Designing Batch Systems for e-Manufacturing

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KEY WORDS

ABSTRACT
In today’s global environment, a true competitive advantage can be attained for companies by designing their batch systems to integrate with technologies for “e-Manufacturing”. Through proper planning, design, and implementation, organizations not only have a means to efficiently automate batch operations, they now have an opportunity to optimize their operations. A properly integrated control domain / enterprise management system provides real time information needed for making timely management decisions. Interoperability of these systems for e-Manufacturing requires electronic data flows dependent upon such issues as production requirements, timing considerations, quality assurance results, resource allocation, and report generation. In addition, conformance with emerging U.S. Federal legislation such as the E-Sign Act (effective October 1, 2000), and FDA’s 21 CFR Part 11 (E-Records; E-Signatures, effective March 20, 1997) can be addressed as an integral part of project design. The importance of understanding the “electronic” requirements of e-Manufacturing provides a basis for designing new systems and upgrading legacy systems to meet each organization’s own enterprise demands. This paper provides insight into the design and requirements of batch process systems for integration with manufacturing and business systems for today’s e-Manufacturing environment.
INTRODUCTION

The need to increase competitive advantage and move from an enterprise-centric to a customer-centric business model is a driving factor for utilizing leading edge technology for commerce, business and manufacturing. In a relatively short period of time, internet technologies have touched upon and changed the way companies have conducted business over the past 15-20 years. The need for accurate and timely manufacturing information has led businesses to utilize internet technologies on the plant floor.

Enterprise management systems are comprised of an organization’s site (or sites) functions such as process controls, batch automation, facilities management, operations, production scheduling, materials management, and business systems integrated to address strategic company objectives. Integrating business and supply chain management (SCM) systems with manufacturing execution systems (MES) and process automation systems (PAS) provides real time information which management can use to make educated decisions to efficiently operate their enterprise as well as manage customer relationships.

The convergence of internet and plant floor systems technologies provides the basis for the creation of a new generation of computing solutions that can dramatically improve the responsiveness of organizations to better communicate with their customers and suppliers. The internet “e” technologies enable businesses to shift from an enterprise-centric to a customer-centric model.

In order to be successful in the world of e-Business and the discipline of e-Manufacturing, companies must still align their business initiatives with company objectives and their manufacturing flexibility with their business initiatives. Business driven projects provide clear requirements that are based upon a company’s need to improve costs, quality, efficiency, customer deliveries or regulatory compliance. E-Manufacturing now provides companies with the capability of evolving manufacturing into a key strategic business advantage.

E-MANUFACTURING, THE NEW ENVIRONMENT

The importance of understanding manufacturing requirements to meet each organizations own enterprise demands and communicating crucial information for collaboration “electronically” via internet web-based technologies provides a basis for the new environment of e-Manufacturing.

E-manufacturing enables information exchanges among various plant level systems with business systems to eliminate data bottlenecks that can occur in conventional enterprise IT architectures. In return, the ability for enabled personnel to readily access in-process manufacturing information provides an organization with the ability to make informed management decisions, efficiently respond to changing business conditions, and reply to customer inquiries in a timely manner.

Through the use of web technology over an enterprise network, data and information exchanges can be seamlessly executed and viewed with a web browser. This technology also allows voice communications as well as video transmittal, each of which can be an integral part of manufacturing operations or captured as a part of production records. The implementation of internet technologies provide a means for electronically managing plant floor operations and the manufacturing of products, tracking customer orders, identifying constraints, and documenting production information.
Through proper planning, companies can now look at existing manufacturing systems as migration paths to optimizing their operations. By integrating process control and automation systems with business management and manufacturing execution applications in an e-Manufacturing model, projects can be identified and designed to meet aggressive corporate business objectives while retiring legacy systems.

When looking at modeling e-Manufacturing, all conventional manufacturing functions of “what” needs to be done must be included. That is, functional requirements remain the same as for traditional manufacturing. For example:

- Systems shall control, manage, monitor, and analyze batch process operations
- Products and orders shall be tracked on the manufacturing floor
- The execution of all manufacturing steps shall be recorded
- Work in process (WIP) and finished goods inventory shall be tracked
- Information will be shared across the supply chain
- Quick access to information and data is needed from any part of the plant/enterprise
- Systems will be flexible for ease-of-implementation at each site, and for standardization at multiple sites

It is “how” these issues are resolved that provides the basis for e-Manufacturing:

- Web-based browser accessibility
- Plant portal solutions for integration and data exchange
- Applications are web-enabled
- Plant-floor systems are linked to enterprise systems via web technology

E-manufacturing is enabled by making an organization’s plant-level production processes and information accessible via internet technologies and defining the use of the accessed data to address company business needs. The endorsement and involvement of senior management is crucial for the successful implementation of e-Manufacturing initiatives. In turn, e-Manufacturing must then become an integral part of an organization’s ongoing strategic business plans for it and the enterprise to succeed in this new age of business.

