Batch Control Systems Market and User Requirements

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ABSTRACT
Standards for batch control systems continue to be developed and incorporated into many current and new automation products. This effort is having significant impact on the increased growth of the global batch control systems market and the automation architecture of the next generation of process control systems.

This paper will include current market sales, forecasts, and strategic issues involved in continuation of this growth. It also will include a discussion of additional user requirements obtained from a survey of users in the food, beverage, pharmaceutical, and chemical industries. It will offer recommendations to address these issues, as highlighted in ARC studies, "Batch Control Systems Market Study 2001" and "Batch Control Systems Market Study 2002." The papers also will address how batch standards, traceability, event management, and change control will become core functions “designed into” future automation systems architectures rather than incomplete add on functions to current systems.
INTRODUCTION

Batch standards have come a long way since their introduction in 1995. They are now a part of most process automation systems and are being used to execute many projects in the chemical, pharmaceutical, food, beverage, and other industries. However, the opportunity for further adoption of these standards and growth of the batch control systems market will be dependent upon continued aggressive product enhancements, additional ease of use tools, and continued development of the standards. FDA ruling 21 CFR Part 11 must also be addressed. Current batch control systems lack many compliance-enabling features and other functionality required by users to meet their business needs. The evolving new generation of process automation systems will provide significant improvements in “core functionality” that will make it easier to achieve and maintain compliance in all of the regulated industries.

This paper will examine market size and potential, additional batch control system functionality required by users, user priorities based on business need versus current supplier priorities, and improvements in the “core functionality” of process automation systems that relate to 21 CFR Part 11 and regulatory compliance.

BATCH CONTROL SYSTEMS MARKET

The worldwide sales of batch control systems and services as defined by the S88 standard were $2.4 billion USD in 2000 with a projected annual growth rate of 5.9%. This growth rate of 5.9% is significantly higher than the 3.9% projected growth rate of all process automation systems. DCS-based systems accounted for 53.8% of all batch control systems. PLC-based systems accounted for 43.3% of all batch control systems. And PC-based systems accounted for 3.0% of all batch control systems. PC-based systems use is growing rapidly followed by DCS-based systems.

Worldwide BCS Market by Type

<table>
<thead>
<tr>
<th>Type</th>
<th>Market Share</th>
<th>CAGR</th>
</tr>
</thead>
<tbody>
<tr>
<td>DCS-based</td>
<td>53.8%</td>
<td>5.8%</td>
</tr>
<tr>
<td>PLC-based</td>
<td>43.3%</td>
<td>4.6%</td>
</tr>
<tr>
<td>PC-based</td>
<td>3.0%</td>
<td>20.9%</td>
</tr>
</tbody>
</table>

Figure 1

Analysis of the worldwide batch control systems market by industry shows that the chemical industry represents almost half of the systems sold, followed by the pharmaceutical industry. These two industries currently represent 75.6% of all batch control systems and services sold on a yearly basis. Although the food & beverage industry accounts for only 8.6% of annual sales, it is the fastest growing industry segment. This might be expected since this industry is dominated by batch processing but has had less involvement with the S88 standard.
Batch control systems represent only 28.8% of all process automation systems sold annually to the chemical industry, while the percentage of batch processes in this industry is much higher. Batch control systems represent 57.0% of all process automation systems sold annually to the pharmaceutical industry. This higher percentage is to be expected in an industry with a significant amount of batch processing. All industries have non-batch process automation in areas such as power and steam generation and waste treatment. In addition, most manufacturing operations are made up of both batch and continuous operations. The statistics for the pharmaceutical industry might lead to the conclusion that this market has limited additional potential. But while the bulk active ingredients plants are usually highly automated, the intermediates plants are not as well automated. In addition, the impact of FDA ruling 21 CFR Part 11 will fuel further growth of newer more capable batch control systems. Batch control systems represent only 10.0% of all process automation systems sold annually to the food & beverage industry, even though this industry is dominated by batch processing. Many interviews with users in this industry indicate that they are aware of the S88 standard and have evaluated currently available batch control systems. Their conclusions are that current systems require increased functionality and ease of use to be justified and to fulfill the needs of their manufacturing operations. They have further indicated that users and suppliers need more collaboration so that enhancements to batch control systems can be determined and prioritized based on user business needs.
industries are seeing less brand loyalty from consumers. Consumers instead are evaluating manufacturers based on product quality and service. Service includes the ability to deliver what the consumer wants, when it is wanted, and where it is wanted. Manufacturing is also consolidating. This is resulting in fewer and fewer plants with an increasingly complex mix of products that must be manufactured upon demand from mass merchandisers, wholesale clubs, and other consumer channels. There is a demand for more and more innovative products from drugs to foods to every type of consumer product. Further up the supply chain ingredient suppliers are also feeling this pressure. Global competition is squeezing margins. Regulatory requirements continue to increase.

