



aspentech™ Pharmaceutical Solutions:
Driving Continuity and Collaboration—
from Lab Floor to Plant Floor to Top Floor

An Industry White Paper

Who is AspenTech?

AspenTech is a global company founded in 1981 with more than 1,300 employees in 36 major locations worldwide. Its deep domain expertise is in the process industries, model-based decision support technology, and industrial operations management. Among its 10,000+ customer installations, AspenTech clients include:

- 9 of the top 10 pharmaceutical companies
- 32 of the top 32 petroleum companies
- 50 of the top chemical companies
- 17 of the top 20 engineering and construction companies

Challenges Facing Pharmaceutical Companies and How AspenTech Can Help

With declining new drug authorizations, rising costs, increasing generic erosion, and a paradigm shift in the regulators' approach to assured quality, the need for pharmaceutical companies to focus on R&D and operations to "build in quality" and "drive down cost" has never been greater. AspenTech has developed aspenONE Pharmaceutical Solutions with these business imperatives in mind, aligning the solution stack directly with the ongoing needs of an industry facing significant challenges.

Solution Alignment with Pharmaceutical Trends

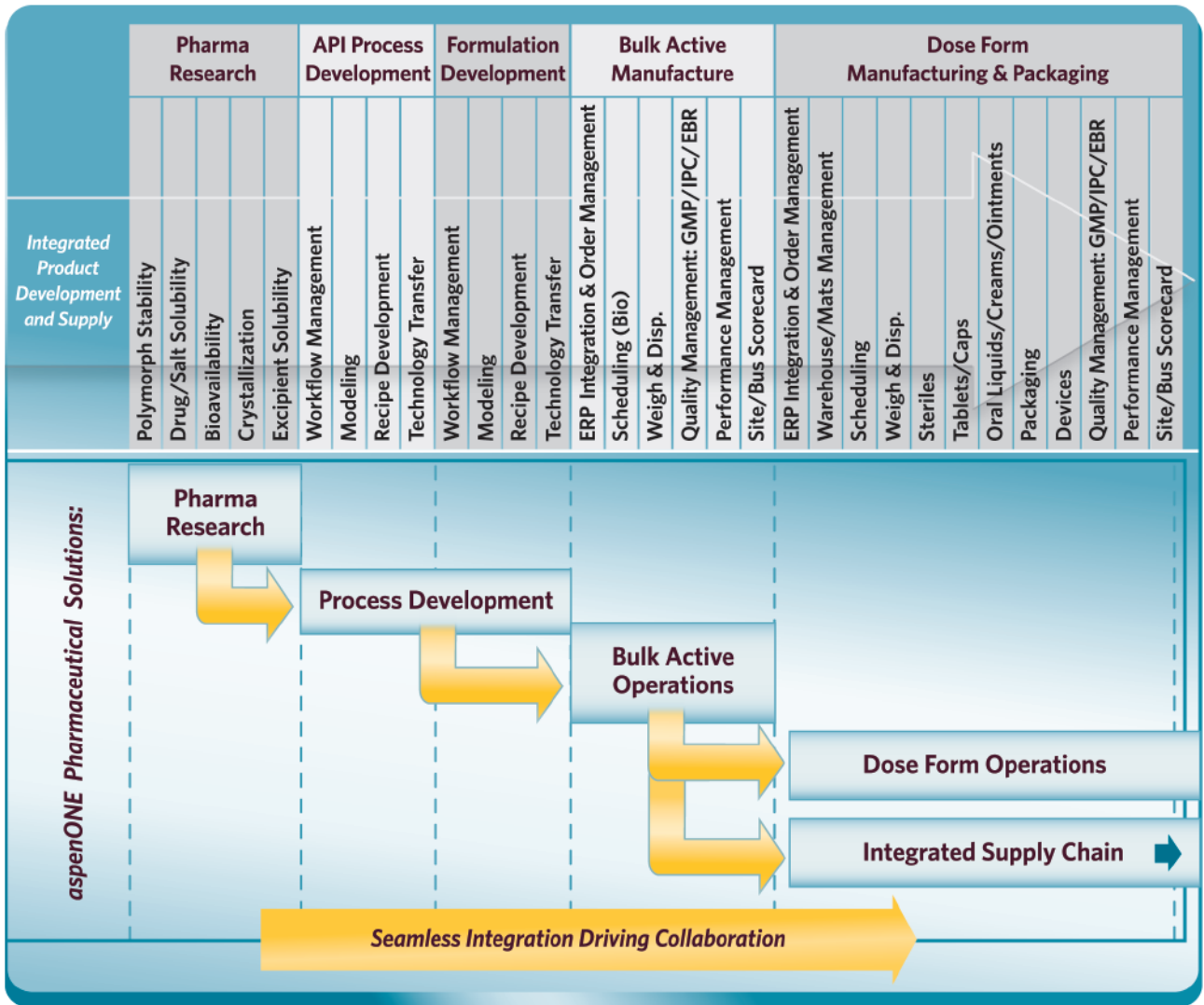
<i>Solution Stack</i>	<i>Alignment with Pharmaceutical Trends and Aspirations</i>
Pharma Research	Enables the prediction of key drug properties with respect to solubility for: <ul style="list-style-type: none"> • Solubility characterization in lead optimization • Better, informed decision making for drug development portfolio • Solubility prediction for API processing and formulation design • Linking NCE lead optimization with early-stage drug development
Process Development	Streamlines the API process development workflow and supports realization of QbD (Quality by Design) and DFM (Design For Manufacturing) culture by: <ul style="list-style-type: none"> • Underpinning the development workflow with a software solution spanning route selection through scale up to final technology transfer • Driving up productivity and reducing development execution costs • Enabling a culture of collaboration and iterative learning
Bulk Active Operations Dose Form Operations	Reduces CoGs and improves operational performance while ensuring full regulatory compliance, including 21CFR Part 11. Aligns with FDA's PAT, process understanding, and quality initiatives: <ul style="list-style-type: none"> • Support the concept of a risk-based approach to manufacture • On-time new drug launch and sustained supply of quality medicines to market
Integrated Supply Chain	Enables a reactive, adaptive, and agile supply network delivering: <ul style="list-style-type: none"> • Reduced inventory/WIP/stock write-off costs • Better customer supply performance On Time & In Full • Higher plant utilization

