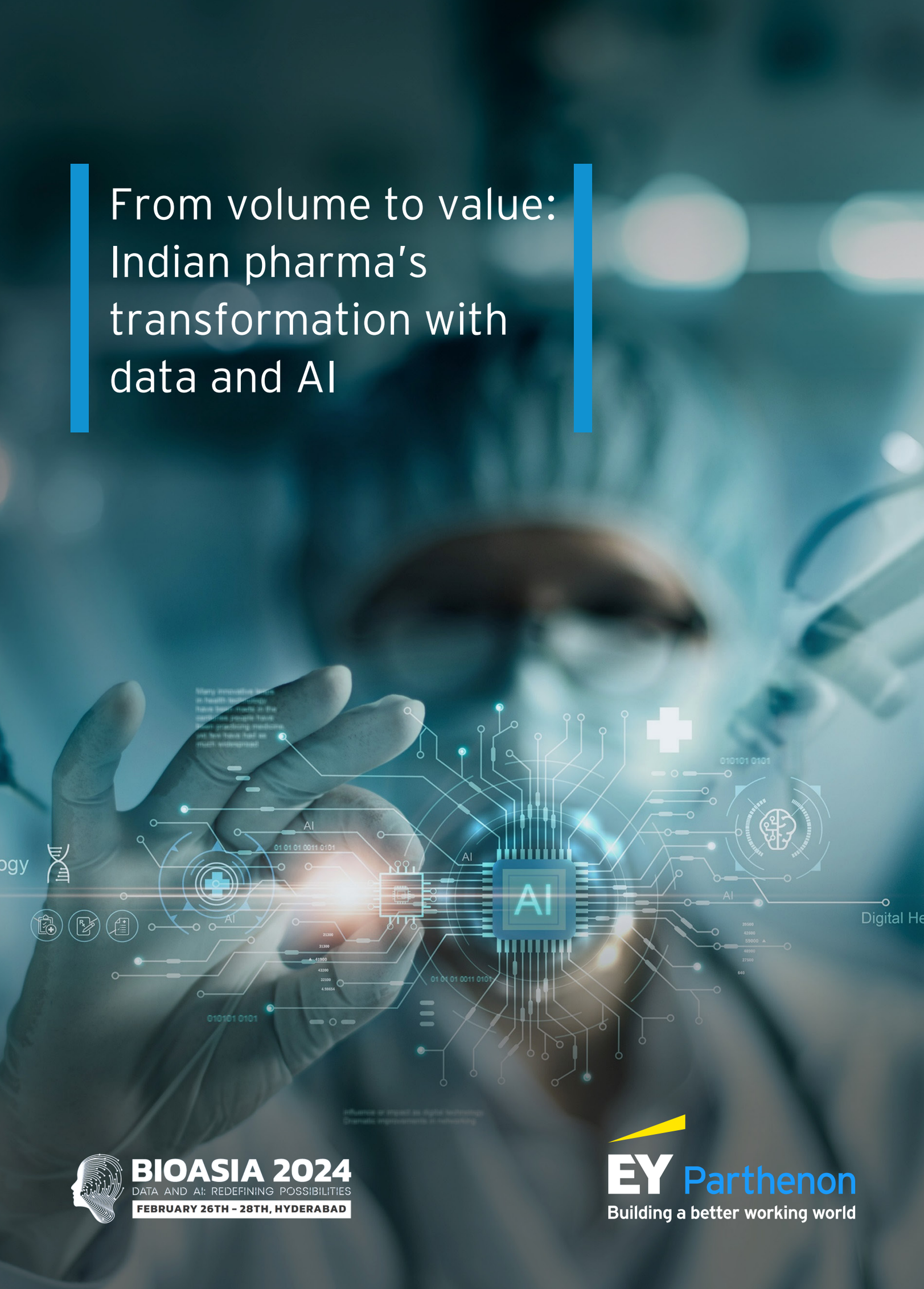
From volume to value: Indian pharma's transformation with data and AI



BIOASIA 2024
DATA AND AI: REDEFINING POSSIBILITIES
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EY Parthenon
Building a better working world

Foreword

India's pharmaceutical industry stands at the cusp of a transformative journey. This journey, fueled by the integration of Generative AI, AI/ML, and data analytics, is not only redefining the contours of innovation within the sector but also repositioning India on the global stage. The essence of this transformation and its implications for Indian competitiveness and the creation of a level playing field in the global market are the focal points of this thought leadership publication.

India's pharmaceutical industry, historically recognized as a global powerhouse in generic drug manufacturing, is undergoing a metamorphosis. Generative AI, AI/ML, and Data Analytics are heralding a new age of efficiency, innovation, and strategic global alignment. The technologies mentioned here are not mere tools for incremental change; they serve as catalysts for a comprehensive overhaul of the entire process of drug discovery, development, manufacturing, and distribution. This will not only help India maintain its edge in generics, but also establish itself as a leader in the development of innovative drugs and personalized medicine.

The integration of these advanced technologies enhances India's competitive stance by dramatically reducing the time and cost associated with drug discovery and development. Generative AI, with its ability to model and predict molecular interactions at an unprecedented scale, opens up new vistas for novel therapeutics. AI/ML algorithms streamline clinical trials, making them more efficient and effective, while data analytics offer profound insights into market demands, supply chain logistics, and patient needs, ensuring that the right medicines reach the right patients at the right time.

However, the transformation goes beyond mere technological adoption; it is fundamentally altering the global playing field. For decades, the high cost of drug discovery and development, coupled with stringent regulatory barriers, has concentrated pharmaceutical innovation in the hands of a few. Today, the democratizing force of AI and data analytics is challenging this status quo. By lowering entry barriers and enabling more players to participate in innovation, these technologies have the potential to create a more level playing field. India can take advantage of this shift and . Hherein lies an incredible opportunity. However, it is important to note that this journey does come with its fair share of challenges. Regulatory harmonization, data privacy concerns, and the need for skilled human capital are among the hurdles that need to be navigated. Moreover, fostering an environment that encourages innovation while ensuring equitable access to healthcare remains a critical balance to strike. This publication delves into the strategic implications and options open to the Indian Pharma focusing on three areas of AI/ML Gen AI in drug discovery, resilient supply chain and lastly on manufacturing, quality and compliance.

EY, in collaboration with Govt of Telangana, is delighted to present this report, “From volume to value: India pharma’s transformation with data and AI” and launch it at the 21st BioAsia 2024 conference at Hyderabad.

Our congratulations to the BioAsia leadership and the Government of Telangana for running this 21st edition of BioAsia, bringing global standards and knowledge to this part of the world.

Suresh Subramanian
Partner, National Life Sciences Leader,
EY Parthenon

Foreword

In healthcare and life sciences, Data and AI are ushering in a transformative epoch. This technological fusion propels advancements in drug discovery, clinical trials, and the realization of precision and personalized medicine. The entire life sciences value chain and healthcare delivery mechanisms are undergoing profound reshaping due to these innovations.

At the forefront of this revolution, today, lies Generative AI, propelling targeted medicine development and advancing precision medicine. Within drug discovery and development, AI holds the promise of heightened efficiency and success rates at a reduced cost. Simultaneously, in manufacturing and supply chain operations, AI fosters agility, efficiency, resilience, and intelligence. Moreover, in drug commercialization and marketing, Gen AI drives personalization and enriches experiences. Notably, GenAI doesn't merely identify optimal targets for complex diseases but also facilitates the design of tailored molecules to treat ailments efficiently while mitigating side effects. Its capabilities extend to modeling patient disease progression and devising patient-specific treatment plans.

In this landscape of innovation and growth, Telangana emerges as a pivotal hub for pharmaceutical and health-tech innovation. With its pioneering efforts in establishing organized clusters for Life Sciences R&D and Manufacturing, the state is poised to ascend as Asia's premier life sciences hub. Through innovation-driven and tech-enabled growth strategies, including the development of pharma villages, Telangana aims to consolidate its leadership position. Additionally, the State is poised to become a global specialized AI hub, fostering innovation and transformation. Telangana's collaboration with the World Economic Forum to establish the first Centre for Fourth Industrial Revolution (C4IR) centre focused on Life sciences and healthcare, will further enhance our focus on digital health delivery and taking affordable healthcare to all sections of the society.

Against this backdrop, the Government of Telangana has partnered with EY to organize the 21st edition of BioAsia, EY's flagship international convention, themed "Data and AI: Redefining Possibilities," from 26-28 February 2024. Over the years, BioAsia has been instrumental in nurturing the life sciences value chain in the state, bringing together industry luminaries, visionary companies, and pioneers from across the globe. As we endeavor to capture global and domestic industry trends, EY presents this thought leadership report. It is our privilege to launch this report during the event. Together, let us explore the transformative potential of data and AI in shaping the future of the life sciences industry and healthcare delivery.

Shakthi Nagappan
Director (Life Sciences and Pharma)
Chief Executive Officer,
BioAsia and Hyderabad Pharma City Ltd

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Introduction

Often hailed as the "pharmacy of the world," the Indian pharmaceutical industry plays a significant role globally, supplying affordable and low-cost generic drugs to millions of people. This industry, which has been a steadfast contributor to the nation's economic growth, has also played an integral role in advancing global public health outcomes.

With heightened demand, the industry has set an ambitious target of $130 billion by 2030, almost a threefold leap from the current $50 billion landscape. The predominant segments that generate revenue today are generic drugs, OTC medicines, bulk drugs, vaccines, contract research and manufacturing, biosimilars, and biologics. With the prevailing growth rate of 6.2%, achieving this target seems improbable within conventional growth paradigms and therefore is an imperative for Indian Pharma to pivot.

Navigating the industry through a transformative journey is vital. Rather than relying on manufacturing simple generics, there is a heightened need to embrace diversification and value addition over volume. Also, revenue augmentation demands a strategic revamp, necessitating a departure from conventional growth models. Up-and-coming areas like biologics and biosimilars, Antibody Drug Conjugates (ADC) linkage products, Highly Potent APIs and cost leadership innovation like an alternate route of synthesis will bring the shift from volume to value.

Along with this, a paradigm shift in the R&D chain is indispensable. While the traditional drug development process is lengthy and costly and has high failure rates, Gen AI presents a promising solution to these challenges, with potential applications across the entire R&D value chain. Gen AI can swiftly predict bioactivity, toxicity, and physicochemical properties. By offering the potential to lower early-stage drug development costs by 25% to 50% and accelerate the identification of failures, Gen AI positions Indian pharmaceuticals as innovators beyond generics.