“How” issues are resolved involves a comprehensive review of the following:

- Understanding your key business drivers
- Your planning process
- Standards, models, and regulations
- Systems design considerations
- Architecture requirements for your applications

**THE IMPORTANCE OF BUSINESS DRIVERS**

Prudent resource utilization and deployment is necessary for the efficient implementation of new systems. Therefore, future compatibility of hardware and software is an essential factor in defining a cost justifiable roadmap for implementing e-Manufacturing solutions and technologies. Successful enterprise operations have identified their organization’s critical success factors and ensure that they are addressed through the strategic planning process. By analyzing management information, factors deemed important to the future success of the enterprise can be identified, and a future state model of operations to address these critical success factors can be generated.
An analysis of operations productivity should start with product quality. Rework, reprocessing, and re-running unacceptable batches all negatively impact materials utilization, resource requirements, production throughput, and customer delivery schedules. Move on to look for other inefficiencies. Identify production throughput bottlenecks. Ask questions. Where can work-in-process productivity be increased? Are batch records and reports available to operations in a timely manner? Are appropriate decision-making production records and reports available to management? Is the batch release approval cycle efficient? Is work-in-process (WIP) backing up and becoming too large to manage? Are batch performance and quality data generated as needed?

Further cost justification is possible by aligning e-Manufacturing solutions with the need to address key performance indicators (KPI) and requirements of batch manufacturing operations. These KPIs may differ in each organization, but should be identified through typical questions previously asked.

**PLANNING – THE KEY TO SUCCESS**

Soliciting the involvement of all groups affected by a new program or technology is highly recommended for plantwide ownership and long term success.

A phased project approach is an efficient way to integrate an entire facility. This approach allows the company to pay for future ventures with savings derived from current projects. It also allows for realistic resource planning. Human resources and capital funding are limited, therefore, providing a phased approach over a period of time allows management the ability to prioritize and allocate needed resources.

Choose your projects wisely. Compatibility factored into the implementation and integration of the projects is how the phased approach will work over the long term. Some criteria for considering the initial projects in an e-Manufacturing program should include:

- High probability of success
- Measurable positive results that are achievable
- Ability to involve affected personnel
- Current situation affects quality or productivity
- Ability to integrate project into the overall solution model

Depending on the level of automation in a given site, projects to consider for migrating batch processes to an e-Manufacturing environment in a phased approach could include:

1. Automation of manual operations
2. Implementation of modular batch concepts
3. Utilization of S88 structured batch control software
4. Generation of batch records
5. Connecting batch systems to manufacturing execution applications as well as ERP
6. Upgrading batch software to intranet/web versions
7. Linking batch systems to “plant (e-Manufacturing) portal”
8. Implementing web-based electronic document management system
9. Implementing an electronic batch record (ERB) system
STANDARDS, MODELS, AND REGULATIONS

In order to lower the risk of any project, consideration must be given to the technologies, operations structure, and regulatory compliance issues affecting each organization and the solutions that may be utilized in their manufacturing processes. Current standards and models can provide the basis for standardizing enterprise-wide applications, simplify the specification and design of these systems, and lower the overall cost of implementation. A common set of terminology, models, and methodologies that may prove useful in batch operations can be derived from:

- ANSI/ISA S88.01-1995, Batch Control, Part 1: Models and Terminology
- ANSI/ISA S95.00.01-2000, Enterprise - Control System Integration, Part 1: Models and Terminology
- 21 CFR Parts 210, 211, etc. defining Current Good Manufacturing Practices, including batch record requirements
- 21 CFR Part 11, Electronic Records; Electronic Signatures
- Computer System Validation: PDA, GAMP

DESIGNING YOUR SYSTEMS

The Internet is the world’s largest and most widely used network. The rapid growth and expanding application capabilities of the Internet has led to the creation of a new “universal” technology platform. To meet the needs of the Internet, new products, services, strategies, and organizations are being built to reshape the way information systems are used in business and everyday life. With the World Wide Web and its Consortium (W3C), a system of universally accepted standards defines the way information is stored, retrieved, formatted, and displayed in a networked environment. [7, p17] It is this set of criteria that is guiding and defining the realm of “Web Technologies”.