aspenONE™ Pharmaceutical Solutions

What are aspenONE Pharmaceutical Solutions?

aspenONE Pharmaceutical Solutions are a software solution stack, designed specifically for the pharmaceutical industry with the capacity to add significant value to research and development, and across bulk active and dose form commercial scale manufacture. It delivers an integrated set of software modules that drive critical functionality, data and model continuity, and collaboration—from lab floor to shop floor to top floor—which are directly aligned with key pharmaceutical company trends and goals.

aspenONE Pharmaceutical Solutions Driving Continuity and Collaboration



These solution sets can be deployed standalone or, leveraging a service-oriented architecture, readily integrated with each other and with client systems such as ELNs, ERP, LIMS, DCS, PLCs, etc. For example, the process development chemist at the lab bench during the lead optimization phase of drug discovery may use the Aspen Solubility Modeler™ for rapid selection of the most appropriate solvent or solvent mixture to optimize crystallization performance. Then, in process development, the crystallization procedure can be incorporated into the evolving API manufacturing recipe in Aspen Batch Plus™. Finally, through a technology transfer to commercial API manufacture, this approach becomes the standard and optimal process for that particular manufacturing step.

The functionalities of each module are sophisticated and extensive:

aspenONE Pharmaceutical Solutions: Solution Stack and Modular Functionality

<i>Solution Stack</i>		<i>Solution Functionality</i>
Pharma Research	Solubility Modeler (Under Development)	Modeler and Predictor for solubility characterization and optimization of multiple API processing steps (e.g., crystallization, phase separation, and distillation). Also provides screening for polymorph stability, optimal chromatographic performance, solubility prediction across pH and complex aqueous and organic mixtures.
Process Development	Bulk Active Process Development	Synthetic route selection, recipe development, scale up, process fit, CoGs analysis, environmental impact assessment, crystallization process development, batch reaction modeling, etc.
Bulk Active Operations	MES & Quality Management	Integration platform, order manager, workflow manager, EBR, master data manager, pre-templated workflows (e.g., W&D), compliance manager, deviation manager, etc.
	APC/(PAT)	Advance Batch Process Analytics and Control (“PAT”) (under development), golden batch profiler.
	Performance Management	Performance manager (historian/process data analytics/SPC/calc engines), process explorer, high-level KPI metrics, and drill down to cause and effect.
Dose Form Operations	MES & Quality Management	Integration platform, order manager, configurable workflow manager, EBR, master data manager, pre-templated workflows [(e.g., W&D, tableting, material management, packaging (under development))], compliance manager, deviation manager, etc.
	APC/(PAT)	Advance Batch Process Analytics and Control (“PAT”) (under development), golden batch profiler.
	Performance Management	Performance manager (historian/process data analytics/SPC/calc engines), process explorer, high-level KPI metrics, and drill down to cause and effect.
Integrated Supply Chain	Global Network	Supply chain management: supply planning, collaborative forecasting, inventory management, and demand management.
	Site/S&OP	Production planning (1yr): capacity utilization, site inventory management.
	Shop Floor	Shop floor scheduler (finite capacity scheduling): both small molecule and macro molecule (biotech) operations.

What’s Unique about aspenONE Pharmaceutical Solutions

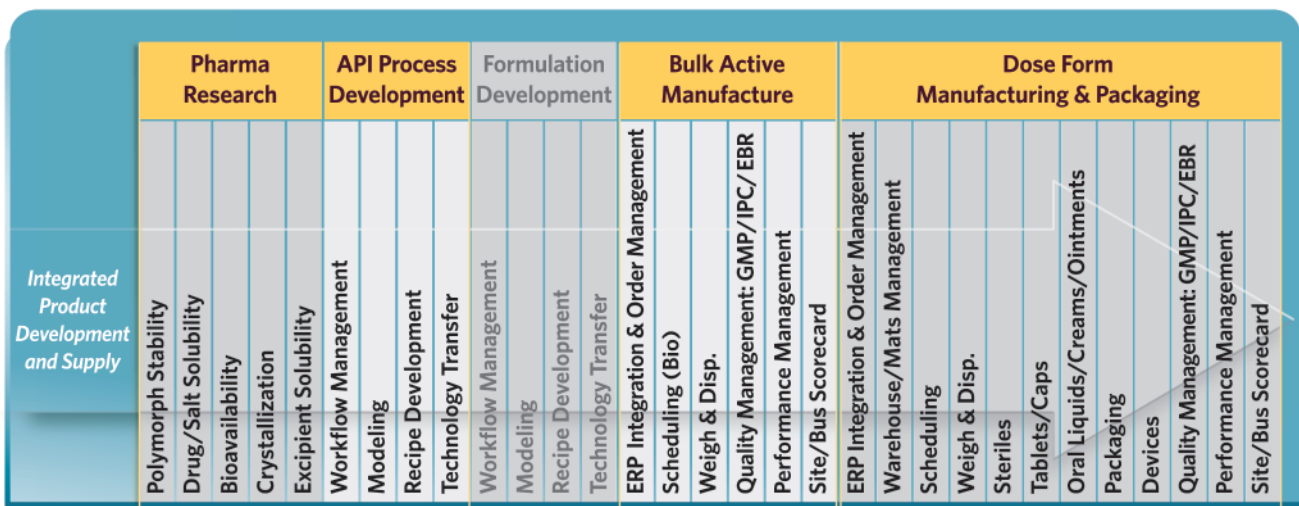
- aspenONE Pharmaceutical Solutions are the only solutions that offer a novel and uniquely powerful modelling capability for new drug solubility profiling, enabling significant process optimization as early as the lead optimization stage of process development.
- aspenONE Pharmaceuticals Solutions are the only solutions that offer a recipe-management capability across API process development, from route selection through scale-up to technology transfer into commercial operations, driving process development workflows toward high levels of efficiency.
- aspenONE Pharmaceuticals Solutions are the only solutions flexible and configurable enough to be deployable in API, DP, and Biotech manufacturing sites.
- aspenONE Pharmaceuticals Solutions are the only solutions that provide true eSOPs (rather than merely “paper on glass”) to deliver configurable total procedural compliance and drive out manual errors from the shop floor, while increasing BRFT (batches right first time) and operational performance metrics.

