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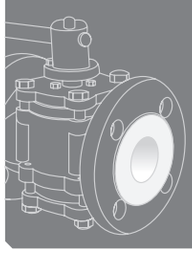

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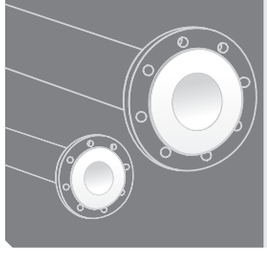

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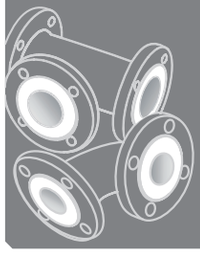

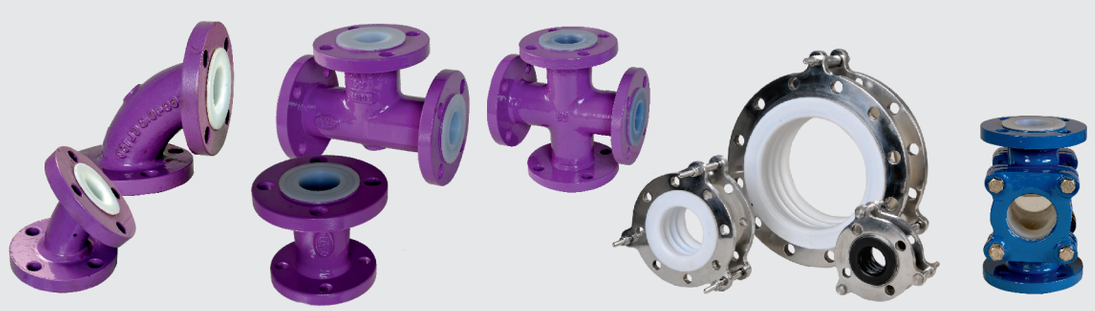

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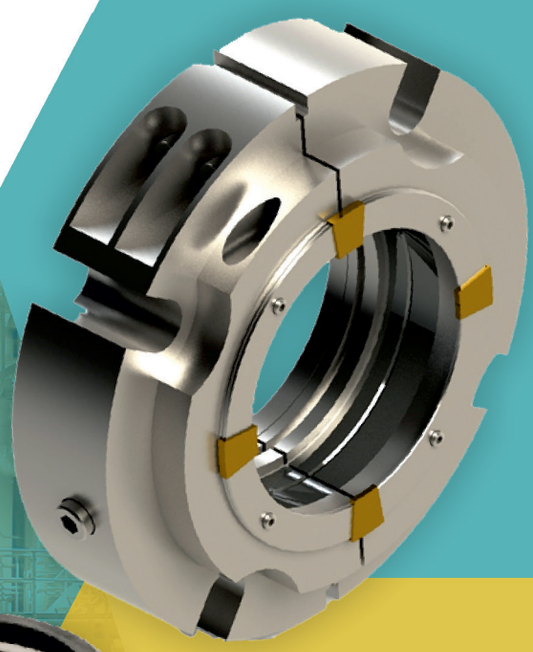

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INTERVIEW

"We are focusing on developing Innovative Formulations in Soft Gelatin Capsules dosage form"

Mr. Badarinarayan Herur
Senior General Manager-Formulations,
Dishman Carbogen Amcis Limited

Mr. Badarinarayan Herur, Senior General Manager-Formulations, Dishman Carbogen Amcis Limited, gives an overview of the Soft Gel Capsules Business, and elaborates its opportunities and challenges.

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Please give us an overview of the Soft Gel Capsules Business?

Softgel capsules are a type of Solid Oral dosage form widely used in the pharmaceutical, nutraceutical and cosmeceuticals. Softgels are typically made of gelatin shell and contain liquid or semi-solid substances such as oils, extracts or suspensions and are designed to provide an easy-to-swallow, efficient method of delivering active ingredients to the body, making them popular for vitamins, supplements and over-the-counter medications. This dosage form is very popular for Accurate & Precise dosing of many potent molecules across the globe.

The global softgel capsule market is expanding rapidly, driven by rising consumer demand for dietary supplements, personalized medicine, potent molecules and non-prescription healthcare products. This growth is further supported by adopting automation in capsule manufacturing technology, challenges in improving bioavailability of many active ingredients and the ease of medication offered by softgel capsules.

What is the market Size of Soft Gel Capsules?

The Softgel Capsules Market was valued at USD 7.9 Billion in 2024, and is expected to reach USD 11.5 Billion by 2029, rising at a CAGR of 7.7%. . This growth is fueled by the rising popularity of Nutraceuticals, an increasing geriatric population, and growing awareness about health and wellness in post COVID era. The market is also benefiting from the increasing uses of Multivitamins & Multiminerals supplement, quick acting pain management, Cough & Cold treatment, Omega-3 fatty acids composition, Skin care formulations and increase in potent molecule market in Softgel like Anti-cancers, Derma care (Anti acne) and Hormones for better bioavailability & quick onset of action as compared to other solid oral dosage forms.

What are the Opportunities and Challenges do you see in Softgel Business?

There are immense opportunities for Softgel business. There is a rising preference for OTC Medication dietary supplements, functional foods, and plant-based products, which presents opportunities for softgel manufacturers to expand their portfolios.

Personalized Medicine: Softgels are well-suited to deliver precise and potent medicine, and advancements in Pharmaceutical field are creating demand for custom formulations.

Expansion of E-commerce business opportunities: Online retailing and direct-to-consumer models are growing, providing new distribution channels for softgel products.

Regional Market Growth: Emerging markets, particularly in Asia-Pacific, present opportunities as consumers' disposable incomes increase, and healthcare awareness rises.

Challenges

The challenges includes Raw Material Costs, Regulatory Hurdles and Competition

Raw Material Costs: The rising cost of gelatin, along with regulatory concerns surrounding animal-derived ingredients, may lead to price volatility.

Regulatory Hurdles: The softgel industry is subject to strict regulations, particularly in pharmaceutical applications, where compliance with Good Manufacturing Practices (GMP) is critical.

Competition: The market is highly competitive, with numerous manufacturers offering similar products, which may lead to price pressure and margin reductions.

What are your expansion plans for Soft Gel Capsules Business?

DCAL has state-of-the-art manufacturing facilities and has spare capacity to fulfil the current demand and to collaborate with new marketing partners.The plant is equipped with 21CFR compliant equipments to fulfil any regulatory requirements.

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The GMP-certified facilities to meet regulatory requirements, especially for pharmaceutical and nutraceutical softgel products to meet the global quality standard.

DCAL Sustainability Initiatives ensures eco-friendly manufacturing practices, such as using biodegradable materials, and reducing carbon footprints and avoiding uses of harmful solvents.

The current annual Softgel production capacity of DCAL is 300 million units for general pharmaceutical category and 50 million units for Developmental and high potent molecules. Further the capacity of general pharmaceutical category commercial can be expanded up to 700 to 800 million units per annum.

Can you brief us about the International Markets expansion?

Several international markets offer significant growth potential such as North America, Europe, Asia-Pacific, Latin America and Africa. The U.S. remains one of the largest markets for OTC softgel capsules, particularly in the nutraceutical and pharmaceutical sectors, while The demand for dietary supplements and functional foods is growing, especially in countries like Germany, the UK, and France.

Countries like China and India are witnessing a surge in demand due to rising disposable incomes, greater awareness of health, and the growing popularity of wellness supplements.

Latin America and Africa is still emerging and are experiencing rapid growth in the health and wellness sectors.

Softgel capsules are widely used for a range of applications. DCAL is focusing on developing innovative formulations, including Nutraceuticals, Pharmaceuticals and Cosmeceuticals. Soft Gelatin Capsule dosage form.

Brief us about the Contract Development and Contract Manufacturing Services segment?

DCAL offer Contract Development services (CDO) where we work with clients to develop new formulations, customize existing products, and ensure the formulation meets the required specifications for bioavailability, stability, and regulatory compliance.

Contract Manufacturing

This service includes the production of softgel capsules on behalf of other companies. It is particularly useful for branded products want to outsource manufacturing to focus on marketing and sales.

Key services in Contract Manufacturing (CMO) may include Formulation development, Scale-up & Technology transfer, Packaging and labelling, Regulatory compliance and Supply Chain Management.

These services are attractive for companies that want to offer soft gel products without investing heavily in their own manufacturing infrastructure.

In summary, the softgel capsule market is robust and growing, with various opportunities and challenges across different sectors. Investment in facilities, Automation, Increasing Production Capacity and International market expansion are key to success in this space. Contract Services are additional avenue for growth, providing value to smaller brands or businesses that need specialized manufacturing capabilities. ■

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Is your data ready for the next level of AI-powered drug discovery?

The ‘killer app’ for AI may well be scientific discovery. To maximize the innovative power of AI, Chris Stumpf - Director, Drug Discovery Informatics Solutions, Revvity Signals, advises that optimizing data should be the first step on your journey, making you fully ready to uncover new insights that can transform productivity.

Chris Stumpf
Director, Drug Discovery Informatics Solutions,
Revvity Signals

As AI in its many forms continues to mature, its true strength as a ‘killer app’ may be emerging. With the Indian biosimilars market estimated at more than US$7 billion and the generic drugs sector valued at around US$25 billion, every slight discovery advantage could represent significant revenue gains. However, although Indian drug companies have embarked on their own endeavors identifying over 200 potential drug compounds since the 1990s, only a handful of these have reached the market. The question then arises – what are the roadblocks hindering the development of an optimized process to establish India within the drug discovery sector?

Among the newest technologies that might deliver the all-important edge, AI is already transforming research and development, accelerating the journey from lab to product.