Simultaneously, the landscape is evolving towards personalized medicine and next-generation therapeutics, fueling demand for just-in-time deliveries and innovative healthcare delivery models. Emerging technologies, including Automation, AI, blockchain solutions, digital twins, etc., when integrated, not only elevate quality control but also enhance efficiency and transparency in the industry across the value chain, including manufacturing and the supply chain.

With high growth prospects and the industry moving towards a customer-centric approach, a resilient supply chain emerges as a critical imperative, calling for the adoption of digitization, localization, and robust Environmental, Social, and Governance (ESG) practices.

India has created a formidable infrastructure for manufacturing finished dosage forms. That said, to fuel growth and to create a value-based market, Pharma companies need to oversee product quality, ensuring compliance with relevant regulatory frameworks and upholding the safety of products. This underscores the significance of Good Manufacturing Practices (GMP). Embracing modern technologies such as digital twin and blockchain, coupled with stringent GMP compliance, ensures the safety and efficacy of medications.

This report delves into three pivotal aspects: the potential of Gen AI to transform drug discovery and R&D in the Indian Industry, the use of advanced technologies to implement GMPs, and the strengthening of a robust supply chain. A strategic embrace of these facets positions the Indian pharmaceutical industry on the trajectory to evolve into a value-driven economy, paving the way to potentially surpass projected targets in the next six years.

Leveraging Gen AI's potential to lower early-stage drug development costs by 25% to 50% and accelerate failure identification, Indian pharmaceuticals can position themselves as innovators beyond generics.

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Gen AI in drug discovery: transforming Indian pharma from volume to value

Massachusetts Institute of Technology researchers have recently unearthed a potent new antibiotic compound capable of treating infections caused by drug-resistant bacteria. Marking a significant milestone, this newly discovered antibiotic, the first in the last 60 years, demonstrated its efficacy through successful laboratory tests and a mouse model. Notably, testing in mice revealed promising results for both Methicillin-resistant Staphylococcus aureus (MRSA) and vancomycin-resistant Enterococcus, a bacterium that has developed resistance to the typical drug used for treating MRSA infections.

Facilitating the identification of this compound was a machine-learning algorithm, surpassing traditional experimental approaches by rapidly screening over a hundred million chemical compounds. This computer model specializes in pinpointing antibiotics with distinct mechanisms from existing drugs and possesses the potential to design novel drugs based on learned chemical structures.

Over the past few decades, the development of new antibiotics has been scarce, with the majority of recently approved antibiotics being slight variants of existing drugs. The conventional drug discovery process has proven both sluggish and costly, requiring numerous cycles of trial and error for candidate identification. Following identification, candidates must undergo pre-clinical trials in animal models before gaining regulatory approval to advance to human trials. Post-clinical trials, the molecule undergoes an extended period of adverse event monitoring before commercialization, with the entire sequence of operations often extending up to 15 years.

Artificial Intelligence (AI), particularly Generative AI (Gen AI), now emerges as an efficient alternative to traditional screening methods, offering a transformative tool with the potential to significantly impact drug development. This impact is particularly crucial in an industry that has witnessed limited progress in recent decades. From reshaping the entire value chain of Research and Development (R&D) through the use of machine learning (ML) and natural language processing (NLP) algorithms, Gen AI accelerates drug discovery, revolutionizes clinical trials, and guides scientists in the development of new drugs for diseases such as cancer, alzheimer's, arthritis, fibrosis, and other rare diseases.

Prominent pharmaceutical companies like Merck and Pfizer are actively harnessing the power of Gen AI. Merck utilizes its proprietary platform, AIDDISON™ to revolutionize drug discovery, while Pfizer employs Gen AI-powered chatbots to deliver personalized messages to clinical trial participants.

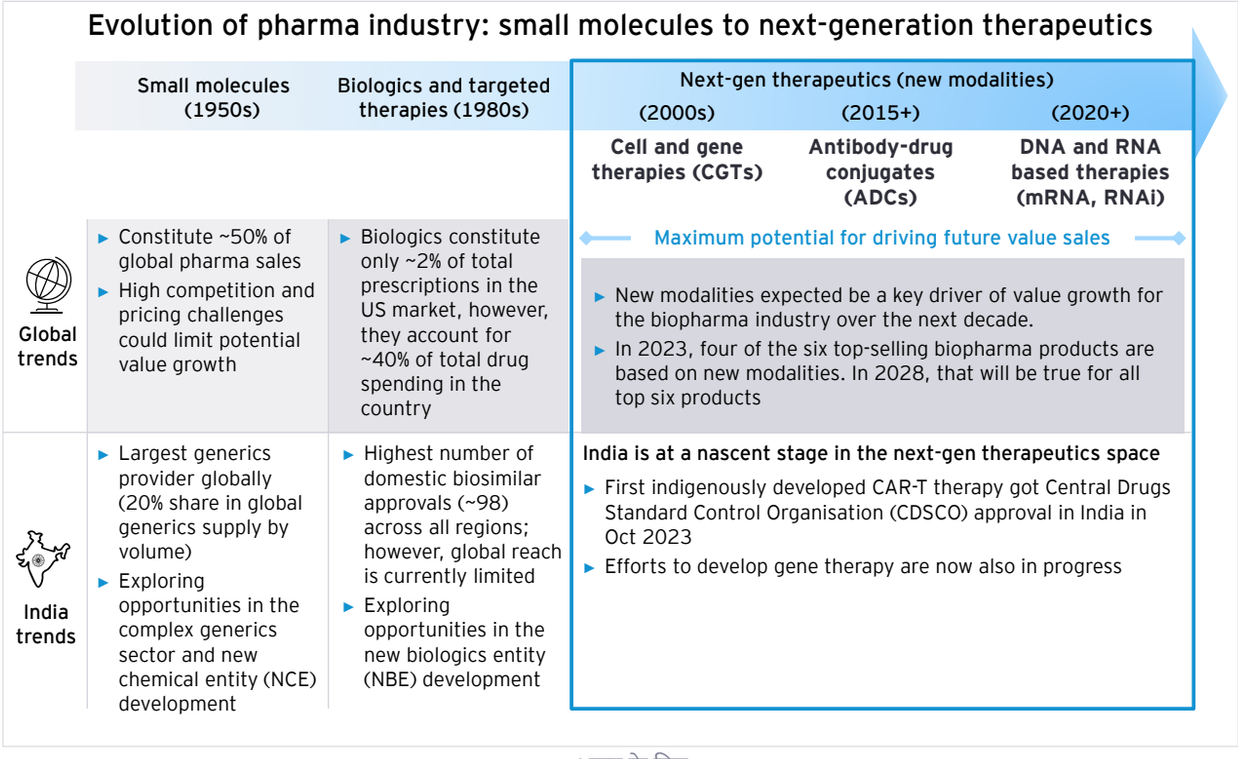
In India, the expansion of biotech incubators and pharma start-ups anticipated to play a pivotal role in propelling the growth of the Indian biopharma industry. Indian companies have increasingly started experimenting with Large Language Models(LLMs) and Gen AI applications in R&D, highly targeted therapies, and operational efficiency improvement.

Indian pharma's R&D journey: challenges and potential

The Indian pharmaceutical industry, renowned for its production of generic medicines and low-cost vaccines, holds the third position globally in terms of volume. Esteemed for its leadership in the global generics sector, the industry accounts for over 20% of the global generics supply by volume and addresses approximately 60% of the worldwide demand for vaccines.

Despite this substantial volume ranking, the industry stands 14th globally when considering the value of its pharmaceutical production. Since the 1990s, Indian pharmaceutical companies have embarked on their own research and development (R&D) endeavors, identifying over 200 preclinical- and clinical-stage development compounds. However, only a handful of these have successfully navigated the rigorous journey to market. While Biocon pioneered the launch of indigenously developed novel biologics in India, the Central Drugs Standard Control Organization (CDSCO) recently approved ImmunoACT's CAR-T cell therapy as India's first indigenously developed treatment of its kind. Despite a robust network of pharmaceutical companies, extensive drug manufacturing facilities, and a substantial pool of scientists and researchers, Indian enterprises are yet to establish a significant presence in the discovery of new blockbuster molecules.

Evolution of pharma industry: small molecules to next-generation therapeutics



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In the traditional method of drug developments, there are three major challenges for Indian companies. First is its long gestational period that takes anywhere from 10 to 15 years from lab to market. The second is the huge cost associated with the traditional method. While novel drug development holds the promise of lucrative returns, its pursuit necessitates careful consideration of the formidable investment in time and resources.

The current average cost of bringing a new drug to market stands at US$2.6 billion, which is a huge investment for Indian companies. Third is the high failure rate associated with new drug research. At each stage of this journey, a significant number of drugs face setbacks, with only one in 15 eventually making it to market.

> The Indian industry possesses the capabilities required for developing a New Chemical Entity (NCE) molecule. However, substantial investments act as a deterrent. Nevertheless, we have begun receiving inquiries from companies, including those in the software sector. The buzz around utilizing AI in drug and formulation development is growing, and I am confident that more entities will explore this avenue. However, it is important to note that we are still at a very nascent stage in this field.
>
> Head, Manufacturing and Operations of a pharmaceutical company

The limitations faced by Indian pharmaceutical companies in making significant strides in drug discovery can also be attributed to a lack of resources for competing with major companies in the United States and Europe. Additionally, some initiatives falter due to the inability to progress a drug beyond Phase 2 clinical research.

Although the majority of new drugs globally originate from the United States and European countries, China has recently entered a new phase in this domain. A notable milestone was achieved by Hong Kong-based biotech startup Insilico Medicine, which created the first fully Gen AI drug to advance to human clinical trials, specifically Phase II trials with patients in June 2023.

Leveraging Gen AI throughout the preclinical drug discovery process, Insilico executed the identification of a molecule target, generation of novel drug candidates, assessment of binding efficacy with the target, and prediction of clinical trial outcomes. In contrast to traditional methods, which would have entailed costs exceeding $400 million and a timeline of up to six years, Insilico achieved these milestones at one-tenth of the cost and one-third of the time. Remarkably, the project advanced to the first phase of clinical trials within a mere two and a half years.

Insilico's approach involved the utilization of a Gen AI platform equipped with multiple AI models, each meticulously trained on millions of data samples to undertake diverse tasks. One prominent tool within this platform, PandaOmics, demonstrated its capacity to swiftly identify and prioritize significant disease-related targets, including the notorious spike protein associated with the virus causing COVID-19. Furthermore, Chemistry42 engine, another integral AI component, adeptly designed potential drug compounds that specifically targeted the identified proteins. Employing deep learning techniques, this generative chemistry tool ingeniously crafted drug-like molecular structures entirely from scratch

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In the OPPI-EY CXO survey, the need for substantial investments over an extended gestation period, coupled with high risk of failure, emerged as the foremost barriers impeding the industry's advancement in the realm of innovation.