In general, available project capital is becoming more limited. Project prioritizations and justifications are being scrutinized. They are being evaluated based on alignment with business strategies and prioritized based on return on assets (ROA) or earned value of money (EVM). More simply stated payback and simple ROI are not enough to justify projects. The entire enterprise is competing for limited capital. Batch control systems purchases are also competing with other needed purchases. In a recent survey, users indicated that increased manufacturing flexibility and product quality were two of the most important benefits derived from use of the S88 standard.

![Figure 4](image)

There is tremendous opportunity for growth in the batch control systems market. Growth can significantly exceed projections, if new functionality addresses these business needs.

**ISSUES & RECOMMENDATIONS TO ADDRESS GROWTH**
Users are continually expressing the need to increase functionality and reduce costs in both engineering and operation of batch control systems. User needs or concerns generally fall into four categories or four questions. How easy is it to engineer and operate? How scalable and modular is the system? How well does it integrate with upstream and downstream operations and other applications? How does it address my needs for traceability (genealogy) or compliance with 21 CFR Part 11?

Ease of Use Tools for Engineering and Operations

**Standard Control & Equipment Modules:** Some suppliers view this as unrealistic. Their experience is that it is difficult to get a user to standardize control modules across a single user organization let alone equipment modules. In addition, it is unlikely that even several large users lack the financial leverage on any supplier. But there have in the past been very successful supplier products that did provide a limited set of standard modules prior the development of the S88 standards. There are also at least a couple of small suppliers focused on configuration tools who are providing their own set of standard control modules. There are even some users who have developed their own standard control and equipment modules for internal use throughout their company.

Developing standard control and equipment modules would require a broad cross section of users in all these industries to identify at least a limited set of common modules before a supplier is likely to be interested. If large suppliers do not chose to develop and adopt common module, several large users may be able to leverage a small supplier whose products are focused on configuration tools.

**Unit and Equipment Modules Visible at the Batch Management Level:** Many operators need this visibility to run their operation. Some users do not want their operators viewing phase level operations.

**Enhanced HMI View to the Span of Operations the Operator Controls:** This is a standard single screen HMI view that allows the operator to see the status of multiple batches the operator is supervising. This would show the current state of each batch and any need for operator action on each batch. It is a simple request and a very important requirement for many users.

**A Common Phase Structure:** A common phase structure would aid in the development of standard and reusable application code and communications between recipe and equipment phases. Consistent code across multiple plants is important to FDA inspectors.

**Standard HMI Object Characteristics:** This would allow each supplier to develop a better HMI library of objects, reduce engineering efforts, and facilitate improvement of operations.

**Tools to convert & change control P&IDs to specifications & control/HMI code:** This is already occurring, but the effort needs to continue. Users have begun to specify this requirement in their bid specifications, identifying one of only a few products currently on the market. Specifying it as a requirement has leveraged further use and development of these products. Only a few years ago no products existed.

**Site to Master Recipe Conversion Tools:** Today most users who do generate and maintain General and Site recipes do so in text or tabular form. The transformation of these recipes to Master and Control recipes are done manually. This is a labor intense and often difficult transformation, limiting the adoption of standard S88 recipe software.
At the moment this may be low on the priority list, but it will likely become reality in order to further the adoption of standard recipe software products.

