Introduction

Exaquantum/Batch is an intelligent and scaleable S88 based Batch PIMS (Plant Information Management System). It provides an analysis and reporting application that collects, stores and displays current and historical data from batch production, equipment and recipe viewpoints. This enables production and recipe management, process engineering and operations staff to easily access batch production information for decision support, production planning and scheduling, analysis, process improvement and quality purposes.

Exaquantum/Batch is the ideal productivity improvements tool that enables you to focus on KPIs (key process performance indicators) using the web based browsing, analysis and reporting user interface and to develop action plans for process improvements.

The key features of Exaquantum/Batch are:

‘Out of the box’ integration with Yokogawa’s CENTUM CS 3000/VP for Batch control systems, providing immediate usability and benefits, based on the S88 standard, without complex engineering and database configuration.

Standard analysis of data providing:

• Automatic calculation and charting of cycle times and unit utilization for each batch.
• Automatically calculated performance ratings for each batch.
• Comparison of batches to peer groups.
• A powerful tool for sorting and comparing batch history data.

A customizable web based user interface providing:

• Batch including the control recipe, master recipe and equipment data accessible from one place – BatchWeb.
• Ad-hoc web access to data without custom display generation.
• Secure data storage with minimal client administration.

Optional support for 21 CFR Part 11 capable functionality through the use of electronic records and signatures.
Figure 1 Plant Wide Data Collection

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1. **Product Overview**

Exaquantum/Batch is a batch plant information management system that collects and stores current and historical batch, equipment hierarchy and master recipe data to provide true batch information management.

![Diagram of Exaquantum/Batch](image)

**Figure 1-1**
2. Features & Benefits

Traditional plant historians present batch data as a list of tags and trend values which users then have to configure to provide a useful view of the data. Exaquantum/Batch’s “Out of the box” functionality provides automatic collection of batch data, thereby freeing users from having to build queries and displays to obtain and view the data.

As batch data is collected it is immediately available for display in BatchWeb, the web based user interface, in a number of standard views available for displaying batch, equipment and master recipe information. Batch and product performance data is also automatically calculated and available for display.

Features

Automatic Batch Data & Master Recipe collection
- Minimizes setup time and engineering
- CENTUM CS 3000 R.3.03+/VP R4.01+ for Batch control Systems

Custom Batch Data collection
- For any control/MES system with an OPC Data Access 2.0 or 2.05a server
- Primary data source or may augment automatic batch data collection

Web based user interface
- Standard display structure based upon S88
- Batch trends, Gantt charts, Data filtering, etc.
- Standard cycle time analysis displays
- Secure access to data
- Access data from any intranet capable PC

Strong batch reporting platform
- Batch, master recipe & equipment data available for any report
- Custom reports
- No artificial limits to the number of data items in a report
- Reports may contain any information stored in Exaquantum/Batch

Standard analysis calculations & charts
- Cycle time & batch performance metrics automatically maintained

Meeting demands for standards based solutions
- Based upon S88 models & terminology
- OPC Batch, Data Access and Alarms & Events
- FDA 21 CFR Part 11 (option)
High level batch solutions coupled with batch control system
- Traditional Time & Tag based PIMS no longer sufficient for batch solutions
- High performance & reasonable cost

Batch Data Archiving
- Reduces the size of online data storage
- Reduces hard disk requirements

Benefits
Decrease costs of batch record keeping
- Minimize up front installation & engineering costs
- Decrease on-going production record keeping costs

Improve quality
- Compare high and low performing batches and products

Improve production efficiency
- Easily monitor actual cycle times for batches and products

Reduce costs associated with regulatory compliance

Release products sooner
- Reduce time spent collecting, storing, viewing & reporting production data

Improve product designs
- Analyze batch performance on a product basis

Improve plant capabilities
- Find equipment bottlenecks and trouble spots using BatchWeb and reporting functions

Enable more accurate forecasting by using historical cycle time data

Give production visibility to all plant personnel and enterprise systems

Improve customer satisfaction
- Raise quality and improving schedule performance

Lower operating costs by finding waste in production

Save money
- Consolidate batch production records into one historian with standard data access and long-term archive capability

Deliver better information to decision makers
Questions Answered by Exaquantum/Batch

- “When did we make batch “B-4290” and what equipment was used?”
- “What products were in production at 14:00, 2 June 2000?”
- “What was unit RXR1 doing at 14:00, 2 June 2000?”
- “How did we make this product in March 2000?”
- “How long does it usually take to make this product?”
- “Which reactor usually makes this product quickest?”
- “What products have the greatest variability in their production?”
- “What is our unit utilization?”
3. Data Collection and Storage

Exaquantum/Batch provides the following four methods of data collection which are dependant on the data source available:

- Automatic Data Collection
- Custom Data Collection
- Trend Data Collection
- Alarms and Events Data Collection.