Less obvious is the critical role played by data in this emerging story. Data-driven decisions have the potential to transform drug discovery by enhancing productivity

and optimizing R&D pipelines, simplifying adherence to regulatory guidelines, and reducing failure rates. The outcome will naturally lead to compressed cycle times, and reduced costs. Having said that, AI can only be as powerful as the data it consumes. Yet while pharmaceuticals and biotechnology organizations work with very large datasets, that data often remains trapped in multiple independent systems, poorly modeled, and hard to access. Only by optimizing the ingestion, storage, organization, and maintenance of data will leaders be able to take full advantage of AI.

Ingestion

Data used in research ranges from highly structured databases to very large unstructured collections of documents, such as spreadsheets and PDFs. Without a solution that normalizes and curates data into a coherent, unified, centralized resource, AI tools may return incomplete or inaccurate results. To illustrate this point, consider if data used to train AI and ML models was biased and unrepresentative, it could directly impact preclinical and clinical trial outcomes and drug discovery by skewing experimental conclusions and making predictions inaccurate.

One of the first steps is to establish data ingestion protocols, to ensure that the data meets FAIR (Findable, Accessible, Interoperable, Reusable) principles to help maximize future value. Creating the foundation for good data practices by standardizing collection and entry will ensure that there is minimum ambiguity in the data ingested and will pay dividends in the long term.

Unfortunately, many scientific organizations use rigid data schemas with predefined structures and strict parameters, forcing scientists to fit their rich, multifaceted data into limited input boxes, often at the expense of nuance and detail that could be crucial for future research. Data bound too early into a rigid schema may lose its potential to inform future analyses or be re-interrogated under a new scientific lens. Additionally, rigid data models can impede the integration of disparate data types, which becomes an increasingly critical capability as research becomes more interdisciplinary. For example, combining biochemical data with clinical observations, patient demographics, and real-world evidence is essential for a full understanding of therapeutic outcomes.

Storage

As well as the fragmentation of resources, data residing in multiple storage solutions tends to lead to complexity, most often caused by broken links, as underlying systems and servers are retired, modified and upgraded. Assorted locations such as internal archives, clinical institutions, and external partners will operate their own storage practices, naming conventions, and quality processes. Within organizations, changes to personnel can disrupt and revise predefined protocols, adding to the administrative burden. Intricacies in data housing gives rise to organizational silos, leading to accessibility concerns, with precious knowledge trapped within proprietary systems. For external resources, changes to subscription terms, expiration of license agreements, and even business collapse can lead to unavailability.

In the context of AI, incomplete and inadequately structured datasets may yield suboptimal or biased predictions, undermining the accuracy, validity, and utility of the derived insights. To remove the non-research overhead, simplify administration, and optimize AI efficiency, finding ways to unify and standardize data management is an unglamorous, but essential piece of foundation work.

Organization

However, data is not enough on its own. Metadata (the 'data about data') contextualizes each piece of information, detailing its origin, nature, and specifications. In research, effective metadata includes the methods used to collect the data, the conditions under which experiments were conducted, the parameters measured, and the protocols followed. Good metadata practice helps to make sure that data is kept to the FAIR principles. When intuitively integrated into the data collection process, enriched metadata enables AI and ML algorithms to perform deep analytics at scale, and to reveal those meaningful patterns for further investigation.

Good metadata practices ensure that AI investments fully deliver on their potential, by maintaining, curating, and securing consistently high-quality data. Ensuring metadata is correctly captured and up-to-date will help researchers to harness the power of AI to enhance the intra and inter-traceability of data, and ensure that crucial historic protocols and methodologies can be

reused. By considering the underlying data engines and embedding best practices, data captured today may be used – often in unexpected ways – to drive evolving AI capabilities that will answer tomorrow's questions.

Research organizations located in India, recognized as a global IT powerhouse, are particularly well-placed to develop leading-edge data practices that will gain the maximum possible benefit from the opportunities offered by AI.

Select an AI-ready data platform

Scientists can drive their AI-readiness by ensuring a strategic approach to data, which almost certainly implies a single, unified platform. The latest software solutions rely on cloud-native technologies, provided on a SaaS subscription model that provide near-limitless scalability and offer capabilities such as an Electronic Lab Notebook, which can be enabled alongside analytics storage, templating and tagging. Ultimately, the objective is to save time and help researchers to focus on their work. ■

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GUEST COLUMN

Scalability: The Key for Biosimilar Manufacturing

Dr. Cyrus Karkaria
President, Biotechnology
Lupin Limited

When we think of medical breakthroughs, we often picture scientists in labs, complex molecules under microscopes, and the relentless pursuit of cures. Yet, behind every vial of biologic therapy lies another kind of breakthrough — one that happens not in the clinic, but on the manufacturing floor. And when it comes to biosimilars, this invisible engine of innovation is where the real battle for access and affordability is being fought.

Over the years, biologics have reshaped the treatment landscape for many chronic and life-threatening diseases. Their precision, efficacy, and potential for personalized care have steadily outpaced traditional small molecule drugs. But biologics are also notoriously expensive. And that cost is not just a function of science; it's deeply rooted in the way these therapies are developed.

From the moment a biologic begins its journey in a cell bank vial to the point it reaches a patient's hands, the process is intricate, expensive, and time-consuming. Companies developing biologics must overcome clinical equivalence requirements, complex regulations, lengthy development cycles, and high capital and operating costs. The result? Delayed access and significant financial strain on both patients and health systems.

Where Scale Meets Access

Let's consider the bigger picture. In the U.S. alone, the FDA has approved over 70 biosimilars across various therapies, with the global biologics market pegged at over USD 350 billion by 2030. Despite that, a single dose of some biosimilars can still cost patients anywhere between USD 300 and 5,000. Why? Because the cost of goods (COGS) for biosimilars continues to hover between USD 50 and 500 per gram.

To change this reality, we need to think beyond labs and clinical studies. We need to think at scale.

Scaling up manufacturing — efficiently and smartly — is not just an operational strategy. It is a moral imperative. When done right, scale brings down fixed costs, improves process consistency, and significantly reduces the cost per dose. At 10,000-liter bioreactor scale, the fixed cost burden drops dramatically compared to a 1,000-liter setup. That's the kind of cost dynamic that moves the needle for healthcare access.

A Case for Smarter, Not Just Bigger

While scale matters, how we scale matters even more.

The traditional fed-batch model has served the industry well, but it is increasingly being challenged by more

agile and high-yield approaches like perfusion-based continuous manufacturing. With this mode, not only can we increase output 5 to 10 times over, but we can also maintain a more stable and controlled environment for cell growth, leading to consistent product quality.

Combine this with innovations in continuous chromatography — especially using multi-column setups for critical steps like Protein A capture — and we have got a process that is not just efficient, but also cleaner and more predictable.

Importantly, process characterization and scale-down modeling must go hand in hand with scaling up. Regulatory agencies want assurance that products remain consistent across sites, scales, and time. That means every manufacturer must invest in understanding the critical process parameters and quality attributes of their product from the start.

Speed, Flexibility, and Market Realities

There's another dimension we cannot ignore — speed to market.

In a world where every month of delay can cost lives, modular manufacturing holds great promise. Centralized drug substance production paired with decentralized drug product filling allows for logistical agility and reduced supply chain costs. This model also supports tailored approaches for local regulations, pricing norms, and patient needs across geographies.

But none of this works unless manufacturers align science with smart economics. For instance, perfusion systems at medium scale (1,000–5,000 L) employing single-use technologies offer a great middle ground — high throughput without the capital intensiveness of traditional setups. Moreover, building modular facilities designed for plug-and-play process shifts can further reduce both time and cost.

Making Every Gram Count

At the heart of biosimilar affordability lies a simple truth: we must do more with less.

That means investing in high-yield cell lines with specific productivity exceeding 40 mg/million cells/day. This would involve reducing the dependency on expensive off-the-shelf media by switching over to cost-effective proprietary nutrient media and feeds — to be prepared using commercially available individual components. Enhancing the reuse life of expensive resins beyond 300 cycles is as important as extracting out the last drop of juice from sugarcane. It even means challenging established norms — like exploring safe and validated reuse practices for otherwise single use items like filters or finding a continuous mode of utilizing a consumable to maximize output per unit.

When manufacturers take such steps, the impact goes beyond margins. It extends to patients in remote villages in India, seniors in Europe choosing medication without the need to forego groceries, and children in Latin America whose medical conditions can now be treated early.

Lupin's Commitment: From Molecule to Market

At Lupin, we've seen this journey firsthand.

Our development of the biosimilar etanercept, used in the treatment of rheumatoid arthritis, is a case in point. From building the manufacturing process from scratch to navigating the clinical landscape and collaborating globally for commercialization, we engineered every part of the supply chain with scalability, compliance, and cost in mind.

Today, Lupin's flexible modular facilities can support various upstream and downstream modes — whether it is fed-batch or perfusion, single-use or stainless steel. This adaptability is essential as we expand our biosimilar portfolio and meet the growing global demand for affordable biologic therapies.

The Road Ahead

Biosimilar manufacturing is not just about regulatory approvals and technical capability. It is about unlocking hope — scaling up science to scale down suffering.

The goal of achieving a COGS of under USD 10 per gram may no longer be a fantasy. With high-throughput processes, next-gen analytics, and a culture of scientific innovation, it is within reach. But it requires every player in the ecosystem — industry, regulators, healthcare providers — to reimagine what is possible.

At the end of the day, biosimilars must do more than just mimic the originator. They must lead the way — towards a future where healthcare is not just effective, but equitable as well. ■

India's Emergence as a Global CDMO Alternative

In pharmaceutical manufacturing, water is rarely the headline act. Yet at some of India's leading pharmaceutical organizations, water system management is becoming a key pillar of digital transformation – with predictive intelligence, operational agility, and environmental stewardship.

