# Accelerating Asia's Digital cGXP Transformation with Industry 4.0 Technologies

**Across Asia, pharma's leaders are working hard to accelerate their Industry 4.0 digital transformation and, in the process ensure current Good Practice (cGXP) compliance. In a recent IDC InfoBrief: "Good Manufacturing Practices for Asia/Pacific Pharmaceutical Companies: Accelerating Transformation with Manufacturing 4.0" sponsored by Cognizant, IDC analysts found Asia's digital transformation is accelerating in response to post-pandemic market dynamics. How can Asia's drug manufacturers throttle up digitisation efforts effectively? Cognizant's Kenneth Teo offers insight into IDC findings as well as fresh strategies on how the region's leaders can improve operations by adopting digital technologies.**

The Asia-Pacific region's dominance in the global pharmaceutical manufacturing sector is growing stronger. According to BioSpectrum Asia Edition analyst Hithaishi C. Bhaskarto, global pharmaceutical companies, especially those with a presence in China, India and Japan, are focusing on optimising value creation across Asian-Pacific (APAC) markets via innovation and growth. Because of the growing demand for pharmaceuticals, governments of the most prominent economies in Asia are under increasing pressure to leverage the most current, effective business models and technologies to deliver the pharmaceutical-based healthcare their societies expect.[1]

The APAC pharma manufacturing industry is driven, notes Bhaskarto, by the increasing uptake of modern healthcare and improving access to modern pharmaceutical-based treatment.

**Key Pharmaceutical Manufacturing Trends Post-pandemic and Beyond**

In its June 2021 *InfoBrief,* IDC's analysts noted regional reactions to the social, economic and market conditions that confronted the pharmaceutical industry in the region because of pandemic. According to IDC, three important trends emerged:

1. Global supply chain vulnerability must be addressed strategically
2. Incentives are needed to increase manufacturing footprints to meet global/regional demand
3. Manufacturing of more pharmaceuticals should move local to better serve home markets

These three trends all point to a growing need for advanced digital and analytical infrastructures to meet the business continuity and growth challenges of companies operating in the region.

While these are regional challenges, they have significant global impact. According to McKinsey, in the past two decades the worldwide value of pharmaceutical goods traded has grown sixfold, from $113 billion in 2000 to $629 billion in 2019.[2] Amid this growth, notes McKinsey, supply chains have become increasingly global, complex and opaque. More companies are outsourcing production to contract manufacturers, adding new modalities (such as cell therapy), and exploring novel ways to reach patients. For some products, this results in supply chains that are so complex that they start in Asia and circumnavigate the globe twice. A tremendous amount of pharmaceutical commerce is conducted in the Asia-Pacific region and anything that disrupts supply chains can have globally disruptive effects.

**Embracing Digitalisation and The Cost-savings and Security Benefits That Come with It**

In a recent DIGICONasia Perspective, Fredholm Best, Asia business lead for digital safety systems company HIMA, asserted the pharmaceutical industry is undergoing rapid change, especially in light of the COVID-19 pandemic. He notes that advanced digital capabilities in areas like systems integration, track-and-trace supply chain transparency and deep learning are beginning to help the industry optimise its supply chain, improve safety and develop new drugs.

While it is true people depend on pharmaceuticals to treat illnesses and improve the quality of their lives, their manufacture is a global enterprise. India alone produces approximately 20% of the world's supply of generic drugs and with any supply chain that is so dispersed, there is tremendous opportunity for manipulation by bad actors.[2]

**Timely Opportunity to Transform Biomanufacturing Digitally**

With the Asia-Pacific region seeing growth in both small and large molecule drug manufacturing, innovator companies and contract development and manufacturing organisations (CDMOs) are introducing new capacity to the region. For instance, of manufacturing capacity globally, it's estimated CDMOs provide nearly 60% and most in the industry expect that number to continue to grow.[3]

BioSpectrum reported a similar impact: "APAC [Asia-Pacific region] has witnessed never before venture capitalism and M&A amidst the pandemic which is a highly positive sign of a prospect in healthcare deliveries across the region."[2]

**Journey to 4.0 Transition**

Even though pharma, in general, has been slow to digitise operations in a transformative, holistic sense, Asia-Pacific's manufacturers are benefitting from the industry's experience so far. Many in the industry attribute the industry's cautious uptake to the fact that many early adopters did not have access to the open secure cloud, or the interoperable, more affordable smart systems now available.

Developing new manufacturing sites without legacy systems constraints is also helping Asia accelerate digitalisation. For example, in China, all new sites are being built with accessible, interoperable cloud-based technologies rather than repurposing legacy sites, which means they can be designed with industry 4.0 in mind.[3]

**Asia:**
**Embracing Pharma's Manufacturing Future**

Bearing in mind cGXP, the pharmaceutical factory of the future seeks to assure overall operational effectiveness (OEE) by integrating the data streams from operational, information and data analytics and eliminating data silos within the organisation. It also must create the means and networks to connect external partners and data sources to facilitate scheduling,

asset operations and identification of quality issues in real time.