- aspenONE Pharmaceuticals Solutions are the only solutions that provide for all ISA-95 and ISA-88 defined activities for batch manufacture in a modular, scalable, and integrated way. They offer the necessary “flexibility with breadth” to focus on a client’s specific business challenges, and comprehensively address their key value levers.
- aspenONE Pharmaceuticals Solutions are the only solutions that come effectively pre-integrated (e.g., buying from one vendor in the MES space simplifies the architecture and integration challenge, smoothing data flows). Uniquely, they deliver EBR, workflow management, scheduling, and process data capture and analysis.
- aspenONE Pharmaceuticals Solutions are the only solutions that handle the SKU complexities of DP scheduling and the routing uncertainties of biotech manufacture, to enable true and dynamic (finite capacity) shop floor scheduling.

How is Value Delivered

aspenONE Pharmaceutical Solutions comprehensively addresses numerous value levers across the workflow:

aspenONE Pharmaceutical Solutions Driving Client Value



Derive millions of dollars in value from:

- Faster, streamlined workflows
- Productive and efficient process development
- Process design and fit
- Improved pilot plant performance
- Robust manufacture from launch
- Continuous process development
- Efficient technology transfer
- Solubility modeling and prediction
- Optimal crystallization processes
- Cross-functional collaboration

Derive millions of dollars in value from:

- Optimal plant scheduling
- Integration with process development
- Yield/Robustness/BRFT
- Plant utilization
- Reduced cycle time
- Quality compliance management
- Deviation management
- CoGs reduction
- Improved customer delivery

Derive millions of dollars in value from:

- Optimal plant scheduling
- Total procedural compliance
- Inventory/WIP reduction
- Process monitoring and improvement
- Yield/Robustness/BRFT
- Reduced cycle time
- Quality compliance management
- Deviation management
- CoGs reduction
- Improved customer delivery

In Process Development:

- Nine of the top 10 pharmaceutical companies use the Bulk Active Process Development module as a key component of their API process development workflows.
- A top-10 drug company deploys the Bulk Active Process Development module across their development workflow, through to the first sites of commercial API manufacture, deriving significant value from increases in productivity and process robustness.
- Numerous top-10 drug companies use the Bulk Active Process Development module for process fit, recipe development, the origination of operating instructions, CoGs analysis, Environmental Impact Assessment (EIA) including emissions calculations, solvent reduction studies, and many more critical development activities.
- Two top-10 drug companies have standardized their solubility modeling (for optimum crystallization processing) on Aspen Solubility Modeler.

In Manufacturing:

- Five of the top 10 pharmaceutical companies deploy all or part of the MES, Quality Management, and Performance Management modules at key strategic manufacturing sites.
- A top-5 drug company runs its cytotoxic sterile manufacturing operation entirely on AspenTech's Dose Form Operations solution, and the solution is deployed at numerous other sites worldwide.
- A leading pharmaceutical raw materials manufacturer achieves "pharma" grade product standards by utilizing the Dose Form Operations solution at sites in North America and Europe.
- A top-5 drug company has standardized its global API manufacture MES on the Bulk Active Operations solution at several strategic API sites, delivering Performance Management, EBR, and Compliance Management

In Supply Chain:

- A leading blood products company deploys the Integrated Supply Chain solution for the planning, distribution, and supply of its complex suite of products.
- A leading biotech contract manufacturer runs their highly complex contract biotech manufacturing scheduling on Aspen Plant Scheduler.

In General:

- AspenTech is the only vendor to specialize exclusively in the process industries, including pharmaceuticals.
- AspenTech possesses demonstrable pharmaceutical domain expertise, including consultants who have worked more than 20 years in pharmaceutical development and manufacturing domains.
- AspenTech delivers full regulatory compliance with cGMP, GAMP, and 21CFR11.
- AspenTech has solutions deployed at leading pharmaceutical companies and has been successfully audited by those companies on numerous occasions. AspenTech solutions have been independently inspected in situ at client sites by FDA, EMEA, and MHRA inspectorates; no 483, critical, or major issues have been recorded against AspenTech software to date.
- AspenTech solutions deliver a return on investment that typically spans six to 12 months and yields approximately \$1 million value benefit per site.
- AspenTech supports software deployments with global services and training, provided either directly by AspenTech or via accredited AspenTech partners.

For more information on aspenONE Pharmaceutical solutions, please visit aspentech.com.



||||||| 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.

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