Shoeb Kurawadwala, Founder & Managing Director, CN Water emphasizes that select set of pharmaceutical organizations are fundamentally transforming how they monitor, maintain, and optimize their purified water systems using the company's remote monitoring platform. They are turning reactive clean utility management into a **real-time, intelligent system** that now helps drive uptime, compliance, and sustainability across its operations.

The global pharmaceutical outsourcing landscape is shifting — quietly but decisively. For over two decades, China has been the go-to partner for U.S. and European drug developers looking to scale research and manufacturing affordably. This paradigm is now shifting.

The U.S. BIOSECURE Act, which is likely to become law soon, will prevent federal agencies from contracting with firms using biotech infrastructure from certain Chinese entities. While the Act is narrowly focused, its implications extend far beyond the U.S. government. Biotech companies — especially those with global ambitions or U.S.-based clinical programs — are beginning to rethink their outsourcing footprint. That re-evaluation is creating space for new partners.

India is emerging as one of the most credible contenders to step into this gap.

Why India Now

The first thing that works in India's favour is scale. With over 585 FDA-approved facilities and more than 2,000 WHO-GMP-compliant sites, India already has the infrastructure footprint to match global demand. There's also a meaningful cost advantage — estimates suggest that manufacturing costs in India are around 60-70% lower than in the U.S. or Europe, even after accounting for compliance and quality investments.

But the more interesting story lies in how Indian CDMOs have evolved. A decade ago, most players were focused on generics — contract manufacturing, low-cost APIs, and volume-driven deals. Today, several mid-sized and large CDMOs are building capabilities in high-potency APIs, sterile injectables, biologics, and early-stage development. Some have begun offering end-to-end services, from discovery through commercial manufacturing.

What's Driving This Shift

India's positioning isn't just about filling a vacuum left by China. Several longer-term trends are converging:

- **The nature of pharma outsourcing has changed.** What used to be a cost arbitrage play has now become a capability and risk-diversification decision. Companies want partners who can meet global regulatory expectations, work flexibly across modalities, and scale quickly.

- **There's more capital available.** Indian CDMOs are drawing significant interest from private equity. Platforms like Cohance, Viyash, and Sekhmet have emerged post covid with significant PE backing and are consolidating the space by acquiring smaller players. There's also much more capital available for mid and larger sized players to establish newer capabilities and also expand capacity.

- **Policy tailwinds are strong.** Government schemes like the Production Linked Incentive (PLI) programme have made greenfield expansion more viable. There's also been progress on IP, regulatory alignment, and export infrastructure — areas where India lagged in the past.

Capability Building Still Has a Long Way to Go

Despite the momentum, there are gaps. India has world-class infrastructure in small molecules, but capabilities in biologics, cell and gene therapies, and novel modalities remain limited to pockets. A handful of players have made early investments — in microbial fermentation, CGT pilot facilities, and oligonucleotide synthesis — but the ecosystem isn't yet deep or broad.

Talent is another constraint. India produces more than 200,000 pharmacy graduates each year, but very few of them are trained in advanced manufacturing or bioprocessing. Without a sharp focus on upskilling and better integration between academia and industry, this will remain a bottleneck — especially as global demand moves toward biologics.

There's also a branding challenge. Many Indian CDMOs continue to position themselves as "manufacturers" rather than as development partners. That mindset may limit their ability to win high-value contracts, particularly in early-phase work where clients are looking for technical collaboration, not just execution.

What Global Biopharma Is Looking For

From conversations with pharma executives and biotech founders, a few themes come up repeatedly. Speed matters — not just in manufacturing, but in tech transfer, documentation, and regulatory responses. Flexibility is valued — particularly for smaller firms that need support across functions, not just a production slot. And trust is critical — clients want visibility, responsiveness, and assurance that their IP and timelines will be protected.

The Indian CDMOs that are winning today tend to deliver on all three. They have audit-ready sites, a responsive BD team, and the ability to navigate client-side complexity. Some are even helping clients with regulatory filings and offering scientific input into formulation and process development — something that was rare just a few years ago.

A Unique Opportunity — If Acted Upon Decisively

There's no question that the global CDMO industry is undergoing a reset. Supply chain risk, regulatory pressure, and political priorities are forcing companies to look beyond traditional partners. India is in a strong position — but this window won't stay open forever.

The challenge now is to scale thoughtfully. That means:

- **Investing in biologics and complex modalities**, not just adding more capacity for APIs or generics.
- **Building differentiated capabilities -** in formulation science, sterile injectables, high-containment facilities
- **Fixing the talent pipeline through industry-** led training programs and better collaboration with universities and research institutes.
- **Positioning more credibly in global markets —** including better communication of scientific strengths, compliance record, and client success stories.

India has long been an essential part of the global pharmaceutical value chain. But the CDMO opportunity now on the table is different – it requires investment and policy changes to make the ecosystem more attractive.

For Indian CDMOs, this is a rare chance to move up the value chain — and to become a core part of how global biopharma is built. ■

Author

Rakesh Gupta
Managing Partner
LoEstro Advisors

Biotechnology: Today and Tomorrow

Biotechnology, a field rooted in ancient practices like plant & animal domestication, alcohol fermentation using yeasts, Sauerkraut preparation, pickling, bread manufacture, Cheese fermentation etc. has evolved dramatically with modern advancements and high level of automated systems. Today, it encompasses a wide range of applications, from genetic engineering, sequencing, metagenomics, CRISPER technology, manufacture of protein therapeutic molecules using recombinant clones and cell therapies to nanotechnology.

Dr. Vishal G. Warke, Director, Cell Biology, HiMedia Laboratories Pvt. Ltd and Dr. Girish B. Mahajan, Senior Vice President, Microbiology, HiMedia Laboratories Pvt. Ltd emphasizes about how Biotechnologies is essential in addressing human needs across medicine, agriculture, forensics, bioremediation, and biosecurity.

Recognized as a major contributor to India's goal of a USD 5 trillion economy by 2047, India's BioE3 Policy aims to foster innovation and sustainability through initiatives in bio-based chemicals, precision biotherapeutics, climate-resilient agriculture, and advanced marine research, positioning India as a global biotechnology leader by enhancing economic, environmental, and employment impacts. Let us walk through some aspects of Biotechnology today and in future.

History and Evolution of Biotechnology

Biotechnology has evolved through centuries, beginning with ancient fermentation techniques used to make bread & alcohol and selective breeding in agriculture. In 1865, Gregor Mendel's discoveries in genetics established fundamental laws of heredity. The field took a quantum leap in 1953 with Watson and Crick's discovery of the DNA double helix, sparking advances in genetic research. The 1970s marked the development of recombinant DNA technology, which allowed scientists to splice genes and laid the groundwork for genetic engineering. The 1980s brought transformative tools like the Polymerase Chain Reaction (PCR), which enabled the amplification of DNA sequences, and the first genetically modified organism (GMO), showing the potential of transgenic technology in agriculture.

In 2003, the Human Genome Project successfully mapped the human DNA sequence, accelerating research in genomics and precision medicine. By 2010, synthetic biology achieved the creation of the first synthetic cell, highlighting the potential to design life at a genetic level. In 2012, CRISPR-Cas9 emerged as a groundbreaking gene-editing tool, allowing precise genetic modifications and opening new possibilities in medicine and agriculture. In 2015, CAR-T cell therapy provided a revolutionary approach to treating certain cancers by reprogramming patients' immune cells. The development of lab-grown meat in 2016 represented a major milestone in food biotechnology, with potential to address food security and sustainability.

In 2018, the creation of the first CRISPR-edited babies in China sparked global ethical debates on human genetic modification. From 2019 to 2021, mRNA vaccines, notably used in the COVID-19 pandemic, demonstrated the power of rapid, scalable biotechnology solutions for global health crises. In 2023, artificial intelligence integrated into biotech, accelerated drug discovery and diagnostics. Biotechnology today

encompasses a continuum from ancient fermentation practices to cutting-edge genetic engineering and biopharmaceutical innovations. It plays a transformative role across sectors like healthcare, agriculture, and environmental sustainability, positioning itself as an indispensable tool for addressing complex global challenges and advancing scientific progress.

Today's Advancements in Biotechnology

Biotechnology, an evolving blend of biological and technological sciences, is at the forefront of addressing some of the world's critical challenges. Rooted in applications across agriculture, healthcare, cosmetic & other industry, and the environment, biotechnology uses sophisticated techniques like synthetic biology and CRISPR gene editing to revolutionize numerous sectors, with promising advances emerging across various specialized fields. Core Areas of Biotechnology today include following.

Synthetic Biology

It focuses on the design and engineering of new biological systems, leveraging genetic modifications and DNA editing. Notable advancements include CRISPR, a tool revolutionizing genome editing. Expected to gain traction in 2024-25, CRISPR-based treatments for conditions like sickle cell anemia and gene editing workflows from several companies hold potential to transform healthcare. An application of synthetic biology is, also in creating biofuels. Typically, this is done by hacking a microbe's metabolism to transform plant waste into fuel. For example, a common yeast, *Pichia pastoris,* has been modified to break down renewable carbon sources into fuel.

Agricultural Biotechnology

Biotechnology plays a critical role in improving agricultural productivity. Through genetic modifications, scientists have developed crop variants with enhanced resistance to pests, weeds, and extreme climates. Such innovations reduce dependence on harmful pesticides and improve yields, offering sustainable food production solutions. Biopesticides, derived from natural materials like plants, animals, and minerals, represent a safer alternative to synthetic pesticides, promoting environmentally friendly practices in farming. Transgenic Bt corn is an outstanding example of successful application of genetic engineering in agriculture. It produces its own insecticide and contains a gene from the bacterium *Bacillus thuringiensis.*

The use of Bt varieties has dramatically reduced the amount of chemical pesticides applied to cotton. Golden Rice is produced by inserting two genes from daffodil and one gene from a bacterium into rice plants so that the rice becomes capable of synthesizing β-carotene, the precursor of vitamin A. Biotechnology researchers at the University of Pennsylvania have discovered that the overexpression of a gene, GRP8, increases the production of root hairs and thus, increased the surface area for water and nutrient absorption. The overexpression of this glycine-rich RNA-binding protein has also been found to improve plant tolerance to phosphate starvation, enhancing resistance to environmental stresses and reducing the need for fertiliser.

