



Optimizing Outcomes Across the Pharma Value Chain Network: The Path Forward In An Ever-Changing World

A Digital Transformation Guide for the Pharma C-Suite

by David Leitham, Senior Vice President and General Manager, Aspen Technology, Inc.



Featuring Research Insights from Axendia,
a Leading Life-Sciences Analyst Firm



aspentech | Executive Brief

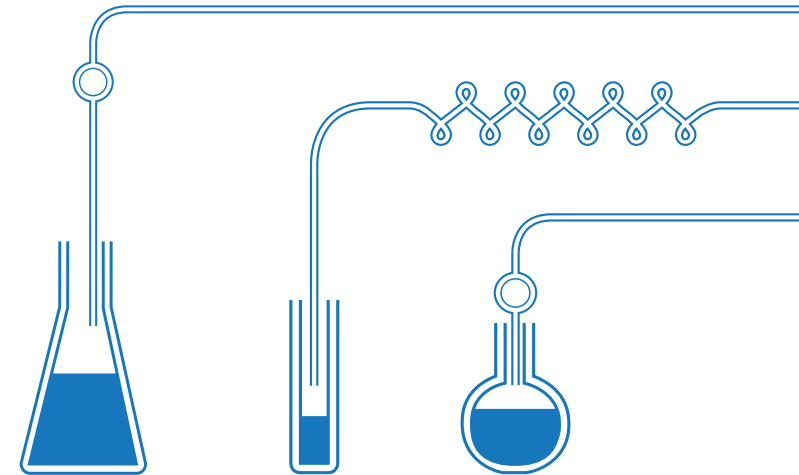
Executive Summary

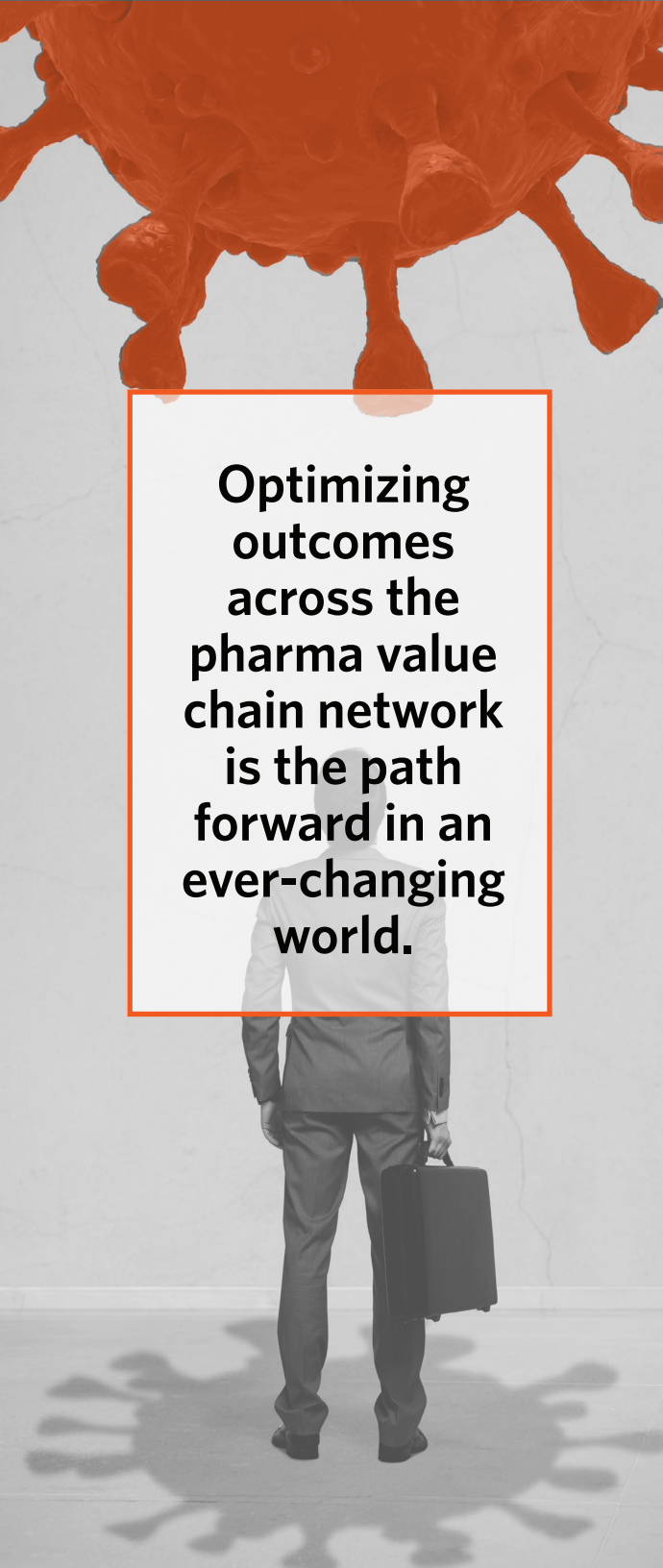
The following brief shares Aspen Technology's vision for the future of pharma and the path forward for realizing it. The vision, approach and best practices provided offer guidance and actionable steps for achieving predictable and profitable performance across any market conditions.

