

SmartPlant® for Life Sciences



BUILD TOP-QUALITY CAPITAL FACILITIES IN RECORD TIME

Active Pharmaceutical Ingredient (API) facilities and manufacturing plants are critical company assets – essential for the efficient production of a pharmaceutical product to quality and regulatory standards. Intergraph helps you improve the design, build, commission, operation, and maintenance of the physical plant by creating and managing engineering information and the evolving configuration of the facility – both of which are essential to support process control and compliance.

The pharmaceutical industry faces its own special challenges, such as time to market, patent window, modular design to allow flexible production, compliance to stringent FDA regulations, unexpected facility audits, and avoidance of heavy fines and penalties. Intergraph® recognizes these challenges, and has developed a total solution, SmartPlant® for Life Sciences, that is tailored to meet the special needs of the pharmaceutical industry, such as:

- Documenting design in compliance with FDA regulators
- Managing design data and documents over the plant life cycle
- Modular design issues
- Procurement and effective materials management
- Compressed design and construction schedules

SmartPlant for Life Sciences offers benefits for your complete plant life cycle.

AE/EPC REVIEW AND HANDOVER WORKFLOWS

SmartPlant for Life Sciences is a standards-based library that manages the engineering data and documents generated from a myriad of Intergraph and third-party applications. Project information can be collated and made available to all authorized parties, local and remote, during the design and build stages – in preparation for the validation, commissioning, and handover of the “as-built” plant information to operations and maintenance. SmartPlant for Life Sciences guarantees a permanency to this information, because changes are never deleted, just marked as obsolete information. This ensures that historic records are preserved intact to provide valuable traceability and audit compliance, plus all data is fully compliant with 21 CFR Part 11.

BOOST DATA VALUE

- Electronically keep data and documents in complete compliance with 21 CFR Part 11 regulations
- Never lose the engineering design basis of assets comprising your facility
- Model best practices electronically in a powerful workflow engine to adhere to company best practices
- Reduce risk of punitive liability to plant managers through improved work process audit trails that retain all historical information and configurations, enabling “rollback” of plant information to earlier dates and times
- Electronically manage relationships between and revisions to URS, requirements, Critical Process Parameters, physical tags, and assets
- Take advantage of a complete electronic GMP library function
- Maintain a full audit history on every piece of data and every document through the entire life cycle of a facility

SAVE TIME

- Reduce time to market for fast-track projects plus modular and stick-built designs
- Reduce commissioning and validation effort through work process automation
- Maximize patent window and minimize time to market by enabling global engineering via 24-hour access to a single source of all up-to-date engineering information – e.g., tags, assets, engineering documents, quality documents, and vendor information
- Expedite the re-configuration of a plant for the production of different drugs through electronically managed plant configuration management
- Track and disposition all deviations using best practice electronic work processes

PROCUREMENT AND CONSTRUCTION MANAGEMENT

Take advantage of SmartPlant for Life Sciences to stay on schedule to maintain your data value. Leverage this information asset in support of efficiently streamlining operation of your facility.

PRE-FABRICATION OF MODULES AND SKIDS

The Intergraph solution works with your pre-fabricated construction plans to help you save time and start production faster.

CONCURRENT PRE-COMMISSIONING AND VALIDATION

With manual solutions, plant owners usually delay validation until the end of construction. But with Intergraph's "smart" data, you can rest assured that all of your data is as-built. This means that you can start validation while construction is still underway, saving time and money.

SmartPlant for Life Sciences provides an accurate "as-built" electronic data source from which a detailed and thorough integrity validation can be performed by the owner. This ensures the plant meets the original specifications, and subsequent production can begin.

Validation in the pharmaceutical industry goes above and beyond that found in many other industries and never truly ends, because processes and products are continually being monitored. SmartPlant for Life Sciences information is kept up-to-date during operations and maintenance in line with the evolving plant configuration and re-configurations for multiple product production.

EARLY OPERATIONS AND MAINTENANCE DATA LOADING

Intergraph helps you shrink the workflow by enabling processes to occur in parallel that usually take place in serial order. Because your data is updated continuously, handover to operations and maintenance can be made continuously instead of in one large event.

AUTOMATED RECORDKEEPING WITH ONLINE ACCESS

Regulatory agencies require documentation for evidence that stretches all the way back to URS that birthed a design with "smart" data. Intergraph's solution addresses issues raised by FDA's 21 CFR Part 11 regulations, which apply to virtually all electronic recordkeeping. SmartPlant for Life Sciences provides better information management and adherence to compliance. Its single source of engineering information facilitates ease of access, and is replacing traditional engineering management systems that would not meet FDA requirements.

WHAT IS A SMARTPLANT?

A SmartPlant knows:

- Its design basis
- Its change history
- Its quality baseline and history
- Its organizational structures and who to depend on for its needs
- Change projects currently in process and their status
- Planned future changes
- How to produce all related documentation
- How to notify the right people at the right time to keep it all consistent and accurate

QUICK ROI

Experiencing just one of these possible results can easily justify the initial investment of implementing the Intergraph solution:

- Avoid one-week delay in plant startup
- Remove multiple data re-entry across systems on a single project
- Avoid one FDA inspection violation
- Avoid one mistake from use of invalid data

ABOUT INTERGRAPH

Intergraph is the leading global provider of engineering and geospatial software that enables customers to visualize complex data. Businesses and governments in more than 60 countries rely on Intergraph's industry-specific software to organize vast amounts of data into understandable visual representations and actionable intelligence. Intergraph's software and services empower customers to build and operate more efficient plants and ships, create intelligent maps, and protect critical infrastructure and millions of people around the world.

Intergraph operates through two divisions: Process, Power & Marine (PP&M) and Security, Government & Infrastructure (SG&I). Intergraph

PP&M provides enterprise engineering software for the design, construction, and operation of plants, ships, and offshore facilities. Intergraph SG&I provides geospatially powered solutions to the defense and intelligence, public safety and security, government, transportation, photogrammetry, utilities, and communications industries.

For more information, visit www.intergraph.com.