Shifting to value-centric R&D with Gen AI

With its world-class capabilities in formulation development, India's R&D ecosystem, coupled with the strategic utilization of government schemes, could enable Indian players to transition from a volume-oriented approach to a value-centric strategy. By leveraging Gen AI, the industry can ambitiously construct a robust innovation pipeline, envisioning the launch or progression into late clinical trial phases of three to five new molecular entities and the introduction of 10 to 12 incremental innovations annually by 2030. As per Gartner, it is anticipated that Gen AI solutions globally will be accountable for identification of more than 30% of new pharmaceuticals and materials by the year 2025.

This evolution aims to elevate the significance of Indian pharmaceuticals beyond generics, extending into biologics, new drug development, and incremental innovations.

Extending from discovering new molecules, Gen AI, when combined with data analytics, holds the potential to revolutionize the entire R&D value chain. With its capability to establish the right structure for drugs and make predictions related to bioactivity, toxicity, and physicochemical properties, can significantly contribute to target identification, predicting drug-target interactions, compound generation, pharmacology analysis, drug formulation design, and safety monitoring. This integration is poised to accelerate the drug development process, ensuring that administered drugs yield optimal therapeutic responses in patients.

These strategic advancements underscore the transformative potential of Generative AI in reshaping the landscape of drug development, fostering innovation, and positioning India at the forefront of pharmaceutical advancements.

AI to standardize R&D

Case Study

An Indian pharma company is incorporating AI algorithms into its R&D operations. AI algorithms are analyzing historical data, helping create standardized procedures. AI is used to generate Standard Operating Procedures (SOPs) and Standard Test Procedures (STP) efficiently. These tools enhance operational consistency and quality across R&D activities.

Gen AI for faster report generation

Case Study

Traditionally, generating reports and scientific protocols has been a time-consuming task in R&D. An Indian company is now harnessing Gen AI to generate comprehensive reports and scientific protocols, ensuring accuracy and compliance with regulatory standards. This will considerably save cost and time.

Precision of AI in target identification and compound screening

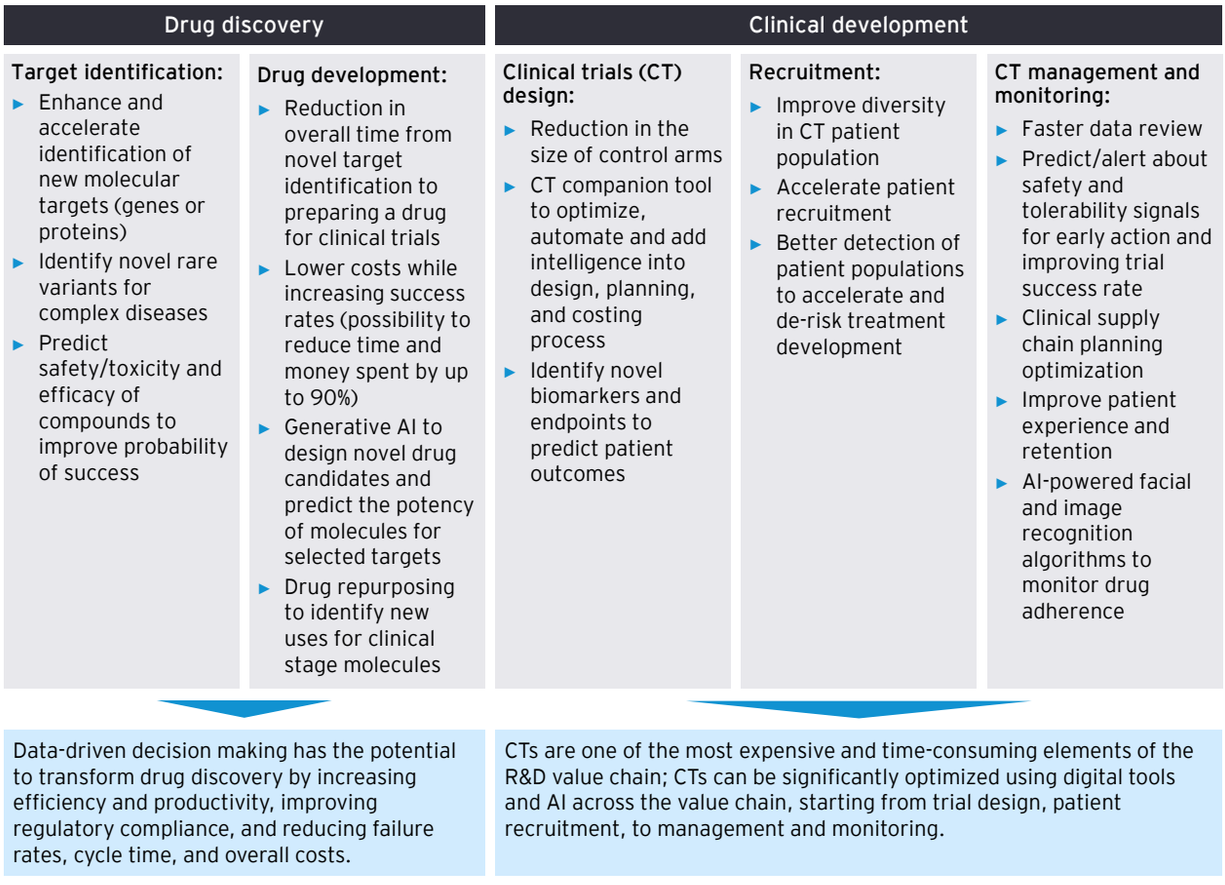
Presently, medicinal chemistry methods heavily rely on a hit-and-miss approach and extensive testing techniques involving large numbers of potential drug compounds to identify those with desired properties. Various AI algorithms, encompassing supervised and unsupervised learning, reinforcement, and evolutionary or rule-based methods, hold the potential to address these challenges. LLMs can extract insights from extensive datasets and literature, keeping researchers abreast of the latest discoveries and aiding in hypothesis generation. They can efficiently analyze vast biological datasets, including genomics, proteomics, and metabolomics, to predict potential drug targets, unveiling novel targets overlooked by traditional methods and identifying new therapeutic indications from existing drug compounds.

Data-driven decision making has the potential to transform drug discovery by increasing efficiency and productivity, improving regulatory compliance, and reducing failure rates, cycle time, and overall costs.

Companies have started using Gen AI tools to predict the binding affinity and potential side effects of drug candidates, assisting in prioritizing compounds for further validation. A notable breakthrough was the remarkable success of AI systems, particularly DeepMind's AlphaFold program, in solving the complex "protein folding" problem—a grand challenge in understanding biological processes and drug-protein interactions. Researchers, particularly those searching for new antibiotics, anticipate leveraging AlphaFold structures to identify drugs binding to specific bacterial proteins.

Generative AI-based virtual screening, such as Adaptyv Bio's platform, predicts the binding affinity of compounds to target proteins, accelerating drug discovery by offering a broader pool of potential candidates.

Digital, data, and artificial intelligence use cases across R&D value chain



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During lead discovery, AI models like Generative adversarial network (GANs) and recurrent neural network (RNNs) innovate by generating novel chemical structures, predicting binding affinities, and streamlining candidate selection. AI aids in optimizing lead compounds, proposing molecular modifications to enhance therapeutic effectiveness and safety, thereby reducing the costs associated with traditional laboratory experiments. By accurately predicting molecular interactions, generative AI empowers researchers to assess candidate viability rapidly, reducing the need for extensive physical testing and expediting the drug discovery process.

Gen AI tools extend their utility to design drug formulations and delivery systems, improving stability, bioavailability, and patient compliance. By generating synthetic datasets and analyzing target interactions, molecular structures, and patient profiles, AI supplements real-world data and enhances model training. Another application of Gen AI involves predicting multi-target effects, potentially unveiling opportunities for drug repurposing or combination therapies. ML techniques and molecular dynamics (MD) simulations contribute to the field of de novo drug design, enhancing efficiency and accuracy.

Predicting safety and enhancing clinical trial outcomes

In preclinical testing, Gen AI interprets extensive datasets to assess safety, efficacy, and toxicity, predicting adverse effects and therapeutic outcomes. This diminishes the reliance on extensive in vitro and in vivo testing. By analyzing vast datasets and recognizing patterns, Gen AI models evaluate the likelihood of adverse effects associated with novel drugs. This proactive approach enables researchers to prioritize safer compounds, thereby reducing the risk of late-stage failures in drug development. Based on its analysis, Gen AI recommends proactive interventions to improve clinical trial outcomes. This could involve adjusting recruitment strategies, identifying potential roadblocks early, or optimizing trial design.

> Only one out of ten drugs become a blockbuster, and the majority of drug research ventures face substantial risks and often yield minimal returns. Despite these challenges, there is a phenomenal opportunity in the field. Previously, data analysis alone consumed significant time. With digitally available data, leveraging algorithms, AI, and ML helps identify patient groups with higher unmet needs or areas where data is lacking.
>
> Head, Supply Chain of a pharmaceutical company

Once a new candidate compound clears pre-trials, numerous opportunities arise to apply Gen AI in human trials for increased efficiency, safety, and reduced timescales. Gen AI can identify potential trial participants by analyzing patient records and social media data, proposing personalized engagement strategies for improved patient retention. It scrutinizes patient data to find suitable trial candidates and optimizes trial protocols. Real-time data analysis during trials aids in identifying safety issues and efficacy trends.

Case Study

AI in clinical trials to enhance efficiency

An Indian company is leveraging AI to streamline processes tailored specifically for the US market. AI algorithms analyze extensive datasets to identify potential drug candidates and predict their efficacy. This innovative approach is not only speeding up pre-clinical trials but also is improving candidate selection, increasing the likelihood of success in the US market. The company is also extending the use of AI into clinical trials, a crucial phase in pharmaceutical R&D. By incorporating AI, the company further aims to enhance the efficiency of clinical trial processes, spanning participant recruitment to data analysis. AI algorithms contribute to precise patient stratification, optimizing trial design and elevating the chances of successful outcomes.

Machine learning models, trained using clinical trial databases, predict trial success in early stages, minimizing unrecoverable costs and allowing for earlier preparation for scaling production. Analytics assist in determining scaling approaches, helping in the selection of sources based on key information about sites and utilizing AI to identify the optimal combination of CMOs and internal sites. Demand forecasting and prediction become crucial, with Gen AI simulating different scenarios, predicting patient recruitment rates, and identifying potential challenges. Leading pharmaceutical companies leverage "clinical control towers" – powered by AI – to consolidate insights and expedite trials. These platforms support operational decision-making throughout the development process.

