

RAPID-BATCH

AN AUTOMSOFT WHITE PAPER

INTRODUCTION

RAPID-Batch is a batch reporting system for manufacturing operations. RAPID-Batch interfaces with existing process control and information systems, allowing visibility through a complete batch reporting system. This technical white paper describes the features associated with RAPID-Batch. It also describes the challenges involved in implementing batch reporting and how Automsoft technology solves these problems.

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BATCH REPORTING

THE PROBLEM

In recent years there has been a significant rise in the number of companies adopting the ISA S88 model for their batch manufacturing activities. The S88 model itself is not a software standard but is rather a good practice guide for structuring a batch manufacturing operation. Although in theory, adoption of S88 could be completely paper-based, most companies employing this model use automated Batch Execution Systems (BES) obtained from software and automation vendors. Typically, a BES is an add-on to a SCADA, DCS or MES package. However, as stated above, S88 is not a software standard. This means that each vendor's BES implementation is proprietary and can differ significantly in terms of adherence to the S88 standard. Such proprietary systems work reasonably well within the confines of a single vendor's other software and system offerings but are rarely suited to a 'best of breed' or heterogeneous software environments.

A further problem with BES implementations is that they are almost exclusively designed and focused on the control of the process. This can lead to difficulties

when extracting pertinent information on batch activities after the batch has run. Batch reporting from these systems is often less than adequate and can require significant custom software development and engineering to produce meaningful reports.

Lastly, adherence to regulatory requirements such as 21 CFR Part 11 and GxP, can prove difficult for custom reporting solutions as support for these requirements must be integral to the solution.

THE SOLUTION

RAPID 3.0 and RAPID-Pharma 3.0 offer a complete solution to these reporting problems.

RAPID 3.0 introduces new, enhanced components and technology to provide a comprehensive solution to batch reporting. These new components collectively called RAPID Batch allow RAPID to collect, store, serve and report on complex S88 data. In addition, RAPID Batch has been designed to meet or exceed regulatory requirements such as 21 CFR Part 11. Figure 1 below shows the data flow through the system for storing and serving batch information.