Commerially available batch and process systems along with manufacturing execution applications are beginning to utilize web-based technologies. For most end-user companies, a path to migrate existing systems into an e-Manufacturing architecture through a phased project approach offers the best alternative. A few leading web-technology components that should be understood and specified to web-enable manufacturing systems and simplify a future migration to web-based systems includes the following (note, this is by no means a complete list):

- Web browsers – the primary interface for accessing networked systems using internet technology
- Web Solution Platform (formerly known as Windows DNA) – consists of a combination of Microsoft® products and technologies
- Middleware applications – solutions that enable users to connect to company intranets via web technology and access common databases and applications for knowledge exchange
- Object oriented programming
- Object oriented databases
- Network protocols
- Security – for systems, networks, applications, electronic records, and electronic signatures
- Wireless technology and wireless application protocol (WAP) to allow personnel the freedom to move about the plant floor while still “connected” to process management and control systems
When implementing batch systems in an e-Manufacturing environment, several issues that are often overlooked should be kept in mind and addressed as an integral part of the overall project:

- Configuration management and change control of the installed process controls and information technology (IT) systems
- Change - in the organization, manufacturing procedures, and equipment used
- Ongoing support to ensure reliability for client/server and process control systems
- Security as needed for proper system administration and as required for regulatory compliance
- Training - everyone affected by these new systems: users, technical support, suppliers, customers

**INTEGRATING CONTROLS AND ENTERPRISE DOMAINS**

After defining your batch and operations requirements for an e-Manufacturing environment, a system architecture can be specified. Final design of your own system should allow flexibility and compatibility for future needs while meeting current needs for integrating control systems, manufacturing execution applications, and enterprise management systems. A conceptual approach to utilizing a plant portal server to enable access to operations information in a batch e-Manufacturing architecture is shown in figure 1.
REGULATORY COMPLIANCE

Supported through United States governmental legislation, the electronic business age is upon us. All companies engaged in commerce today are affected by current regulations such as 21 CFR Part 11 and new technological directions being defined. A headline from a July 1, 2000 Philadelphia Enquirer article emphasize this point:

President makes e-signatures legal
Legislation signed at Congress Hall in Philadelphia;
“E-Sign Act” effective October 1, 2000.

21 CFR Part 11 introduces regulations pertinent to electronic records and electronic signatures. Part 11 has far reaching ramifications that affect all industrial companies that are subject to FDA regulations and are utilizing (or planning to utilize) electronic records and/or electronic signatures in their enterprise operations. With the rapid growth of e-commerce, it is only a matter of time before other governmental agencies enact similar legislation. Simply stated, this legislation requires a company to be in full control of their electronic records and electronic signature systems, and that failure to do so is in violation of the regulations. Keep in mind, the law does not dictate that electronic signatures must be used. Being able to use electronic signatures is a benefit that successful companies will take advantage of to reduce their need to track batch tickets forever. Legislation can greatly impact an e-Manufacturing program. Plans should include initiatives to address all regulations that are expected to present issues regarding compliance. As an example, here are just a few requirements of 21 CFR Part 11 that could impact any system design:

- The ability to determine the existence of invalid or altered records.
- System access is limited to authorized individuals.
- There is a secure, computer-generated, time-stamped audit trail that records the date and time of operator entries and actions that create, modify, or delete electronic records.
- Operational systems checks exist that enforce permitted sequencing of steps and/or events as appropriate.
- The identity of an individual is verified before the individual's electronic signature, or any element of such electronic signature, is established, assigned, certified, or otherwise sanctioned.
- Transaction safeguards are used to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.

CONCLUSION

An enterprise-wide e-Manufacturing solution incorporating batch operations can be implemented to replace legacy systems while increasing manufacturing efficiencies to optimize enterprise operations. Since automation introduced into operations generally changes the way people perform their jobs, there is apprehension and reluctance to change by many of those people. Soliciting the input of all personnel in the groups to be affected by the e-Manufacturing program is highly recommended for plantwide ownership and long term success. By utilizing a phased project approach for system integration, long-term operational changes are derived from a series of successfully implemented short-term projects. System functionalities that maximize flexibility in the integration program, ensures the compatibility of
future long-term integration projects as they are phased into the plantwide e-Manufacturing program. This approach allows management to prioritize and allocate resources as needed to maximize productivity and properly manage the impact of change and risk within the organization. The implementation of this new generation of computing solutions can offer tangible benefits to innovative organizations. As stated in the introduction, “e-Manufacturing now provides companies with the capability of evolving manufacturing into a key strategic business advantage”.

REFERENCES AND BIBLIOGRAPHY