**Increased Scalability and Modularity**

**Provide Batch Executive in Controllers:** In many small batch control applications, such as weighing, dosing, mixing, pressurization, heating/cooling, and material transfer, the small size coupled with financial and schedule constraints, precludes the implementation of a conventional workstation or server based batch control solutions. The cost of workstation or server-based engines is also a factor in such decisions.

In some cases, this approach is justified due to the flat structure of the application that have no real need for scheduling and arbitration, simple recipes, and no batch tracking requirements. In many small to medium applications users are hard coding recipes in DCS controllers or PLCs. Some users lack the knowledge to handle sophisticated software and prefer the simple hard-coded ladder logic. This makes long-term support and future changes more difficult. This is a very important functional requirement for many users. It is a major limiting factor to growth.

**Monolithic to Multiple Processor/Server Capability:** This is often referred to as distributed batch. It is needed to conform to the requirements of many manufacturing operations where there are multiple operators needing multiple HMIs to run multiple operations. It can also help reduce the cost structure and improve system availability. This is a very important functional requirement for many users. It is a major limiting factor to growth.

**Eliminate the Need for More than one Package per Process Area:** Because of the current monolithic approach to batch management packages it is not unusual for a site to require more than one package. This is not desirable because it requires the maintenance and compilation of two distinct databases, increasing engineering and maintenance cost.

**Data Buffering and Network Time in the Controller:** Data buffer and an accurate time stamping in the controller appear to be requirements to facilitate compliance with 21 CFR Part 11 and minimize loss of a batch due to lack of quality records.

**Expansion of S88/S95 Model across the Enterprise**

**Improved and Better Integrated Material Tracking Modules:** Most material tracking modules in current batch control systems do not have the capability of tracking materials from source to finished product in the warehouse. In addition, many users have purchased warehouse management systems (WMS) that have their own material tracking modules. Users would like the material tracking module to interface with any suppliers BCS execution software.

**Recipe Expansion to include Upstream and Downstream Continuous Process:** As stated earlier, the “batch” defined as a product needs expansion of the definition of product. The recipe definition needs to be expanded to include all processing required to make a “product”. Many users’ recipes that define a finished product include both batch and continuous processing as well as packaging. They do not have a product until all these operations are complete.

**Link Recipe Procedure to Equipment Control other than just Phases:** One of the main purposes of linking recipe procedures to equipment control other than just phases is to allow the purchase of equipment with an embedded controller that already includes
phases, operations and/or unit procedures. This type of OEM equipment is common throughout the pharmaceutical and food & beverage industries.

**Common Database Data Definitions:** In a typical manufacturing plant utilizes many databases. This was formerly identified in the need to improve material tracking modules. As stated, there is a need for integration of multiple databases used for traceability. Users also have a need for common database definitions among the various dynamic optimization software packages. If this can be achieved, it could also lead to direct conversion of a simulated batch process to S88 based control code.

**Enhanced Functionality to Address Traceability and 21 CFR Part 11**

**Batch Historian:** Certainly, the batch historian capabilities of most batch control systems need to be improved in the areas of size and performance, data architecture, limited types of data collected, audit trail, security, etc. This is also a subject where detailed recommendations are well beyond the scope of this paper.

**Change Control:** This generally falls into three major categories, paper documents that are authored and approved, new versions of standard vendor supplied system software, and changes to the control system configuration (system, control code, HMI).

The following is focused on the latter as it relates to improved BCS functionality. Some current DCS-based systems have common systems services that provide secure, managed configuration code archiving and a single configurator or device editor for each function, such as system, control, and HMI. This has enabled them to provide some limited form of change control and role based access rights. It has put these suppliers in a position to help users more easily achieve compliance with FDA regulations including this segment of e-documentation covered under 21 CFR Part 11. PLC-based and other systems typically have multiple, unsecured archives and multiple device editor capability for each function. They can be on any PC, which can then be attached to the device or the network. There are advantages to this approach, but change control requirements for compliance is not one of them. These suppliers will need to invest significant effort in enhancing their system to enable compliance in this area of change control documentation and role based access rights.
There are also third party software products on the market that keep track of control and HMI code changes. They monitor change either by scanning (interrogating) devices or by exception monitoring. It is important for users to understand that there should be insufficient time between each interrogation of a device to assure that a change cannot be made and then changed back to the original code. Regardless of the method any system or third party software provider uses, there must be assurance that all changes can be detected in order to achieve compliance.

