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Paper-To-Process

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ABSTRACT

Plant floor automation has kept American manufacturing at the forefront of the world in efficiency and quality; however, paper based business systems often surround and support these “islands of automation”, limiting their impact on the organization’s capabilities. In order to realize the next level of manufacturing efficiency and quality, paper based records must be "integrated" into the existing automation and information technology systems of today's plants. This paper will present a case study on the integration of paper based records with existing plant automation in the life sciences industry using leading edge technology.

The paper will detail the justifications for integrating paper-based records by presenting the specific business drivers for this project and demonstrating their applicability to all manufacturers. Further, the paper will describe the architecture of the system, including the capability of integrating manual data entry with automatic historical data collection. The solution will demonstrate the benefits of automating paper-based processes by allowing for real-time data entry validation, data review and compliance.

The paper will also present solutions to the unique challenges of testing and validating the system. Finally, the paper presents a flexible solution capable of future expansion.

The resulting system has replaced all legacy data collection and provides a single central repository for all manufacturing data, both manually entered and automatically collected. The data repository is both secure and allows for a multitude of third party tools be used for data analysis. The system has improved operations by standardizing training processes for all operations personnel, reducing data entry errors and reducing batch record review time. The data repository supports the organization's research group in process modeling and manufacturing improvement efforts. The system provides a flexible workflow model based on ISA S95 standard, integrating paper based records and automation.

Introduction

Paper to Process seeks to improve manufacturing efficiency and quality by integrating paper based records into automation and information technology systems that exist in today's plant. Despite technical advancements in business systems and automation, companies still do business in a legacy paper paradigm, where work instructions, data collection and operating procedures are bound to paper. The goal of Paper to Process is to link paper records into the automation, removing time delays, double entries, quality issues, and errors. There are a variety of technologies that enable a Paper to Process environment.

For a life sciences company, an opportunity to integrate paper to process presented itself as a new product was approved from clinical trials and plans were made to augment production capacity. With this increased production demand, data collected for process analysis would grow exponentially and managing that data would be critical.

Background

Manufacturing operations are governed by a set of controlled documents known collectively as SOP's (Standard Operating Procedures) or Batch Sheets. Data is captured on these sheets to document the activities of manufacturing. The first step in the analysis of this data involves the transcription of the data from these batch sheets to a set of spreadsheets, post process. The development of the product from small scale to large scale manufacturing has forced the evolution of a data collection system that was largely manual. Each run began with thaw and culture, each vial having a lot and number. As cells grow, data was collected and media was transferred to larger and larger reactors. The merging and splitting of media creates additional data complexities; some lots being retired and some moving on in the process. A "spreadsheet set" was created and released for each manufacturing run. The data captured on the spreadsheets for each run was represented by 16 worksheets in two documents. Current production saw the creation of approximately 50 runs per year; however, with a new manufacturing facility coming on line, that number would increase. Beyond data collection, analysis of the data was difficult as the raw, transcribed data needed to be summarized into a second set of spreadsheets, where data could be compared across production runs. Even with the summarized data, powerful analysis tools were not being utilized as the data was not available in a relational format. Data needed to be audited and re-audited to verify authenticity. The need for structured, secure data storage was necessary.

System Goals

The business goals of the system, as stated by the assembled project team, are to simplify the process of data collection and to create a state of the art data repository for data analysis. The system would replace current manual transcription for data collection by adopting a Paper to Process approach for data collection; integrating data collection activities into a consistent, secure system. The results would be a new electronic "data mart" for manufacturing data with data available for analysis and actionable decision making. Additionally, it is envisioned that training requirements will be reduced and better visibility and oversight of the process will be attained. The system would be flexible, allowing deployment in multiple manufacturing environments, some automated and some not. Finally, the system would be validated and comply with all corporate quality standards.