How manufacturers perform during periods of volatile, uncertain, complex and ambiguous market conditions can make the difference between merely surviving in the nearer term and thriving and ensuring sustainability in the long run. The recent market disruption that came with the COVID-19 pandemic underscored and reinforced the need to transform the supply chain for greater agility and resiliency during market swings and periods of volatility. The guidance within shares the formula for doing so, providing manufacturers with a blueprint to transform their supply chain into a higher-performing pharma "value chain network" that delivers on time and in full, including during shifts in supply and demand.

Optimizing outcomes across the pharma value chain network using a holistic approach to digital transformation is the path forward in an ever-changing world. The approach ensures the security of supply and pushes the boundaries and limits of what is possible for optimization, multiplying performance gains from digital transformation. This brief features research insights from leading Life Sciences Analyst Firm

Axentia. Implementing the recommendations provided will drive maximum performance and returns for the pharma company and greater accessibility for the patients they serve.





Optimizing outcomes across the pharma value chain network is the path forward in an ever-changing world.

Introduction

Managing supply chain risk and disruption in pharmaceutical manufacturing has increased in intensity and attention given by pharma companies over the decades due to natural disasters, healthcare pandemics, impurity-triggered recalls and dependence on single-sourced and globally sourced suppliers.

The vulnerability of the supply chain isn't new, and the COVID-19 pandemic exacerbated it. At the same time, despite the tremendous supply chain disruptions the industry has faced during the pandemic, the impact of the pharmaceutical industry on global health has been profound. The innovation, collaboration and productivity the world experienced due to high-speed vaccine manufacturing were remarkable, and the pharmaceutical industry will never be the same. Expectations are higher now.

As we move forward, it is clear that speed to market for high efficacy pharmaceuticals will remain a top business imperative. A key challenge for pharma companies will be to efficiently manage their suppliers and contract partners while accelerating speed to market consistently, efficiently, safely and profitably across product lines and all market conditions. Given the trends towards personalized medicine, the increase in complex modalities and biologics in the pipeline and the need to source reliable suppliers with agility, meeting this challenge will be no small feat.

"The path forward to ensure sustainability in an ever-changing world calls for pharma manufacturers to fuel their digital transformation journeys with a holistic approach that optimizes outcomes across the pharma value network," commented Daniel R. Matlis, President of Axendia. This approach will shape the future of pharma by enabling pharma companies and their partners to meet market demands, manage the increasing complexity and prosper in market conditions that include pressure to deliver products at a lower cost. The end result from implementing the approach will be predictable and profitable performance using proven technologies that are available today. "In fact, the FDA supports and encourages the use of automation, information technology and data solutions throughout the product lifecycle," added Axendia's Matlis.¹

The vision, approach, enabling technologies and best practices discussed in this brief encompass and build upon the early successes of Pharma 4.0, the pharma-specific version of Industry 4.0 as defined by the International Society of Pharmaceutical Engineering (ISPE) and lessons learned during the pandemic. Following the full guidance provided will enable pharma companies to maximize their margins and returns by producing a greater variety of products with the agility and resiliency required for daily operational excellence inside the plant and across all stages of production and delivery.

A Vision for the Future of Pharma

By expanding the digital transformation journey across end-to-end operations, pharma companies of the future will gain powerful new capabilities and the agility needed to produce therapies with greater efficiency and effectiveness in all market conditions.

We envision a future where each pharma company digitally connects to all the businesses they are intertwined with for manufacturing and delivery, allowing the data generated at every location to be accessed and leveraged. This level of connectivity is game changing. With end-to-end data access and visibility in place, there is more opportunity to analyze, monitor and optimize using Industrial AI and integrated software applications. Pharma companies will have an increased ability to improve results at every stage of production, delivering an impact greater than the sum of its parts.

