aspentech

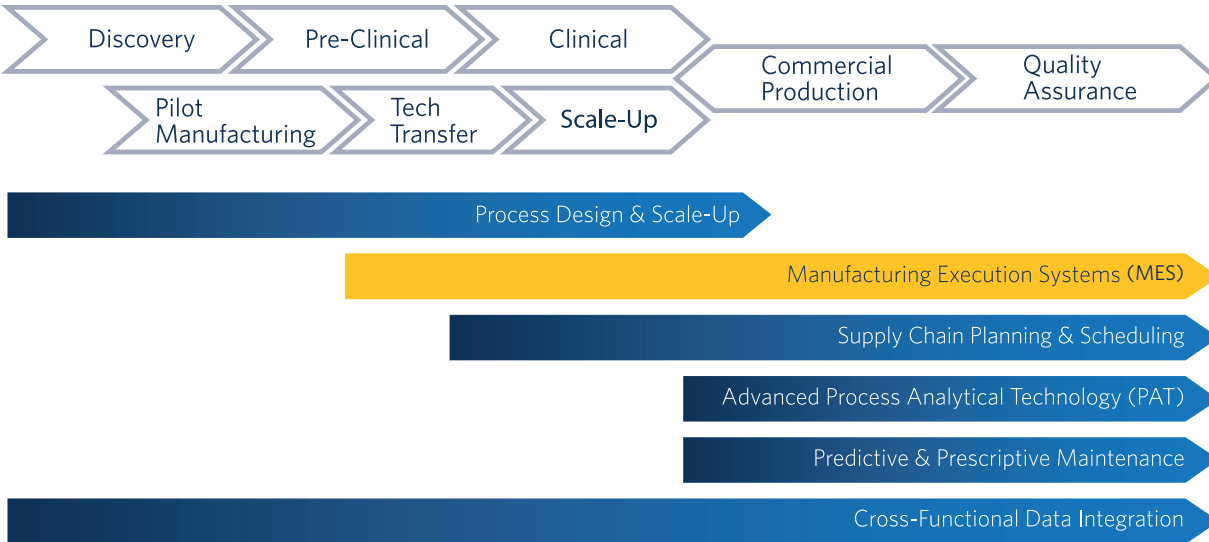# Manufacturing Execution Systems for Pharma

Improve Agility and Consistency in Large and Small Molecule Manufacturing

Discovery → Pre-Clinical → Clinical → Commercial Production → Quality Assurance

Pilot Manufacturing → Tech Transfer → Scale-Up

Process Design & Scale-Up

Manufacturing Execution Systems (MES)

Supply Chain Planning & Scheduling

Advanced Process Analytical Technology (PAT)

Predictive & Prescriptive Maintenance

Cross-Functional Data Integration

As drug pipelines and portfolios become increasingly diversified, pharma and biotech manufacturers are fully recognizing the imperative to increase their production agility, while ensuring SOPs are executed accurately and efficiently. Companies on their Pharma 4.0 journey need tools that foster compliance and are compatible with their existing hardware and digital ecosystem, so they can manage today's dynamic environment.

Backed by 40 years of innovation and partnership with industry, AspenTech's flexible Manufacturing Execution Systems (MES) solution automates, guides and digitally records SOPs according to cGMP guidelines, reducing human error and minimizing risk of deviations. It provides the foundation for digital transformation, safeguarding data integrity while enabling users to extract more value out of their data with aggregation and analytics.

What MES can do for you:

Reduce cross checking hours by **52%**

Decrease batch review deviations by **14%**

Simple Integration, Rapid Deployment

Our MES technology delivers customizable templates from the AspenTech General Manufacturing Library (GML). The 40+ GML templates, combined with vendor agnostic software, streamline integration and implementation for rapid deployment while fully adhering to regulatory guidelines.

To advance your digitalization journey and accelerate development times, visit aspentech.com/pharma.

AspenTech's Comprehensive MES Solution

Reduce Errors and Improve Execution

Aspen Production Execution Manager™ (APEM)

Achieve right first-time manufacturing by digitally guiding SOP execution and increasing visibility throughout production. APEM provides automation for order, recipe and workflow management according to cGMP guidelines and is accessible at the production through a web-based client optimized for touchscreens.

Build processes using over 40 customizable templates from the AspenTech General Manufacturing Library (GML)

- Equipment logbook and calibration
- Weigh and dispense operation
- Material, container and equipment handling
- Yield and reconciliation operations

Aspen InfoPlus.21® (IP.21)

IP.21 is an industrial process historian and the foundation of a digital production environment. It stores real-time and historical data from multiple production sources to build a complete picture of operations.

Safeguard data integrity and transparency

- Secure infrastructure that scales for increased collaboration
- Real-time computation engines for analysis across an enterprise
- Aspen Enterprise Historian manages data across sites

Aspen Production Record Manager™ (APRM)

Improve batch performance and process order tracking with APRM. This ISA-88 compliant batch historian captures, stores and contextualizes processing data from historians, lab systems and quality systems in a central repository for better traceability and quality assurance.

Improve manufacturing traceability

- Batch-to-batch analysis
- Real-time batch deviation analysis

1

Compliance-ready for regulated production environments

- Full cGMP compliance
- Data integrity per FDA 21 CFR Part 11, EU Annex 11

2

Flexible to fit your existing processes

- Vendor agnostic
- Configurable templates

3

Agile for diverse product mix

- Automated, paperless process execution and records
- Aggregated batch data for track and trace

To advance your digitalization journey and accelerate development times, visit aspentech.com/pharma.