Business challenge	Impact of using Gen AI
R&D cost savings	Potential impact of US$60b to US$110b considering ~20% of annual revenues are spent on R&D of a drug spanning over a period of 10 to 15 years.
Reduction in development time	Significant reduction in overall time from novel target identification to preparing a drug for clinical trials (e.g., Astra Zeneca reduced the design-make-test-analyze cycle from ~6 weeks to ~2 hours).
Reduction in regulation submissions	Generative AI in drug filing can significantly reduce the time required for regulatory submission. Based on a study analyzing the impact of AI on submission of new drug applications to US FDA, use of AI reduced submission time by up to 60%.

Fast regulatory approval

For regulatory submissions, AI automates the analysis of complex data, ensuring a comprehensive and accurate evaluation of drug approvals. Natural language generation (NLG) tools convert data tables into written content suitable for submission to regulatory authorities. Post-approval, AI systems continuously monitor adverse effects and safety concerns, ensuring real-time tracking and swift responses to new findings.

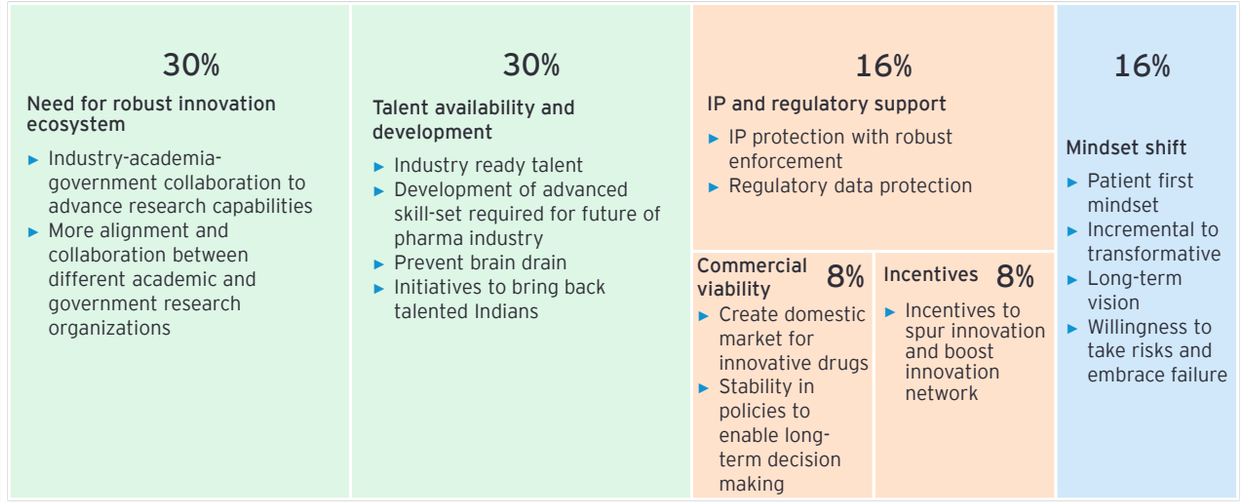
PRIP Scheme for innovation

The Indian government envisions a substantial growth in the pharmaceutical industry, to reach $130 billion target by 2030 through enhanced R&D and innovation. Recent initiatives, including the National Policy on Research and Development and Innovation in the Pharma-MedTech Sector, along with the Promotion of Research and Innovation in Pharmaceuticals and Medical Device (PRIP) scheme, aim to foster R&D in high-priority areas. With an INR5,000 crore financial outlay over five years, the scheme intends to cultivate an R&D-friendly ecosystem within India.

Gen AI in drug development has begun to drive value in two broad areas. AI-enabled drug discovery companies like Exscientia and Recursion report early-stage development cost savings between 25% to 50%. Assuming cost savings of 10-30%, firms can achieve economies at every stage of preclinical development using AI. Some AI-enabled drug developers have reported the ability to discover drug candidates by synthesizing ~1/10 the number of molecules and the ability to "fail fast" in preclinical development to de-prioritize non-viable molecules early.

Assuming improvement in preclinical and Phase I success rates can lead to ~50 molecules being approved in a 10-year period. As numerous Indian companies embark on their journeys into ADCs, DNA and RNA-based vaccines and therapies, and cell and gene therapy, India is poised to undergo a transformative shift, progressing toward its Discovery 1.0 phase a big move in its volume to value transition.

CXO survey results: research and innovation enablers for value-driven innovation



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While AI holds significant promise in drug discovery, there are noteworthy challenges and limitations that necessitate careful consideration. Ensuring ethical and fair AI use in the development of therapeutic compounds is paramount. If the data used to train machine learning (ML) algorithms are biased or unrepresentative, resulting predictions may be inaccurate or unfair. The risk of Intellectual Property (IP) compromise in drug discovery is also substantial, given that Gen AI models are trained on the organization's clinical data. Unauthorized access could lead to potential IP theft, highlighting the importance of pharmaceutical companies investing in cybersecurity measures like encryption, secure data hosting, and privilege access management. These investments are crucial in mitigating the risk of IP loss, ultimately impacting the growth and development of pharmaceutical companies.

Advancing new drug discovery necessitates coordinated efforts from both the government and the industry. A comprehensive infrastructure and regulatory framework supporting innovation aligned with international standards are essential. Minimizing costs, expediting discovery, and reducing failure rates, Gen AI's potential in drug discovery offers significant benefits for the Indian pharmaceutical industry in drug development and clinical trial analysis. Given India's robust IT capabilities, the nation possesses the opportunity to lead in this domain. Coupled with favorable government schemes and regulatory reforms, the Indian pharmaceutical sector could transform from a volume-driven to a research-driven approach, focusing on innovation as the pathway to sustainable growth.

02

Making a resilient supply chain

COVID-19 posed a significant challenge to global supply chain operations. Like other sectors, the pharmaceutical industry faced the impact of the pandemic on its supply chain operations. Despite playing a crucial role in developing and delivering vaccines and antivirals, the sector experienced unpredictable demand patterns, manufacturing constraints, goods movement restrictions, and infrastructure limitations. These challenges resulted in longer product cycles, increased financial obligations, and substantial repercussions on consumer demands and preferences, making the pandemic the most vulnerable supply chain disruption in recent history for the industry.

While grappling with the disruptions caused by the pandemic, the pharmaceutical manufacturing and delivery network faced additional stress from geopolitical tensions, including the Russia-Ukraine conflict and the Israel-Hamas War. These tensions led to shortages of essential goods, disrupted local manufacturing units, impacted workforce availability, and affected logistics operations.

COVID-19 underscored a critical vulnerability of the pharmaceutical industry — its heavy reliance on a singular source for most requirements. The global pharmaceutical supply chain heavily depends on China, which produces and exports around 40% of Active Pharmaceutical Ingredients (APIs) and is a major producer of Key Starting Material (KSM). The US, Europe, and India heavily rely on China for APIs, creating a strain on their pharma supply chain. For example, about 80% of the Indian Pharma Market's API requirements are fulfilled by the Chinese Pharma Market. The disruption of trade supplies from China during the pandemic highlighted India's excessive dependence on the country for APIs and KSM, risking substantial shortages.

Another significant challenge for the pharma supply chain is the lack of visibility. Medications and biologicals, being expensive to produce and perishable, require effective inventory management and end-to-end visibility. Supply shortages in the pharmaceutical industry not only impact individual health outcomes but also affect the broader healthcare system. The industry is governed by strict international regulations concerning trade, public health, product safety, and industry standards, making the supply chain a complex process with varying requirements across countries.

The cumulative impact of the pandemic and geopolitical factors has compelled global stakeholders to reorganize supply chains, reduce dependency on a single country, and diversify suppliers to enhance resilience.

The increasing need for resilience

supply chain includes the sourcing of raw materials, manufacturing processes, distribution, and the delivery of medications to patients. Given the involvement of diverse stakeholders in the supply chain network, meticulous coordination and strict adherence to regulatory guidelines at every stage are imperative to ensure patients receive safe and effective medications.

CXO survey: key priorities for manufacturing and supply chain function

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Recent years have witnessed notable trends within the industry, including heightened pressures related to pricing and inflation, the digitization of operations to enhance efficiency and ensure precision and compliance, and a greater emphasis on Environmental, Social, and Governance (ESG) factors to establish

sustainable supply chains. Additionally, the industry is undergoing a transformation with a shift toward personalized medicine and next-generation therapeutics, leading to an increased demand for just-in-time deliveries in cell and gene therapies and innovative healthcare delivery models directly to patients. These trends contribute to the growing complexities within manufacturing and supply chain operations, serving as crucial catalysts that necessitate a re-evaluation of priorities and a transformative approach to the pharma supply chain to enhance its resilience.

Digitization, localization, and the implementation of ESG practices are identified as key measures to bolster the resilience of the supply chain. These strategic initiatives are crucial for adapting to the evolving landscape of the pharmaceutical industry, ensuring a robust and responsive supply chain.

Digitization for visibility

Digitization plays a key role in maximizing efficiencies, enhancing agility, and ensuring end-to-end visibility across the value chain. Major pharmaceutical companies are now leveraging dedicated digital tools to bolster supply chain risk monitoring, fostering cost reduction, increased efficiency, and addressing environmental, social, and governance (ESG) concerns within the supply chain.

Indian pharmaceutical companies have integrated various digital systems, including electronic lab notebooks (eLNBs), electronic quality management systems (eQMS), Laboratory Information Management Systems (LIMS), SAP, and Enterprise Resource Planning (ERP) systems. Larger pharmaceutical companies, in particular, are placing a strong emphasis on automation throughout the value chain to streamline workflows, minimize handovers, and ensure transparency in costs and business value.