Challenges

In developing a system to address these needs, two early challenges presented themselves:

- The volume of data would grow exponentially, so the ability to streamline the process of accurately collecting the data from the production process would be critical.
- The data set, which had been largely manual, would now become increasingly automated. Data could now be collected from an increasing number of electronic devices (chart recorders, PLCs, and other intelligent electronic devices).

The second challenge addresses the need for a flexible data collection system, which will allow for deployment and use in any situation, from an entirely manual environment to a highly automated environment. The system would first be deployed in a manual environment, where data capture was done by operators recording readings from mechanical instruments. Ultimately the system, once proven in the manual environment, would need to be implemented in the new production facility which would be much larger in scale and benefit from a completely modern automation infrastructure (PLCs, Network, and SCADA).

Defining the System

The company quickly recognized the impact a system like this would have on the organization. The project, driven by the needs of research and engineering, became one of the most visible in the organization, involving research, operations, engineering information systems, quality, and validation groups. The system would replace existing data collection processes, impacting operations, require links to automation, involving engineering, and need hosting and support from information systems.

A structured, lifecycle approach to system design would be employed which emphasizes planning and communications with the goal of capturing all requirements prior to system implementation. User and functional requirements would be gathered first and consensus would be forged from various stakeholders. The Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture was employed to facilitate requirements traceability and define testing requirements leading to a validated system.

User requirements

Capturing user requirements involved identifying participants from each of the key stakeholders in the organization then interviewing these users individually several times. As User Requirements documents were issued, comments were solicited and more interviews and clarifications took place until a consensus document was approved. User requirements were captured and approved in a concentrated one month effort.

Functional requirements

In developing functional requirements, the key stakeholders from each organizational department were brought together in a series of meetings. The informal meetings allowed all users to voice their desires and concerns as a system structure and components were identified to satisfy the user requirements. The functional requirements were written carefully to prevent the specification of a product, as the solution which was best for the company might not be a product.

In this early stage of the project, prioritizing requirements was essential. For each need, many possible solutions were discussed. Requirements were categorized to manage scope and provide a system that would serve the current needs and allow for expansion in the future.

Additionally at this stage of a project, it was important to arrive at consensus on various design and implementation issues and document that consensus. The goal being that each member of the team sees the value of the decided approach and takes ownership of system as design and implementation move forward. For example, operations groups currently "write" data onto the batch sheets and other paper logs. Would the new system require that data be entered directly by operators on the plant floor, or could the data continue to be collected as it is now and entered into the new system afterward? This one question presented major concerns for operations, which could not afford disruption to a process they were currently working to perfect. Ultimately, it was agreed that the system should allow for both. In early stages of deployment, the system would allow for transcription of data and in the future the system could be used directly in production.

Capturing functional requirements began soon after URS (User Requirements Specification) approval and after six iterations was approved taking three months.

Key Design Considerations

From this consensus building, key design considerations influenced system requirements.

– Manual data entry should be streamlined. Currently batch records are transcribed to spreadsheets by locating the appropriate values on the batch sheet and placing them into the spreadsheets. Unique, localized knowledge was required to perform this task. If we are going to enter this data electronically, then the electronic interface should "represent" the batch sheets (look like them), yet the system should extract and store the data with the context that was provided by the spreadsheets. This ability would not only simplify data entry post-process, but lend to a system that could be used in-process, in the future. A key concern stemming from this requirement was how to ensure that the electronic presentation of the batch record remained "in-sync" with changes to the paper based record, for the time in which the two coexisted.

- All data should be stored in a relational format. The relational format (in a relational database) would allow for the widest application of tools to the job of data analysis. Some of these products had been identified and still others may be used in the future.
- The system should be capable of importing and exporting legacy data. In doing so, the system would immediately become beneficial to end users by providing a wealth of data for analysis. Secondly, it was envisioned that the system could be tested by reviewing the results of analysis from data that had already been analyzed by a manual process.

Design Approach

Project Management

During the implementation of the project, a cross-functional team of key stakeholders representing operations, engineering, information technology, quality assurance, and validation where assembled. Regular project updates, technical discussions and resource requirements would be discussed at bi-weekly meetings. Project leaders would then report to a smaller steering committee team, whose purpose was to give the project proper organizational visibility and set long term milestones for resource and scheduling requirements.