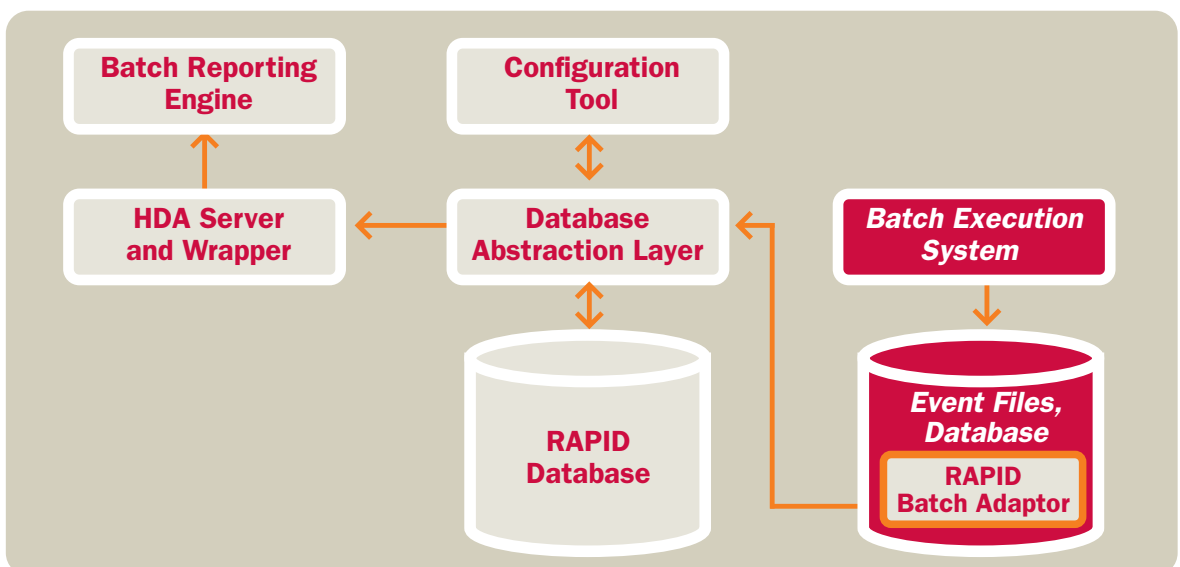


Figure 1. Batch Data Flow

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BATCH ADAPTOR

To solve the heterogeneous problem of the lack of a software standard for BES, RAPID introduces the RAPID Batch Adaptor component. This is a software component installed on the BES which collects data and sends it to the RAPID database. The adaptor collects all batch data (including procedures, alarms, events, phases, operations, recipes, formulae, and equipment) as the batch is executing in real-time. There is an adaptor for each major batch system and it is the only BES specific component in the RAPID Batch solution¹. Depending on the target BES, the adaptor will both parse and transmit batch journal (.EVT files) files as XML documents or use the native data replication of the BES database (usually Microsoft SQL Server) to the Database Abstraction Layer (DAL).

DATABASE ABSTRACTION LAYER

The DAL component has been extended with new COM interfaces to allow insertion and retrieval of batch data. These new interfaces are fully documented and

are available to integrators for programmatic use. The DAL also functions as a concentrator for inserting batch data from multiple BES in complex batch manufacturing environments. The RAPID Database schema has changed significantly to allow batch data to be efficiently stored and queried.

CONFIGURATION TOOL

The Configuration Tool has been extended with new functionality to allow visual configuration of a BES within RAPID. The user selects the target BES and RAPID retrieves the equipment model, existing batches etc. from the BES through the adaptor.

Figure 2 below shows a configured batch system ('dv'), with the top level equipment model in the left-hand pane view and a listing of all batches in the right-hand pane.

Item Classes are integral to batch reporting and are explained below.

¹Please contact Automsoft for a list of supported batch execution and control systems