“Connected companies working together to improve outcomes will also become part of a pharma value network that offers unmatched advantages for ensuring the security, safety and supply of high-quality products,” states Matlis. “The network has built-in resilience if a supplier within it runs into production issues. With advanced notice, the workflow would move to another ‘node’ or supplier as needed using established processes for tech transfer.”

In the future, the challenges of getting better at feedback loops, measuring results with more complete data and tying results to real-world impact are addressed and handled seamlessly. For instance, a pharma company of the future will measure the efficacy of its therapies using richer contextual data that assesses how pharmaceuticals are distributed, ingested and disposed of by augmenting clinical trial data with real-world outcomes and distribution data.

In the case of the COVID-19 pandemic, the optimization process for efficacy would have included data regarding whether or not a vaccine met the storage temperature requirements at all times. Manufacturers could also assess and determine the best way to dispose of packaging and leftover APIs and excipients. Data would be collected and acted upon that measures waste and harmful effects on the environment, such as APIs potentially making their way into water distribution systems.

The vision for the future of pharma encompasses applying the right technologies across the complete product lifecycle, the pharma value chain network and the thousands of decision points happening daily.

The Modern Value Chain Network

The supply chain of the future is no longer a chain. Redefined in its name and how it functions, the modernized value chain network enables optimization across every decision point, from research and development through manufacturing and distribution to consumers.





**The Approach:
Expand the digital
transformation
journey across the
complete product
lifecycle and the
pharma value chain
network.**

Making the Vision a Reality

Achieving the vision with the approach, value opportunities and enabling technologies that follow will unleash new levels of operational excellence and provide manufacturers with the agility and resiliency needed to meet market demands with greater profitability.

The Approach

The approach behind making the vision a reality is outcomes-driven, based on prioritized use cases and initiatives; it is focused on four key steps, which can be implemented in cycles then expanded and extended as digital transformation initiatives grow.

Step One: Assess the organization's digital maturity with emphasis on the most significant opportunities for improvement. Start by gaining a holistic view of all the data generated inside and outside the plant associated with manufacturing and delivery. An overarching digital reference architecture can unify and integrate data from existing systems to give complete visibility into operations. Connecting suppliers is a critical part of the process with data governance, access and security protocols in place.

Step Two: Digitally transform paper processes as part of the strategy to aggregate data for a complete view while eliminating costly manual processes. Advanced software applications for planning, scheduling and batch records can help fill gaps in providing valuable data that can

be collected, analyzed and used to improve outcomes.

Step Three: Determine cloud strategies early on. Moving to the cloud can be accomplished in stages, and it becomes imperative when an on-premise solution can no longer handle the data volume required to support operations effectively. Cloud solutions can augment validated on-premise solutions, and data can be extracted to feed machine learning. They also help with greater ease of implementing advanced digital solutions in remote locations where there is limited to no IT support available.

Step Four: Incorporate Industrial AI capabilities into advanced software solutions and information technology (IT) to integrate workflows and empower industrial systems to operate semi-autonomously (and eventually autonomously) to improve patient care and drive maximum profit.

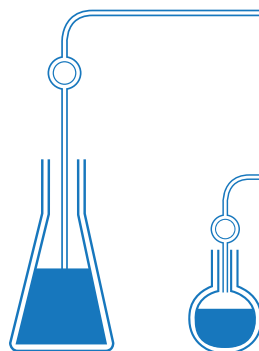
Following these steps unlocks the full potential of digital transformation and fuels it with the power of Industrial AI to drive greater efficiency, resiliency, quality and performance. At the operational level, workers are supported with knowledge, insights and recommendations to guide their workflow and drive operational excellence. Complete automation of processes can occur when closed-loop systems are implemented.

Multiply the Value Gained from Digital Transformation

While organizations are achieving high-impact performance gains through digital transformation today, they can multiply these benefits by applying the guidance in this brief. Remarkable results can be realized across the value opportunities below, in addition to gaining the ability to optimize across a wide variety of desired outcomes.

- **Faster time to market.** Companies will benefit from a more efficient production cycle that ensures quality, automates time-consuming processes, reduces risks, removes unplanned downtime and prevents bottlenecks. Processes and complexities are managed effectively with a digital workflow powered by Industrial AI across planning, scheduling, production and asset management functions.
- **Security of supply and smart-sourcing agility.** Pharma companies will gain a widespread view of their entire network, including where the supply sits, which supplier has the capacity and which supplier will deliver with the highest quality. This level of visibility allows workers to be incredibly agile. They can proactively spot potential supply problems, make any needed adjustments and ensure high-quality products are released on time while meeting regulatory requirements.