Environmental Biotechnology

Extending beyond agriculture, environmental biotechnology focuses on ecosystem conservation and restoration. It encompasses strategies for the safe disposal of farm waste and the development of sustainable crops. Through bioremediation techniques, contaminants in soil and water are mitigated, contributing to healthier ecosystems and aiding in climate change mitigation. Environmental biotechnology is widely adopted by the modern industrial sector for

cost-efficient green production and to reduce the environmental hazards. Some major processes and applications include biomarkers, bioenergy, agriculture, pulp and paper industry, and bioremediation and biotransformation. Eight promising biotechnology tools were selected by experts as potentially impactful game changers: (i) the Wood–Ljungdahl pathway, (ii) carbonic anhydrase, (iii) cutinase, (iv) methanogens, (v) electro-microbiology, (vi) hydrogenase, (vii) cellulosome and, (viii) nitrogenase. Their respective roles were well explained in review by Werner Fuchs et al (2023, https://doi.org/10.3390/microorganisms11061514).

Industrial Biotechnology

Combining sustainability and industrial utility, this branch aims to replace conventional industrial processes with eco-friendly alternatives. Biofuel production, ranging from ethanol and biodiesel to methane, exemplifies this effort. Additionally, scientists are creating biodegradable materials from renewable resources like starch and cellulose, replacing conventional plastics and reducing environmental pollution. Missouri and Kansas, with their agricultural and manufacturing strengths, exemplify regions where such innovations can drive sustainable economic growth, generate jobs, and reduce fossil fuel dependence. Environmental biotechnology is widely adopted by modern industrial sector for cost-efficient green production and to reduce the environmental hazards. Some major processes and applications include biomarkers, bioenergy, agriculture, pulp and paper industry, and bioremediation and biotransformation. India is among the top 12 destinations for biotechnology worldwide. The Department of Biotechnology (DBT), under the Ministry of Science and Technology, has placed great emphasis on developing an ecosystem for the development of excellence and research in a variety of biotechnology fields in India.

By creating and using a variety of tools at its disposal, such as vaccines, antivirals, diagnostic tests, and other tools, the biotechnology industry has been at the forefront of the fight against the Covid-19 pandemic.

Medical Biotechnology

In healthcare, biotechnology is pioneering approaches like precision medicine, which tailors treatments based on a patient's genetic makeup. Biopharmaceuticals, such as bi-specific antibodies and oligonucleotide therapeutics, are advancing cancer and genetic disease treatments, marking significant progress in personalized medicine. These therapies target diseases at a molecular level, offering new hope for conditions previously deemed untreatable. Cancer treatment holds a dominant position in the medical biotech market, with companies like Pfizer and IBM leading in areas like immuno-oncology research.

Developing new medicines is a complex, costly, and time-intensive endeavor, with only a small percentage of drugs ultimately gaining regulatory approval. To improve efficiency, AI and machine learning are increasingly used to enhance early-stage predictions about a molecule's performance, potential effectiveness, and toxicity. Even a minor increase in success rates can translate into significant cost savings for biotech companies. Personalization has become a key trend in modern healthcare, where genomic medicine, particularly pharmacogenomics, enables customized treatment by analyzing the relationship between individual genetic variations and drug response. This collective effort across biotech teams—scientists, researchers, and data technology experts—is driving transformative advances in products and therapies that positively impact the health and lives of millions worldwide.

Ethical and Societal Considerations

With biotechnology's profound capabilities come ethical considerations, particularly in areas like gene editing and stem cell research. Ethical guidelines underscore the importance of protecting human subjects in clinical trials, ensuring affordability and accessibility of biotech solutions, and safeguarding genomic privacy. Addressing potential bioterrorism threats and navigating sensitive areas like stem cell research require careful adherence to ethical standards to maintain public trust and foster responsible innovation.

Biotechnology in Tackling Global Issues

Biotechnology is instrumental in addressing global issues like food security and climate change. Modified crops are being developed to withstand harsh conditions, while animal breeders are using biotechnology to enhance livestock traits, both contributing to a more resilient food supply chain. In the energy sector, methane capture from agricultural waste exemplifies how biotechnology can provide renewable energy sources while reducing greenhouse gas emissions. As climate change intensifies, biotechnology's role in mitigating environmental impacts and promoting sustainable practices becomes increasingly vital.

Future Scope in Biotechnology

Synthetic Biology is a way of engineering living systems for creating bio-based materials, sustainable alternatives, and programmable organisms. It is a rapidly advancing field within bioengineering and is driven by cutting-edge innovations in laboratory techniques and equipment. This discipline enables microbiologists and geneticists to design new biological systems with unprecedented speed and precision by streamlining living cells into simplified forms known as chassis. Real-world applications of synthetic biology are already making significant impacts across diverse sectors, from cosmetics to the development of sustainable fuels. Each industry is leveraging synthetic biology's versatile potential to pioneer novel, application-specific solutions.

In the area of Gene Therapy and Regenerative Medicine, the rapid advancement of biological methodologies over the past decade has generated substantial interest in the regeneration of human tissues. Breakthroughs in stem cell research, gene therapy, and tissue engineering have significantly propelled tissue and organ regeneration technologies forward. However, despite notable progress, several technical challenges remain, particularly regarding the clinical application of gene therapy. The goals of gene therapy include enabling cells to produce essential proteins, silencing the expression of overactive proteins, and genetically modifying or repairing cellular functions that impact disease conditions.

Nanobiotechnology involve use of nanomaterials for drug delivery, enhancing plant growth in agriculture, and next-generation vaccines. Researchers and companies are pioneering novel nanomaterials and expanding the applications of nanotechnology across various fields. The development of green nanotechnology and cost-effective solutions will further support the integration of these advancements. In healthcare, nanobots enable precision surgeries and significantly improve patient care, while nanotechnology also enhances the efficiency and targeting of drug delivery systems.

Biotechnology in space exploration, including synthetic biology for life support systems and space agriculture for long-term space missions. Unraveling the mysteries of space is no longer confined to science fiction; biotechnology has become instrumental in advancing space exploration by addressing critical challenges like astronaut health, and food and water scarcity. By merging biology, engineering, and space science, biotechnology provides innovative tools and techniques that enhance astronauts' adaptability and resilience in extreme environments. This fusion supports sustainable and efficient exploration, enabling higher-impact missions beyond Earth's orbit.

Further trends and scope in biotechnology

Several forward-looking trends signal biotechnology's evolving landscape. Artificial intelligence (AI) and machine learning (ML) are being integrated into biotech research, enabling advancements in data analysis, drug discovery, and personalized medicine. Bioprinting and tissue engineering are pioneering developments with the potential to address organ shortages and advance regenerative medicine. Mergers and acquisitions are expected to shape the industry's financial landscape, increasing consolidation among biotech companies. Additionally, firms are increasingly partnering with specialty contract research organizations (CROs) to expedite innovation while managing costs.

In a recent interview with Labiotech, Bill Coyle, Principal at ZS, shared insights on 2023 biotechnology trends and priorities. He highlighted cancer, antimicrobial resistance, and sepsis as key areas of transformative potential, while also noting biotech's expanding role beyond life sciences, with promising applications in tackling climate change and enhancing food security. Despite challenges, ground breaking health initiatives driven by biotechnology are poised to reshape our future, addressing critical global issues across health, medicine, and agriculture. ■

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Pharmaceutical Market in India – The sector of opportunities

Amid global challenges about healthcare accessibility and affordability, India has emerged as a promising leader with aspirations to be the "Pharmacy of the World." The country's pharmaceutical sector is renowned for its combination of quality and affordability, serving as a lifeline for millions of patients worldwide. **Sagar Pawar, Partner and Lead for Life Sciences & Medical Devices, KPMG in India** emphasizes about the dynamics of the Indian pharmaceutical sector, highlighting its growth opportunities, and substantial impact on the global healthcare landscape.

Sagar Pawar
Partner and Lead for Life Sciences & Medical Devices
KPMG India

Industry studies show that India currently ranks as the third-largest pharmaceutical industry in volume and the fourteenth largest by value, holding a significant share of global generic exports.

Growth of the Healthcare Sector

India's healthcare market, valued at USD 181 bn in 2023, is poised for remarkable growth. Projections show a CAGR of 12% and is expected to reach. Projections show a CAGR of 12% and is expected to reach USD 394 bn by 2030.

Several key factors drive this expansion:

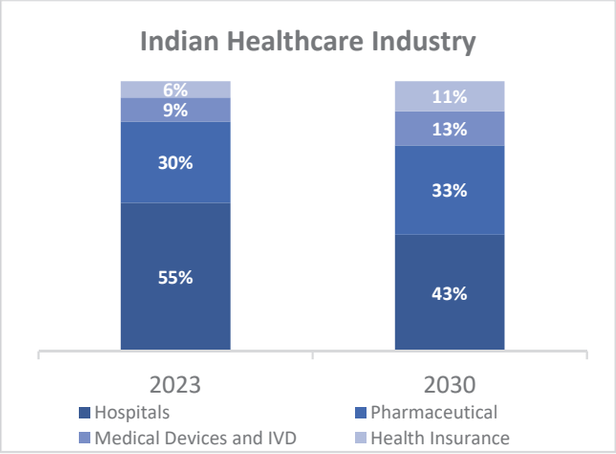
- An ageing population
- Increasing chronic disease burden
- Heightened healthcare spending
- Proactive government initiatives

Indian Pharmaceutical Market

API Market: Valued at USD 13 Bn in 2023, it's projected to grow at an 8.3% CAGR, reaching USD 23 bn by 2030. Growth is driven by increased exports and reduced dependence on China, supported by government incentives like the PLI scheme and drug park developments.