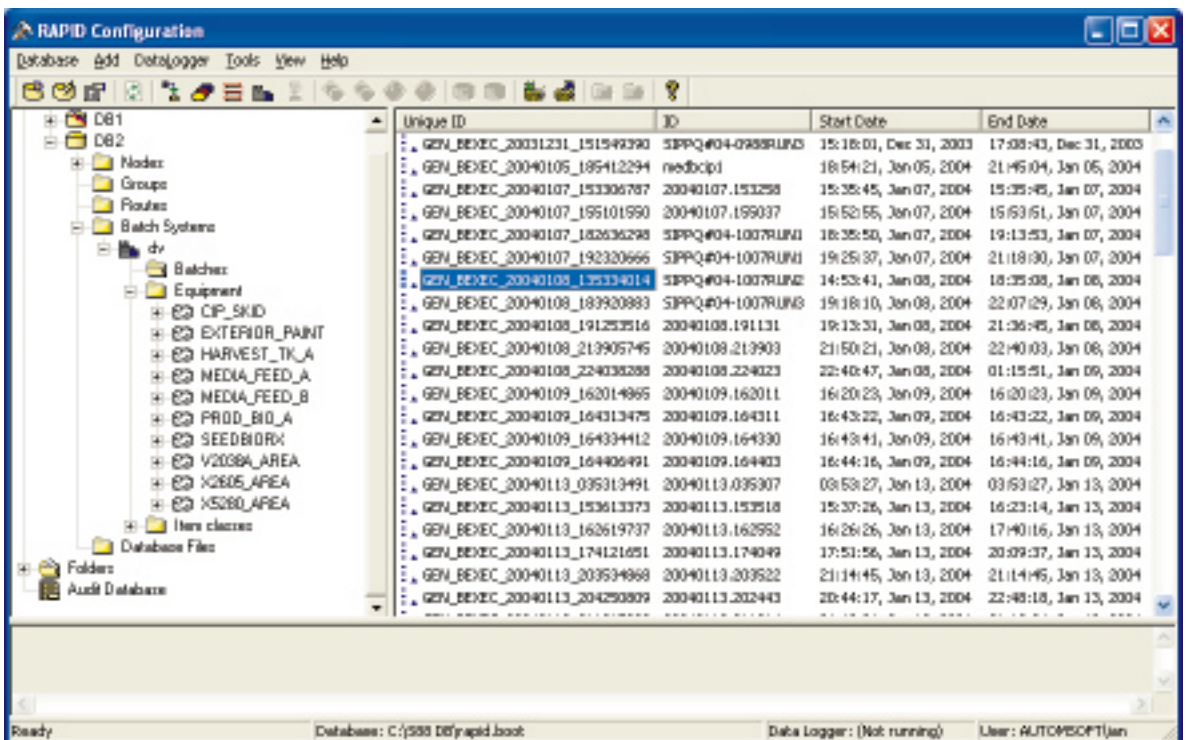


Figure 2. Configuration Tool

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HDA SERVER

The HDA Server (and Wrapper) component has been extended with new COM interfaces to allow browsing of the batch data model (metadata) and for retrieval of batch data. The HDA Server can connect concurrently to multiple DAL instances and can therefore provide a unified view across multiple batch systems. Again, these interfaces are fully documented and are available to system integrators for programmatic use. The interfaces are used by the Batch Reporting Engine.

RAPID 3.0 includes three new components specifically for batch reporting:

- Batch Reporting Engine
- Batch Report Designer
- Batch Reporting Tool

All components have been designed to meet (or exceed) the FDA 21 CFR Part 11 ruling and are described below.

BATCH REPORTING ENGINE

This new server component is the core of the RAPID Batch product. It is responsible for creating batch reports in response to user requests. Batch reports are created in XML format and are dynamically rendered into either PDF or HTML format for display. The batch reporting engine is also responsible for digitally signing a report via Adobe Acrobat 6.0 and Self Sign. Reports are saved in the RAPID Hierarchical Universal Storage for Binary Objects (HUSBO) database for later recall.

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BATCH REPORT DESIGNER

This tool allows the user to configure (design) batch report templates. A batch report template can be either a comprehensive report or an exception report. An exception report template is configured to only produce some report elements by exception. For example, if an analog value exceeds a set point, then produce a trend graph of the value over the life-time of the batch run. Exception reports are very useful to QA personnel who do not require great detail in a report, but need to know if exceptions occurred and exactly what caused them. The batch report templates are stored as XML documents in the HUSBO database. Figure 3 below shows the tool with a report template open for editing.

Report templates are configured in a top-down hierarchical manner. A template is composed of one or more sections, and a section may contain conditions (for exception reports), tables (for alarm or tag data), images (GIF or JPEG format), trends and (sub-) sections. A section may also contain batch filters, for example, filter by procedure, unit procedure, etc. At run-time the template is rendered from the top to the bottom, processing all subsections along the way. If a condition evaluates to True then any item immediately below the condition is rendered to the report.

