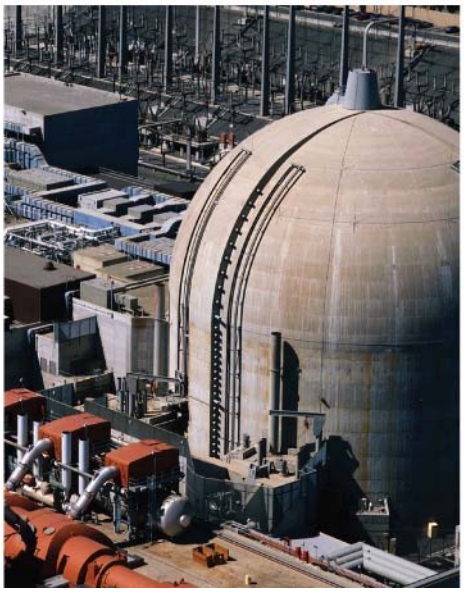
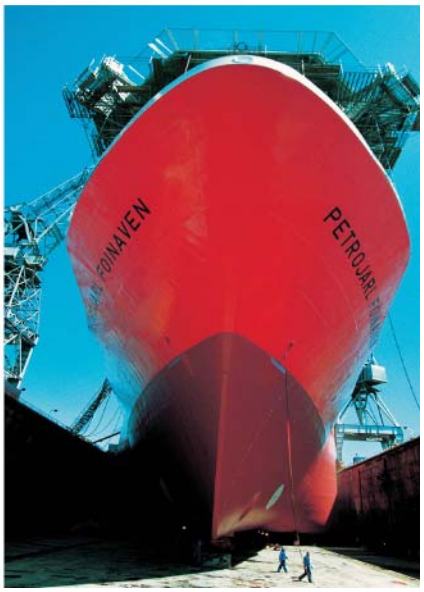
Process, Power & Marine

Optimizing the Pharmaceutical Asset Life Cycle





A Management Overview White Paper

INTERGRAPH

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Prepared by Intergraph Process, Power & Marine, a division of Intergraph Corporation

Optimizing the Pharmaceutical Asset Life Cycle Management Overview

Executive Summary

The design, build, and operations of pharmaceutical facilities are improved by efficient creation and management of both the plant asset information and the evolving configuration of the facility.

Pharmaceutical facilities are critical company assets. They reflect the final investment phase in the development of pharmaceutical products that take many years and hundreds of millions of dollars to bring to market. Establishing and maintaining the documented efficacy of these processes and products is critical to generating expected revenue and upholding corporate and regulatory quality standards over the life of these facilities. Performed effectively, management of this critical information helps the manufacturer improve time-to-market and sustain regulatory compliance in operations.

Taking advantage of the data set used in the creation of these assets is a new and vital step in addressing the shifting pharmaceutical business model. This ensures that plant asset information is available across the organization for validation, operations, and maintenance activities.

Information should be created once and re-used many times, maximizing integrity and minimizing risk.

New solutions are now available that meet FDA requirements and enable owners to manage plant asset information on a life cycle basis. Intergraph Process, Power & Marine delivers technology solutions that pharmaceutical companies use to create and manage plant asset information during facility design and build, validation, and operation. These solutions manage information for plant components from many disparate sources, such as utilities, equipment, and instrumentation, and manage the evolving plant configuration.

Management of plant asset information enables companies to enhance quality, reduce operating costs, maximize the patent window, and optimize the delivery of products to the consumers who need them.

The ability to leverage new technology will dictate a company's success in adapting to the new pharmaceutical business model, in which critical information is available across the entire organization.

The current regulatory climate of increased inspections and scrutiny from the FDA on manufacturing, combined with the uncertainty of the equity markets, has elevated cGMP compliance to a long-term business strategy. The impact of well-documented FDA violations has resulted in devastating consequences in company share price and production revenues.

Pharmaceutical companies' ability to demonstrate effective change control procedures will be one of the leading areas of FDA review, and is an area of opportunity for pharmaceutical companies to take advantage of new technology. Details of all changes undertaken during planning, approval, and implementation must be retained. Effective change management provides the ability to roll back plant information to an "as-was" status, reflecting earlier dates and times. The resulting true, accurate, and historically valid picture of plant operations is ***rigorous enough to meet related FDA and other regulatory demands.***