CRAMS Market: Valued at USD 16 bn in 2023, it's expected to grow at a 12% CAGR, reaching USD 35 bn by 2030. Opportunities in vaccines, HPAPIs, peptides, and sterile injectables are driving growth. Favorable policies and emerging high-value segments could bolster this market.

Formulations Market: Valued at USD 55 bn in 2023, its set to grow at a 10% CAGR, reaching USD 130 bn



Note: Break-up of the market share for each segment of the healthcare industry [1]

by 2030.3 The sector thrives on diverse therapeutic areas and government support through 'Make in India' schemes. Challenges include regulatory compliance, pricing pressures, and competition from MNCs.

The industry is focused on generic medicines, representing about 97% of total revenues

Domestic Market Dynamics

The domestic pharmaceutical market commands a 54% share, primarily due to lower production costs and the availability of skilled human resources. The top ten therapeutic areas contribute collectively to 65% of the market, with cardiac therapies leading domestic sales at USD 3.2 Bn.

Export Market Dynamics

During FY24, drug formulations and biologicals constituted a significant share of 78% of pharmaceutical exports. The United States remains the leading export destination, accounting for over ~32% of total exports.

Regulatory Landscapes

Drug regulation in India is a complex process managed mainly by the Drugs and Cosmetics Act of 1940 and by multiple ministries, including the Ministry of Health and Family Welfare. In recent years, the GoI has taken multiple measures to promote domestic manufacturing capabilities, such as the PLI scheme, manufacturing clusters, and 100% FDI, along with increased coverage of the PMJAY scheme for citizens over 70+ years.

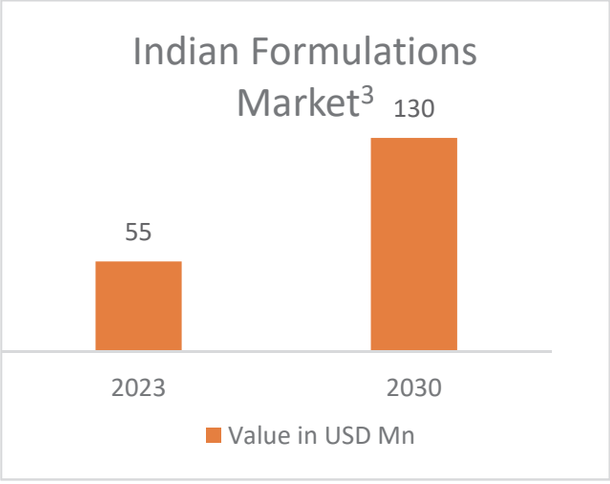
Challenges and Drivers

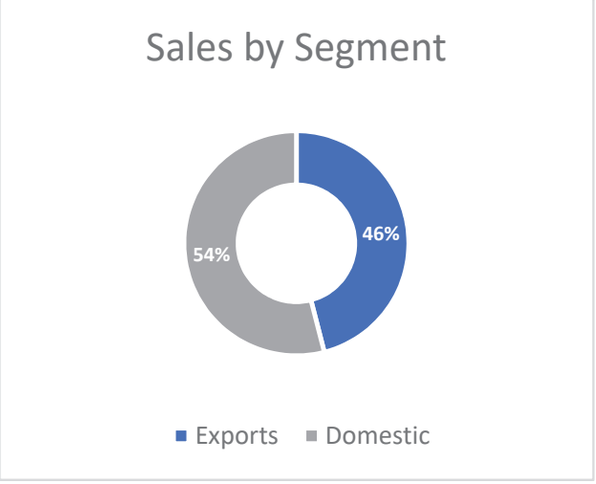
Despite its impressive growth trajectory, the industry faces significant challenges, including a high dependence on imported Active Pharmaceutical Ingredients (APIs). This reliance raises concerns about self-sufficiency and competitive pressures in global markets, emphasizing the need for continuous innovation and strict regulatory compliance.

However, promising growth drivers, such as government initiatives, aim to reduce import dependency while boosting local manufacturing capabilities. These initiatives, coupled with strategic partnerships, reinforce India's global pharmaceutical position.

Growth Opportunities

Indian pharmaceutical companies are leveraging strategic partnerships, technology, and regulatory shifts to drive growth domestically and internationally.





Note: Break-up of the market share for each segment of the formulation market in 2023 [5]

Regulatory Shift	Details	Goal
Atmanirbhar Bharat (Make in India) and PLI Schemes/ Promotion of Bulk Drug Parks	Launched a PLI scheme (~$770 Mn) in 2020 focused on the promotion of domestic manufacturing of Key Starting Materials (KSMs) or Drug Intermediates (DIs), and Active Pharmaceutical Ingredients (APIs). This was followed by PLI 2.0 scheme covering other API and formulations. Development of Bulk drug parks to create conducive ecosystem & shared cost for being cost competitive in API manufacturing	Reduce import dependency on China and promote indigenous manufacturing of API Enabling backward integration of the Indian Pharmaceutical players driving more cost competitiveness in their generic formulations through captive consumption
Controlled FDI	100% FDI allowed for greenfield investments. For brownfield investments up to 74% is allowed under the automatic route scope to increase to 100% through government approvals	Attracting foreign investment and creating conducive environment for domestic manufacturing
Overhaul of the approval process by DoP	The proposed policy includes shift to a system of 'Single window' and 'deemed approval' aims to reduce the time for regulatory approvals of innovative products.	Promoting innovation and expedited drug approval thereby reducing the time to market
IP Rights Evolution	Simplification of procedures, allowing expedited examinations to various categories of applicants, electronic certificate delivery, videoconferencing, automatic allotment of examiners, automating renewal etc.	Increase in number of patent applications and grants

Strategic Partnerships & Collaborations

- MNCs planning to launch innovative drugs from their global pipeline seek local sales know-how and market expertise to drive their product penetration in the Indian market.
- MNCs have leveraged the established infrastructure and local expertise of Indian pharma companies to get into co-marketing, in-licensing, manufacturing, or sales & distribution partnership opportunities with established Indian companies.

Rx to OTC Strategy

- MNCs planning to launch innovative drugs from their global pipeline seek local sales know-how and market expertise to drive their product penetration in the Indian market.
- MNCs have leveraged the established infrastructure and local expertise of Indian pharma companies to get into co-marketing, in-licensing, manufacturing, or sales & distribution partnership opportunities with established Indian companies.

Inorganic asset acquisition for growth

- While MNCs are hiving off non-core assets, Indian pharma companies have invested in acquiring strategic smaller assets (domestically and internationally) for relatively minor valuations, allowing them to capitalize on newer opportunities and geographies to drive growth.
- Key focus by these Indian players for these acquisitions are portfolio expansion and penetration into specialty segments.
- Moves are more aligned with the financial health and cash generated by the companies and the availability of brands or assets in the US and Europe being divested by multinationals for strategic reasons.

Patent Expiry

- The patent cliff is estimated to be USD ~$300 Bn by 2028 and presents a substantial opportunity for generic companies to capture the market, share and generate revenue.

Value chain element	Feature	Impact
R&D	AI & ML	Streamlining research and speeding up drug discovery processes.
Manufacturing	Internet of Things (IoT)	Streamlined production processes, improved product quality and reduces operational costs
Supply chain Management	Blockchain	Reducing the risk of counterfeit drugs entering the market and ensuring transparency
Sales & Marketing	Data analytics and digital marketing	Enhanced customer engagement, driven sales, and improved brand visibility
Regulatory Compliance & Quality control	AI and big data analytics	Lessen the risk of non-compliance and elevates the overall quality

- With significant patent cliff opportunities in the coming years, Indian pharma companies are already strengthening their generics pipeline for the developed markets.
- India has nearly 1400 WHO-GMP-approved Pharmaceutical Plants, and 253 European Directorate of Quality Medicines (EDQM) approved plants , indicating strong, established infrastructure and technical know-how.
- Indian pharma companies cater to 40% of the US's generic medicine demand, 25% of the UK's medicine demand, and 60% of global vaccine production, indicating dominance and penetration across the globe.

Leveraging Technology to optimize the value chain process flow

- Technology has significantly transformed the Indian pharmaceutical market by enhancing efficiency, productivity, and innovation.
- In recent years, Indian pharma players have heavily invested in research and development, utilizing advanced technologies such as AI, machine learning, and big data analytics to improve drug discovery and development.

Biologicals and biosimilars

- The biopharma industry in India has grown significantly in recent years, and its impact on healthcare is becoming increasingly significant. India's pharmaceutical industry benefits from lower drug development costs, taking only 3-5 years for biosimilars compared to 8 years in the EU, at a lower cost.
- Key Indian pharma players are innovating and entering international markets, while India fulfils over 50% of global vaccine needs, driven by substantial R&D funding.
- Government initiatives aim to boost domestic API manufacturing and biotechnology innovations, further enhancing India's position in the biologicals market.

Biosecure Act 2024

- The Biosecure Act, also known as H.R. 8333, was introduced by the United States Congress in 2024.
- This law seeks to enhance the nation's biosecurity by limiting federal funding or contracts with certain biotechnology companies that have ties to nations of concern.
- This presents an unprecedented opportunity for Indian pharmaceutical companies to expand their global footprint.

PE- VC investment landscape

- With increasing domestic manufacturing capabilities and in-house innovation, recent years have witnessed increased M&A and PE investments in Pharma and Biotechnology.
- Pharma has witnessed an investment of USD 690 Mn and Biotechnology has witnessed USD 92 Mn as of quarter 3 of 2024.