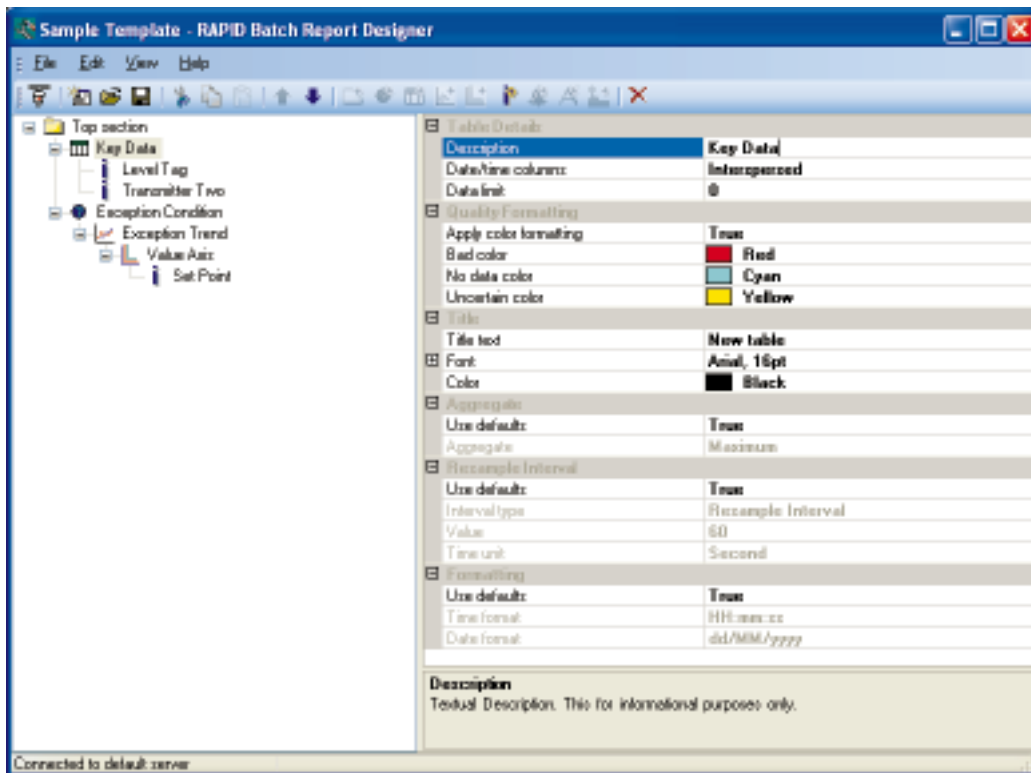


Figure 3. Sample report template

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Item classes are a method of abstracting an I/O point (or tag) such that it does not need to be explicitly referenced in a report template. This is very useful in situations where the physical equipment on which a batch will run, is not known at design time. For example, a batch may run on one of four available reactor vessels but there is no way of knowing which vessel will be selected prior to the batch being executed. Without a mechanism such as item classes, the user would need to configure one report template per unit and then select the appropriate template after the batch run. Clearly, this presents a very large maintenance problem. The RAPID Batch solution is to categorize each I/O point into an item class, and have one item class per I/O point category, for example, level transmitter class, temperature class, etc. The item class is then specified in the report template, and at report runtime, the Batch Report Engine selects the appropriate I/O point to populate the report. Item classes are configured in the Configuration Tool described earlier.

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RAPID BATCH REPORTING TOOL

This web based tool, a .NET application, allows the user to select batches and run reports against a selected batch, procedure, unit procedure or operation. Extensive filters are available to drill down to a specific batch or collection of batches matching the filter criteria. Users may filter by database, batch system, time or may specify procedural, equipment and formula selection criteria. Figure 4 below shows the Batch Reporting Tool populated with batches.