Design Teams

Three (3) different manufacturing sites (a manual process, a semi automated process and a new green field highly automated facility) would need to be supported. The same system would be deployed to all areas; however, data collection would range from almost entirely manual to almost entirely automated. A high level system architecture was conceived from requirements and divided into four functional areas supporting manual data entry, automatic data collection, legacy data import/export and database storage. For each functional area, a design and implementation team was assigned. Each team would be responsible for issuing separate detailed design documents, internal test and review documents and ultimately factory acceptance tests. Team roles were identified and staffed accordingly. Some roles required unique, dedicated technical resources while other roles allowed for coordination between the teams and project management.

Manually Entered Data

Key process variables from the batch data sheets needed to be included in this data repository. The system would need to provide a user interface for entering this data with the necessary security and validation checks for accuracy. The manufacturing environment requires tracking data associated to batches and lots for multiple days as multiple manufacturing campaigns are running at various levels of progression. The users would need to easily know where they were in the process, so that data could be accessed, entered and reviewed accurately. Presented “forms” for manual data entry would be created using web based technologies. As a result, the team was staffed with engineers knowledgeable in web based technologies and design. Specific roles identified for this team were forms designer, peer code reviewer and system architect.

Automated Data Collection

Additional process data would be collected from process equipment, chart recorders and PLC (Programmable Logic Control) systems which existed on the plant floor. These data points would provide a rich set of data for analysis and must be collected reliably and securely. The system implemented must be able to support multiple manufacturing locations, each of which would support a similar manufacturing process, but with varying levels of automation. The team roles identified to support this design effort were automation engineer, communication protocol engineer, peer code reviewer and system architect.

Legacy Data

Data collected over the course of several years would need to be included in the system, to enable immediate benefits to the process analysts who would use the system. This data would need to be brought into the system and validated to ensure accuracy when the data was transferred. A design team would require a programmer familiar with Excel automation, peer code reviewer and the system architect.

Database Design

A challenge of this system would be to store the automatic, manually entered, and legacy data with the same context, so they can be associated to the proper process steps. The data collection system must also support the capability to compare an automatically collected data point to an equivalent manually entered data point. The database would be the ultimate storage repository for each of the three distinct data sets; however, the database also has independent requirements and could not be owned by any one team. Therefore a separate design team was forged to support database implementation and data integration requirements for the overall system. The system architect, which was a role in each of the other teams, would be the key player in fostering this system integration effort. Additionally, database design roles called for a network engineer, database programmer, and hardware platform engineer.