Conclusion

In conclusion, the Indian pharmaceutical industry is on a robust growth trajectory, supported by favourable government policies, strong R&D capabilities, technological advancements, and expanding market opportunities. By leveraging these growth levers and addressing the challenges, the industry is well-positioned to achieve sustained growth and contribute significantly to global healthcare. ■

Contract Development and Manufacturing Organizations in India's Pharma Sector: A Growth Catalyst

India's pharmaceutical market (IPM) has witnessed rapid growth, recording a 9.0% CAGR over the last five years, with projections indicating a 9.6% CAGR until FY28. The market is expected to grow from ₹ 1,317.5 billion in FY19 to ₹ 2,852.6 billion by FY28, driven by an increasing chronic disease burden, urbanization, and a growing aging population. These factors have made India an attractive destination for pharmaceutical companies seeking cost-efficient and reliable manufacturing solutions.

Arushi Jain, Director - Growth and Excellence, Akums Drugs and Pharmaceuticals emphasizes about CDMO industry playing an important role in driving innovation in existing therapies to address unmet needs. She also spoke about the challenges and outlook for India's CDMO sector.

Contract Development and Manufacturing Organisations (CDMOs) play a pivotal role in supporting this growth. Offering cost reductions, scalability, and compliance with global standards, Indian CDMOs enable pharmaceutical companies to focus on core activities such as R&D and marketing. Leading firms like Akums are driving innovation, particularly in complex formulations and emerging therapeutic areas like injectables and oral solid dosages, which dominate the domestic market.

CDMOs also help multinational corporations overcome India's unique regulatory landscape, providing a streamlined approach to market entry and production. Most of the leading pharmaceutical companies In India are now increasingly rely on CDMO partners to meet growing demand, highlighting the sector's crucial role in India's pharma ecosystem. With a focus on efficiency and quality, Indian CDMOs are well-positioned to continue their growth trajectory, contributing to the country's status as a global pharmaceutical manufacturing hub.

Scaling Global Impact

In the global CDMO landscape, companies of various scales bring unique strengths to the industry. For instance, Lonza, a prominent CDMO, serves over 7,000 customers worldwide, highlighting its extensive capacity. Regional players like Procaps Group, with a focused client base of around 120, demonstrate the impact of a more specialized approach. Likewise, Indian CDMOs such as Akums have achieved notable growth, now reaching over 1,500 clients. Catalent, another key player, serves approximately 1,200 customers, illustrating the breadth of service models that contribute to the sector's ability to meet diverse customer needs worldwide.

Why third-party manufacturing is important

Third-party manufacturing, particularly through CDMOs, is vital for pharmaceutical companies looking to stay competitive. Outsourcing the manufacturing process enables these companies to focus their resources

on core areas such as research, development, and marketing. CDMOs offer the expertise, infrastructure, and scalability required to meet the high demands of drug production. This model has become increasingly important in the global pharmaceutical landscape, and India's CDMO sector is at the forefront of this evolution.

India offers an up to 40% reduction in operational and production costs compared to other global regions, making it a go-to destination for pharmaceutical companies looking to optimise expenses while maintaining quality and adhering to regulatory standards. Multinational corporations have been particularly attracted to India for this reason, especially as the country's regulatory environment continues to improve, further enhancing its appeal as a manufacturing hub.

The rising demand for injectable drugs, particularly in oncology and other high-value therapeutic areas, has driven the need for specialised CDMO services. Injectable formulations offer higher returns due to their therapeutic efficacy, which makes them attractive for both pharmaceutical companies and manufacturers alike. The complexity of producing these formulations underscores the growing importance of CDMOs, who possess the requisite skills and infrastructure to meet these specialised production demands.

Indian CDMOs are also playing a crucial role in supporting late-stage clinical trials, particularly for pharmaceutical products destined for highly regulated markets like the US and Europe. The Drug Technical Advisory Board's (DTAB) decision to waive late-stage clinical trial requirements for certain drugs from these markets has significantly lowered costs, making India an attractive destination for pharmaceutical outsourcing and innovation.

Accelerating innovation in pharma

India's CDMO industry plays an important role in driving innovation in existing therapies to address unmet needs. The sector is increasing focus on manufacturing by engaging in research and development, focusing on improving therapeutic options and patient outcomes. By utilizing new technologies and expertise, Indian CDMOs contribute to developing solutions that meet the changing demands of healthcare, helping to ensure that patients have access to effective treatments tailored to their specific needs.

A notable instance of innovation includes the recent development of India's first Advanced Anti-Reflux Antacid, a Sodium Alginate + Potassium Bicarbonate Chewable Tablet, approved by the Drugs Controller General of India (DCGI). This formulation offers effective relief for acid reflux patients. Also, the launch of Rabeprazole + Levosulpiride SR Capsules marks a breakthrough for gastrointestinal tract (GIT) disorders, being the first time such a formulation has been made available in India. Both products reflect how CDMOs are playing a pivotal role in bringing novel treatments to the market.

Another example is the approval of Hydroxyurea Oral suspension by Akums. Akums is advancing pharmaceutical innovation with its production of Hydroxyurea, a key medication used in the management of sickle cell anemia. By leveraging its cutting-edge manufacturing facilities, Hydroxyurea exemplifies therapeutic advancements and addressing unmet medical needs in both domestic and international markets. Similarly, the development of Estradiol + Progesterone Capsules for menopause relief, the first FDA-approved bio-identical combination hormone therapy, scores a major advancement in women's health.

Growing demand for nutraceuticals in preventative health

Nutraceuticals and functional foods are gaining momentum as global demand for preventative health solutions rises. These products, ranging from vitamins to gummies, cater to various demographic groups, addressing health concerns such as immune support, cognitive function, and overall wellbeing. Nutraceuticals designed specifically for women, children, and the elderly are becoming increasingly popular. CDMOs in our country have been pivotal in introducing innovative products, especially for women in prenatal and postnatal phases. These include prenatal vitamins containing essential nutrients like folic acid, calcium, and DHA, which are critical for fetal development. Postnatal supplements help nursing mothers replenish vital nutrients like vitamin D and iron and even support breast milk production. Additionally, CDMOs have

developed nipple sore creams to address common issues faced by breastfeeding mothers, offering relief and helping prevent cracked skin.

The market for nutraceuticals has also expanded into skincare, with products infused with collagen and hyaluronic acid witnessing popularity for promoting healthy skin and hair. Probiotics and prebiotics, essential for digestive health, are also on the rise. New forms like mouth-melt powders and gummies are preferred for their convenience, taste, and rapid absorption. Gummies, in particular, are popular among children, often featuring playful designs and natural sweeteners like stevia.

CDMOs facing challenges in India

India's CDMO sector is on a growth trajectory, with immense potential for expansion. However, like any dynamic industry, it faces opportunities for improvement. Adhering to stringent regulatory requirements, particularly for quality control and approvals of small molecules and biologics, encourages CDMOs to enhance their standards.

Rising raw material costs present challenges, but this also creates an opportunity for CDMOs to innovate, optimize processes, and increase cost-efficiency. Investing in technological upgrades and operational improvements is crucial for staying competitive. Moreover, with stronger support from both government and private sectors, the industry can unlock further potential in research and development. Such initiatives will empower CDMOs to introduce novel therapeutics and specialized formulations, propelling India's role as a global pharmaceutical leader.

Future prospects and path ahead

The outlook for India's CDMO sector is promising, with several factors contributing to its continued growth. The COVID-19 pandemic significantly spiked the demand for vaccines, antiviral drugs, and medical products, prompting pharmaceutical companies worldwide to turn to Indian CDMOs for expanded production. Additionally, geopolitical tensions such as the Russia-Ukraine war disrupted global supply chains, yet Indian CDMOs have shown resilience by diversifying sources and concentrating on domestic production capabilities.

The rising demand for biologics, injectables, and advanced therapies, coupled with increased investments in the sector, will likely sustain future growth. Government initiatives like the Production Linked Incentive (PLI) scheme provide financial support, promoting the production of essential starting materials (KSMs), active pharmaceutical ingredients (APIs), and other components. This initiative strengthens India's position as a global manufacturing hub while encouraging growth across both large corporations and SMEs.

Collaboration between private companies and government bodies is further fueling the CDMO sector. Strategic partnerships within the pharmaceutical industry, along with public-private partnerships (PPPs), are enhancing India's global competitiveness in drug development and production.

By adapting to trends like personalised medicine and sustainable practices, CDMOs that invest in advanced technologies will be well-positioned to thrive. As the global healthcare landscape evolves, Indian CDMOs will remain crucial in driving medical innovation and ensuring the efficient production of life-saving treatments. ■

Author

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Advancing Biopharma: Cutting-Edge Technologies That Are Transforming the Scope of Biopharmaceutical Manufacturing

Biopharmaceuticals represent some of the most promising therapeutic approaches in modern medicine, providing targeted and effective treatments for conditions once deemed untreatable, as well as for emerging infectious diseases.

Alex Del Priore, Senior Vice President, Manufacturing Services, Syngene International. emphasizes about the technologies that is transforming Biopharma industry. He also spoke about how contract research organisations (CROs) can benefit from Artificial intelligence (AI).

As the demand for these therapies increases in the post-pandemic era, the biopharmaceutical contract manufacturing market plays a crucial role in ensuring their availability and accessibility. The market is expected to grow at a CAGR of 7.38% from 2024 to 2030, reflecting the industry's rapid evolution driven by new technologies and methodologies. However, biopharma development remains complex, lengthy, and costly. Traditional methods can span over a decade in the journey from discovery to market, with low success rates and high financial investment.

Recent advancements, particularly in artificial intelligence (AI), machine learning (ML), and data-driven innovation, are transforming the biopharma ecosystem, making processes faster, more efficient, and scalable. In this article, we will explore how these technological advancements are streamlining drug discovery, enhancing process efficiency, and creating new possibilities in biopharmaceutical manufacturing.