Automatic Data Collection

Exaquantum/Batch is designed primarily to collect data in S88 format from an Exaopc Batch Server which is then entered directly into the Production database and is immediately available for viewing, regardless of the batch status. Automatic Data Collection runs as a service on the Exaquantum/Batch Server and requires the user to choose the target Exaopc Server required to begin collecting data. The Exaopc Batch Server is used to collect:

Batch Data

Exaquantum/Batch automatically detects the existence of batches and their contents, while batch and unit recipe properties are collected at their start and end. The detection of new batches and the collection of properties are recorded, with time stamped entries, in the Production database.

Equipment Data

Exaquantum/Batch automatically detects the current equipment hierarchy, including properties, and changes to it over time. The detection of new equipment items, deleted equipment items and equipment property changes is recorded with time stamped entries so that the equipment hierarchy at any point in time can be reconstructed.

Master Recipe data is also automatically collected from CENTUM CS 3000/VP for Batch control systems and is entered directly into the Production database. Master Recipe Collection runs as a service on the Exaquantum/Batch Server and requires the user to choose the target Human Interface Stations (HIS) to monitor. As new recipes or new versions of existing recipes are loaded they are copied to the Production database and recorded with time stamped entries so that the master recipe contents at any point in time can be reconstructed.

Batch and Unit Recipe performance ratings are automatically calculated/re-calculated as each batch or unit recipe ends to provide instant analysis in the BatchWeb user interface.
Figure 3-1 Data Flow for Automatic Data Collection
Custom Data Collection

Custom Data Collection is used to collect batch data when an Exaopc Batch Server is not available. This function may be used in conjunction with Automatic Data Collection or by itself to collect batch data from systems other than CENTUM CS 3000/VP for Batch Control systems. As long as a system has an OPC Data Access 2.0 or 2.05a Server then data may be collected using Custom Data Collection.

When Custom Data Collection is used Exaququantum/Batch must be configured to map trend data collected by Exaququantum/Batch into the Production database and equipment hierarchy data must be manually entered. Exaququantum/Batch does not collect master recipes as part of Custom Data Collection. A custom batch data configuration tool is provided to map data into the Production database and create S88 based batch data records. This is achieved by assigning an Exaququantum tag or value as a ‘trigger’ for collecting a set of Exaququantum tag values which have been assigned as properties and formula items for a specific batch, unit recipe or operation. The data collected is then entered directly into the Production database.

As for automatic collection, Batch and Unit Recipe performance ratings are automatically calculated as each batch or unit recipe ends to provide instant analysis in the BatchWeb user interface.

An equipment hierarchy configuration tool is provided to enable an S88 based equipment hierarchy to be created.

Figure 3-2 Data Flow for Custom Data Collection
Trend Data Collection

Exaquantum/Batch contains an embedded data historian (‘Exaquantum’) that collects and stores process values that can be used by Exaquantum/Batch to display batch trends.

Alarms and Events Data Collection

For both automatic and custom data collection methods, alarm and event data is collected by the Exaquantum OPC Alarm & Event client and stored in the Alarm & Event database. When used with CENTUM CS 3000/VP for Batch control systems the alarms and events can be associated with batch IDs and units for reports and display on the BatchWeb GUI.

Trend and Alarm & Event Data Storage

Data collected and stored in the Trend and Alarm & Event databases is controlled using the provided Exaquantum/Batch Historian Management Tool. This Tool enables a System Administrator to set up auto-archiving and deletion routines from the online database to archive media.

When using Automatic Data Collection, data in the form of tag values from the Trend database are used to produce batch trends. This trend data is not copied into the Batch database and must therefore be obtained each time a request is made through BatchWeb to display the trend.

