



## aspenONE™ Production Management & Execution for Pharmaceuticals

*Enables compliance,  
operational efficiency,  
cost reduction and  
customer supply  
excellence in API & DP  
pharmaceutical  
manufacturing*

### |||||| Overview

*aspenONE Production Management & Execution for Pharmaceuticals* improves end-to-end operational efficiency, from order dispatch through execution to order fulfillment and batch release. The solution drives efficiency through full paperless operation, 21CFR11 compliance, comprehensive process data capture, and analysis and improvement. In addition, it integrates fully with existing legacy systems, leveraging your investment. Companies deploying *aspenONE Production Management & Execution for Pharmaceuticals* achieve positive ROI in months, instead of years.

### |||||| The Challenge

Manufacturing costs have risen 20-25% over the last decade. The pharmaceutical industry is not only faced with a need to dramatically reduce costs, but to also maintain regulatory compliance and meet growing and complex market demands. To maintain competitive advantage in the increasingly demanding pharmaceutical market, companies must:

- Reduce manual errors, reworks and deviations
- Reduce process variability and increase process reliability and yield
- Reduce order receipt to fulfillment cycle times with reduced work in progress (WIP) and finished product inventory
- Improve overall current Good Manufacturing Practices (cGMP) & 21CFR11 compliance, enabling full paperless operations
- Reduce overall cost of goods (CoGs)
- Improve customer service and delivery performance

“Consensus in the need for performance improvement in pharma manufacturing comes from all quarters, including regulators. ...today significant opportunities exist for improving the efficiency of pharmaceutical manufacturing...”

— FDA (Framework for Innovative Pharma Manufacturing & Quality Assurance, August 2003)

## aspenONE™ Production Management & Execution for Pharmaceuticals

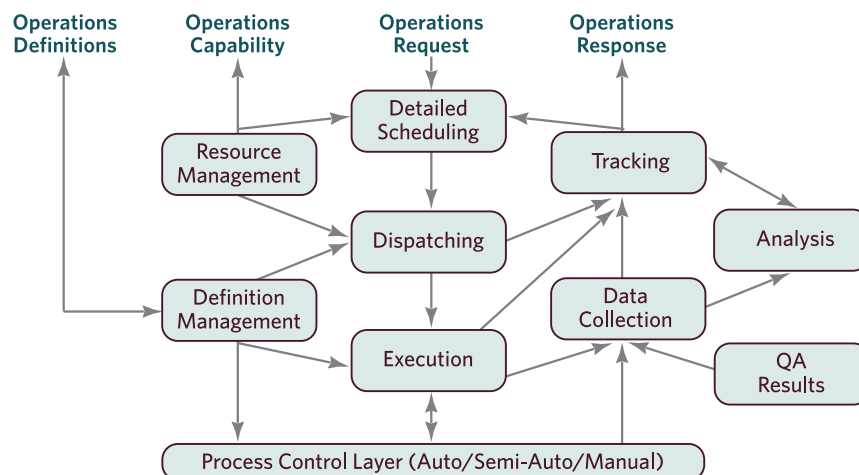
### |||||| The AspenTech® Solution

aspenONE Production Management & Execution for Pharmaceuticals is specifically designed to help pharmaceutical companies meet these challenges by improving operational reliability, visibility, and flexibility. aspenONE Production Management & Execution for Pharmaceuticals delivers major performance improvements by bringing order and control to the “execution gap” that exists between enterprise resource planning (ERP) systems and the many data sources and control systems on the shop floor. The solution is uniquely designed to apply to both API and DP manufacturing scenarios, thereby enabling collaboration and integration across each product value stream. aspenONE Production Management & Execution for Pharmaceuticals delivers:

- **A Roadmap** Allows the controlled and progressive implementation of site or network wide solutions, aligned with your current business challenges, strategies and objectives
- **Simplicity** Reduces complexity through the use of modular, scalable and integrated products, making deployment easier and faster
- **Lower Total Cost of Ownership (TCO)** Enables customized designs which can be rolled out across multiple sites, thereby avoiding duplication and rework, and delivering a sustainable long-term solution

The solution includes a powerful and configurable workflow engine that delivers “total procedural compliance” encompassing best practices into interactive Standard Operating Procedures (SOPs) and driving out manual errors. It uniquely enables companies to truly drive operational excellence and assured quality throughout their manufacturing operations.

aspenONE Production Management & Execution for Pharmaceuticals is based on the internationally accepted ISAS95 workflow model defining all batch manufacturing operations:





## Function

*aspenONE Production Management & Execution for Pharmaceuticals* provides a complete manufacturing solution for both API & DP pharmaceutical manufacture, delivering:

- Shop floor planning & finite capacity scheduling—driving asset utilization up & manufacturing cycle time down
- Order dispatching from ERP to shop floor work center—feeding accurate & timely consumption data back to ERP
- Order execution via a configurable workflow manager—driving total procedural compliance into manufacturing execution & eliminating manual errors
- Track & trace of batch activities - providing historical & genealogical process data
- Full electronic batch record (EBR)—enabling efficient EBR & batch record deviation, QA review, analysis & batch release
- Routine & extensive process data capture & analysis—driving continuous improvement
- Equipment status management—enabling real-time control of equipment utilization
- Role-based view of production metrics—both process specific & high-level KPIs
- Full compliance with pharmaceutical regulations—including 21CFR11
- Integration with client site systems—ERP, LIMs, DCS, etc
- Fully modular and scalable solution—accommodating small single sites up to highly complex multi-site operations

## Benefit

Value, measured in US\$ millions, has been realized at client site level deployments from various sources by enabling:

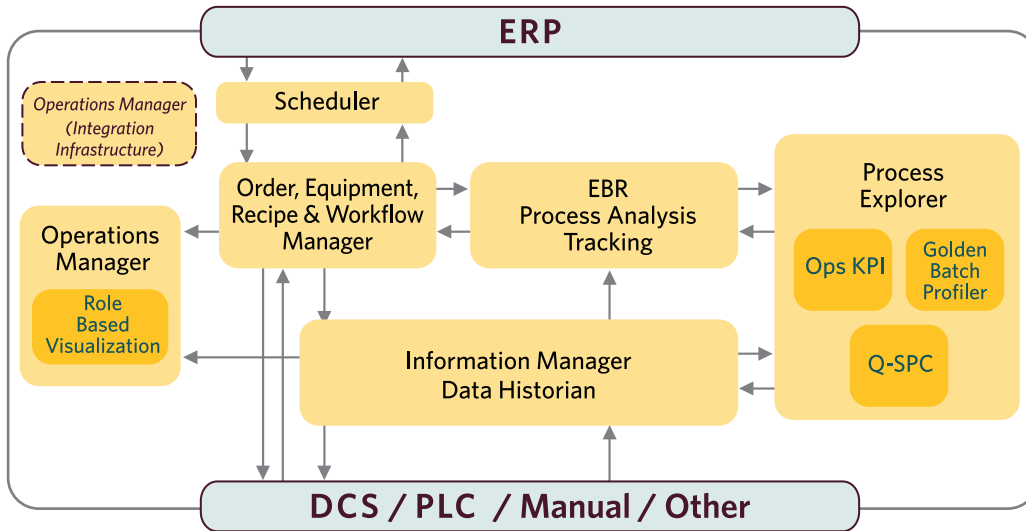
- Higher process yields and overall robustness through SPC and cause and effect correlation and analysis
- Reduced documentation and procedural errors through configurable workflow execution, and the achievement of FDA inspected and approved paperless operations
- Optimized shop floor scheduling and resource utilization
- Easier and quicker to manage batch deviations / QA review and release
- Improved overall compliance with cGMPs and 21CFR11 requirements, facilitating successful regulatory inspections
- Reduced “virtual”, “rework” or “hidden” factory activity
- Reduced work in progress (WIP) and finished product inventories
- More agile and responsive “order focused” operations with improved customer supply metrics (including fewer stock-outs and order arrears)
- Integration with existing ERP and LIMS systems

Combined with the proven experience of AspenTech’s leading services team, companies are able to speed up implementation, ensuring a rapid return on investment and low total cost of ownership. Additional support for client IQ/OQ/PQ is also available, as is full ongoing and comprehensive user support.

***AspenTech’s solution “provides reliable workflow management and seamless integration to the business system that drives the entire manufacturing process and allows us to improve manufacturing consistency and control.”***

— **Francesc Catalán**, IT Director, AlconCusí, S.A.

# Production Management & Execution



## ||||||| aspenONE Production Management and Execution for Pharmaceuticals

aspensONE Production Management and Execution for Pharmaceuticals integrates seamlessly with other aspenONE business area applications for process development, advanced process control and process engineering. AspenTech's aspenONE solutions are designed to align with the key industry business processes, providing manufacturers the capabilities they need to optimize operational performance, make real time decisions, and synchronize the plant and supply chain.

## ||||||| About AspenTech

AspenTech is a leading provider of award-winning process optimization software and services. AspenTech's integrated aspenONE™ solutions enable manufacturers to reduce costs, increase capacity, and optimize operational performance end-to-end throughout the engineering, plant operations, and supply chain management processes, resulting in millions of dollars in cost savings.

For more information, visit [www.aspentech.com](http://www.aspentech.com).

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