AI-driven innovations in drug discovery

Artificial intelligence (AI) has significantly changed how researchers approach drug discovery. Early on, AI primarily aided in data processing, but recent advances have introduced machine learning models capable of analyzing massive datasets, identifying patterns, and providing actionable insights. These improvements in data processing power and algorithmic sophistication have accelerated every phase of drug discovery, from target identification to clinical trial optimization.

Let us look at each of these in detail

Target identification

Identifying a disease-associated molecular target is the first step in drug discovery. This process has traditionally relied on lengthy research, where candidates often fail in clinical trials due to issues with efficacy or safety. AI-driven systems, however, allow scientists to analyze large biological data repositories, identifying high-potential therapeutic targets by assessing multiple parameters simultaneously. By examining genetic data, patient records, and even medical literature, AI algorithms can prioritize disease targets more effectively and with greater accuracy, ensuring that resources are spent on the most viable candidates.

Lead optimization

Once a target is identified, researchers focus on finding lead compounds that could influence it therapeutically. Here, AI algorithms streamline the process through virtual screening and predictive modelling. AI optimizes the design-make-test-analyze (DMTA) cycles by

predicting how different molecules might behave in the body, how they could be optimized for efficacy, and their likely safety profile. This allows for faster iteration and refinement of promising leads, reducing the overall time spent in this critical phase.

Preclinical testing

Preclinical testing assesses a compound's safety and efficacy before it reaches human trials. AI's predictive capabilities in pharmacology enable researchers to anticipate potential side effects or toxicities. By modelling interactions in silico, AI provides a safer pathway toward clinical trials by screening out compounds with higher risks and focusing on candidates with robust safety profiles. The accuracy of AI in predicting these outcomes has already demonstrated a higher success rate for compounds advancing to human trials, reducing the likelihood of costly failures later in development.

Clinical trial optimization

Clinical trials often represent the most time-consuming and expensive stages of drug development. AI is now being used to streamline trial design, patient recruitment, and data analysis. Predictive analytics can identify the ideal patient populations, reduce trial times, and help researchers make data-driven adjustments in real-time. Adaptive trial designs powered by AI enable trials to be more flexible, with protocols that adjust as data accumulates, improving efficiency and increasing the chances of regulatory approval.

How CROS can benefit from making AI a part of their daily workstreams

AI largely mirrors traditional drug discovery processes—identifying a target from scientific data, screening compounds for selectivity, and refining efficacy and safety. The difference lies in the computational power of AI, which accelerates these steps and even enables some to run concurrently.

To maximize AI's potential, it's essential to focus on targeted scientific and operational challenges and embed AI fully into research workflows rather than using it as a standalone tool.

Although AI poses challenges for traditional contract research organisations (CROs), they must adopt a proactive stance by implementing AI-driven methods and strategies to thrive in an industry increasingly focused on data-centric drug discovery. The pressure to enhance efficiencies in R&D processes and the DMTA cycle is mounting. By integrating AI into operational workflows, CROs can improve efficiency, accelerate decision-making, and optimize experiment design, ultimately boosting customer satisfaction.

Historically, CROs have adhered to protocols dictated by their clients, but this strategy may not guarantee sustainable success as AI becomes more integral to the drug development lifecycle. To maintain their competitive advantage, CROs must focus on innovation and delivering the highest quality products and services.

Addressing challenges in AI implementation

Despite the potential benefits, the integration of AI into biopharmaceutical processes is not without challenges. Companies and research institutions often face issues related to data availability, regulatory requirements, and the high costs associated with adopting AI technologies.

AI models rely on high-quality, comprehensive data to function effectively. However, biopharmaceutical data is often fragmented across platforms, lacking standardization. Organisations are now focusing on data harmonization and establishing data-sharing frameworks and consortiums like the Syngene Data Consortium to address these issues. Syngene's SynSight is an opt-in consortium of clients who consent to anonymized usage of their data towards predictive models with higher reliability and broader applicability, leading to better decision-making, timelines, and outcomes on their projects. This collaboration among stakeholders is key to unlocking the full potential of AI.

Secondly, implementing AI systems in biopharma requires significant investments in computing infrastructure, data management systems, and skilled personnel. Some organisations, especially smaller firms, find these costs prohibitive, limiting widespread AI adoption.

Integrating AI into biopharmaceutical R&D also demands specialized knowledge and skill sets that many companies are still developing. Beyond technical expertise, there's also a need for cultural adaptation to encourage a data-driven approach across all levels of an organisations.

Finally, the use of AI in healthcare involves significant ethical considerations, especially in patient data privacy and transparency. Additionally, stringent

regulatory requirements add complexity, as AI-driven drug discovery and manufacturing solutions must meet rigorous safety and efficacy standards before approval.

Transforming biopharma through advanced technologies

The biopharma industry is undergoing a transformation through advanced technologies, with AI-driven approaches now playing a significant role in drug discovery and development. For instance, companies have developed AI-based pipelines that facilitate target identification and lead discovery. These AI systems help in identifying novel disease associations and prioritizing them through multiparameter risk-benefit analyses, with applications extending into fields like drug repurposing and animal health. The lead discovery process includes virtual screening and molecule generation, optimized for small molecules, peptides, and antibodies, allowing for precise and efficient lead optimization.

In AI-integrated drug research and development, three critical aspects stand out. First, AI brings context and clarity to data, enabling researchers to synthesize and analyze vast datasets to guide decision-making. Second, predictive models allow scientists to forecast drug properties, outcomes, and potential liabilities, reducing the need for exhaustive lab testing. Lastly, AI shows promise in prescriptive roles, suggesting actions and even guiding design at every stage. Generative AI, for example, is advancing the ability to explore novel chemical and biological spaces, ultimately aiding experts in identifying unique targets, designing innovative molecules, and formulating hypotheses.

An AI-native R&D ecosystem, such as Syngene's Syn. AI, exemplifies how companies integrate AI to enhance project data integration, optimize target prioritization, predict molecular properties, and improve molecule screening and design processes. This system ties into broader capabilities, making organisations more robust in drug discovery. Future plans include expanding into new modalities and adding translational tools for clinical applications, with enhancements in biologics design using generative models, animal health analysis, and clinical trial optimization.

Furthermore, as ethical and regulatory shifts push for reduced animal testing, AI-driven in vitro and in silico models are increasingly significant. Platforms like HepTox exemplify efforts to develop non-animal toxicity testing, aiming for regulatory acceptance and accurate replication of biological systems without animal subjects. These initiatives reflect a growing commitment to ethical science and a future-focused approach to drug discovery and development.

The path forward

The future of biopharmaceutical manufacturing lies in the successful harnessing of cutting-edge technologies to overcome existing challenges and drive innovation. As AI, machine learning, and advanced data analytics become increasingly integrated into biopharma processes, they will not only enhance efficiency and precision but also unlock new possibilities for therapeutic development. The ability to rapidly analyze complex biological data, streamline drug discovery, and optimize production processes promises to transform how medicines are developed and delivered.

Moreover, the shift toward a more data-driven approach in biopharmaceutical manufacturing will encourage greater collaboration among industry stakeholders, fostering an environment where knowledge is shared and innovations are rapidly adopted. As regulatory frameworks adapt to these technological advancements, the biopharma industry is poised to deliver a new era of healthcare solutions that are more personalized, effective, and accessible to patients worldwide.

In an era where precision, speed, and adaptability are essential, the biopharmaceutical sector is positioned to deliver transformative healthcare solutions more efficiently than ever. Through continued investment in technology and collaborative efforts to address challenges, the industry stands to make significant strides in tackling some of the most pressing health issues of our time. ■

Author

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Biotechnology Breakthrough: Newest Breakthroughs in Curing Cancer Bring Hopes

In the latest development scientists have taken a revolutionized step in the battle against cancer, by using cutting-edge biotechnology to develop new approaches for preventing it. Unlike traditional therapies, in contrast, that attack cancer when it has taken root, these new methods attack the disease in its most primitive forms, offering new hope for high-risk individuals.

Sonal Bansal, Director, Shashvi Remedies emphasizes about the newer breakthroughs in curing Cancer and how Immunotherapy, is being researched in growing numbers for preventive therapy use.

A Turn in the War on Cancer

For over a decade, researchers have been unlayering complex molecular processes in cancer, specifically in cases with predispositions including BRCA1 and BRCA2 mutations. By contrast, this new strategy aims at early molecular events even before full-blown cancer takes form, potentially halting its development even before it can start.

While traditional radiation and chemotherapy have saved countless lives, such therapies have a high cost in terms of secondary effects and function best only when a strong root of cancer has taken hold. In contrast, such a new biotechnology-based therapy is a preventive one, working long in advance of when even cancerous cells can form.

The Science Behind the Breakthrough

At the heart of such a new direction is utilizing gene-edited and molecular therapies specifically targeting causative genetic mutations for susceptibility to cancer. Through RNA interference and other advanced techniques, the technology can block the accumulation of harmful mutations in cells, especially in breast tissue, where these mutations are most common.

Advanced CRISPR technology can make gene edits with unprecedented accuracy, correct mutations that can lead to cancer. Unlike older, less efficient techniques, such methodologies act at a cellular level, and gene edits become less and less invasive and specific.

Another critical achievement is in epigenetics, a branch of study concerned with altering gene function but not with altering the sequence of DNA. By regulating when and under what conditions genes are produced, through small compounds and drugs, one can decelerate the accretion of mutations that can produce cancer over a long period of years.

Immunotherapy: Moving Beyond Treatment

Immunotherapy, long a tool for treating ongoing malignancies, is being researched in growing numbers for preventive therapy use. Researchers have constructed vaccines for malignancies that can instruct the immune system to recognize and destroy precancerous cells in an attempt to stop them becoming malignant tumors.