User Functional Enhancement Priorities

Figure 5, 6 and 7 show the initial results of a survey being conducted to determine user priorities for batch control system functional enhancements. Users were asked to rate 20 functional enhancements by importance, not at all, somewhat important, important, very important, or critically important. User responses came from almost all industry segments, chemical (28.6%), pharmaceutical (26.2%), food & beverage (28.6%), others (16.7%). Approximately 20 percent of users rated 50 percent of the functional enhancements as critically important to them or their company. Approximately 20 percent of suppliers rated only 20 percent of the functional enhancements as critically important.

The top four user priorities were a standard library of control modules, a standard library of equipment modules, better integrated view of the batch, and common phase structure. The least important to users were, increased execution system size, tools to convert P&IDs to user requirements specifications, tools to convert P&IDs/functional specifications to control code, and General/Site to Master recipe conversion tools. Users rated increased manufacturing flexibility and improved product quality consistency as the areas of greatest achieved benefit, followed by reduced engineering. These benefits are consistent with the business realities formerly discussed.
Supplier priorities were generally aligned with user priorities, but suppliers thought very few functional enhancements were critical other than the top four user priorities. Of the top ten critical user priorities, most suppliers placed low importance on a common phase structure, a standard library of equipment modules, and data buffering and time stamping in the controller.

**User Batch Control System Functional Requirements**

**Figure 7**

<table>
<thead>
<tr>
<th>Prioritized User Requirements</th>
<th>Suppliers Aligned with Users</th>
<th>Suppliers Somewhat Aligned with Users</th>
<th>Suppliers Marginally Aligned with Users</th>
<th>Suppliers Not Aligned with Users</th>
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<tr>
<td>1. Standard library of control modules</td>
<td>✗</td>
<td></td>
<td></td>
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<tr>
<td>2. Standard library of equipment modules</td>
<td></td>
<td></td>
<td></td>
<td>✗</td>
</tr>
<tr>
<td>3. Better integrated view of batch control</td>
<td></td>
<td></td>
<td></td>
<td>✗</td>
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<tr>
<td>4. Common phase structure</td>
<td></td>
<td></td>
<td></td>
<td>✗</td>
</tr>
<tr>
<td>5. Improved product traceability records</td>
<td>✗</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Enhanced data collection &amp; historian</td>
<td>✗</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>7. Data buffering &amp; time stamping in</td>
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<td></td>
<td></td>
<td>✗</td>
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<tr>
<td>8. Improved change control</td>
<td>✗</td>
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<tr>
<td>9. Improved material tracking module</td>
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<td>✗</td>
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<tr>
<td>10. Batch execution in controller</td>
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Traditionally automation products and systems have been designed based on available technology rather than business requirements. This no longer needs to be the case. The challenge for this generation of process automation is to clearly understand the requirements placed on operational excellence for overall business success and translate them into an effective solution.

The evolving process automation system will be a Collaborative Process Automation System (CPAS). The primary role of the CPAS is as an infrastructure for applications. It is work-process-centric enabling a commitment to achieving best practices and operational excellence. It closes the loop on business, plant and process performance.

The heart of the CPAS is a unified communications structure, including pervasive Internet technology. The unified communications framework (UCF) includes a unified field framework (UFF) hosting sensors, actuators, and logical devices plus a unified application framework (UAF). UAF is enabled by S88, S95, Open Modular Architecture Controls (OMAC) Users Group standards for packaging, the GERM EBR model, and URS standards. The CPAS includes core process plant applications, third party applications such as Application Specific Appliances (ASAs) and Pervasive Internet Applications (PIAs), and enhanced core system functionality.

