

Utilizing InfoBatch to Generate Clean-in-Place (CIP) Reports



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Abstract

Many sterile manufacturing facilities find it difficult to manage Clean-in-Place (CIP) reports and are searching for a solution. InfoBatch is a flexible electronic batch reporting application that can be configured to create and maintain CIP reports for manufacturing facilities. The flexibility of InfoBatch allows the user to configure reports to include relevant data used to determine whether the CIP cycle has passed or failed. Automatic generation of CIP reports is another useful feature of InfoBatch which allows personnel to receive reports upon completion of a specific batch event. Electronic CIP reports generated by InfoBatch will replace paper-based records, improving accuracy and traceability.

Introduction

Clean-in-Place (CIP) is a process of cleaning the interior surfaces of pipes, vessels, process equipment, and associated fittings, without disassembly. CIP is used to ensure all production equipment is free of inorganic and organic contaminants in manufacturing industries that require high levels of hygiene such as pharmaceutical, biotech, cosmetic, personal care, and processed foods. At the laboratory level, equipment can be disassembled and cleaned manually; however, manual cleaning is impractical in large-scale production processes. Instead, cleaning solution is sent through the process path, or CIP circuit, without disassembly. Over time, CIP has evolved into an automated system with programmable controllers, multiple balance tanks, sensors, valves, heat exchangers, data acquisition, and specially designed spray nozzle systems.

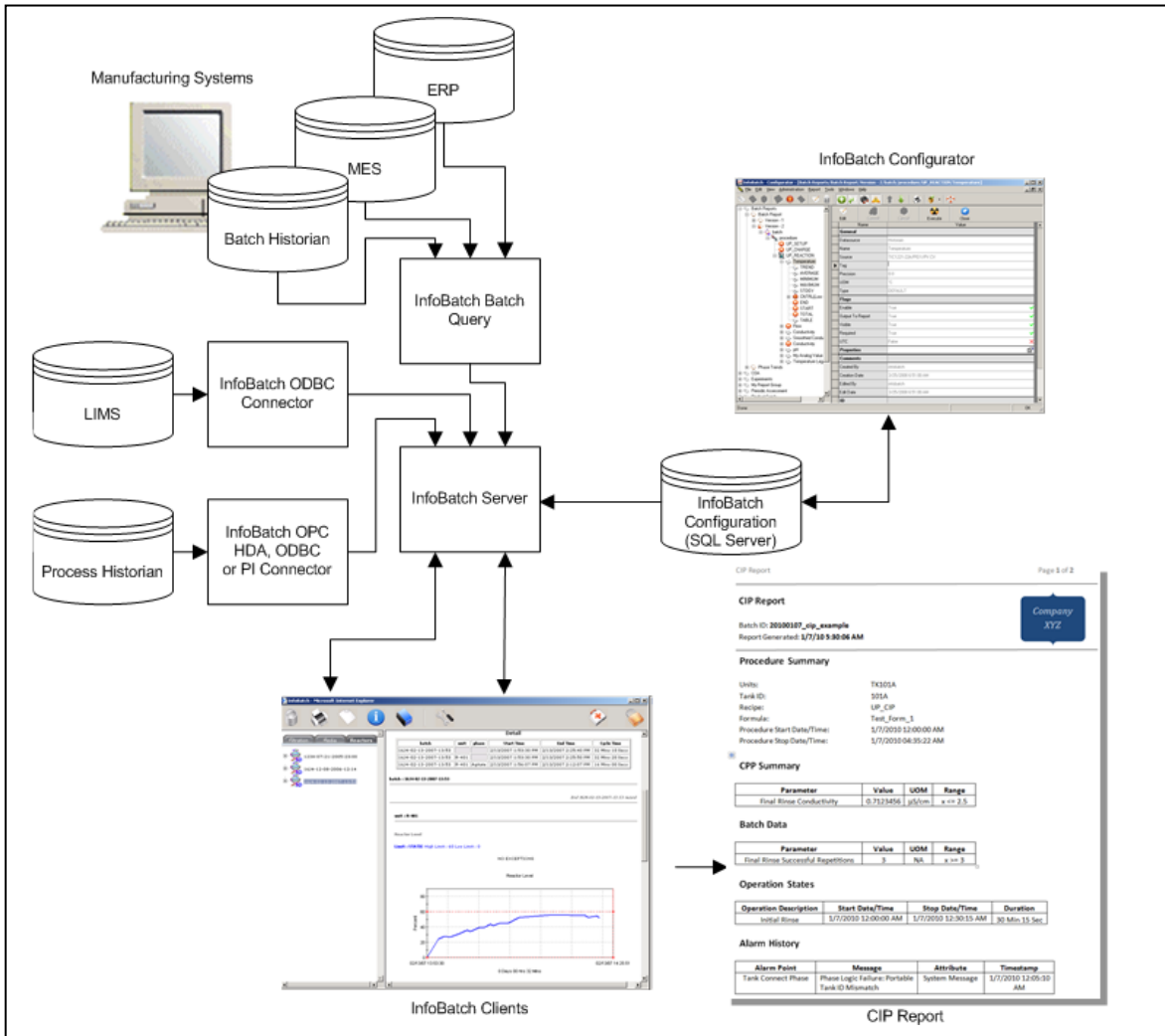
Most production facilities utilize multiple CIP skids to provide cleaning for the entire facility. A CIP skid is a standalone piece of equipment composed of the tanks, pumps, cleaning agents, valves, heat exchangers, control system, and instrumentation required to mix, heat, and deliver cleaning solution and rinse water to the equipment being cleaned. These skids respond to requests from process units to drain, rinse, clean, wash, and perform final rinsing on “dirty” production equipment.