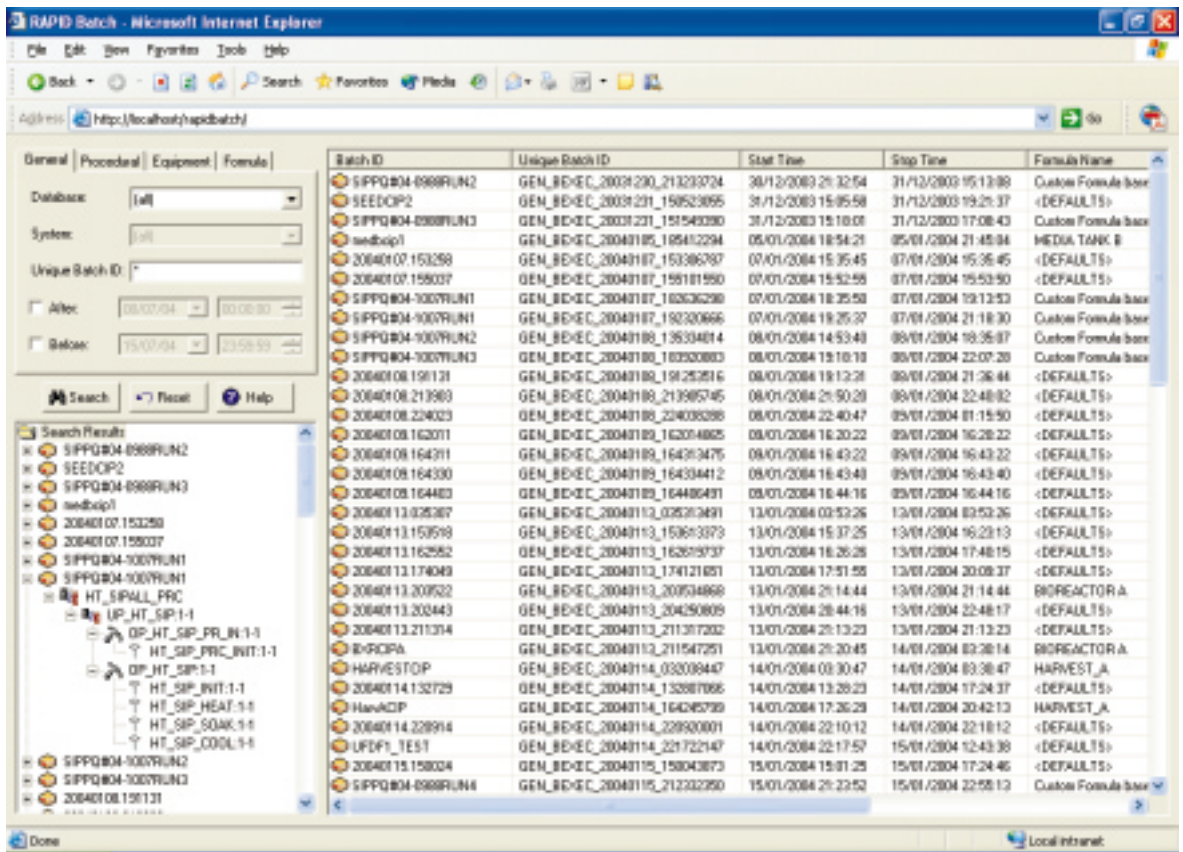


Figure 4 – Batch Reporting Tool

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Right-clicking on an item in the tree or grid allows selection of a report template for that item. Figure 5 below shows a sample report.