When using Custom Batch Data Collection, data values are obtained by mapping Exaquantum tags to produce batch data which is then associated with equipment. These values are stored in the Batch database.

Data Storage

Data collected by Exaquantum/Batch is stored in either the Trend, Alarm & Event or Production databases. The Trend and Alarm & Event databases are contained within Exaquantum however the Production database is unique to Exaquantum/Batch.

Data from all three databases is available to BatchWeb displays and reports.

Data Archiving

A Data Archiver utility is provided to enable systems administrators to manage the amount of online Formula Item and Report data stored on disk. The Data Archiver should be used to reduce the amount of data stored before free disk space is reduced to a critical level.
4. Automatic Analysis Features

A unique feature of Exaquantum/Batch is the provision of automatic batch data analysis information that provides users with a basic level of analysis capability without performing any custom programming.

Upon completion of a batch or unit recipe, Exaquantum/Batch automatically calculates a set of metrics for the batch or unit recipe and updates statistical values for the master recipe the batch is based upon. These metrics are then consolidated into a ‘Performance Rating’. The automatic analysis feature is independent of the method of data collection used.

The types of metrics collected are:

**Cycle time**
Cycle time is calculated from the time a batch or unit recipe starts until it was completed.

**Percentage of time in hold**
The percentage of time the batch or any of its unit recipes or unit instruments was in hold.

**Number of times held**
The number of times the batch or unit recipe was placed in hold.

**Number of events**
The number of alarm and event messages associated with a batch or unit recipe.

**Was it aborted?**
Indication if a batch or unit recipe was aborted, e.g. stopped prior to its normal completion.

**Performance Rating**
The Performance Rating is based upon other batch metrics and indicates the relative performance of a batch as compared to other batches based upon the same master recipe revision. It is used to quickly identify top and bottom performing batches and may be used in BatchWeb to filter and sort historical records for browsing or for inclusion in reports.

Upon completion of a batch or unit recipe, Exaquantum/Batch automatically calculates a performance rating for a batch or unit recipe.

Analysis of performance ratings may then be used to support improvement action plans and Six Sigma programs.

In Exaquantum/Batch, a performance rating is an integer percentage between 0 and 100 that reflects how a batch or unit recipe performed during production. A value of 0 % represents the worst performing batches and unit recipes and 100 % the best performing batches and unit recipes.

The rating is based upon standard properties such as batch cycle time and whether it was held or aborted and by comparison of these values to other batches based upon the same revision of the master recipe.

A tool is provided to modify the performance rating calculation parameters.
5. BatchWeb

Exaquantum/Batch’s operational user interface is a data driven, web based application called ‘BatchWeb’. BatchWeb is presented as a web portal with individual web pages, populated with data stored in all Exaquantum/Batch databases, organized as a web site. This permits the same web page layouts to be reused with different data as requested by a user with no display building required by the user. For example the same table or chart may be displayed with batches for the year 2000 then displayed again with batches for the year 2001.

Some of the main features of BatchWeb are listed below.

Standard web page layouts

All pages, called ‘Views’ in BatchWeb, are available to display batch data immediately with no engineering or display building required.

Simple data browsing

Menus are provided to easily navigate between views. Batch, equipment or master recipe data for single or multiple batches may be displayed for each batch in a list or chart view.

Automatic data analysis

Batch and unit recipe performance ratings are automatically calculated and displayed in various views.

Reporting

Custom templates are available to run reports based on the data set you have selected.

Data Filtering

On screen tools are provided to filter and sort batch data and display only the data required.

Related ‘Views’

Specific batch data displayed in one view may be selected and then displayed in another view. For example, a number of batches may be selected in the ‘Batch List’ view and then displayed in the ‘Cycle Times’ chart view. The chart displays the cycle times for each batch selected.

Save data and view together

Using the ‘MyList’ feature, batch data and the view in which it is displayed may be saved (bookmarked) and then re-displayed at any time, regardless of the current data filtering set.

View all types of batch data in one application

BatchWeb views obtain data from the Batch, Trend and Alarm & Event databases so that all data specific to a batch may be displayed using BatchWeb.

View Exaquantum mimics, trends, alarms & events and tag and function block data

BatchWeb provides navigation through the Plant view to Exaquantum data.
Browse other web sites

Using the ‘QuickLinks’ feature, users may create a list of links to intranet and internet web sites.

