



# Good Manufacturing Practices for Asia/Pacific Pharmaceutical Companies

## Accelerating Transformation with Manufacturing 4.0

IDC #AP2412371B



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# Pharmaceutical companies face increasing market pressures

## Technology is supporting opportunities for success

The Asia/Pacific pharmaceutical (pharma) market is driven by market developments and growth in Australia, China, India, Indonesia, Japan, New Zealand, South Korea, Thailand, and Vietnam. This is largely due to the significant population base and a rise in the number of pharma companies in these markets.

Regional reactions to industry, economic, and health pressures from the coronavirus have culminated in these three major trends:



1 Global supply chain instability



2 Incentives to boost local production



3 Growing local markets

IDC research shows that pharma manufacturers in the Asia/Pacific region are responding by driving efficiency and productivity outcomes and innovation through new technologies to transform their business models and operations.

Organizations are undergoing digital transformation through Manufacturing 4.0: a journey built on an Industry 4.0 foundation, with capabilities to ensure good manufacturing practice (GMP) compliance.



In the long term, digital innovation is the strategic priority driving the greatest benefit for Asia/Pacific pharma companies\*. This requires companies to simultaneously focus on productivity while seeking opportunities for new markets and products.

Pharma companies need transformation programs to reap short-term benefits with a view to long-term capabilities.

**Read on in this IDC InfoBrief to learn about use cases to help companies draw a roadmap that allows them to build on these foundational technologies to develop a strategic vision that creates a sustainable and competitive future enterprise.**

\*Data for pharmaceutical respondents was directionally aligned with the Brand-Oriented Value Chain (BOVC) segment of the IDC 2020 Asia/Pacific Industry 4.0 survey, June 2020



# Unique country challenges are driving transformation in the Asia/Pacific pharma sector



## India

- Largest provider of generic pharma, accounting for 20% of the global export volume.
- Increasing rates of heart disease and pharma sector expansion driving industry growth and competitiveness.
- Highly fragmented market — companies may seek consolidation or partnerships to address cost pressures and focus more on continuous manufacturing efficiencies.



## Singapore

- Leading biomedical and pharma hub in Asia; home to facilities for 8 of the top 10 pharma companies and host to a wide range of pharma company headquarters.
- The Biomedical Sciences initiative launched in 2000 more than tripled manufacturing output, and the industry contributes around 3% of the nation's GDP.
- Singapore's corporate governance, legal, and technology foundations continue to attract investment in pharma research and innovation, as well as technology adoption.



## Indonesia

- Aspiring to achieve self-sufficiency in pharma manufacturing, the government offers tax incentives to companies that undertake research & development and innovation activities, which can be used to offset costs.
- The government's 'Making Indonesia 4.0' policy supports Industry 4.0 technology adoption, including pharma and medical device production.



## Thailand

- One of the world's fastest aging societies; the pharma industry heavily relies on imported APIs (active pharma ingredients). Only 5% of GMP-accredited pharma vendors can produce APIs.
- As a result, Thailand is vulnerable to price fluctuations and increasing raw material costs.
- Thailand 4.0 manufacturing technology investment policy will go some way to mitigate costs.



## China

- The government aims to make healthcare affordable as it is one of the largest expenditure areas along with housing and education.
- This will grow investment in the fine chemical industry and continue China's rise as the world's leading source for APIs.
- 'Made in China 2025' policy targets the pharma and biotech industry to lift China to a high value-add economy.



## Japan

- Population is aging faster than any other country on the planet; the government is adopting cost-efficiency measures such as promoting generic drugs and biennial price reviews.
- An "off-year" pricing review in 2021 could potentially place additional cost pressures on pharma manufacturers.
- Joint ventures are increasing to drive efficiencies and cater to demand for generics.