By embracing Industry 4.0, it is possible to find savings in terms of operational productivity and efficiency, and to drive risk and uncertainty out of countless operations and processes. Digital transformation also creates highly collaborative data and information sharing that ensures reliable supplies of quality products reach patients in need. IDC analysts outlined several use cases in their *InfoBrief* presentation:

- **Scheduling in Real-time.** Production scheduling and sequencing are completed in an analytic model that is directly connected to execution. Through the real-time assessment of current demand and available capacity, operations and production schedules are continuously and intelligently re-sequenced.
- **Dynamic Material Supply Transparency.** A more flexible and dynamic process allows for material requirements to evolve as the R&D process progresses. This must include the ability to identify alternative material options that may outperform initial selections or provide contingency options during periods of disruption.
- **Predictive Equipment Monitoring and 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 can then be optimised through a tiered support structure, depending on the issue, type of asset, criticality and so forth.
- **Automated Root Cause Identification and Mitigation.** Connected quality metrics can create an analytic model that supports the automated analysis of quality anomalies with the ability to identify and mitigate root quality processing issues in an automated way.
- **High-fidelity Molecule Discovery.** Precision data acquisition and management supports pharma innovation and the more efficient discovery of new compounds and formulations. With high integrity data comes the ability to identify, catalogue and simulate (at the molecular level) the therapeutic and commercial potential of compounds, as well as model multiple use-case opportunities for individual molecules.
- **Data-driven Digital R&D Collaboration.** Through collaborative platforms, data-driven insight can increase the efficiency and accuracy of commercial research and development (R&D) and deliver great value to any organisation. This results in more efficient, cost-effective R&D operations, increased development program effectiveness and, ultimately, faster go-to-market timelines for high potential compounds.

**Accelerating Asia's Digital Future**

For any drug manufacturer, the journey to digitalisation may seem long and the outcomes uncertain. But, like any journey of significant discovery, it starts by understanding where to start and which direction to go in. That requires a strategic roadmap, leaders who know the topography of the enterprise and the perseverance to follow it to the end.

To assure more successful implementation, Asia's leading drug manufacturers should also seek to engage transformative partners that can help implement a full technology stack. Similarly, the industry should carefully consider engaging industry expertise to address technology and GMP compliance requirements – accurate scoping and implementation are key here.

It is equally important to ensure there is dynamic and pervasive sharing of data across information silos to create collaborative workflows. Finally, the enterprise should exploit platforms that capture and analyse patient data, R&D data, market data and operational data – the kind that creates actionable information to support quality innovation, and better patient outcomes.

**Case Study: Major Pharma Player Drives its Manufacturing 4.0 Roadmap**

In IDC *InfoBrief*, analysts presented a case example of a global healthcare company that digitally transformed its operations to be better at delivering quality and value to patients.

According to IDC, the company wanted to increase operational and capital efficiencies, including overall equipment effectiveness (OEE), across the company's 20-plus sites.

The company was hoping to achieve early wins to demonstrate to the organisation and shareholders the value of the investment and help sustain the momentum of its digital transformation. Their intention was to focus on implementing the foundational digital technologies effectively and then, building on the expected efficiency gains, support the company's long-term business planning, drug development strategies, and deliver continuous improvement to products and processes.

**Building a Roadmap to Digital Agility**

As part of its digital transformation journey, the company built a digital transformation roadmap that allowed it to undertake a series of projects focusing on both data use and systems innovation. The aim was to add value and operational agility while building a framework for future implementation.

The company's digital transformation roadmap yielded:

- Manufacturing Excellence System (MES) implementation
- Asset management driving operational and capital efficiency and OEE
- Data blueprinting, data pipeline generation and design to underpin integration between sites, products and service teams, and to facilitate future digital transformation initiatives that will integrate R&D and CMO partners.
- Wide-scale digitisation across the enterprise, with automated data acquisition and electronic batch record systems enabling more efficient compliance processes and record-keeping, plus task automation for manufacturing sites.
- Advanced analytics, from neural networks and digital dashboards to increased data integrity and improved operational and asset performance management on site.

According to final IDC data, the pilot's respiratory product's manufacturing lines avoided $255 million in capital spend with the scaling of pilot technologies resulting in an additional $184 million in operational cost savings.

Overall production speed improved by 21%. The increased capital efficiencies resulted in reduced downtime and increased yield, said IDC, delivering an OEE improvement of 10%. Automation of manual records, documentation, and logbook entries save man-hours and enable tighter controls around products and digitised compliance processes, while decreasing cycle times for order preparation and overall time to market (from R&D to medicine delivery).

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