After a CIP cycle is complete, CIP reports are generated within the production facility to provide operators with a summary of data. These reports assist the operators to determine whether the CIP cycle has passed and if all acceptance criteria were met. Reports can include critical process parameters, alarms, events, operator actions, batch commands, trends, cycle times, and detailed exception and/or limit violation summaries. InfoBatch, a flexible electronic batch reporting application, can be configured to create and maintain CIP reports.

How InfoBatch Works

When generating a CIP report, InfoBatch connects to the manufacturing information systems through an InfoBatch Connector, and retrieves data from the source without replication. The InfoBatch Connector library includes generic data interfaces, such as ODBC and OPCHDA protocols, as well as specific connectors for common process and batch historians. Data from virtually any modern manufacturing information system may be combined into a single “virtual database.” InfoBatch incorporates a unique hierarchical structure that mirrors product and

process genealogy. The recipe or cycle structure from a genealogy source is used to structure information from process data sources. A typical genealogy source for a CIP report would be a batch historian or an event log containing cycle start and end times.



CIP reports are generated on demand through the InfoBatch Navigator or the InfoBatch Web Client. The Navigator is an intuitive desktop client application where users can issue report requests manually. The InfoBatch Web Client is a web-based Navigator which can be accessed by any authorized user with a desktop web browser on the server. The InfoBatch Clients enable the user to query batches, drill down through unit procedures and operations, and generate reports corresponding to selected CIP cycles.

Using the InfoBatch Configurator, privileged users create comprehensive reports that, upon release, are available through the InfoBatch Clients. Configuration of report elements can be made for each procedure, unit procedure, operation, and phase of a batch. Since configuration is a matter of simple point-and-click operations, comprehensive reports can be created by users with limited software knowledge.

InfoBatch AutoGen enables batch reports to be automatically triggered, printed, and saved as Adobe Acrobat PDF documents. Automatic generation of batch reports can be based upon batch events, ad hoc events, or periodic rates. Triggers can be time-based, recipe-based, event-based, or triggered from an external system. For example, the user may want to automatically generate a CIP report at the end of a CIP cycle. AutoGen supports configurable disposition by report; therefore, reports can be sent to a specific printer or saved as a PDF file as well.

InfoBatch is designed to comply with the most stringent interpretation of FDA 21 CFR Part 11; Electronic Records; Electronic Signatures. Security and version control provide complete traceability. InfoBatch incorporates a secure browser to ensure that batch reports never exist in an electronic format that can be modified, thus satisfying a key element of Part 11 compliance. In addition, InfoBatch includes a detailed configuration audit trail. All tasks related to report configuration and maintenance are logged to the secure audit trail. The audit trail contains details regarding object modifications such as the reason for the change, the user who made the update, and the object values before and after the change.

CIP Reporting

The utilization of InfoBatch CIP reporting can help any facility answer the following questions: Is the CIP system working as intended? Has the CIP process cleaned all process equipment to the level required? Were there any alarms or exceptions during the CIP process?

CIP reports can be configured to include specific instrument values and process parameters such as temperature, pH, conductivity, concentration, duration, and flow rate. Analysis of the data can be performed by InfoBatch and output in the CIP report as well. Typical CIP reports may contain the following sections: procedure summary, critical process parameter summary, batch data, operation states, alarm history, batch commands, and route summary.

Each InfoBatch report contains a header which includes the batch ID as well as the date and time of report generation. A procedure summary can be included in the CIP report too, which may list information regarding the equipment, recipe, and formula used during the batch as well as the start and end dates and times for the CIP cycle. InfoBatch reporting capabilities are not limited to the examples described and shown here. InfoBatch can be configured to include any information relevant to a facility in the report format desired.

CIP Report

Batch ID: 20100107_cip_example
 Report Generated: 1/7/2010 4:37:06 AM

**Procedure Summary**

Units: TK101A
 Tank ID: 101A
 Recipe: UP_CIP
 Formula: Test_Form_1
 Procedure Start Date/Time: 1/7/2010 12:00:00 AM
 Procedure Stop Date/Time: 1/7/2010 04:35:22 AM
 CIP Cycle: **PASSED**

A duration for any event with a start and end time is calculated by InfoBatch and can be included in the CIP report. For example, the duration is calculated for the Initial Rinse operation shown in the Operation States section below. The hierarchical structure of InfoBatch enables the application to combine event data with genealogy and time-based data. Typically, a recipe from a batch historian will supply the genealogy data for CIP reports. However, InfoBatch can be configured to gather CIP cycle information from an event log and structure it into genealogy data.