- **Quality assurance and compliance confidence.** Using Quality by Design (QbD) principles and process analytics, manufacturers can monitor critical quality and performance attributes to ensure final product quality within a compliant environment.
- **Outcomes-driven decision making.** Manufacturers can make the right decisions by modeling outcomes against different scenarios that consider asset utilization, changing supply and demand, product line pricing and other factors affecting quality, profitability, delivery and performance. Having the agility to adjust operations based on outcomes gives pharma manufacturers the ability to make the best use of their facilities every day while maximizing their financial impact.



Achieve More Now with Enabling Technologies

The technologies that will shape the future of pharma are proven, widely used and accessible now. Companies inside and outside the industry utilize the key enabling technologies below to achieve tremendous performance gains and vast improvements to their top and bottom lines.

- **A scalable digital IoT infrastructure** connects, integrates and visualizes data from existing and future data systems, software applications and sensors.
- **Cloud technology** enables scalability, robust processing power and having the data delivered at the right time and place at a lower overall cost.
- **Industrial AI** combines the first principles of engineering (physics, chemistry and math) with artificial intelligence capabilities and domain expertise in advanced software solutions to enable self-optimizing, semi-autonomous and fully autonomous processes.
- **Digital twins** provide virtual models that mimic and predict the evolving real-time historical, current and future behavior of a product, process or asset.
- **Integrated planning and scheduling** solutions tightly align production execution,

process optimization and planning and scheduling, bringing the actual performance closer to the plan across all relevant timescales.

The Enabling Technologies:

Drive maximum performance and operational excellence through a scalable digital IoT infrastructure, cloud technology, Industrial AI and integrated software applications.

- **Electronic batch record systems** contain the logic and rules that enforce the manufacturing workflow. They improve data integrity, remove opportunities for error, enable efficient batch review by exception and capture contextualized data to power Industrial AI and advanced analytics. Audit trails, electronic signatures and documentation needed for compliance are part of the feature set.
- **Process performance monitoring** becomes a network of online models (first principles, AI and hybrid) supervising desired operational indicators and key performance

metrics. The models will provide automated 24x7 insights and propose adjustments for batch and continuous processes.

- **Batch control** solutions are emerging and serve to predict batch results, anticipate deviations from target and automate corrective action, enabling more consistent and efficient operations. These solutions have an additive effect when coupled with the use of advanced process control solutions for continuous processes as well.
- **PAT (Process Analytical Technology)** is the implementation of at-line and in-line advanced measurement systems to provide full visibility on the behavior of the critical process parameters and their effect on the critical quality attributes. PAT is a powerful enabler for QbD, the principle of ensuring product quality through judicious process design, monitoring and control, rather than resorting to eliminating bad product quality by inspection after the fact.
- **Predictive maintenance** leverages prescriptive analytics, built on Industrial AI, to track equipment performance and predict breakdowns so companies can maximize uptime, implement timely and efficient maintenance only when needed and ensure safe operations.

Realize Remarkable Results

Market Leaders Gain Millions of Dollars in Margin

- **Eli Lilly** improved performance engineering for its spray drying process using digital twins and Industrial AI to reduce the time needed for experimentation, leading to a shortened development period. Improved outcomes included faster time to market and lower costs.
- **GSK** drove production process improvements while reducing data integrity risks with an electronic batch record system that automated its processes. They achieved a 35 percent reduction in paper batch record entries, eliminated over 2.5 million manual data entries per year, reduced cycle time for order preparation by 95 percent and cut review time by 50 percent.
- **GSK** also invested in digital predictive maintenance technologies to protect key

assets and minimize disruptions in the supply chain. Disruptions from seal replacements and related lifecycle costs were reduced by 60 percent, and capital expenditures and associated lifecycle maintenance costs were reduced by 50 percent. Millions of dollars of benefits were identified over the initial sites.

- **Lonza** used integrated planning and scheduling technology to “tame the scheduling beast” and increase facility production and throughput by 20 percent with better utilization of over 200 assets to be scheduled with up to 3,000 batch activities at any given time.²
- **GE Healthcare** used a real-time PAT solution that enabled in-line monitoring to stop chemical reactions at the right time. Gains in process understanding and product quality were achieved and over \$300K USD in batch losses were avoided.