Core Functionality

Each core functionality of the next generation system is required to enable the level of improved business performance needed in this new “Information Revolution”. Some are also needed to reduce the cost and time to achieving and maintaining compliance with FDA Ruling 21 CFR Part 11.

Common Systems Services: This includes systems management for diagnostics, health monitoring and maintenance, and the master time keeper. These services, which do not fully exist in current systems, are also enablers for compliance with 21 CFR Part 11.

System Management: On-line and off-line diagnostics should be provided to assist in system maintenance and troubleshooting. Diagnostics should be provided for every major system component and peripheral, firmware, and individual application. The
system must detect and provide an error indication for the failure of these devices and
applications. The Application Executive used to monitor the health and connectivity of
applications is first likely to be embedded in the plant critical application, Automation
Asset Management, before suppliers place it in the core functionality of the system.

**Master Time keeping:** Any CPAS station should have the capability to host the system
clock, either as a primary host or redundant host. If the station designated as primary
fails the master should automatically be regenerated on subsequent stations. CPAS wide
time resolution should be based on either the master clock or an outside “tick” such as the
Global Positioning Satellite (GPS) and have <1ms resolution using the Network Time
Protocol.

**Common Presentation:** CPAS is envisioned as being HMI agnostic. Basically any
Internet enabled HMI can be used as a presentation mechanism. It also contains common
role-based access security required for 21 CFR Part 11 compliance.

**Event Management:** The ability of a system to comprehensively manage events is
fundamental. CPAS will use GPS synchronized SNTP (Network Time Protocol) for
event management. Event management includes change control and notification, while
the critical plant application, Automation Asset Management, is the secure storage
location for such things as application code. Event management combined with this
critical application must deal with such things as whether or not this changed code
becomes the default code upon re-initialization. Many of the functions just described are
also required for 21 CFR Part 11 compliance.

**Data Validity:** It is critically important for applications to be operating on valid data.
Data should be quality stamped at its source and applications that are modifying data
should tag their results accordingly, as also required for compliance. Foundation
Fieldbus has made provisions for this.

**Traceability or Genealogy:** Traceability is a documented audit trail from constituents
through shipped product. In addition, some materials used in the process, used to make
the product, or a by-product of the process requires documented audit trails. This is not
just a regulatory issue. It is a business/commercial requirement necessary to deal with
such things as product recalls and hazardous materials security.

It requires enhanced data attributes definition at the function block level. Additional core
functionality should center on data attributes definition and closer coupling of the “write
and record” functions. Both need some explanation. Traceability is not a single data
attribute, but rather multiple attributes. Let us consider several possible traceability
attributes. If a data point is defined as traceable it should automatically be archived to a
secure data record location. Because there could be a network or application
communications failure, it would be necessary for the controller to know and redirect the
information to its local data storage buffer until communications are restored. Attributes
should include high and low operating ranges determined in the validation process. These
are not the same as the high and low ranges in current systems. Operating out of these
ranges should automatically trigger an event to Event Management to forward to the
reconciling authority or authorities. Extra function blocks should not be required.

Manual ingredient addition can serve as a good example of the difference between
traceability and data quality at the core functionality level. In many processes, a sample
is weighed out and then added to a mixing vessel by the operator. The weighing system
may be on-line sending the weight reading to a secure data location and even the remaining weight of the container it came from, but how do you validate that the portion was added to the mixer? Data attributes should include additional discrete and/or analog confirmations that the action occurred. In the case of manual ingredient addition this could be confirmation that the vessel door was opened and closed in a time consistent with this procedure. It may include the final weight of the total batch from load cells on the mixer. Although the load cells may not be sensitive enough to pick up the weight of a single ingredient addition, it may be sensitive enough to pick up the total weight of ingredients added.

**Common Configuration:** The process control community is converging on a single configuration standard IEC61131-3. It follows that the CPAS should adopt the same standard. However it is important to note that 1131 is incomplete and unsatisfactory for future requirements.