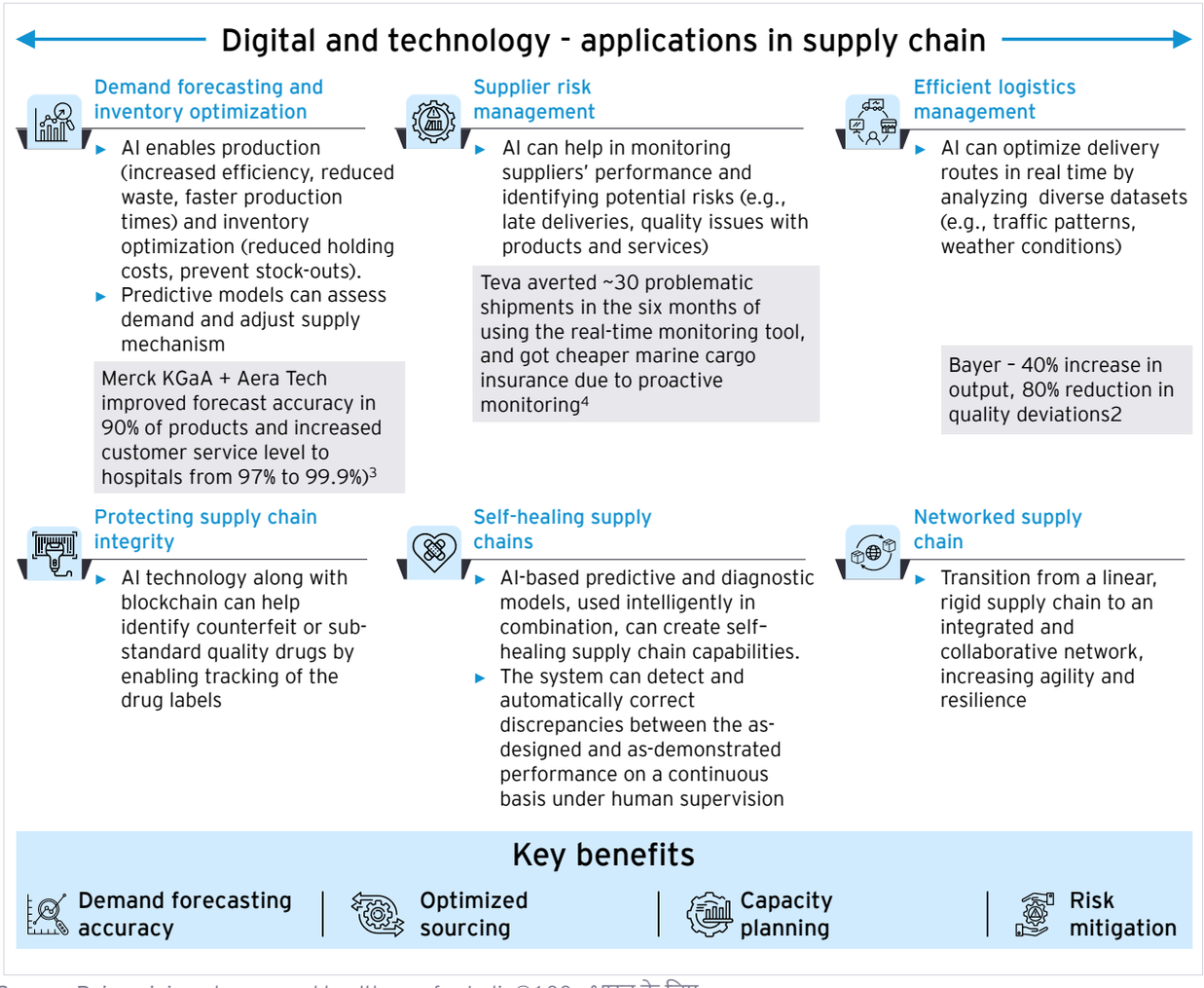
Companies are also transitioning to end-to-end integrated planning and adopting smarter systems to shift from a reactive to a predictive approach. AI plays a crucial role in supply chain functions, aiding in supply forecasting, demand planning, fleet and inventory optimization, and the automation of supplier selection and evaluation. A supply chain diagnostic system, supported by quantitative analytics and qualitative performance assessments, identifies critical areas for performance improvement.

> Visibility and traceability are increasingly evolving and gaining acceptance. The imperative to secure the supply chain and leverage technology for this purpose is now crucial for everyone. Recent cases in African nations, where Indian manufacturers faced scrutiny, albeit potentially isolated incidents, have raised broader questions about operations and supply chain practices. Initiatives are underway to incorporate technology in processes to prevent such situations and ensure robust supply chain security.
>
> Life Sciences & Healthcare Sector Head, Business Development of a Supply Chain Company

This three-pronged approach involves the identification and access of relevant data for analysis, an AI model for data analysis, and a profound understanding of upstream changes' relevance in the life sciences industry. The digital solution initiates with an analysis of category trees and associated risk exposures, determining risk indicators for suppliers and materials. AI algorithms then analyze both online public sources and proprietary pharmaceutical company data to distinguish genuine risks from irrelevant "noise". The digital solution assesses whether the identified pressure falls within acceptable boundaries or might cause bottlenecks and delays in the company's supply chain.

This ongoing analysis, coupled with Generative AI tools, will provide companies with continuous updates,

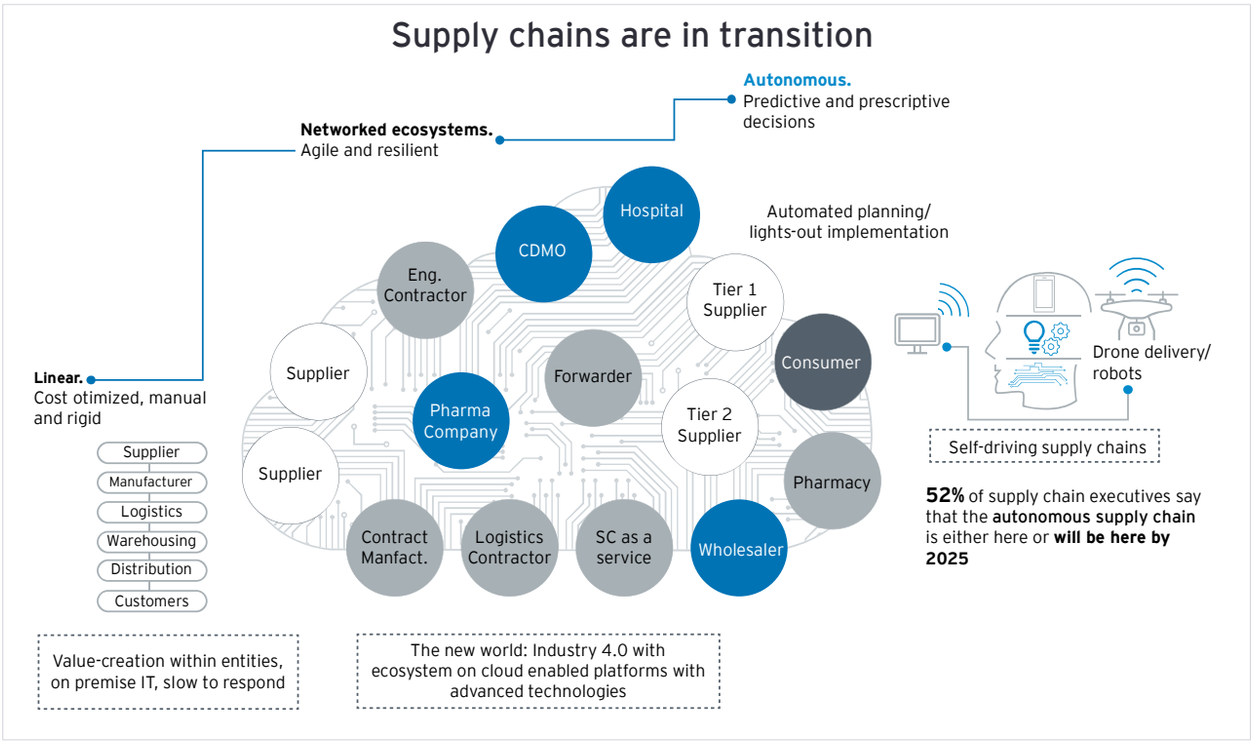
including automatically generated alerts, monthly briefings, and other managed service offerings and will generate proactive measures for managing upstream risk. Gen AI tools can also aid in the design of logistics networks, considering factors such as warehouse locations, transport links and demand patterns to generate the most efficient configuration. This leads to reduced delivery times, lower costs and improved service levels.



Source: Reimagining pharma and healthcare for India@100 - भारत के लिए

A smart inventory management approach ensures alignment with the manufacturing process, creating the right product quantity to meet patient demands. Scenario analysis for responding to over and under supply contributes to a more resilient process. Predictive trace and tracking optimize modes of transport, leveraging warehouse data to minimize distribution costs while meeting customer demand.

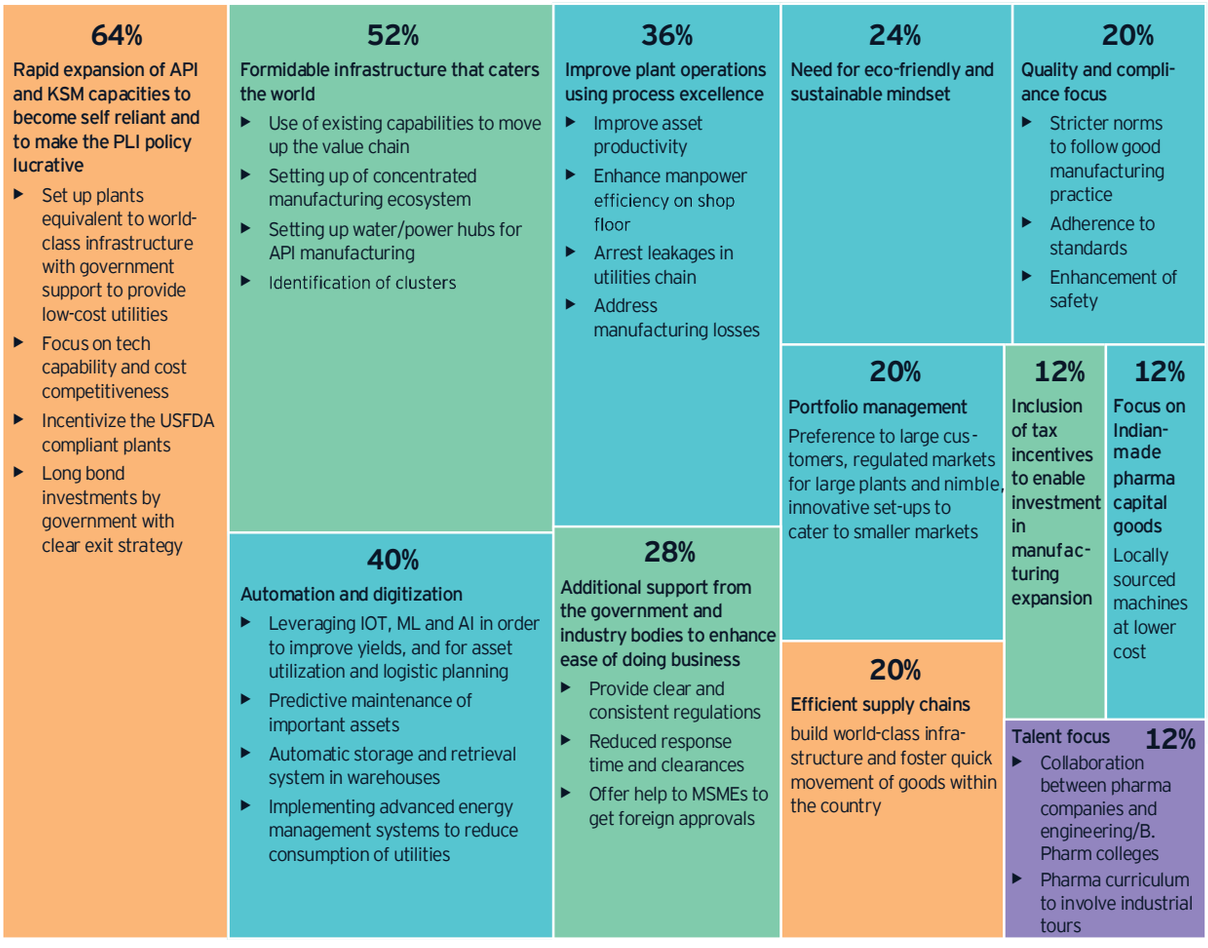
However, these advancements come with challenges, particularly concerning data privacy and cybersecurity. Resolving these issues is crucial to enable seamless end-to-end visibility. Moreover, building and scaling the necessary digital infrastructure for this approach requires a significant commitment of time and financial resources.