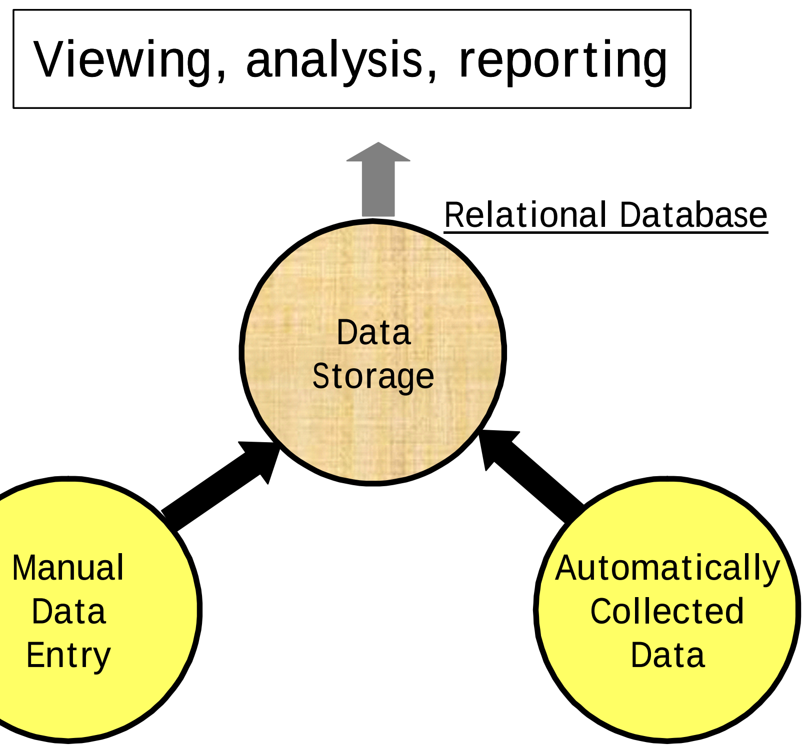
Implementation

The first goal of the teams was to review requirements and review products that might fulfill these requirements. For automatically collected data, data historian products were reviewed. The product space for data historians is mature and many products exist which have distinguishing features and benefits. Influencing the decision to use a data historian would be capacity, protocol support, and the ability to obtain access to the data from relational tools using ODBC (Open Data Base Connectivity) drivers. For manually entered data, the product space is far less mature. Few products exist which fulfill a majority of the requirements without painful customization. For both automatic data collection and manual data entry, products were ultimately identified to satisfy most requirements. Few compromises were made to the original intent of the requirements in choosing the commercially available solutions.

Data Collection

Three classifications of data were identified in the environment. Data for the current process was either available from equipment automation or was manually entered by users from batch data sheets.

Additionally, the system would need to incorporate data maintained in legacy format. The database would be designed to store and relate these three classifications of data for external analysis.



Manual Data Entry

Much of the data collected involved manual user entry. The new system did not change this approach, but rather accommodated it. A key requirement influenced the design; the data entry should present the user with a familiar, easy-to-use interface. Since batch records are currently used to collect the information initially, the presentation of user entry "forms" should match the batch sheets as closely as possible. The user entry forms would then be familiar to data entry users and would also follow the process. Another concern was ensuring that the right amount of data was collected in support of the data analysis requirements. The system was designed to prompt the user for only the data that was required for entry, thus the documents became "intelligent"; following the process.

Since manual entry was now going to be accomplished electronically, the design should also provide additional features that would improve the data entry process. Each user form was designed to provide feedback to users when data is entered out of range, in a bad format, or if required data elements are left blank. Data entry forms can also be "circulated" for review, editing, and final approval. Moving manual entry to an electronic paradigm allows for more collaboration and faster, more accurate work flow from the users. Users may work on data entry from the same manufacturing campaign or multiple campaigns simultaneously. A graphical representation of the work progress in all manufacturing campaigns allows users and supervisors to quickly review the current status of data entry and know what responsibilities they have been assigned in the system.

An additional benefit of electronic documents is the capability to integrate the documents to automatically collected data. Data from automatic data sources may be captured in a manual entry form.

The final set of data entry forms contained over 11,000 data entry items on 80 forms. Data entry was presented in list form or tabular form, just as on the batch sheets.

Automatic Data Collection

In this manufacturing environment, a collection of intelligent factory equipment and systems exist. The data from these systems needed to be related to the manually entered data for the same process. The technology chosen to accomplish this was a data historian. The data historian provides key elements which make its choice a natural fit for this application. Data historians provide a wide collection of interfaces for communicating to the various equipment and systems found on the plant floor. The support of the OPC protocol to multiple systems was of particular importance. The data historian also allows for high volumes of data to be collected at speeds which accurately reflect the plant floor operations.

In support of a key requirement of this project, the data collected by the historian needed to be accessible in a relational format for analysis by future data analysis systems. Using a relational data format allows for a wide choice of analysis tools supporting current and future process analysis needs.