The figure below shows the data driven nature of BatchWeb. The Exaquantum/Batch web server uses page layouts and data from the Batch, Trend and Alarm & Event databases to build web pages that are displayed on a web browser. Most of the pages are designed to be read only, however a few pages permit users to enter data into the database.

![Data Driven Nature of BatchWeb](image)

**Figure 5-1**

Data browsing enables users to view the data in the Production, Trend and Alarm & Event databases on a batch basis, with data based on production-oriented keys such as batch ID, product ID, and master recipe ID.

The Exaquantum/Batch analysis capabilities are targeted to provide simple analytical feedback on common batch production KPIs (Key Performance Indicators) such as batch cycle time, equipment utilization, product summaries, and batch performance ratings. More complex and application specific analysis may be performed by using third party analysis packages in conjunction with Exaquantum/Batch.

In BatchWeb you may select custom configured report templates to run against batch, master recipe or equipment data. Reports can span multiple items such as batches or cover a single item as in a batch report. The report output may be printed, e-mailed or stored on disk as an archived report. Previously archived reports may also be viewed.
5.1 Browsing

The BatchWeb user interface provides the ability to browse current and historic batch, equipment and master recipe items and their properties, based on S88 models.

Through a set of standard displays, called ‘Views’ in BatchWeb, and standard menus and links, users may navigate between views and drill down using selections and on screen filters to the specific data required. Using BatchWeb there is no requirement to build queries or have knowledge of SQL to obtain data.

The following on screen tools and features are provided:

Filter / Advanced Filter

The filter and advanced filter tools allow users to filter data by:

Date

Batch

• Batch ID - A specific batch or group of batches may be selected.
• Master Recipe ID - Batches based on a specific or set of master recipes may be selected.
• Product ID - Batches with a specific or set of product property values.
• Unit(s) Used - Batches that ran on a specific or set of units.
• Batch Performance Rating - Include batches within a specified range.

MyList

The MyList on screen tool allows users to save batch data and the view in which it is displayed into a named group. This group may then be selected for display at any time, regardless of the current data scope. Users then have the following options for managing their groups:

• Add or remove items from the group.
• Export the group to share the data with a colleague. The data is converted to XML format so may also be imported and used in other Microsoft Office applications.
• Import a group from a colleague.
• Create a new group and add items to it.

QuickLinks

The QuickLinks on screen tool allows the user to add or remove hyperlinks to intranet and internet addresses. Based on the user’s privileges, hyperlinks may be globally added or removed for all users.
**Item selection**

In a number of BatchWeb ‘List’ views specific data items may be selected for display in another related view. Through item selection, users may:

- Simultaneously compare two or more batches from any time using standard charts.
- Specify batch comparisons based on both time and batch property criteria.
- View trends for multiple batches from different times on the same chart using both absolute and batch relative times.
- View production summary data.
- View batch and master recipe summary and detail data.
- Manually enter performance ratings batches.
- Manually enter formula item data for batches.
- View event and trend data for time period specified by batch events (e.g. batch start, batch end).
- View Gantt charts showing batches and unit recipes over time and then compares them in relative time.
- View alarms and events for batches.
- Search for batches by a number of batch properties such as batch ID, the units used, the product manufactured and the master recipe on which the batch was based.

**Printer friendly version**

In some views, as the number of batch records cannot be shown in one page, hyperlinks 1 2 3 4 etc. are provided to view other pages of records. To allow users to view all records in one long list, the ‘printer friendly version’ hyperlink may be selected. This pops up a new window populated with a table containing all batch records in the currently selected block. The table may then be printed using the window menu.
5.2 Data Scope

Since the Exaquantum/Batch databases are able to contain data for a large number of batches and master recipes over a long period of time, users are provided the means to limit the scope of data their session of BatchWeb uses. The following techniques are provided for adjusting the data scope:

Table 5-1

<table>
<thead>
<tr>
<th>Technique</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter and Advanced Filter</td>
<td>Each user session has one active filter. Filters may limit the scope of data by time period, item ID (i.e. batch ID, master recipe ID) or other properties. Once set, Filter settings are retained for future sessions of BatchWeb for that user.</td>
</tr>
<tr>
<td>Item Selection</td>
<td>Users may select specific items within a view to be used by other related views.</td>
</tr>
<tr>
<td>MyList</td>
<td>MyList is a user generated and maintained list of batches, equipment items, and master recipes that may be saved, re-used, and shared. MyList may be associated with a specific view so that when re-used the view and data scope are used by BatchWeb.</td>
</tr>
</tbody>
</table>

5.3 Analysis

BatchWeb provides analysis of batch data, based on cycle times and performance ratings, through the provision of standard charts and reports.