Localization to reduce dependence

Globally, the journey toward building a resilient system is prompting a strategic shift within the industry toward localizing manufacturing and sourcing. Employing various measures, from securing local inventories of finished goods to the more ambitious goal of consolidating the entire end-to-end manufacturing process within a national or supranational region, localization carries political benefits. Countries are motivated to reduce dependence on potential rivals and secure end-to-end control of production capabilities, especially amid geopolitical tensions.

Manufacturing and supply chain enablers



Source: Indian Pharmaceutical Industry 2021: future is now

The investment required for localization varies across different stages of the manufacturing process. For instance, localizing secondary packaging, a relatively straightforward task, may involve establishing a local Good Manufacturing Practice (GMP)-approved and licensed site, achieved through in-house efforts or outsourcing to a local Contract Development and Manufacturing Organization (CDMO). This requires infrastructure for receiving and storing the primary packaged product from earlier stages of the supply chain.

While comprehensive localization enhances supply chain agility, it comes at the cost of efficiency due to the need for local infrastructure, services, and talent. Heavy reliance on local sites increases risk exposure and extends timescales for bringing innovations to local markets, reducing reliability by separating operations from established centers of excellence. To address the challenges of single sourcing, the pharmaceutical industry has already embraced initiatives such as multi-sourcing and leveraging local CDMOs for supply chain resilience. Certain approaches yield immediate benefits, while others require long-term investment and commitment. The industry can also consider the 'Hub and Spoke model' as a potential solution to balance both globalized and localized operations. Within such a system, the manufacturing of a product – either end-to-end or in part – can be localized, while a full-scale manufacturing site acts as a global hub, where smaller-scale supply chain operations can be executed.

Sustainable practices to ensure robustness

Efficiency in the pharmaceutical supply chain relies on agility, resilience, and sustainability. Sustainability is a critical factor in establishing robust and effective pharmaceutical supply chains. Supply chain managers must prioritize environmental, social, ethical, and governmental considerations to ensure profitability.

The industry's operations, from raw material extraction to drug disposal, have a significant carbon footprint. In the past year, some areas of supply chain sustainability, such as human rights protection, worker welfare and safety, and energy savings and renewable energy, have significantly increased.

Source: Reimagining pharma and healthcare for India@100 - भारत के लिए

While improvements in packaging are often associated with sustainability, the use of single-use plastics for medicinal sterility and protection poses environmental challenges. Companies are actively exploring alternatives such as blister packs and dry ice.

Sustainable packaging faces regulatory hurdles, requiring a delicate balance between recyclable and disposable materials to maintain medication efficacy and quality.

> There is a deliberate commitment to sustainability. We are actively transitioning a significant portion of our products to be transported by ocean, as this shift reduces carbon footprint by nearly 90% compared to air transportation. Initiatives promoting environmentally friendly practices, such as go-green initiatives, utilization of natural lighting, and implementation of fuel-efficient measures at the warehouse level, have been prioritized. A notable emphasis over the past two to three years has been on plastic waste management. We are exploring the adoption of recyclable packing materials that can be reused multiple times before eventual disposal.
>
> Director, Supply Chain of a pharmaceutical company

Transforming with digitization

The pharmaceutical sector stands at the cusp of transformative trends, including digitization and the adoption of Pharma 4.0. With an ambitious target to increase the pharmaceutical industry's size to $130 billion by FY2030, Indian pharma companies have started diversifying their sources and taking steps to strengthen their portfolios, including developing capabilities for more differentiated and complex generics, investing in innovators, and building capacity for biosimilars. Government initiatives, such as the production-linked incentive (PLI) scheme and API Parks scheme, aim to boost competitiveness in indigenous manufacturing, but escalating costs pose challenges to scaling up local production.

These innovations promise increased resilience, flexibility, and responsiveness in manufacturing and supply chain processes. However, a parallel evolution in the supply chain is vital to fully capitalize on these advancements. As the pharmaceutical sector charts its course forward, the convergence of these trends — localization, digitization, and sustainability — will shape a more resilient, efficient, and responsible supply chain. Navigating these transformative currents requires strategic foresight, collaboration, and a commitment to overcoming challenges on the path to a future-ready pharmaceutical supply chain.

03

Beyond cheap pills: digital upgrade to boost manufacturing, quality and compliance

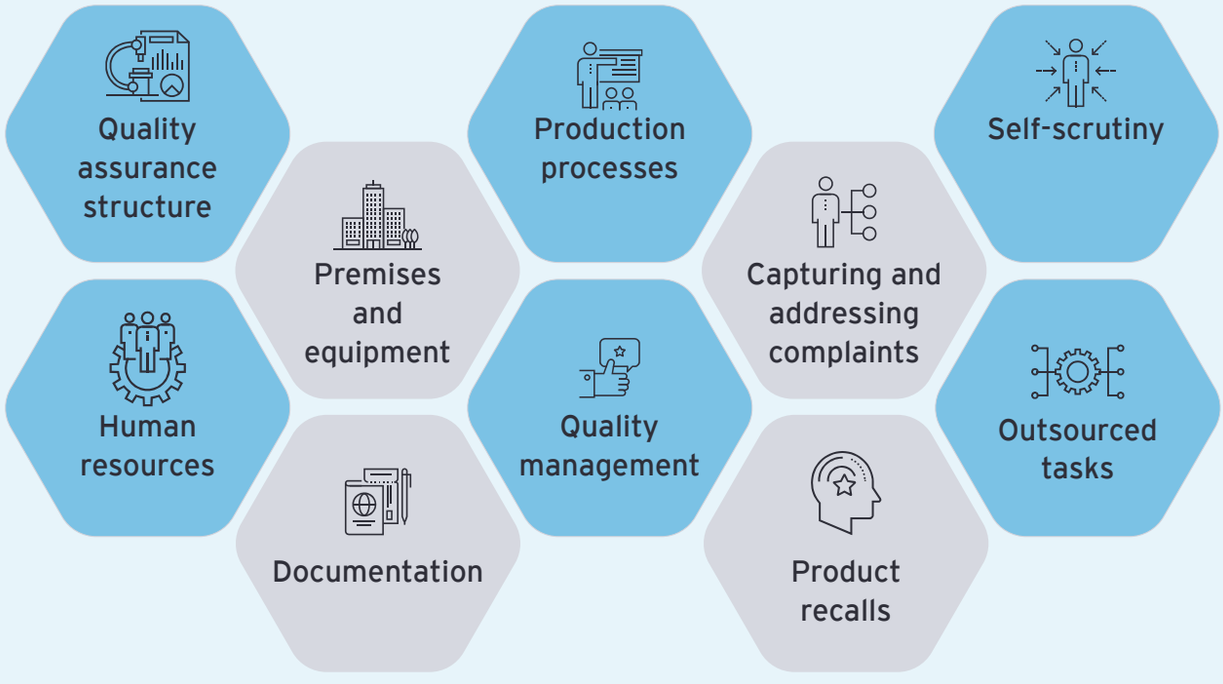
With over 10,500 pharmaceutical manufacturing units, India manufactures a significant portion of the world's active ingredients for generic drugs, positioning itself as the global leader in the generic market. India has the highest number of United States Food and Drug Administration (USFDA) approved pharmaceutical plants outside the US, coupled with a substantial count of WHO GMP-compliant facilities. This robust pharmaceutical sector serves as the source for more than 90% of medications used in the US and contributes to over 60% of global vaccine production.

Capitalizing on key strengths such as manufacturing prowess, cost-effectiveness, and a skilled workforce, the country has set an ambitious vision to elevate its pharmaceutical industry to an ambitious growth in the next few years. Achieving this ambitious target necessitates accelerating the industry's growth rate to a CAGR of 12%. While we are one of the volume leaders, there is a strong need to enhance production capabilities to generate value-based pharmaceutical products.

To achieve the set target and enhance overall value in the next six years, India must urgently address gaps in its pharmaceutical production process. This is especially crucial in light of recent recalls of Indian-manufactured pharmaceutical products in the US and other countries, which were linked to deviations from GMP – a set of standards aimed at ensuring consistent production and control of medical products while upholding quality standards.

Illustrating the seriousness of the situation, the Drug Controller General of India (DCGI) took decisive action in 2023. This involved revoking licenses for 18 pharmaceutical companies and issuing notices to 26 firms for producing spurious and adulterated drugs, along with violating GMP. These deviations pose a huge risk to patients and emphasize the urgent need to address and rectify these shortcomings in the pharmaceutical production landscape.