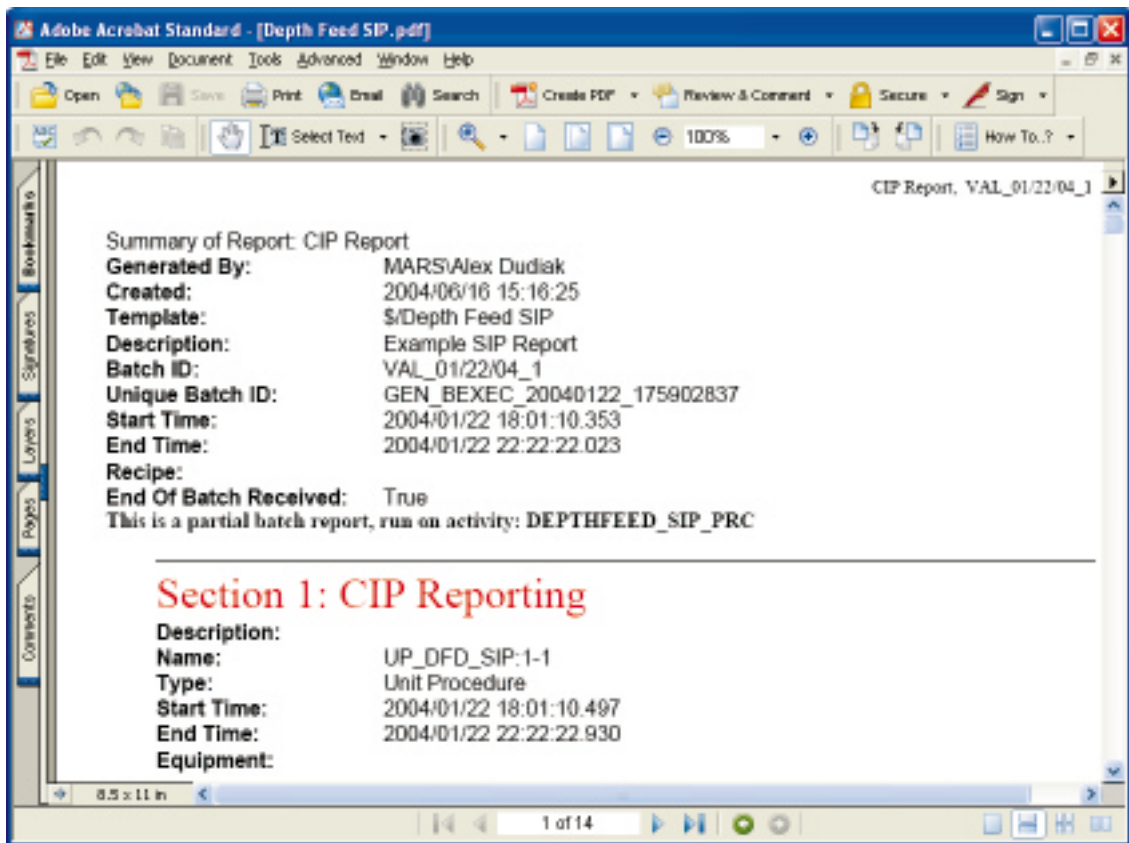


Figure 5 – Sample Report

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Reports are presented in HTML for display and may be optionally saved in PDF format in the HUSBO database. The PDF form of a report may be digitally signed using Adobe Self Sign technology. The signing is created using the user's system credentials; Windows user name and password. An optional reason for the signing may also be specified. Reports may have additional signatures, for example, as part of a review process applied to them with the existing Report Viewer tool. Digital signing requires that Adobe Acrobat 6.0 is installed and licensed on the RAPID server computer.

CONCLUSION

The RAPID-Batch components are based on the RAPID family of software products that are designed to help manufacturers improve global manufacturing performance. Automsoft's RAPID-Batch includes a comprehensive set of batch reporting and analysis tools to help improve batch operations. The RAPID Batch components provide unparalleled ease of batch reporting and management and provide manufacturers with the most powerful solution available today.