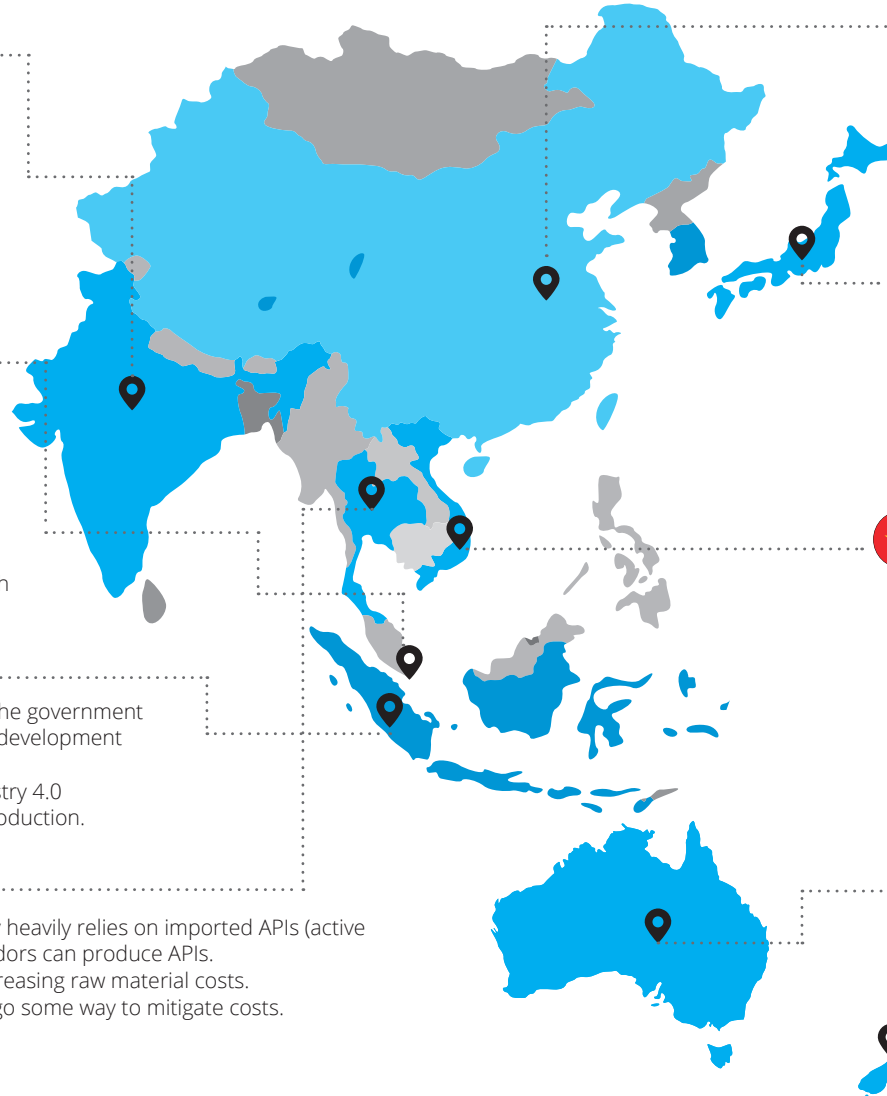
## Vietnam

- Historically, Vietnam imported over 90% of pharma ingredients, half from China.
- Raw materials costs have been escalating, partly due to currency fluctuations.
- Government's pricing controls prevent charges from being passed on to patients, and the increased cost pressures are forcing companies to improve efficiencies.