Industry 4.0 Front Runners See Impact at Scale

In collaboration with McKinsey & Company, the World Economic Organization designated, studied and recognized companies as “lighthouse organizations” for their achievements in being among the most advanced in the world in realizing high impact results using Industry 4.0 technologies, including Bayer Garbagnate and GSK Ware. The performance gains attained were wide ranging across industries, and improvements of 50-90 percent were commonly achieved across various metrics, including speed, quality, agility, capacity and many others.³

These early adopters achieved impact at scale by innovating in the production process or the end-to-end value chain.⁴ Extending Industry 4.0 technologies across both of these dimensions will amplify these already strong returns.



Accelerate Success Along the Journey

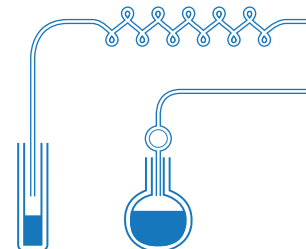
Best Practices for Operationalizing the Approach

Companies can move forward with their digital agendas in smaller or bigger implementation cycles, and they will continue to become stronger with the ability to optimize more and more as they scale.

No matter where an organization is with its digital maturity, it can leapfrog ahead by following the best practices below. Using them will fast-track results with lessons learned from Industry 4.0, Pharma 4.0, the COVID-19 pandemic and other periods of market disruption.

- **Prioritize where the pains are.** Make the business case for improving outcomes in mission-critical initiatives that address significant pain points and how they happen (why, when and where). With each win, the learning gained can be applied to the next steps and contribute to a higher cumulative impact.
- **Determine connectivity and cloud strategies early on.** Properly addressing these areas will help companies remove data silos, avoid duplicate data, scale effectively and reduce cost over the long run. Give focused attention to creating a connected pharma value chain network and harness greater efficiency, quality, flexibility and resilience.

- **Anticipate the performance gains and act.** Don't wait to react to a negative quality, yield or downtime event that could have been mitigated if solutions were already in place.
- **Source with agility.** Having multiple supplier options available using smart sourcing strategies enables agility. Selecting suppliers can be based on the most important criteria at any time, such as quality, demand, urgency or changing market conditions.
- **Find a strategic partner.** Think grander than finding one or more technology partners that offer point solutions. Find a strategic partner that can support the entire digital transformation journey with solutions that leverage investments already made, and identify issues that may not be on a manufacturer's radar. A partner offering services at this level should have a proven track record in providing integrated digital infrastructure and technology solutions across end-to-end operations that are purpose-built for Industrial AI.

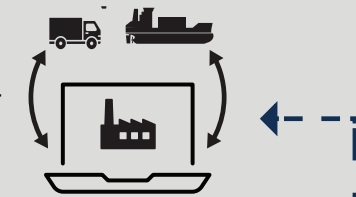


The Path to Optimizing Outcomes Across the Pharma Value Network

These are the critical steps for maximizing the performance and returns possible from digital transformation. Repeat the steps in cycles as outcomes-driven initiatives grow. Use the best practices provided to accelerate results on the journey.

Step 1

Digitally connect to suppliers across end-to-end operations.



Step 2

Digitally transform paper processes and bring more data together.



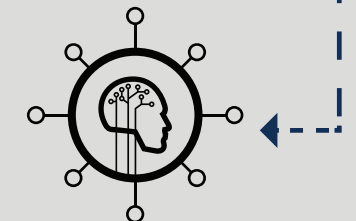
Step 3

Determine cloud strategies early on and begin moving to the cloud.



Step 4

Incorporate the power of Industrial AI into advanced software solutions.



Be a Part of Shaping the Future

The wave of innovation flowing through the pharmaceutical industry at this time is unprecedented. It has opened up new challenges to master and more opportunities for those who want to lead and be a part of shaping the future.

While market uncertainty and complexity will continue, one thing is certain: Widespread digital transformation will play a vital role in pharmaceutical manufacturing in the years to come.

In the latest “Smart Pulse Survey” performed by *Pharma Manufacturing*, almost all manufacturers surveyed agreed that the pandemic would alter the industry’s perspective on digitalization, with 65 percent specifically believing that the pandemic will increase the industry’s use of technology to collect and analyze data in real-time.⁵

Axendia research indicates that 76 percent of digital transformation initiatives are being accelerated by “black swan” events like the COVID-19 pandemic.⁶

Matlis from Axendia stated that the world experienced “the use case for digital transformation” with the pandemic and that digital transformation “is an imperative” for manufacturers. “We had to contend with supply chain issues and shortages of materials, excipients and APIs. We haven’t been able to bring people

into work. We must digitally transform to drive resilience in the face of disruption, as well as improve patient outcomes and sustainability.” The guidance outlined in this brief provides the formula for doing so. Manufacturers will be equipped to plan, schedule and manage with new levels of agility, giving them the ability to address changing market conditions and meet market demands with greater profitability.