A Critical Process Parameter (CPP) Summary would be a key indication of whether or not the CIP cycle passed or failed. This is normally the first section on the CIP report because it includes information important for regulatory compliance. The CPP parameter name, value, unit of measure (UOM), and limits can be included in the CPP Summary section, allowing reviewers to identify out of range parameters promptly. Conductivity is a common CPP parameter included in a CIP report because it indicates whether or not the system is free of contaminants.

CPP Summary

Parameter	Value	UOM	Range
Final Rinse Conductivity	0.712	µS/cm	x <= 2.5

Other parameters that may not be as critical to the process as CPPs could also be included in the CIP report under a separate section. These parameters can be listed in a Batch Data section. An instance of a Batch Data parameter could be the number of CIP route repetitions, which can be determined and reported by InfoBatch. For example, the facility may need to run three successful final rinse repetitions in order to pass the CIP process. InfoBatch can be configured to determine how many final rinse repetitions occurred and report the number of successful repetitions for each CIP route.

Batch Data

Parameter	Value	UOM	Range
Final Rinse Successful Repetitions	3	NA	x >= 3

An Operation States section may be important to include in the CIP report, to show how long it took to perform a list of specific steps during the CIP cycle. This will allow personnel to ensure that each critical step during the CIP cycle ran to completion. The Route Summary section of the CIP report is similar to the Operation States section except that it focuses on the CIP routes instead of the steps. This section can also be configured to include a status column, which will indicate whether or not a particular route has passed or failed. This column allows the operator to immediately determine whether the CIP process ran the correct routes and if all routes passed.

Operation States

Operation Description	Start Date/Time	Stop Date/Time	Duration
Initial Rinse	1/7/2010 12:00:00 AM	1/7/2010 12:30:15 AM	30 Min 15 Sec
Caustic Rinse	1/7/2010 12:30:15 AM	1/7/2010 01:02:11 AM	31 Min 56 Sec
Wash Rinse	1/7/2010 01:02:11 AM	1/7/2010 01:17:31 AM	15 Min 20 Sec
Acid Rinse	1/7/2010 01:17:31 AM	1/7/2010 01:37:49 AM	20 Min 18 Sec
Final Rinse	1/7/2010 01:37:49 AM	1/7/2010 01:53:58 AM	16 Min 09 Sec

Route Summary

Route	Status	Start Date/Time	Stop Date/Time	Duration
Sprayball	Pass	1/7/2010 12:45:20 AM	1/7/2010 12:45:55 AM	35 Sec
Vent	Pass	1/7/2010 12:45:59 AM	1/7/2010 12:46:09 AM	10 Sec

Examples of other report sections that may be included in the CIP report are as follows: Alarm History, Batch Commands, and Route CPP Performance Requirements. The Alarm History can be configured to include critical alarms that occurred during the CIP cycle. This section can include the alarm point, the alarm message, the attribute, and the time the alarm occurred. The Batch Command section would apply to CIP cycles with manual steps.

Alarm History

Alarm Point	Message	Attribute	Timestamp
Tank Connect Phase	Phase Logic Failure: Portable Tank ID Mismatch	System Message	1/7/2010 12:05:10 AM

The Batch Command table shown below can be configured to list the unit, the recipe step, the description, the user, and the timestamp for each type of operator action. For example, personnel may only be concerned with Hold, Restart, and Abort commands. This section of the CIP report will allow them to review when each command occurred, who initiated the command, on what unit, at what time, and during which recipe step. If operator prompts were also of interest, they could be included in this section or a similar section of the report as well.

Batch Commands

Unit	Description	User	Timestamp
TK101A	State Commanded: HOLD	Operator: J_Smith Operator Name: John Smith	1/7/2009 11:59:34 PM
TK101A	State Commanded: RESTART	Operator: J_Smith Operator Name: John Smith	1/7/2009 11:59:59 PM

The Route CPP Performance Requirements list the acceptable range for each CPP along with the unit of measure for each parameter. This section could be configured to appear as a separate table, like below, or these ranges could be included in the CPP Summary section as well. Again, it's all up to the customer!

Route CPP Performance Requirements

CPP	UOM	Range
Temperature	deg C	56.00 <= x <= 85.00
Sprayball Flow	lpm	77.00 <= x <= 150.00

InfoBatch CIP reporting may help a facility increase efficiency and reliability of cleaning process equipment, reduce operating costs, improve employee safety, and maintain environmental regulation compliance. The ability to send CIP reports directly to a printer located near the reviewer will decrease the review time, ensure immediate response to process deviations, and therefore, increase the overall productivity of a facility and its employees.

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Company
XYZ

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Acid Rinse	1/7/2010 01:17:31 AM	1/7/2010 01:37:49 AM	20 Min 18 Sec
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