## Australia & New Zealand

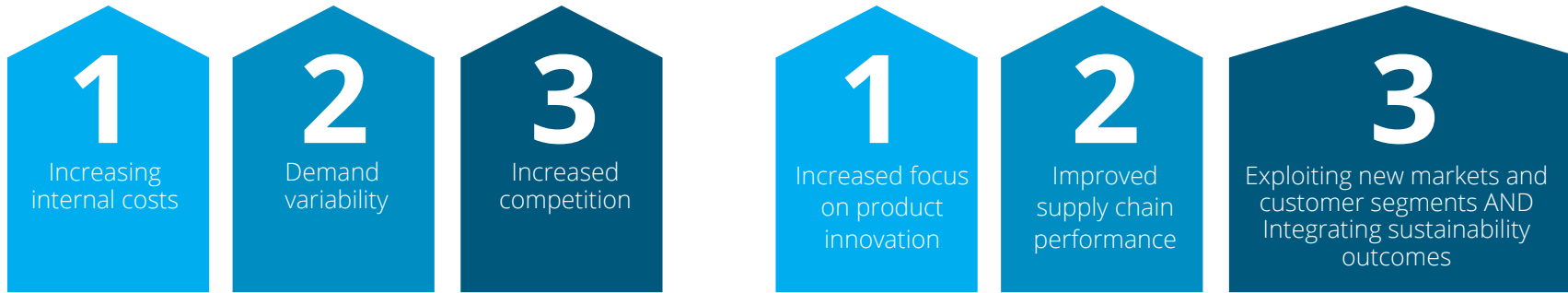
- Rising expenditure on pharmaceuticals due to ageing populations.
- Disruptions from Chinese and Indian supply chains are forcing Australian operators to improve their domestic supply chains.



# Future outlook: Pharma manufacturers seek innovation opportunities

Asia/Pacific pharma manufacturers are having to address industry, economic and health-related pressures, which are culminating in three major challenges:

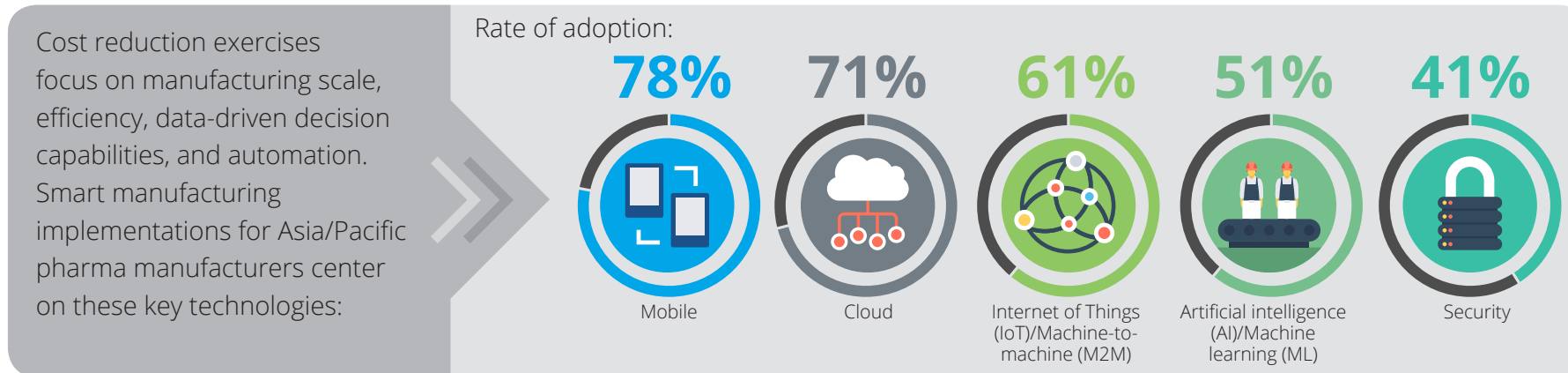
The top three priorities for Asia/Pacific pharma companies over the next 3-4 years:



## What is Manufacturing 4.0?

Manufacturing 4.0 refers to the integration of new tools and processes that enable smart factories, the integration of operational and external data sources with IT systems, decentralized production, and manufacturing flexibility and automation, while ensuring a secure environment, suitable risk management, and GMP compliance.