Batch, equipment or master recipe data items are first selected from listings based on the current data scope. Through a menu selection, a number of standard charts are available for display:

- Batch cycle times for multiple batches from any time
- Batch cycle time frequency for multiple batches from any time
- Batch performance ratings for multiple batches from any time
- Batch performance rating frequency for multiple batches from any time
- Batch trend displays for batch properties, for multiple batches from any time
- Unit utilization.

In addition, each chart has a number of options for configuring the display to increase or reduce the amount of information displayed.
6. Reporting

Exaquantum/Batch provides the ability to create, run, view and approve reports. Reports may contain batch, equipment and master recipe data from the Exaquantum/Batch Trend, Production and Alarm & Event databases.

The Report Template Manager Tool is provided to create report templates and set up schedules for running of reports, which may be either event driven (such as batch end) or based on a fixed time period.

Reporting Activities

In Exaquantum/Batch, reporting consists of the following three activities:

Creation and management of report templates

- Report templates are used to specify the contents of reports.
- Report templates may be run any number of times.
- Templates allow parameters to be assigned to vary the content of a report.
- Templates are created using the Report Template Manager tool.

Report output generation and management

- Each time a report template is run a report output file is generated.
- Report output files may be checked out/in for editing.
- Report output files may need to be approved.
- The report output may be distributed via email or print and is saved in the archive for later reference.

Report archiving

- All report output and template files are saved in the report archive.
- Archived reports may be accessed at a later date.

Creating and Running Reports

The Report Template Manager Tool is used to create a reusable report template, which is then stored in the report archive.

When a report is run, the template is populated using data in the Production, Trend and Alarm & Event databases to build the report output. The report output is stored in the report archive and may be viewed using BatchWeb, distributed via email or printed.

Reports may be run from a BatchWeb client or automatically using the Report Template Manager’s periodic and batch scheduling features.

The report archive maintains copies of report output files. Access to the archive is limited and the contents of the archive may be configured to permit reports to be checked in/out. Authorized personnel may delete report output files from the archives.
6.1 Report Templates

Report templates are designed in the Microsoft Excel environment using standard Excel files and contain parameterized queries which are linked to batch data and may be edited as required to specify the layout and data content of a report.

Template Creation

Authorized users may use the Report Template Manager tool to create new report templates. New reports have an initial status of 'Not Approved'.

Template Test

Report templates may be tested in the Excel environment prior to their being saved.

Template Approval

Report templates must be approved prior to being used in BatchWeb. The Report Template Manager tool is used to approve a template. Report template approval is recorded in the audit trail. Once approved, the report template’s status is changed from 'Not Approved' to 'Approved'.

Template Use

Report templates are used by running them manually using the BatchWeb user interface or automatically through the scheduling function within the Report Template Manager tool.

Template Modification

The Report Template Manager tool is used to open an existing report template for modification. If the report template status is ‘Approved’ it is marked as 'Not Approved' when modified. The existing ‘Approved’ template version is left available to be run from BatchWeb until the new version is approved.

Template Retirement

Report templates are placed ‘Out of Service’ in order to prevent them from being run. This provides an option other than deleting a report template when it should not be run any longer.

Reports may be un-retired, approved and placed back in service. A retired report has a status of ‘Out of Service’.

Template Versions

The Report Template Manager tool automatically assigns version numbers to reports.

New versions of reports are created whenever an approved template or a template being approved is modified. Multiple modifications and modification sessions may be made to the same report template without having the version changed.

When a newer version of a report template is approved it is used when that report is run unless an older version is specifically identified to be run.
Audit Trail

The following report template lifecycle events are recorded in the Exaquantum/Batch audit trail.

- Creation
- Approval
- Use (each time a report is run the report ID and the template used is recorded)
- Modification (changes to templates, whether they are approved or not).