**Data and Information Synchronization:** The CPAS requires that data be defined only once, is uniquely named, and becomes part of a distributed database without programming, as we know it today. Objects are the key to this architecture. Synchronization is data/information synchronization and defined as being available to applications when required with no transport delays. This is not time-based synchronization. In the context of CPAS synchronization will be accomplished with publish & subscribe architecture.

**Availability:** Availability is not redundancy, safety or security. It is a measure of time a device performs its primary function between unplanned interruptions. The future system architecture will facilitate and will require no single point of failure. It should be available for 75 years without interruption. Markov models and transition probability matrixes shall be used as the basis of these calculations.

**Layered Robustness:** Layered robustness is the ability to closely correlate functionality to cost. You should only pay for the level of robustness you need for any component or functional area of a system. This is not likely to be achieved in the early stages of the next generation system.

**Summary**

A common infrastructure with data synchronization will lead to common presentation and common systems management functionality. It will also facilitate the ability of the Asset Management application and its Automation Asset Management subset to communicate with all hardware and software components of the system. In this model suppliers will automatically be required to provide “plug and play” products. Due to the proprietary nature of current systems, the total cost of ownership (TCO) is dependent on matching the system to the user applications. The proprietary nature of these systems also limits the potential for asset optimization. The CPAS will level the field on TCO and allow realization of greater return on assets (ROA). User evaluations will be able to emphasize ROA and de-emphasize TCO.

**CONCLUSIONS**

Most users in the chemical, pharmaceutical, food, and beverage industries recognize the benefits of using commercial off-the-shelf (COTS) batch control systems, but cannot
justify current COTS batch control systems. The two major reasons are cost and lack of functionality. For smaller users it is cost of both product and engineering. For larger users the cost of using their homegrown solutions is still offset by the benefits they have achieved. This will remain the case until additional functionality and enterprise-wide capability are added to current batch control systems. Growth of this market can be expected to be proportional to addressing user functional needs, initial cost, and the return on assets. To address this requires the commitment of a more diverse user group to identify common needs that can be used to help focus and leverage supplier development and opportunities.

References
Batch Control Systems Worldwide Outlook, ARC Advisory Group, 2001
Fisher, T., A User’s Wish List for Batch, World Batch Forum, 2001
Brandl, D., Breaking from Equipment in General Recipes, World Batch Forum, 2001
The Future Collaborative Automation System, ARC Advisory Group, 2002
### Appendix

#### Acronym Reference

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<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<th>Description</th>
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<tr>
<td>ASA</td>
<td>Application Specific Appliance</td>
<td>HMI</td>
<td>Human Machine Interface</td>
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<td>ASIC</td>
<td>Application Specific Integrated Circuit</td>
<td>OMAC</td>
<td>Open Modular Architecture Controls</td>
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<td>BCS</td>
<td>Batch Control System</td>
<td>PC</td>
<td>Personal Computer</td>
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<td>CAGR</td>
<td>Compound Annual Growth Rate</td>
<td>PIA</td>
<td>Pervasive Internet Application</td>
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<td>COTS</td>
<td>Commercial off The Shelf</td>
<td>PLC</td>
<td>Programmable Logic Controller</td>
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<td>CPAS</td>
<td>Collaborative Process Automation System</td>
<td>ROA</td>
<td>Return on Assets</td>
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<td>CPG</td>
<td>Consumer Packaged Goods</td>
<td>ROI</td>
<td>Return on Investment</td>
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<td>DCS</td>
<td>Distributed Control System</td>
<td>SNTP</td>
<td>Simple Network Time Protocol</td>
</tr>
<tr>
<td>EBR</td>
<td>Electronic Batch Records</td>
<td>TCO</td>
<td>Total Cost of Ownership</td>
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<td>EVM</td>
<td>Earned Value of Money</td>
<td>UAF</td>
<td>Unified Application Framework</td>
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<td>FDA</td>
<td>Food &amp; Drug Administration</td>
<td>UFF</td>
<td>Unified Field Framework</td>
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<td>GERM</td>
<td>Good Electronic Records Management</td>
<td>URS</td>
<td>User Requirements Specification</td>
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