## Key technologies enabling Manufacturing 4.0 capabilities for Asia/Pacific pharma manufacturers



Source: IDC 2020 Asia/Pacific Industry 4.0 survey, June 2020

# Transformation through Manufacturing 4.0 drives future opportunities, with a focus on immediate benefits today

Asia/Pacific pharma manufacturers have a renewed focus on adopting Manufacturing 4.0 solutions and transforming efficiency-oriented operations to collaborative, innovation-led organizations to build future enterprise capabilities that allow for business sustainability. The short-term objectives center around productivity and efficiency targets that address immediate business concerns.

In the long term, Asia/Pacific pharma companies seek to ensure open innovation and collaboration to increase economies of scale, share the burden of R&D costs, and increase competitiveness. This will drive transformation in the short and long term.

IDC predicts:



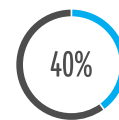
## 2021



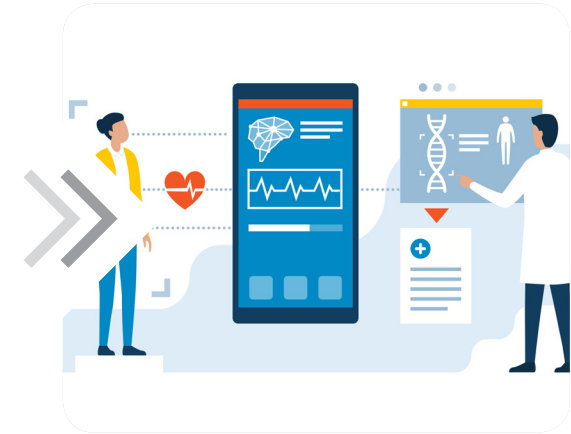
By the end of 2021, **90%** of all manufacturing supply chains will have invested in the technology and business process necessary for true resiliency, resulting in productivity improvements of **15%**.



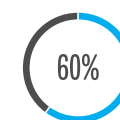
## 2022



By 2022, to support autonomous operations, organizations will increase their investments in data governance, digital engineering organizations, and digital operations technologies by **40%**.