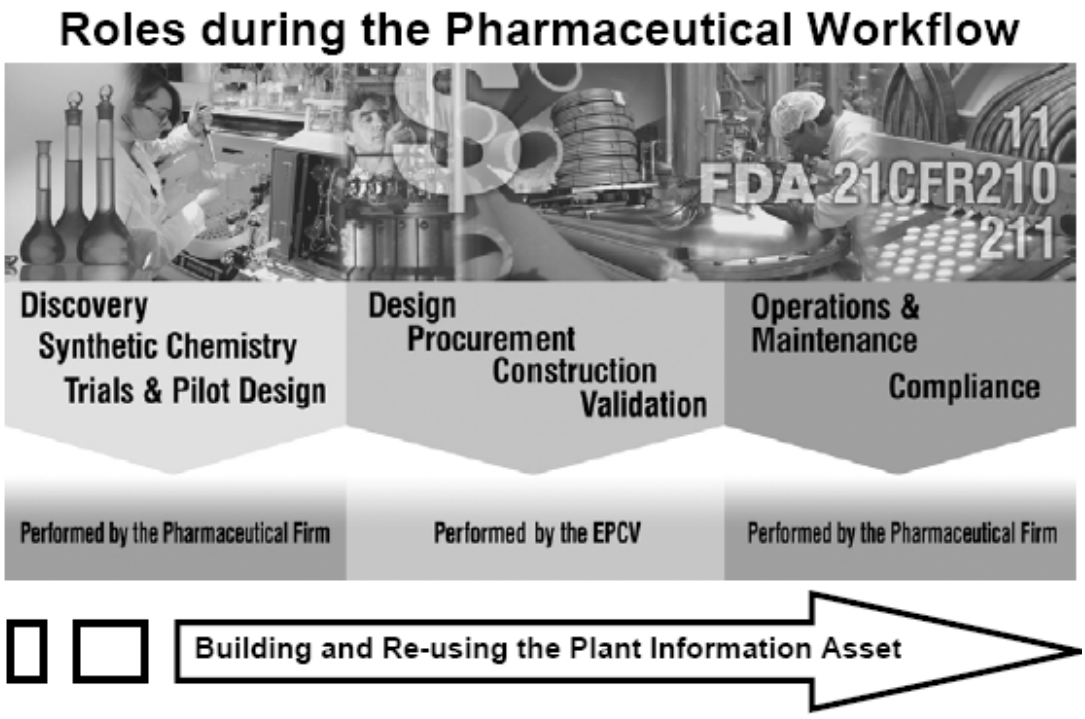
Optimizing the Project Workflow

Intergraph's plant design software has been used to design and build process plants and create plant asset information for 25 years.

There are many activities, parties, and components involved in plant upgrades and capital projects. Companies external to the pharmaceutical owner undertake engineering and construction activities that generate the majority of the plant asset information. Care must be taken to ensure that the right information is handed over, in a usable format, for validation, operations, and maintenance.

Many parties in the pharmaceutical life cycle rely on the integrity of asset information for their downstream activities.

Intergraph provides a technology platform that promotes the exchange of information in a timely and secure environment. This eliminates wasted time in data transfer and re-entry, delivering a consistent basis for change control during the entire plant asset life cycle.



Experience shows that the keys to optimizing the best use of plant asset information include:

- *Understanding how business processes use plant asset information*
- *Improving communications across the supply chain*
- *Re-using plant asset information throughout the life cycle of the asset*

Discovery through Pilot

From the outset of discovery through the clinical trials, process information is being created that makes it possible to ultimately generate and sell a pharmaceutical product. This information is critical in providing contractors, suppliers, and plant operations the basis of design to implement the manufacturing process and achieve regulatory approvals.

Design

During the design phase, a vast amount of information is generated by many third parties – information that will be essential to achieving regulatory approval and ensuring sustainable compliance for the plant. Market window demands often require the overlap of development, design, and construction activities, creating the need for information sharing and flexible and effective change control.

Optimizing the Project Workflow

The common denominator in all of these workflows is the evolving information, which is the basis for the physical plant asset.

Procurement

Pharmaceutical facilities are complex and often require special materials. With the demands of fast-track project execution, the procurement phase can present many challenges. Managing vendor data and relating it to the design specifications can be a challenge for existing engineering design and data management solutions, and can impede efficient validation activities.

Construction

With many diverse organizations and suppliers contributing to the creation of the end-facility, communicating effectively and setting the boundaries of scope can be difficult. The deliverables to support construction need to be flexible and produced in formats that meet the specific needs of subcontractors and mechanics. The ability to compile design information in multiple and various configurations is essential for efficient capital project and compliance activities.

Information is created and used by many different contractors and suppliers. Information is most accurate at validation and commissioning.