Each audit trail entry includes some or all of the following as appropriate:

- When the action was performed
- Who performed action
- What action was performed
- Where the action was performed
- Why the action was performed
- How the action was performed.
Generating a report

A report may be generated using any approved template available to the user in the BatchWeb 'Report Template' view.

Selecting a template and running the report populates the template with batch data, renders it as an Adobe Acrobat PDF file and adds it to the list of available report files for viewing in the 'Report Archive' view.

Note: The report produced will contain all applicable data available in the Exaquantum/Batch databases. It is not based on the data scope current at the time the report is run.

Reports may also be scheduled to run on a time basis or to run when a batch or unit recipe completes.

Approving a Report

After running, the initial report status is 'Not Approved'. The report may then be viewed by all users or only by authorized users, depending on the option selected in the Report Template Manager tool. The report may be quickly approved by an authorized user through a few simple selections and is then available for viewing by all users.
7. Security

The basic security model of Exaquantum/Batch is built around Windows based User Groups. Users are allocated to different User Groups to give them the privileges appropriate to their task or role. A basic set of User Groups is provided and installed with Exaquantum/Batch and can be supplemented with additional groups to suit local requirements.

Examples of privileges which may be assigned to each user account are:

Access to BatchWeb
If an unauthorized user attempts to access the site their browser will display a standard web page stating that they are not authorized to access the requested page.

Edit Report Templates
Creating and editing report templates is usually restricted to engineers or administrators.

Approve Reports
In general, users may only view approved reports.

Manually enter data
Formula item values and performance ratings may be manually updated.
8. Licensing Policy

Exaquantum/Batch is licensed according to the following:

- Number of users
- Number of Recipes
- Number of Exaquantum tags
- Inclusion of 21 CFR Part 11 Capable functions
- Inclusion of the Custom Batch Data Collection Interface.

A single license key is issued containing an authorization code for all products purchased which determines the conditions of use and the components that may be installed by the user.

For added security, the license key contains an expiry date, after which software cannot be installed.
9. S88 Capable

The introduction of the ANSI/ISA-S88.01 standard has provided a framework for developing applications that can utilize batch data for analysis and process improvement programs.

Exaquantum/Batch has been developed, based on the S88 standard, to work primarily with Yokogawa's Exaopc Batch Server, providing automatic batch data collection with minimal configuration requirements.

Batch data may also be collected from other suitable OPC Data Access Servers by utilizing the Exaquantum/Batch Custom Data Collection functionality.

Exaquantum/Batch collects batch, equipment and master recipe data based on S88 models and terminology to integrate with S88 based batch control systems.

Physical Model

ISA S88.01 defines a Physical Model consisting of seven levels as shown in the figure below.

Custom Data Collection

For Custom Data Collection the Equipment Configuration Tool enables a user to create a hierarchy based on the S88.01 Physical Model shown.

Automatic Data Collection

Equipment data collected is based on the Plant Hierarchy created in the CENTUM CS 3000/VP for Batch control systems. This is configured around the S88.01 Physical Model shown, with the exception of the Enterprise level, to integrate with the Batch database schema.

![Figure 9-1 S88.01 Physical Model](image-url)
Control Activity Model

ISA S88.01 defines a Control Activity Model consisting of seven activities as shown in the figure below.

Exaquantum/Batch is concerned with the Production Information Management activity.

![Control Activity Model Diagram](090102.ai)

Procedural Control Model

In a batch process, operating procedures and manufacturing procedures are changed according to the product to be made. The S88.01 standard permits the Procedural Control Model to be expanded or collapsed. Exaquantum/Batch supports the Procedural Control Model as shown in S88.01-1995 Figure 14. The figure below is a hierarchical representation of these procedures.

In this diagram the recipe contains a procedure, unit procedures and operations, while phases are implemented as equipment logic in the equipment operation. The equivalent terms used in Exaquantum/Batch are shown in brackets.

Data is collected at these levels using both automatic and custom batch data collection methods.

![Procedural Control Model Diagram](090103.ai)
10. **FDA 21 CFR Part 11 Capable**

Exaquantum/Batch provides functionality supporting the U.S. FDA regulation 21 CFR Part 11 for the secure, long term storage of electronic records and the application of electronic signatures. This is an optional feature and includes:

**Controlled access to Exaquantum/Batch data, providing a closed system.**

**Audit trail - A comprehensive audit log within the Exaquantum/Batch database that registers:**
- Changes to data values and the reason for those changes (user-supplied)
- Full name of the user and the machine that performed an action
- Tag and Function Block creations, movement, deletions, changes such as renaming, and status changes such as setting tags off-line for calibration.