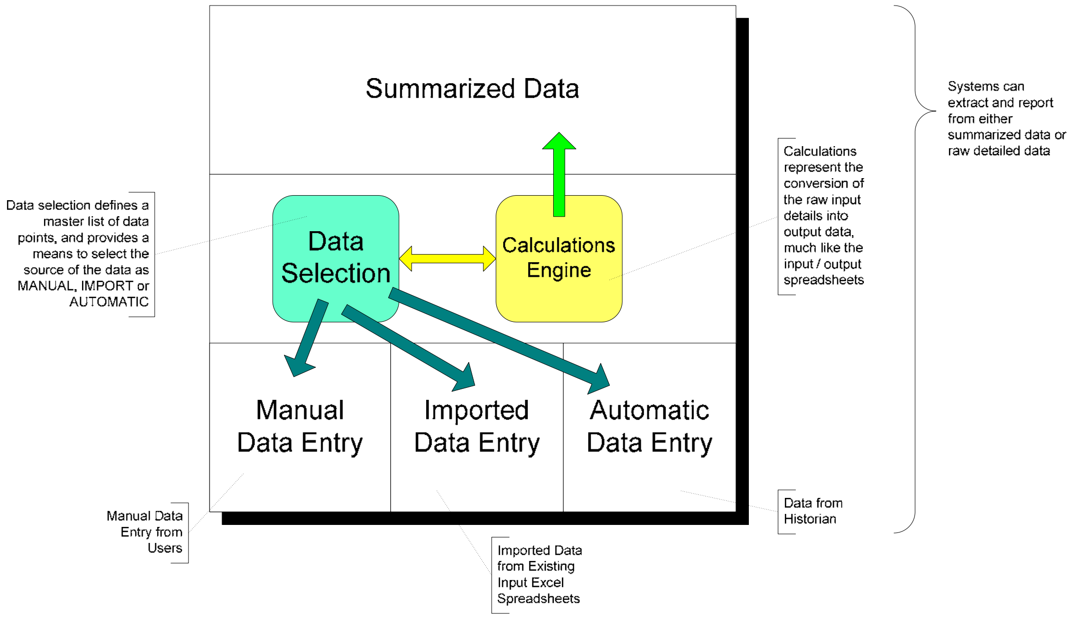
Legacy Data

Making the analysis of the newly entered data even more valuable, existing data would be imported into the new system database. While the import of this data would be a single event, the import process required particular scrutiny for accuracy of the import process. The import process was accomplished using custom scripting in Microsoft Excel® and the Microsoft Bulk Copy program (BCP) from Microsoft SQL Server. To validate the process, data was inspected in the database and also exported back to its original format for comparison to the input data.

Data Storage

The project goal was to create a single data storage system for these different sets of data, where the data from these different sources would be related at various levels. The data from these sources is stored in a single relational database. Relating the data from these different data sources would require a context model to be built. Each data point would have a unique variable name, but would also be defined to exist in a specific work cell, area and site. The S95 data model was used for this context. S95 provided a data model independent of any product, yet the products utilized supported data associations within an S95 plant model. Additionally, future products which may be utilized within manufacturing from the same vendors will be able to "snap in" to the existing system framework by use of a common data model. This was a key consideration for engineering in implementing the data historian for this project. Engineering was looking long term to the uses of a data historian for performance monitoring and production scheduling. The S95 model allowed for the implementation of the historian for this project and the layering-on of other solutions, separate from this project, at later dates.

Related by key fields and definition tables, data from manual sources, automatic collection, and legacy are related. A data model, depicting the general data arrangement is displayed below. An important design requirement is met with this approach. As manufacturing becomes more automated, the need for manual data collection will be supplanted by the ability to collect data from automation. The system needed to provide a way to allow for a data point to be collected first manually and then ultimately automatically. The change of a data source for a particular data point is handled by changing the data points source (and a change control procedure), but not a major redesign and revalidation of the system. All the data, now available in one database, is available for 3rd party analysis tools and systems.



Code reviews and testing

Design, peer code reviews and internal testing were completed within 5 months. This included the execution of four separate factory acceptance tests. Stakeholders and end users reviewed internal test documents and participated in all final testing.