Validation

Federal regulation in the pharmaceutical industry goes above and beyond that found in other industries. The FDA tightly regulates the validation process to ensure consumer safety, confirming that the components and installation are completely in accordance with the original specifications. Associating design information to specific asset/system validation protocols allows pharmaceutical companies to streamline commissioning and validation activities, mitigating the time it takes to achieve regulatory approvals and begin production.

Enhanced capital project performance and sustainable compliance relies on this information during and after the completion of a project.

Operations and Maintenance

The final stage of the workflow encompassing operations and maintenance is crucial to complete the plant asset management cycle. The requirement for ongoing change control, ensuring that equipment and processes remain in compliance during the plant asset life cycle, is becoming increasingly important to manufacturing operations. Establishing and maintaining a secure, consistent, and accurate information base and supporting effective change control are essential to achieving sustainable compliance and avoiding FDA violations in the current regulatory climate.

Formulating an Enterprise Approach

A staggering amount of plant asset information is generated for pharmaceutical companies by a multitude of contractors and suppliers. This information must be maintained and managed by a pharmaceutical company during the life cycle of the plant asset. Sharing this information in a secure and consistent manner among various departments across the entire organization and supply chain is the key to effective information management and regulatory compliance.

An enterprise approach to managing this information can be successfully implemented when supported by a matching IT strategy. The IT solution should address the needs of the individual departments and functions that use and manage this information on a daily basis, while adhering to corporate goals.

Unique challenges and the ever-changing regulatory landscape provide compelling reasons to proactively manage the critical information that is required to demonstrate regulatory compliance. This information is needed to position existing assets in a constant state of readiness for expansions, upgrades, and shifting manufacturing objectives.

The pharmaceutical industry faces an ever-increasing number of regulations. The most recent regulation with enormous impact is FDA 21 CFR Part 11, which covers electronic records and signatures that affect product, quality, and distribution.

By establishing an overall management approach for FDA 21 CFR Part 11 plus Parts 210 and 211 in relation to cGMPs, in addition to employing electronic information management tools, pharmaceutical companies can efficiently and effectively attain compliance and optimize plant asset information throughout the life cycle.

The overall strategy should:

- Establish electronic information standards early in the life cycle
- Clearly define information management requirements in contractual agreements for new capital projects
- Assess current electronic information management systems
- Develop a centralized management philosophy for Part 11 and cGMP compliance
- Develop a long-term implementation plan and success criteria

Conclusion

Effective management of plant asset information helps maximize the huge investment in bringing pharmaceutical products to market.

In summary, there are many opportunities to improve time to market and achieve sustainable compliance by considering plant information as an asset to be re-used throughout the life cycle.

Managing disparate information repositories adds tremendous burden to successful compliance with regulations. ***Organizations can reap real competitive advantages by integrating plant asset information into a consolidated and managed source, and using today's technology to make it readily available to people and processes.*** It will position manufacturing operations to be ready for, and react rapidly to, the changing requirements that the marketplace demands, while sustaining regulatory compliance.

To succeed, companies should implement IT solutions that reflect the challenges the pharmaceutical industry faces, and solution providers must have an understanding of how this information is created and used during the normal course of operating.

Intergraph Process, Power & Marine helps pharmaceutical companies take advantage of these opportunities with software, services and solutions to fit your needs backed by:

- Financial stability
- 25 years of experience in high-quality engineering IT solutions
- Life cycle solutions focused on the pharmaceutical industry
- Turnkey approach including requirements analysis, software configuration, data capture, and production implementation
- ISO 9001:2000-certified Global Services Enterprise Engineering Services organization

Intergraph solutions help gain competitive advantage through effective information management that:

- Improves time to market
- Mitigates project re-work
- Minimizes plant downtime
- Ensures consistency and uniformity across multiple plants
- Enhances safety and quality through information-enabled personnel
- Ensures compliance with FDA regulations
- Saves money throughout the plant life cycle

Intergraph solutions help achieve sustainable compliance by:

- Meeting FDA requirements for 21 CFR Part 11 and cGMPs
- Providing a consolidated and managed source of asset information
- Tailoring secure access configurations
- Ensuring traceability and auditability of changes
- Providing historical view "as-was" plant configurations
- Maintaining effective change control

Headquarters
Process, Power & Marine
Intergraph Corporation
300 Intergraph Way
Madison, AL 35758
1-800-260-0246 or 1-256-730-3707

For Process, Power & Marine International Locations

Americas	
Canada	1-800-661-8134
Mexico	52-55-5525-5594
Venezuela	58-212-959-5344
Asia-Pacific	61-2-9929-2888
Europe	
Central	49-89-96106-0
Eastern	48-22-5658-800
Southern	39-02-57545-1
Western & Africa	44-1793-492500
Middle East	971-4-3367555

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