Plugging quality gaps based on Good Manufacturing Practices



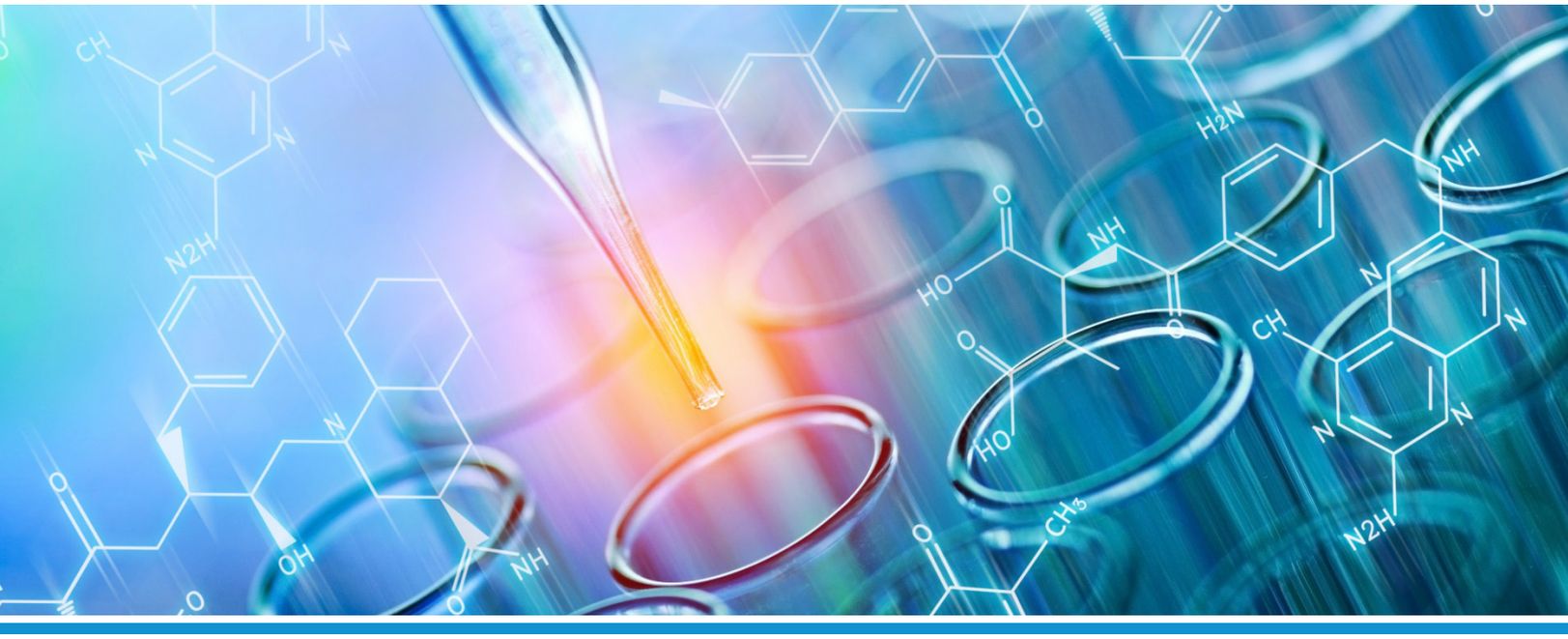
Among our 10,500 pharmaceutical production units, a serious disparity exists between well-established large-scale facilities and smaller local entities (a majority of which fall under the MSME category) in quality and compliance. Only about 2,000 units adhere to the WHO-GMP standards. Under the revised Schedule M rules, manufacturers bear the responsibility of ensuring the quality of their products. This involves strict adherence to the GMP norms at their production facilities, making sure the facilities are suitable for the intended use, comply with license requirements, and do not pose risks to patients due to inadequate safety, quality, or efficacy. Schedule M adherence has been made mandatory in the new Drugs, Medical Devices and Cosmetics Drafts Bill 2022.

According to media reports, Rajeev Raghuvanshi, Drugs Controller General of India said that the revised Schedule M will be implemented in totality and that will not only improve quality but also help pharma manufacturers to upgrade themselves to boost the growth of the Indian Pharma sector. The government has provided a 12-month window for units to achieve the compliance. Furthermore, the proposed Drugs, Medical Devices, and Cosmetics Bill aims to consolidate regulatory requirements for the import, manufacture, distribution, and sale of drugs, with a primary focus on ensuring quality and safety.

Adopting tech

Modernization of manufacturing facilities, embracing digital technologies and embarking on Industry 4.0 digital transformations could help Indian Pharma to adhere to GMP compliance and improved business results. Initiatives such as smart tech transfer and autonomous batch release create a faster route to market by aligning with established sourcing and procurement approaches and incorporating regulatory requirements into the production process. Emerging technologies, such as AI/ML, cloud computing, and big data analytics, hold the promise of significantly enhancing transparency, traceability, and accountability throughout the pharmaceutical supply chain.

This shift towards digitalization, as reflected in recent surveys like the EY CXO survey, underlines the commitment of the Indian pharmaceutical industry to continuous improvement and upholding the highest quality standards. By closing the quality gap through rigorous GMP compliance and embracing digital transformation, India can further solidify its position as a global leader in safe and affordable medicines.



Automation for better compliance

Automation in pharmaceutical manufacturing holds multiple benefits, largely in terms of safety, efficiency, reliability, and cost. Most importantly, enhanced safety in formulation, labeling, and packaging addresses the serious concern of human error. It also facilitates compliance with new GMP Rules with minimal effort.

Automatic handling under controlled parameters can lead to improved reliability and consistency, resulting in enhanced quality assurance, greater operational agility, and fewer production stoppages that are costly.

With automation and modularity at the core of their strategy, manufacturers can maintain flexibility and scalability in production from clinical trials to high volumes. Distributing control systems with a virtualized architecture further reduces maintenance, minimizing system downtime.

There are cost benefits as well, since expeditious manufacturing lowers the overall manpower costs and automation allows manufacturers to process various device formats on the same line, further optimizing costs.

> Automation is the optimal approach for both manufacturing and testing in our industry. We currently rely heavily on manual labor, leading to potential challenges and issues related to human errors. These issues are predominantly people-related, and incorporating automation is crucial for addressing them effectively. When machines handle tasks, the workflow is more streamlined, efficient, and error-free. From the beginning of the process, if human intervention is minimized or eliminated entirely, we can anticipate a smoother and trouble-free operation, ensuring a seamless and reliable outcome.
>
> President - Quality & Compliance of a pharma manufacturing firm.

A prime example of manufacturers aiding customers in mitigating risks and meeting high-quality requirements is through the integration of robotics for visual inspection. Robotic processes ensure superior fully automated inspection performance for high-value small batch treatments without human intervention. While robots in the pharmaceutical industry are currently limited to dispensing, sorting, kit assembly, machine-tending, and packaging, they are also addressing drug shortages caused by manufacturing delays for products like pre-filled syringes.

However, to get the best out of technology, before adoption, companies must ensure that the chosen technology is flexible enough to align with existing processes and quality standards. For instance, automation of GMP processes must begin with selecting compliant GxP computerized systems.

There are several examples of successful automation integration. For instance, a prominent manufacturer was able to reduce production time by 30% after implementing robotic automation on its packaging line. This also reduced the company's overall costs.

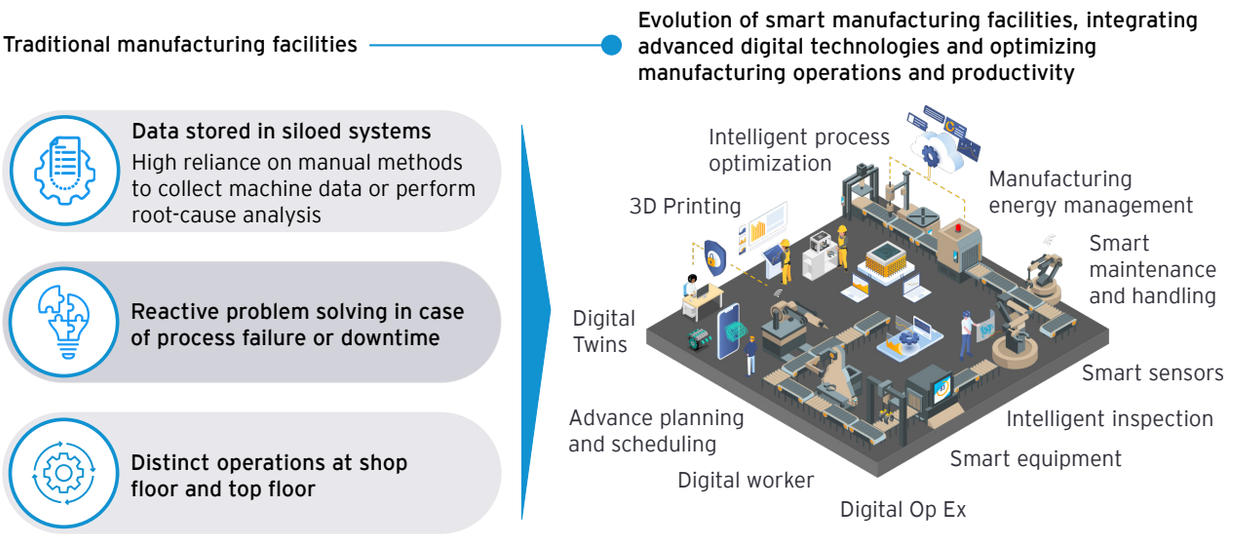
To thrive in Pharma 4.0, companies need not only to add automation but also to integrate digitization, encompassing data, connectivity, and AI.

AI for quality control

AI offers numerous opportunities for the pharmaceutical industry, including process optimization and control, intelligent maintenance, and trend monitoring for continuous improvement. AI can pave the way for Industry 4.0, a networked and digitalized pharmaceutical value chain. Cloud applications impact oversight of pharmaceutical production data, emphasizing the need for data integrity and quality. AI finds application in manufacturing processes, such as monitoring and maintenance of equipment, continuous improvement, supply chain logistics, and raw material characterization. The Internet of Things (IoT) increases data generation, impacting data management practices while machine learning algorithms predicting equipment failures, recommending process improvements, and discovering new drug formulations.

Real-time monitoring enabled by IoT ensures quality control at every step. Deep learning models in automatic inspection machines increase defect detection while minimizing false reject rates, enhancing cost efficiency and quality. That said, standards are necessary for the development and validation of AI models used for process control and release testing.

Future of integrated manufacturing and supply chain systems



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Blocking counterfeit drugs

Enhancing quality control, smart contracts on the blockchain prevent counterfeit drug distribution by automating data collection and verification, ensuring efficient compliance with regulatory standards. For instance, several blockchain based networks are utilized by companies for end-to-end tracking of prescription drugs, encoding each product with a tamper-proof and traceable identifier. This not only secures critical information like drug formulas and manufacturing processes, but also prevents intellectual property theft, fostering innovation. Additionally, it streamlines data integrity and regulatory compliance by creating immutable, time-stamped records for manufacturing and shipment information.

