of products provides full compliance with the 21 CFR Part 11 regulation by offering the auditor option, and provides a high quality operator interface.

In association with secure data acquisition the ‘Review’ software offers an easy way to access data via the Ethernet network. The remote view provided by the ‘Bridge’ software provides a secure view of the data as if you were at the unit itself. This requires hardware cost (generally relatively low), some configuration (much simpler than software programming), changing the SOPs (Standard Operating Procedures) and validation of the data logging system (made easier by the availability of validation protocols).

This option is probably the most common method of remediation and does provide a relatively straightforward way to gather data, generate an audit trail and produce reports as required.

There is another option to achieve compliance, however, which is now offered by Eurotherm. This is to use a compliant ‘front end’ approach, as described below:
Option 4: Add a compliant Eurotherm ‘front end’ to the existing control system

None of the previous options, with the exception of the first, which is expensive, address the control system interface itself. This fourth option does just this.

A common scenario is as follows. The control system may consist of a PLC (Programmable Logic Controller) plus an operator interface of some kind, perhaps a simple two-line panel or a multi line panel with some graphics. This system does not meet compliance requirements for Electronic Records or Electronic Signatures. This situation is repeated many times throughout the plant, hence the dilemma of achieving remediation at reasonable cost.

The compliant ‘front end’ remediation strategy involves replacing the non-compliant operator interface with a compliant operator interface. In simple terms the existing panel is unplugged and replaced by the new, compliant interface. This has several advantages over conventional remediation strategies:

1. The control strategy of the PLC is totally unaffected, thereby considerably simplifying the complexity of re-validation and hence the time and cost. Only the operator interface is re-validated as the process control is unaffected.

2. The operator interface is greatly enhanced with full color graphics and touch screen. The SOPs will need to be changed to accommodate the new operator interface.

3. Data is now collected locally, in internal memory and removable media and via the Ethernet network, providing a high level of integrity of the solution.

4. Implementation cost is relatively low for the high reward achieved.

Eurotherm offers two solutions to achieve option 4

The first is the Eurotherm Chessell Series 5000 product with master communications and the second is the Eurotherm Process Automation T800 product. Both of these offer 21 CFR Part 11 compliance features, batch ability, time synchronization, etc.
Both solutions also have validation protocol information available, greatly simplifying the task of validation.

1. Eurotherm Chessell – Series 5000B / 5100V and 5180V models with Auditor option

The Series 5000 B and V models have a master communications option which enables the unit to communicate with external Eurotherm devices such as data acquisition or control products. In addition, the 5000 unit can also communicate to external equipment such as PLCs.

Provision of up to 6 custom screens either ¼ VGA or full VGA provides a high quality operator interface. Up to 96 parameters can also be accessed via this operator interface.

The interface can interact with analog and digital parameters inside the PLC and read and write to the registers, as permitted by the existing PLC programming.

The ‘Review’ software provides the ability to read the secure data files and to export data in either .csv or .pdf format. The software can also automatically print out data at the end of a batch.

The ‘Bridge’ software provides a remote view of the live data and can be used as a full interface if required. All 21 CFR Part 11 features apply as if you were in front of the V series recorder. The B series is “blind” and requires the use of the Bridge software.

The 5000 Series products are configured, not programmed, which simplifies the task of creating the interface you require.
2. Eurotherm Process Automation – Visual Supervisor T800 with Auditor option

The full VGA version of the T800 is a more powerful operator interface than the Series 5000, with up to 99 enhanced featured custom screens, and up to 512 parameters. A further enhancement of this product is the ability to customize access for each parameter in terms of signing and authorization rather than the generic approach of the Chessell 5000. A local printer output is also possible. This unit is programmed rather than configured and thereby offers more flexibility.

The facility exists to have a central repository of the passwords in order to centrally address the requirement of the periodic changing of the passwords. This system also has the ability to interface with Eurotherm Suite, which is a WonderWare based operator interface. A point of significance here is that when the operator interface is created for the T800, the database can be imported directly into the Eurotherm Suite software without further engineering apart from the creation of the operator screens and any other advanced features you may require.

For a full description of the features of both products, please see the respective data sheets available on request. A point of note is that the T800 can also be configured as a full process control system by interfacing to the Eurotherm 2500 Control I/O system or foreign I/O devices.

How are different communication protocols accommodated?

Different PLCs and control systems use different protocols, so how are these connected to the Eurotherm Chessell Series 5000 or the Eurotherm Process Automation T800?

The Series 5000 can have an optional Modbus protocol operating via a serial connection or via Ethernet. The T800 has Modbus fitted as standard and can have Profibus fitted if required.
To communicate with devices which do not use these protocols, we use a range of communication converters. These enable the registers in the control system to be addressed directly from the Series 5000 or T800 by simply converting the protocol, or language, to the one the control system uses.

Conclusion

The range of remediation solutions from Eurotherm offers a highly cost effective way to achieve compliance with the 21 CFR Part 11 regulation with the minimum impact on the existing control scheme.

>click here< to download our Remediation brochure.

For a hardcopy of the Remediation Brochure and for further information, please contact:

Mr. Jim Overturf
Eurotherm Inc.
741 Miller Drive, SE
Suite F
Leesburg, VA 20175
U.S.A.
Tel: +1 (703) 669-1355
Fax: +1 (703) 669-1300
Email: jim.overturf@eurotherm.com
Web: http://www.eurotherm.com/pharma/