## 2024

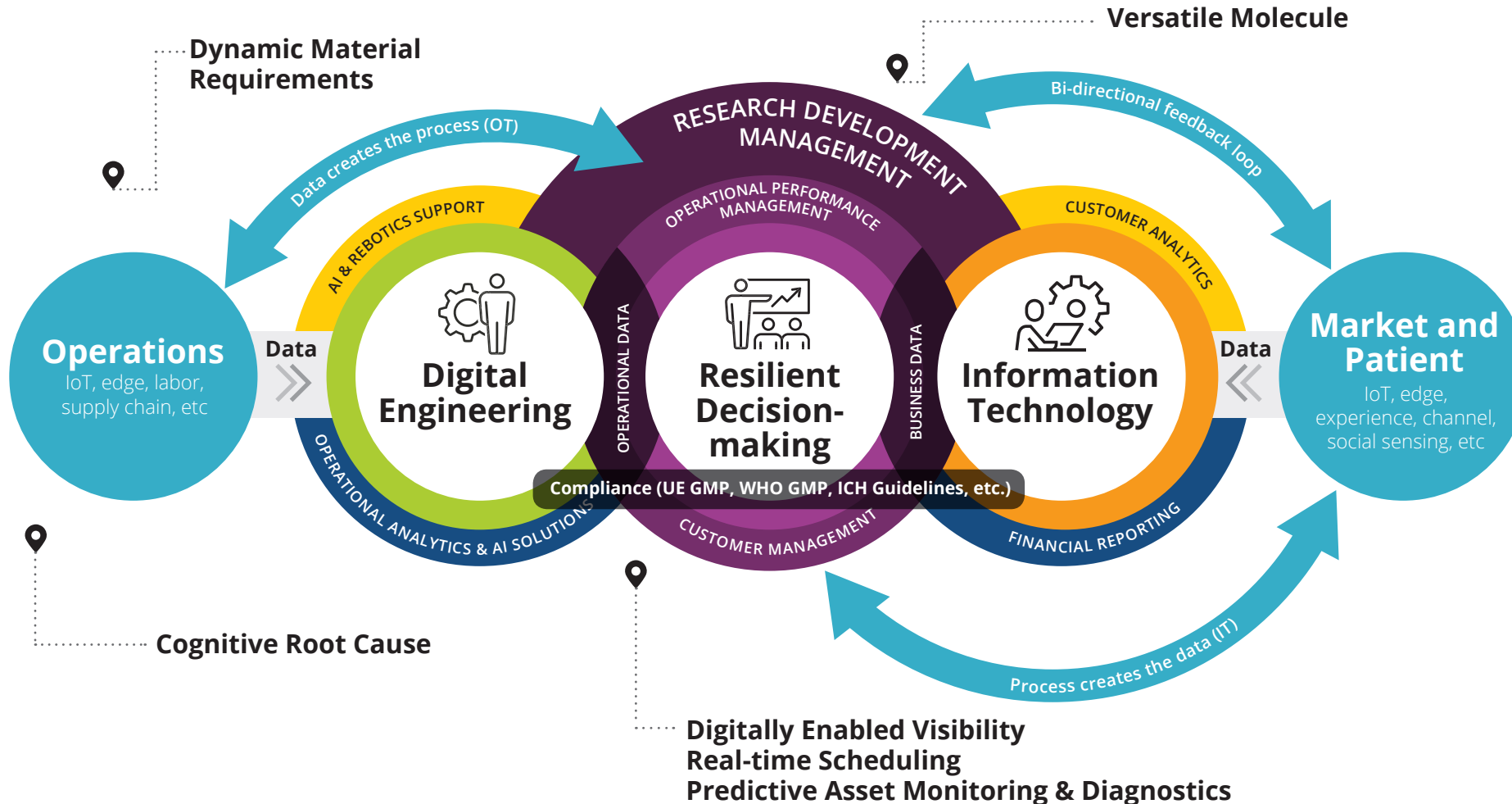


By 2024, **60%** of industrial organizations will integrate data from edge OT systems with cloud-based reporting and analytics, moving from single-asset views to sitewide operational awareness.

Source: IDC FutureScape: Worldwide Manufacturing 2021 Predictions (Oct 2020)

# Manufacturing 4.0 – achieving the digitally mature end-state

As pharma companies seek to improve efficiencies in the production of safe, high-quality, compliant, and cost-effective products in a more agile way, they look to digital transformation through Manufacturing 4.0 solutions. Companies can select use cases that drive business impact based on the desired outcomes, building a resilient data-driven enterprise.

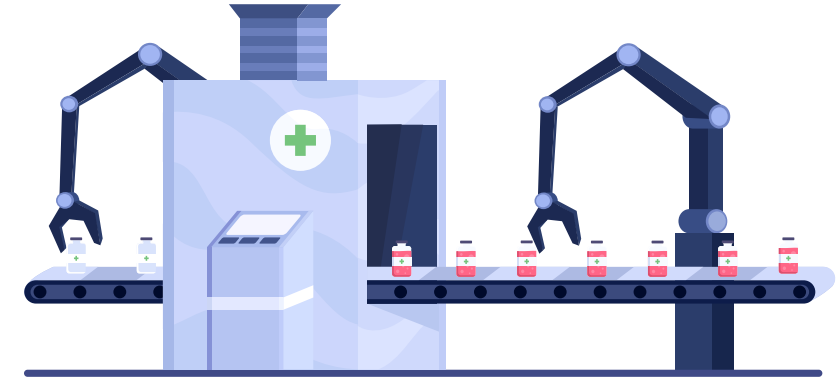


## The mature future state is characterized by:

- Full-stack technology that is interconnected, standardized, interoperable and systems-based ecosystems.
- Intelligent, smart and automated processes
- Physical and virtual integration.
- Desired levels of visibility, control, flexibility, adaptivity, and innovation.
- Integrated risk and compliance management.
- Balancing continuous improvement with capabilities that enable rapid document generation for compliance.