System Testing and Validation

Separate IQ (Installation Qualification) and OQ (Operational Qualification) qualifications were written and executed for manual data entry, automatic data collection, legacy data import and database storage. The PQ (Process Qualification) was executed with the entire system during a one month burn-in period, where operators were trained to use the system in parallel with the existing business processes, documenting discrepancies as discovered. Validation was completed by year end for manual entry and legacy data import, completing an aggressive project schedule from inception and requirements gathering to production in less than 12 months.

Manual Data Entry Challenges

The manual data entry system design was completed, amassing a total of 80+ forms with more than 11,000 data inputs for the complete process batch record. In most cases, far fewer data entries are actually recorded based on process variations; however, to validate the system, every data entry point would be checked. Additionally, every data entry point that provided range checking, format checking (dates, strings) or group validation would require multiple data checks.

– For example, if a data element is left empty, does the system accept this if designed not to?

– In the case of range checking, what would the system do for data entry elements above the range, on the range, in the range and below the range of the data set?

Some data entry on the forms was created from the common reuse of data entry objects, which allowed for exhausting testing of a single object and review of the configuration of the remaining instances of the same object. This approach, however, did not reduce testing complexity to the degree desired. Ultimately, a software product was employed to perform automatic testing. Once validated for use through some trial tests, the product allowed testers to perform data entry to all form elements from a preconfigured data set. More importantly, the same test script, authored in the product which controlled the test software's interaction with the forms, could be used with multiple data sets, representing high values, low values, target values, etc. By using automatic test software, system test time and documentation (result reports are generated by the product) were reduced from a prediction of months to weeks.

Automatic Data Collection

Testing automatically collected data was more straight-forward. Existing chart records had internal data stores which could be utilized to generate a parallel data collection to the historian. These data sets would then be compared for accuracy. Aside from point verification, the data historian would ultimately grow in importance and size. System load tests were planned for on site execution to determine the systems performance under "stressed" conditions.

Legacy Data Import

Checking legacy data import was also simplified by providing a facility to export the imported data to a set of spreadsheets identical to the imported data. The two spreadsheets could then be compared for accuracy. The legacy data import was a key milestone in on site activities, since the import had to be closely timed to the cut-over date from the existing data collection process to the data collection paradigm with manual entry and automatic data collection taking center stage.

Summary

A strong effort to capture requirements and build a system that met current and future needs has resulted in the successful implementation of the Bioprocess Data Collection System. The project involved challenging requirements to accommodate manual data entry and automatic data collection in various mixes at three production sites. The requirements called for a flexible system architecture which would allow for expansion and reconfiguration without reengineering and revalidation efforts. The resulting system delivered meets these needs by integrating the best products for each key functional area of the system and by using a common plant model to describe each data point independently of how the data is obtained.

System Value

The system was immediately accepted due to strong management support and continual end user involvement during design, testing and implementation. Soon after validation activities, operators were trained and ran a "live" PQ process. Once qualification was completed, the systems' tools became the business practice of the company. New operators are trained on the system. The energies of the company are now focused on the analysis of the data available to them, rather than the effort to obtain the data.

The output from the system is a complete batch record, printable or reviewable electronically. The record contains manual and automated data integrated into a single view. Version control features allow for review of the changes made to a batch record. Reports available from the system are essential to the batch record review process, highlighting the trouble spots of a process which is documented in 80+ pages over a multi-week campaign. Ultimately, the ability to rely upon these features of a validated system allows for resources to be focused on addressing the most important production issues, ensuring high quality and shortening batch quarantine and release times. Reports are also the key to allow quality and operations management to view the current work load and generate accurate capacity analysis for scheduling.

Paper to Process

The Paper to Process initiative was born from successful project experiences such as the system presented here. Technology has provided the tools to allow for integrating complete workflows involving both manual and automated elements. The level of integration and automation desired is not dictated by the products used, but rather by the requirements of the system. Integrating paper based records into the production process results in more accuracy, timely execution, collaboration and streamlined process analysis.