**Security features to identify users:**
- Authority checks using standard Windows Authentication
- Logged on User’s Name permanently on display
- A system of account IDs and passwords working as electronic signatures for identification purposes.

**IMPORTANT**

21 CFR Part 11 contains a number of stipulations that are provided by the United States FDA Department.

In this document, FDA 21 CFR Part 11 Capable means the capabilities of Exaquantum/Batch provided by Yokogawa conform to these stipulations. They are developed by Yokogawa in accordance with Yokogawa’s interpretation of the stipulations in 21 CFR Part 11.

The users of Yokogawa products need to examine the conformities of Exaquantum/Batch to the stipulations in 21 CFR Part 11 and compare the features and capabilities to the security policy and SOP (Standard Operation Procedure) of users so as to operate and manage the use of Yokogawa’s products.
11. How to Use Help

The BatchWeb QuickHelp tool window, located at the bottom left of the screen, provides users with an easy way to access information for the view currently being displayed. The QuickHelp text changes as a user navigates through BatchWeb views, showing a brief description of the current view’s properties. Selecting the ‘Read more...’ hyperlink displays full information for the current view.

Exaquantum/Batch help consists of a number of web pages. When the ‘Read more...’ hyperlink is selected, a single page containing information for the current view is displayed. At the top of the page is the ‘Show’ hyperlink which when pressed launches the main help file.

Main Help File

The main help file provides the following for obtaining information on Exaquantum/Batch:

Contents
Pressing the Contents button opens a table of contents for the help. This consists of a number of books which each contain links to pages of information. Selecting a page then opens it in the main display area.
Some pages contain hyperlinks to other pages or images which will either pop-up in a new window or replace the current page. You may navigate through previously viewed pages by using the browsers ‘back’ and ‘forward’ buttons or by selecting them in the table of contents.

Index
Pressing the Index button opens a list of all index entries for the help.
Each entry in the list is a hyperlink to the relevant page. Where there is more than one page available which contains the index entry, then a list of available pages will pop up when the entry is selected. Selecting a page on the pop up then opens it in the main display area.
Above the list, a field is provided in which specific text may be entered. As you enter the text, the closest match in the list is highlighted for selection.

Search
As for the Index, when the Search button is pressed a field is provided in which specific text may be entered. Pressing the ‘Go’ button then populates the blank area below the field with a list of pages which contain the text for which you have searched.
Each page in the list is a hyperlink to that page which then opens in the main display area.

Glossary
Pressing the Glossary button provides a list of terms used in Exaquantum/Batch. Selecting a ‘term’ from the list then displays the term definition in an area below the list.

Printing
As for any web page, a user may print the current page and any linked pages, through the browser print functions. Web pages or popup screens may also be printed by right-clicking and selecting the ‘Print’ option from the menu.
Help Navigation

Users may navigate through the help using the table of contents or the standard Microsoft Internet Explorer paging controls.

Once a topic is open, it may contain a number of hyperlinks to display more information. Each hyperlink is preceded by an icon which determines the behavior of that hyperlink. See the table shown below for more details.

Table

<table>
<thead>
<tr>
<th>Icon</th>
<th>Behavior</th>
</tr>
</thead>
<tbody>
<tr>
<td>Link icon</td>
<td>Selecting the hyperlink replaces the current page with a new one.</td>
</tr>
<tr>
<td>Popup icon</td>
<td>Selecting the hyperlink pops up more information in a separate window. Clicking outside of the new window then closes it. Dropdown</td>
</tr>
<tr>
<td>Dropdown icon</td>
<td>Selecting the hyperlink displays hidden text below the hyperlink. Pressing the hyperlink again hides the text.</td>
</tr>
</tbody>
</table>

Help in Tool Windows

The Filter, MyList, QuickLinks and QuickHelp tool windows are located down the left hand side of the BatchWeb screen. Each screen contains an icon which when clicked pops up a single page showing help for the selected tool window. At the top of the page is the 'Show' hyperlink which when pressed launches the main help file.
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