# Building a roadmap: integrating the Factory of the Future

The biopharma factory of the future requires integration of data streams from operational, IT, and external data sources to facilitate scheduling, asset operations, and identification of quality issues in real time. This provides real savings in terms of operational productivity and efficiency, as well as ensuring a quality product that drives positive patient outcomes.



## Real-time Scheduling

Production scheduling and sequencing are completed in an analytic model that is directly connected to execution. Real-time assessment of current demand and capacity availability continuously and intelligently resequences work in the factory.

### Key Technologies

- Servers
- Storage
- Cloud
- Cognitive/AI
- IoT
- Manufacturing execution system (MES)/Enterprise resource planning (ERP)

## Dynamic Material Requirements

Enable a more flexible and dynamic process that allows for material requirements to evolve as the R&D process progresses, including the ability to identify alternative material requirement options that may outperform initial selections or provide contingency options during periods of disruption.

### Key Technologies

- Servers
- Storage
- Cloud
- Social
- Supply chain management (SCM)
- Cognitive/AI
- IoT
- Service level management (SLM)
- Customer relationship management (CRM)
- ERP

## Predictive Asset Monitoring & Diagnostics

Machine learning algorithms that build an accurate predictive model of potential failures that can be used to alert maintenance teams in real time; maintenance resources that can be optimized through a tiered support structure, depending on the issue, type of asset, criticality, and so forth.

### Key Technologies

- Servers
- Storage
- IoT
- Mobile
- Big data & analytics
- Cognitive/AI/ML
- Cloud
- ERP/MES
- Asset performance management (APM)
- SLM

Short Term

Long Term

# Building a roadmap: data-driven GMP is the key

The success in advanced technology adoption lies in the ability of organizations to create a roadmap for implementing use cases that address critical requirements in the short term and building on those foundational technologies to address strategic business priorities over the mid to long term, such as bringing innovation to patients in a safe and compliant manner.



## Cognitive Root Cause

Connected quality metrology feeds an analytic model that can support automated analysis of quality anomalies with the ability to adjust processes in an automated way.

### Key Technologies

- Servers
- Storage
- Mobile
- Big data/analytics
- IoT
- Cognitive/AI/ML
- Cloud
- ERP, MES
- Product lifecycle management (PLM)
- Enterprise asset management (EAM)

## Digitally-enabled Visibility

Visibility into current and historical experimentation through a collaboration platform is enabled, including internal efforts and visibility into strategic suppliers. This results in higher levels of R&D effectiveness, faster time to market, and lower R&D failure costs.

### Key Technologies

- Servers
- Storage
- IoT
- Mobile
- Social
- Big data & analytics
- Cloud-based collaborative platforms
- PLM, ERP, MES, CRM, design and service management software
- Security

## Versatile Molecule

Molecular-level innovation is employed to discover new compositions, with the ability to identify, catalog, and simulate at the molecular level to seek out multiple use case opportunities for individual molecules. This aims to reduce time, cost, and waste, and gain efficiency in the innovation, R&D, and production processes.