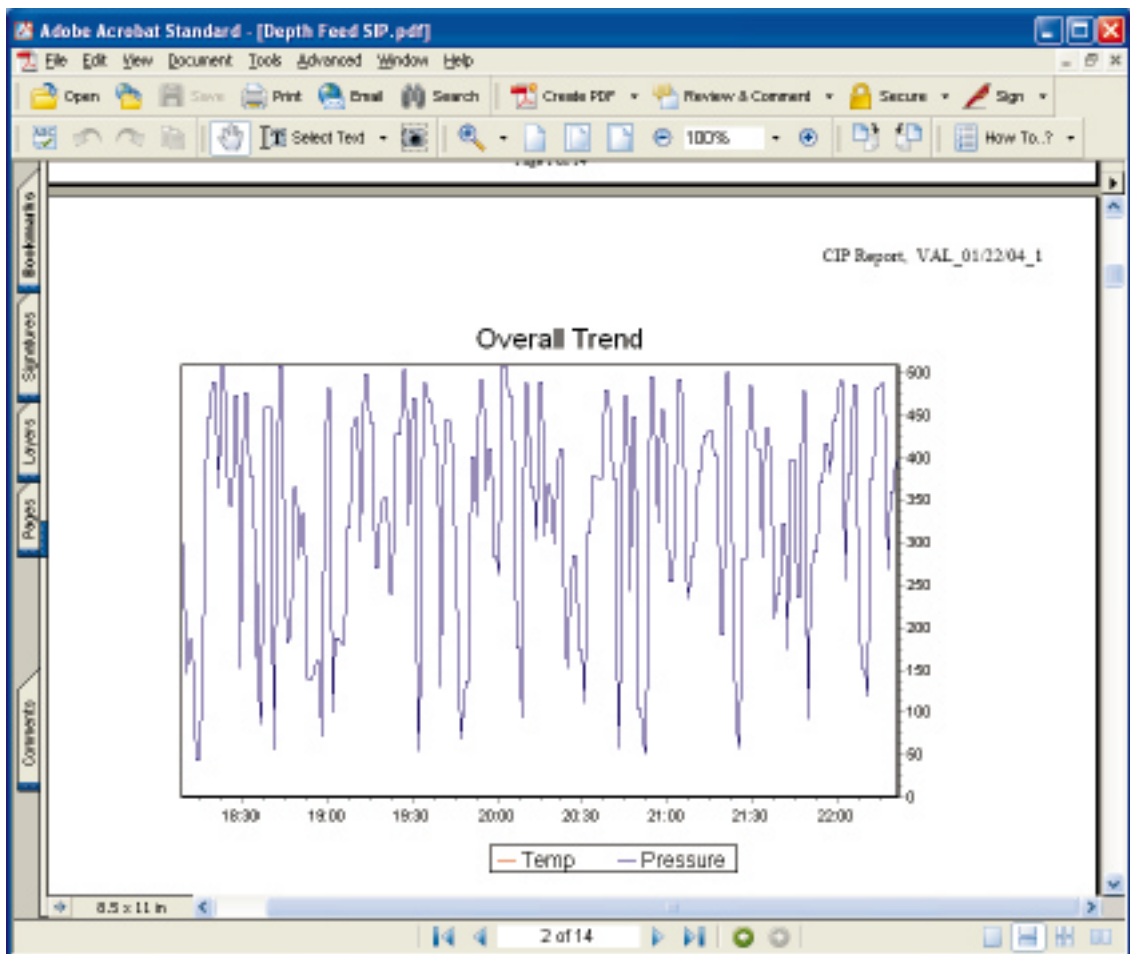


Figure 5 – Sample Report

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ABOUT AUTOMSOFT

Automsoft is a leading global provider of advanced manufacturing intelligence systems for process industries across a range of sectors, utilizing advanced database software to collect and store, consolidate and analyze production data and bridge islands of data within the plant and the enterprise. Its core product suite RAPID™ has been configured for the requirements of different industries while from an early stage, its specialist RAPID-Pharma™ system has been focused on the specific needs of the life sciences sector. In recent years that has notably involved the compliance requirements of FDA 21 CFR Part 11 while more recent development involves supporting the new Process Analytical Technology (PAT) approach to manufacturing sponsored by the FDA.

The experienced development and support team of automation professionals has earned an international reputation for its expertise. At the same time the leading edge development of Automsoft RAPID software has been to a great degree in collaboration with industry partners, addressing real manufacturing challenges and anticipating trends in manufacturing technology.

Founded in 1997, Automsoft has its United States of America head office in New York and its European Union head office in Dublin, Ireland. Automsoft has customers in the United States and Canada, in the EU, Norway and Switzerland.

Automsoft is a member of the OPC Foundation and International Society for Pharmaceutical Engineering (ISPE) and is quality certified to ISO 9001:2000.

For further information, please visit www.automsoft.com