Blockchains track the origin of pharmaceuticals, drug transport, and raw material procurement, enforcing real-time business rules throughout the supply chain. This granular visibility enables stakeholders to swiftly identify and remove expired or fraudulent products, address supply chain issues, and efficiently redistribute inventory.

Blockchain registries can also be used as a verification system to meet regulatory compliance standards. It offers a synchronized and secure approach to track and trace the drugs they produce and distribute. Blockchain also removes the need for individual wholesalers to handle extensive product lists and manufacturer addresses.

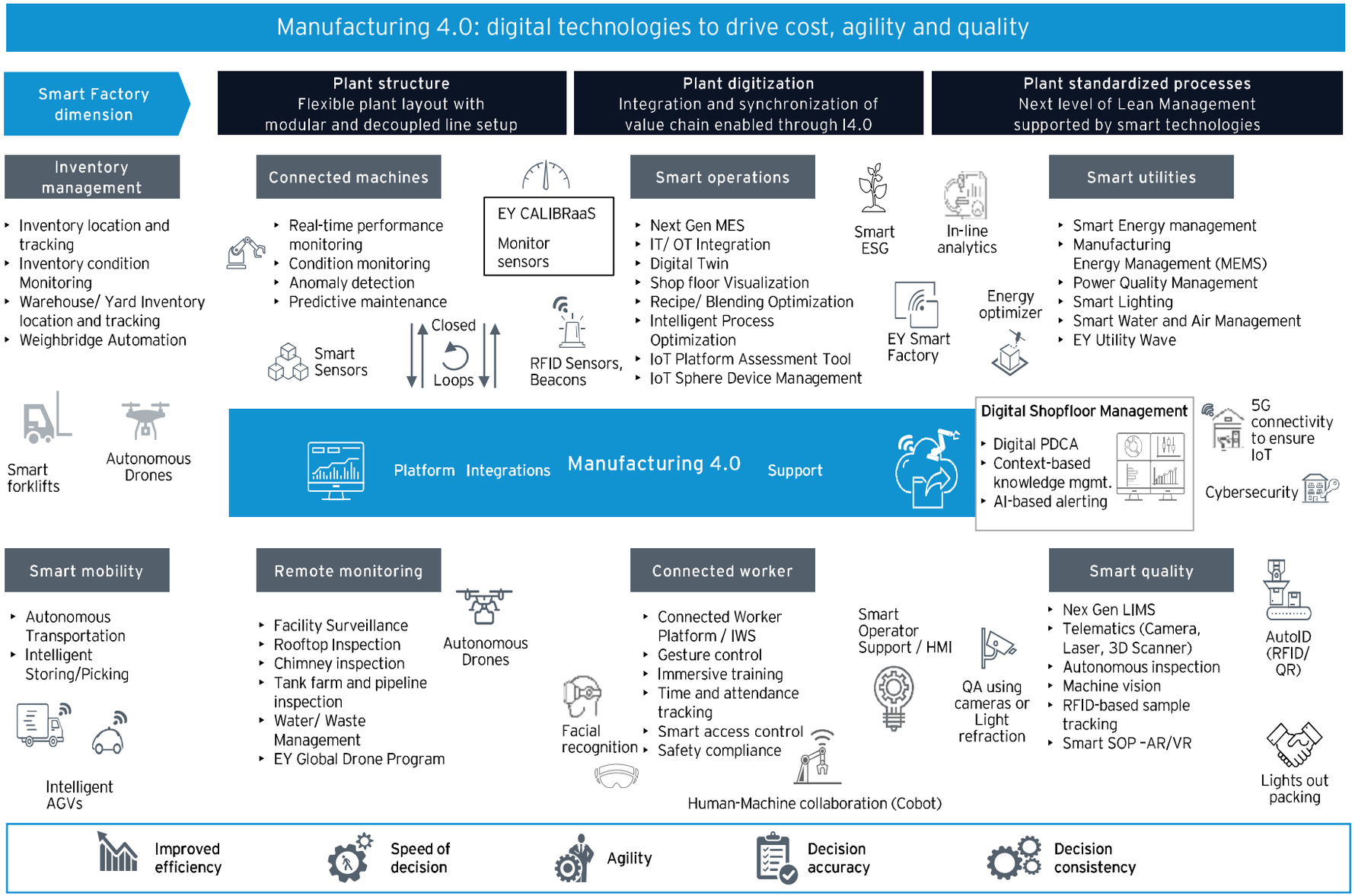
Digital twin and golden batch

Digital twins significantly contribute to adhering to GMP by establishing accurate control models, predicting variations, and assisting in setting precise control specifications and limits to reduce deviations and out-of-spec events. Predictive control models utilizing advanced data analytics provide precise models of complex bioprocesses by seamlessly predicting the future based on historical and present data. Continuous process improvement is achieved by incorporating machine learning algorithms into the model, improving accuracy over time.

Producing the optimal quality drug yield, or the "golden batch," within specified parameters, is a complex undertaking. This involves meticulous coordination among the process, product, and machine settings. Digital twin applications empower manufacturing teams by utilizing sensor and machine data to provide insights beyond the capabilities of traditional physical methods. These valuable insights enable factory managers to make informed decisions, significantly enhancing their production capacities.

Moreover, they predict drug yield quality based on pre-defined parameters or conditions and provide real-time monitoring of operations and can alert plant operators promptly in case of sudden failures. With the digital twin solution, operators can also simulate batch production and predict quality outcomes before actual manufacturing. They also have the flexibility to adjust parameters in these simulations to enhance overall product quality.

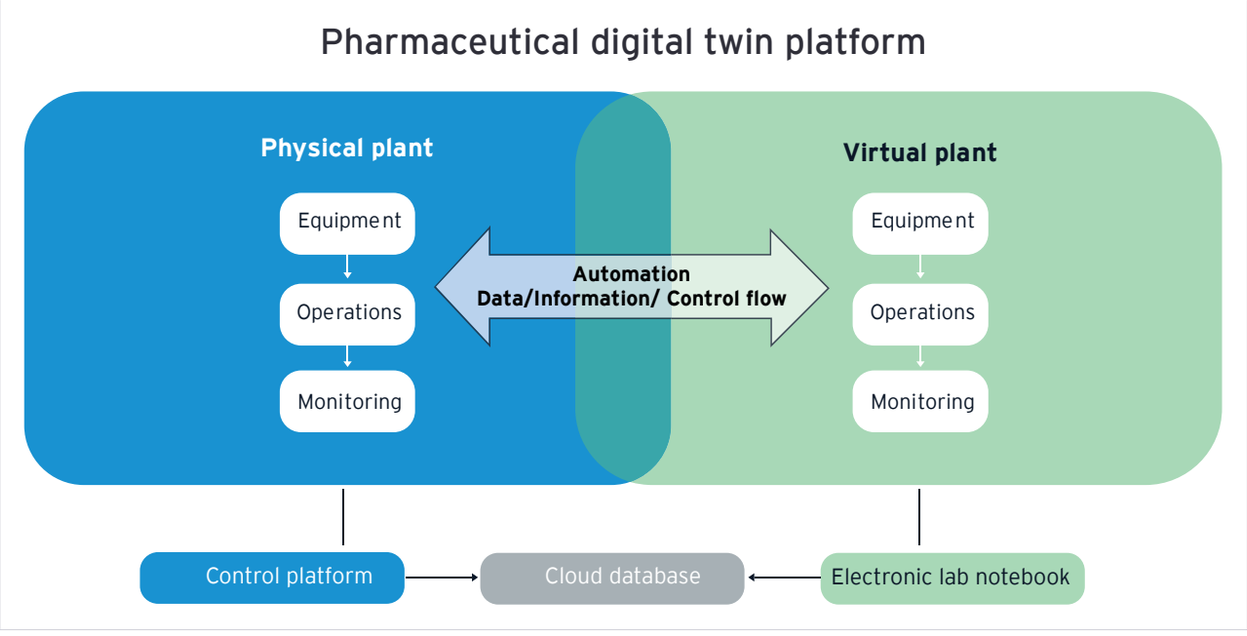
With the Smart Factory capability and operational excellence, companies can significantly accelerate their performance through phase maturity



Digital twin models operate based on data from sensors reporting on the physical system and process, enhancing process development and optimization. Analysis of real-time sensor data and employing conditional monitoring facilitates predictive and preventive maintenance by creating patterns that aid in anticipating potential failures. If the current configuration of a machine indicates a likelihood of failure, technicians can proactively prepare for it. Localizing the issue, understanding its criticality, and devising an action plan for mitigation become feasible through data-driven decision-making.

Given that many Indian companies run older machinery, it is worthwhile to repurpose the machines by integrating sensors for data collection and analysis becomes an avenue for enhancing management. Improved data integrity and reduced infrastructure costs are added benefits.

However, for the Indian industry to see significantly improved GMP and cost competitiveness, companies must face some challenges, such as connecting machine data and implementing analytical dashboards capable of augmenting and replacing human efforts.



Plant digitization is crucial in both the near and distant future. Through digitization, pharmaceutical factories can achieve enhanced flexibility with a multidirectional layout, modular interconnected plug-and-play line setups, and environmentally sustainable production processes. In a smart factory, all equipment, devices, computers, and systems are interconnected, creating an environment conducive to big data analysis and self-correcting procedures, aiming for minimal downtime.

This transformative approach, driven by new technologies and innovative thinking, is reshaping the biopharmaceutical drug production industry, giving rise to the concept of "the factory of the future." This entails full integration across the entire value chain, including suppliers, manufacturing, manufacturing line modules (equipment and systems), and the patient, blurring traditional boundaries.

A digital future

To achieve India's target by 2030, the country must prioritize setting up large-scale plants, both for APIs and formulations. Modernization is imperative for the industry's progression, as automation and technology adoption become inevitable for staying competitive and meeting global standards. Reducing human intervention in pharmaceutical processes is considered a key strategy for enhancing medicine quality and standardizing procedures, promising improved efficiency and high standards in manufacturing.

The path forward is clear: double down on quality, embrace Industry 4.0 technologies, and prioritize innovation. By rigorously enforcing GMP compliance across all players, both large and small, India can guarantee the safety and efficacy of its medications. Investing in automation, AI, and blockchain solutions will not only enhance quality control but also boost efficiency and transparency throughout the manufacturing and supply chain operations. Fostering research and development in areas like genomics and personalized medicine will ensure India remains at the forefront of pharmaceutical innovation, catering to the ever-evolving needs of global healthcare.

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EY Solutions & assets

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			EY Compass	Post Merger Integration
			Cyber SOC	Restructuring
			HITRUST	

Note: Credentials are not exhaustive

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