### Key Technologies

- Servers
- Storage
- Mobile
- Big data/analytics
- Blockchain
- Cognitive/AI/ML
- Cloud
- Security
- ERP

Short Term

Long Term



# Major pharma MNC drives its Manufacturing 4.0 Roadmap

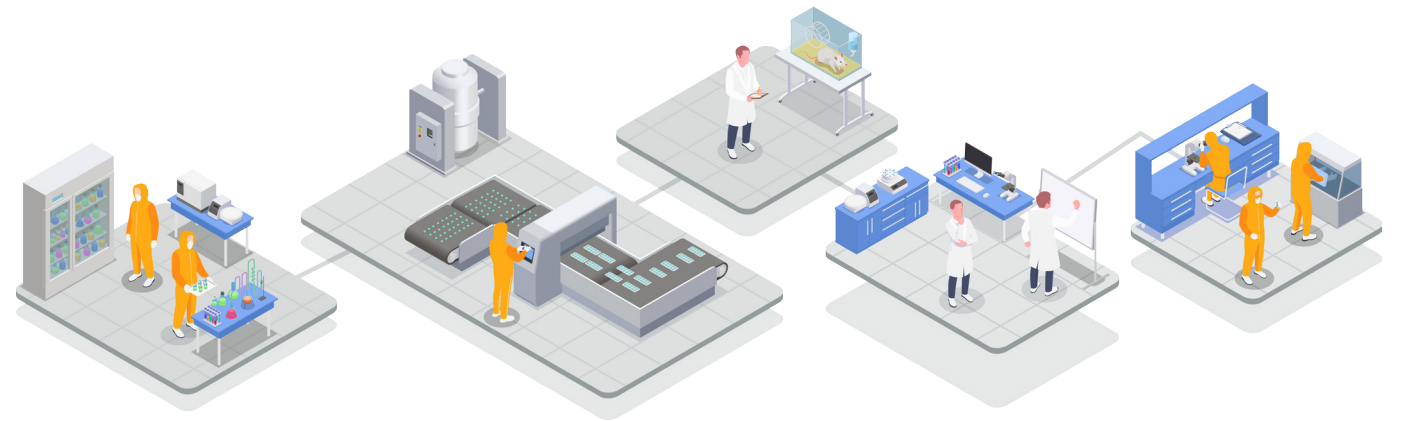
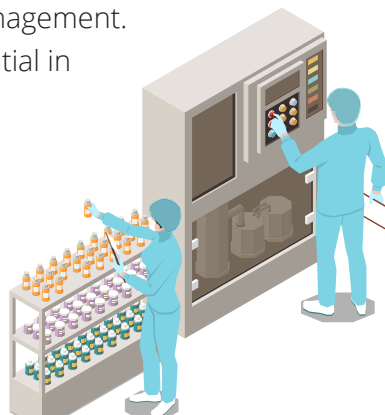
## Organization:

The global healthcare company focuses on delivering quality, service, and value to patients through their research and development of a broad range of innovative medicines, vaccines, and healthcare products.

## Challenge:

To increase operational and capital efficiencies, including overall equipment effectiveness (OEE), across the company's more than 20 sites (including primary and antibodies sites, BioPharm and steriles sites, and respiratory and HIV sites). Inefficiencies affected costs, yield, and time to market, and improvement was required while addressing compliance. Quick returns were necessary to ensure digital transformation (DX) momentum while building foundational technologies that will build on efficiency gains while enabling long-term R&D innovation in product and process, and increased collaboration with R&D and contract manufacturing (CMO) partners. Additionally, as projects progressed and production and asset-related data volumes grew, it was necessary to address underlying data governance and management.

The extraction of value from the data is essential in linking business processes to data systems. The lack of integration hindered the ability to use data to contribute to business outcomes quickly.



## Solution:

As part of its ongoing journey, the company built a DX roadmap that allowed it to undertake a series of projects focusing on data use and systems innovation to add incremental value while building a robust framework for future transformation. The roadmap aims to deliver value across the full Manufacturing 4.0 technology stack, which included:

- MES implementation
- Asset management to drive operational efficiency, improve capital efficiency, and OEE.
- Data blueprinting, data pipeline generation and design to underpin integration between sites, products and service teams, and to facilitate future DX initiatives that will integrate R&D and CMO partners.
- Wide-scale digitization, with automation of data collection and electronic batch record systems to enable the automation of manual compliance and record-keeping tasks for both batch and continuous manufacturing sites.
- Advanced analytics, neural networks, and digital dashboards to increase data integrity and for improvements to operational and asset performance management on site.