“Lighthouse” organizations from around the world that are front runners and among the most advanced in using Fourth Industrial Revolution technologies used two main routes to scale the impact of their digitalization initiatives. They innovated in the production process or the supply chain.⁴ The approach shared in this brief delivers more by applying digital technologies across both.

Manufacturers that embrace the innovation and challenges that came with the pandemic and expand the digital transformation journey across their entire operations will have an opportunity to gain speed to market and first-to-market advantages. Late adopters will need to play catch up as the industry moves forward with digital transformation with a new sense of urgency.

“We must digitally transform to drive resiliency in the face of disruption.”

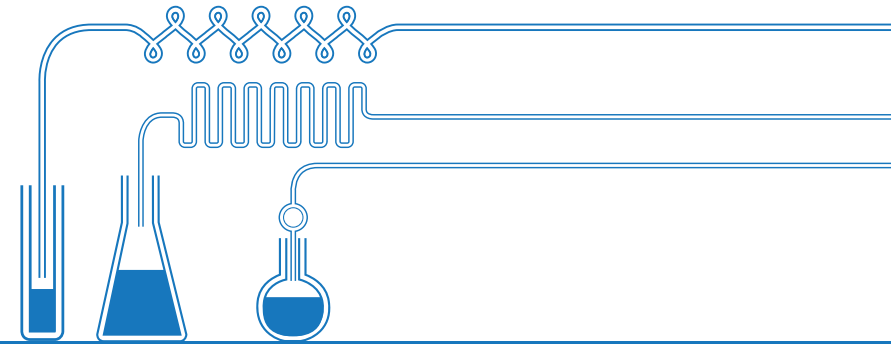
- Daniel R. Matlis,
President, Axendia

The Path Forward

Conclusion

While pharma's digital transformation journey has traditionally lagged behind other process industries, the pandemic made it clear that progressing digitalization will be fundamental to operations in the years ahead. This brief's systematic approach offers pharma companies a clear path forward in achieving new levels of operational excellence across all market conditions.

Regardless of where an organization sits on the digital maturity spectrum, leapfrogging forward is more attainable by tapping into technologies and strategic partners that can help it minimize unplanned downtime in manufacturing, enable faster time to market and increase security of supply. Companies can spend less time reacting to volatility in the market and instead, realize greater returns from lessons learned and the value gained by optimizing outcomes across the pharma value chain network.



Citations:

1. *Axentia, FDA Share Insights on Digital Transformation & Manufacturing Modernization, January 2021.*
2. *Taming the Scheduling Beast, Pharma Manufacturing, February 2010.*
3. *Operations Can Launch the Next Blockbuster in Pharma. McKinsey & Company, February 2021.*
4. *Fourth Industrial Revolution Beacons of Technology and Innovation in Manufacturing. World Economic Forum in Collaboration with McKinsey & Company, January, 2019.*
5. *Pharma Finds Its Digital Groove, Pharma Manufacturing, August 2020.*
6. *Axentia 2021 Forecast for the Life-Sciences Industry, February 2021.*





Technology That Loves Complexity

About AspenTech.

Aspen Technology (AspenTech) is a leading software supplier for optimizing asset performance. Our products thrive in complex, industrial environments where it is critical to optimize the asset design, operation and maintenance lifecycle. AspenTech uniquely combines decades of process modeling expertise with machine learning. Our purpose-built software platform automates knowledge work and builds sustainable competitive advantage by delivering high returns over the entire asset lifecycle. As a result, companies in capital-intensive industries can maximize uptime and push the limits of performance, running their assets safer, greener, longer and faster.

aspentech.com

About Axendia

Axendia is a leading analyst and strategic advisory firm focused exclusively on the Life- Sciences market. Industry stakeholders and regulators rely on Axendia for trusted advice on Business, Regulatory and Technology issues and trends based on trusted sources. Axendia serves the entire Life-Science ecosystem ranging from Start-ups to Fortune 100 companies including: Life-Science Organizations, Technology and Service Providers and Regulatory Agencies. Axendia is recognized as a Top 10 Analytics Consulting Company by Pharma Tech Outlook and as one of the 20 Most Promising Life Sciences Technology and Services providers by CIORReview.

For more information, visit axendia.com