# Major pharma MNC drives its Manufacturing 4.0 Roadmap

## Competitive benefits to date:

- Pilot project in respiratory product production lines yielded savings of GBP 180 million (USD 255 million) in capital spend.
- Scaling of pilot technologies resulting in an additional GBP 130 million (USD 184,200) operational cost savings.
- Overall line speed improved by 21%.
- Increased capital efficiencies resulting in reduced downtime and increased yield, delivering an OEE improvement of 10%.
- Automation of manual records, documentation, and logbook entries save man-hours and enable tighter controls around products and digitized compliance processes, while decreasing cycle times for order preparation and overall time to market (from R&D to medicine delivery).
- On sites where the company has implemented continuous manufacturing, support from enabling technologies has had a significant impact on increasing asset utilization, reducing process scheduling complexity, cutting down hold times between batch processing stages, and improving control over quality, compliance, and critical process parameters. In the Singapore facility, for example, improved efficiencies and expanded capacity enable faster manufacturing of the company's assets, reduced medicine production times, and faster production of APIs for clinical trials, while cutting costs and reducing the facility's environmental impact by about 50%.
- Implementing continuous manufacturing capabilities allow for an 83% reduction in water use, and a 42% fall in solvent use, cutting costs and its manufacturing carbon footprint.



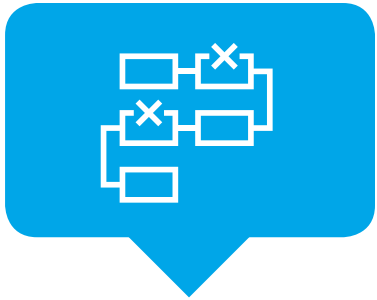
## Other benefits:

A site in Europe was named as part of the World Economic Forum's (WEF) Global Lighthouse Network of advanced manufacturers to showcase leadership in Industry 4.0 technology adoption for improving operational and environmental impact.

Having a technology partner helped the company meet daily operational requirements while implementing a series of advanced technology projects. The value of such a partner lies in their understanding of the process of adoption in the pharma and biosciences industry – from pilots and experimental projects through to final projects, resulting in increased speed to deployment on top of operational efficiencies.

# Essential Guidance

As Asia/Pacific pharma manufacturers face additional cost and competitive pressures, they will be pushed to make critical investments to increase efficiencies, innovation, and collaboration. There is also the opportunity to expand to expand into new markets. Competing in today's environment will require employment of the right people, processes and technology at a trajectory that allows for productivity gains in the short term, while maintaining a long-term strategic focus.



**Build a roadmap** for your Manufacturing 4.0 journey – why is transformation necessary for your business, what outcomes are expected, and what will be necessary to get there. Select use cases that will build on technical capabilities with consideration for short-, mid- and long-term objectives.



**Determine who should lead** the initiative, utilizing expertise from IT as well as the line of business (LOB). Expect that as the Manufacturing 4.0 journey progresses, there will be increased collaboration between IT and LOB, and the use of technology partners to address gaps.



**Seek transformation partners** that can implement a full technology stack that will address Manufacturing 4.0 requirements and assist in change management as the organization evolves with the technology implementations.



**Consider the importance of industry expertise** to address technology and GMP compliance requirements particular to the pharma industry. The right partner can assist with use case selection as well as addressing any DX skills gaps that exist.



**Ensure there is movement of data** through the integration of information silos to enable collaborative workflows between functions and provide visibility.



**Explore platforms** that bring in patient data, R&D data, market data and operational data to enable innovation and build capabilities for future growth and long-term business sustainability.

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## Life Sciences Solutions



Applications



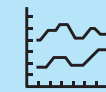
Infrastructure



Business Operations



Cloud



Analytics



ERP



Medical IoT