One such example is personalized cancer vaccines, which allows a patient's specific immune profile to be leveraged to produce a strong and concentrated immune response. By ruling out common antigens

found in many forms of cancer and training the body to detect and destroy them, scientists are planning to fight against the dangerous disease.

Additionally, monoclonal antibodies, a long-standing tool in cancer therapy, are now being explored for disease prevention. Engineered in laboratories, these antibodies can bind to and neutralize molecules that promote disease, effectively halting its development in the early stages.

Real-World Impact and the Road Ahead

The implications of this biotechnology-driven approach are vast. It could become a breakthrough not just for breast cancer but for a variety of other cancers as well. Researchers are already working to adapt this technology for high-risk groups, ushering in a new era of personalized, preventive medicine.

For example, pancreatic cancer—one of the most lethal forms—often goes undiagnosed until it reaches an advanced stage. Experts hope that early intervention through gene-editing and molecular techniques could significantly reduce the incidence of this aggressive cancer. Similarly, colorectal cancer prevention strategies are being optimized to target individuals with Lynch syndrome, a genetic disorder that predisposes people to early-onset cancer.

While clinical trials are still in their early phases, initial reports have shown promise. Experts remain cautiously optimistic, emphasizing the need for more comprehensive data to fully evaluate the long-term effectiveness and safety of these therapies. Regulatory agencies like the FDA will play a crucial role in assessing and approving these new treatments for widespread use.

A leading oncologist underscores the importance of continued research, stating, "If we can intervene before cancer even has a chance to develop, we could revolutionize the landscape of cancer treatment and prevention forever. It's an exciting time for biotechnology and for cancer patients around the world."

Ethical and Societal Considerations

As with any emerging biotechnology, social and ethical issues must be part of the discussion. Gene and molecular interventions raise important questions about accessibility, cost, and unintended consequences. While these powerful new technologies have the potential to save countless lives, it's crucial that they are accessible to all patients, regardless of socioeconomic status.

Moreover, the risks of unforeseen genetic changes and long-term side effects must be carefully monitored. Experts urge caution and call for strict regulatory oversight to ensure these interventions are both safe and effective for widespread use. Public education will also be vital to build trust and awareness among those who could benefit from these cutting-edge technologies.

A Future Without Cancer?

As more research emerges, there's hope that these breakthroughs will become pillars in the fight against cancer, offering new tools to individuals at high genetic risk. With continued advancements in gene therapy, molecular medicine, and immunology, we can envision a future where cancer is not a looming threat but a disease we can prevent or even eliminate.

While the journey ahead is long, the progress made so far offers a glimpse into a future where cancer is not just a reality we face, but a challenge we can overcome. With ongoing investment, collaboration, innovation, and prevention, the quality of biotechnology has the potential to transform how we fight cancer, securing a healthier future for generations to come. ■

Author

Sonal Bansal
Director
Shashvi Remedies

Role of mature Quality Culture to prevent drug shortages

Over the past few years, the term **"Quality Culture"** has become quite a buzzword. **Subhrangshu Chaudhury - Vice President & Head of Quality-Centaur Pharmaceuticals Pvt. Ltd** emphasizes about how quality culture plays significant role in pharma industry.

A study of 650 physicians in US found that 79% of physicians had patients who experienced difficulty obtaining a medicine due to drug shortage. In case of cardiologists, dermatologists, and rheumatologists, the percentage was over 85%. As per the report published by USFDA 62% of the drug shortages in the calendar year 2013 to 2017 are mainly due to Quality issues. The percentage was reduced to 40% in 2022 – 2023.

The supply disruptions were mainly due to two reasons such as Bad inspectional outcome and Market recalls due to quality concerns.

Inspection Management

Our focus need to be change from compliance centric to patient centric. We are dealing with Drugs and if a small dosage of the drug can cure then a small impurity present in the same drug can be life threatening to the patient. Audit or inspection is a bare minimum regulatory requirement which is nothing but a license to sell our medicine.

So we cannot contemplate 5 days or 10 days inspection will determine our quality of the medicine. We need to remember that might be our family members could consume the medicine. We are dealing with sick people, sometimes with the people who are in the roller coaster ride of life and death; they are taking our medicine with high hopes that they will be cured after taking our medicine. So, in simple words we are dealing with a field where we bring ray of hope in the darkest phase of a patient life.

In other industry if quality of a car or a mobile is substandard then we can replace the same with another car or mobile but in pharma we cannot replace a life with another life.

Supply disruptions: Supply disruption can happen due to recalls like the Nitrosamine saga we all are aware of or some products that is developed in hurry to meet the deadline to achieve the market may fail in the commercial production. So here also it relates to culture of the organisation.

Other frequent causes of supply disruption may be found in day to day events such as

- **Out of Specifications**
- **Deviations**
- **Machine breakdowns**

In such scenario, we need to understand that to reduce these disruptions we need to improve our quality culture; like when we are investigating an OOS; what is our culture to close the investigation? Is our culture to somehow invalidate the OOS and release the batch or to identify that exact root cause and find the true quality of the batch and take a CAPA so that similar OOS should not happen again?

Similarly when we are closing a deviation whether our culture is to just close the deviation in the month end and release the batch with 'Training' as a CAPA or are we trying to identify the exact root cause so that in future this deviation should not come and disrupt our day to day activity or more over similar market complaint should not come in future.

What is our culture to perform the preventive maintenance? Are we doing predictive maintenance instead of preventive maintenance?

Before having an out of specification there will be some out of trend so are we taking proactive measure to prevent the out of specifications during out of trend investigation? Similarly, before going for a machine breakdown, machines will give some alarms. So as a company culture are we trending those alarms or trying to predict when the breakdown may happen and taking a proactive preventive maintenance which is called predictive maintenance?

So it all encapsulates to "Quality culture" but who hold the baton of quality culture - management or shop floor?

Culture always start from the TOP. Leadership plays a crucial role to set the tone of the organisational culture. So when we are canvassing about the strategies to promote the transparency in the organisation, incipiently we have to think that whether the senior leadership in the organisation are ready to hear bad news? Because down the line at operator level or analyst level people will only divulge those things which are preferred by their higher authority and leaders. To promote transparency, we need to promote the "speak up" or "VoE" (voice of employee) culture in the organisation. Operators and analysts are the only person who know the real picture of shop floor so if we pay attention to their words and encourage them to share the real picture then definitely we can incorporate lot of precautionary measures in our system proactively.

To promote accountability, we need to promote empowerment. If we only promote "speak up" or "VoE" culture without empowerment then we all will get to hear the same line "yeh toh sab ko pata hai" (Everyone knows it). "Sab ko pata hai" (everyone knows) is ok but the onus lies with whom to correct the same? If we take example of the automobile industry in Japan, we can easily find out, they empowered an operator also to pause the production line if any inaccurate incident happened and rectify it. Similarly, we also need to empower our lowest down the line person to take the necessary action in case of any inaccurate incident.

Finally, in Quality Management Maturity white paper published by USFDA it is eloquently written that "Quality culture is an environment in which those who have responsibility for oversight and control over manufacturing taking ownership for quality. Empowered employees will be always engaged and engaged employees understand and care about how their roles within the organization impact patients and consumers, product quality, and product availability. Engaged employees at all levels take ownership and are empowered to identify, communicate, escalate, and initiate changes that continuously improve processes, procedures, and practices". ■

Author

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Harnessing Data for a Smarter & Faster Biopharma Industry

In today's era of rapid scientific advancement, the biopharmaceutical industry plays a pivotal role in global health, navigating complex biochemical landscapes to develop life-saving therapies. **Ashok Kumar, Head of Bio4C Commercial – Asia Pacific, Merck Life Sciences - Bio4C** discussed how biopharma industry is likely to witness consistent growth in the years to come and brings new challenges in developing and commercializing innovative therapies.

From drug discovery to production scale-up and ensuring broad accessibility, biopharma companies are essential in building a healthier, safer, and more sustainable world. However, this path is fraught with challenges, including lengthy processes, stringent regulatory compliance, supply chain inconsistencies, and a deluge of data.

To meet evolving market demands—speed, agility, sustainability, value, and quality—the industry is undergoing a transformation. At the core of this shift is patient centricity, ensuring safety, efficacy, and access to quality therapies.

To overcome current and future challenges, biopharma companies are turning to automation and digital technologies like process automation, robotics, data analytics, artificial intelligence (AI), and machine learning (ML). These technologies optimize drug development, streamline manufacturing, and ultimately improve patient outcomes. The concept of Biopharma 4.0 encapsulates this transformation, envisioning an industry where digitalization and automation are fully integrated. However, achieving this vision requires a phased approach, with incremental milestones yielding tangible benefits along the way.

A key focus of this transformation is commercial manufacturing, which is not only the revenue engine but also critical for regulatory compliance. Despite significant investments in digital technologies, there is no standardized approach to implementation due to the complexity and variability of operations. Regardless of these differences, one constant remains: data is at the heart of operations. Manufacturers need to invest in right technology for automation and analytics to fully realize the potential of Biopharma 4.0, and companies must establish ecosystems to integrate disparate systems and processes to enable single source of truth for data. Companies must ensure this data is accurate, relevant, and actionable, transforming it into insights that drive timely, informed decisions. While advances in technology address parts of this issue, the real challenge lies in how effectively companies harness data science and analytics to deliver innovation across the entire value chain.

This raises a critical question: How can biopharma companies effectively manage and analyse the growing volumes of data from both digital and non-digital sources to generate insights and drive innovation?

Bio4C ProcessPad Software

To address the critical need of the industry Merck has released Bio4C ProcessPad Software and still investing in it to add further capabilities that

align with the evolving need of the industry. Bio4C ProcessPad Software as a potential solution to address the data management and analytics need of the biomanufacturers.

Bio4C ProcessPad Software is a data visualization, analytics, and process monitoring platform that enables bioprocess lifecycle management, reporting, investigations, and continued process verification (CPV). The solution intelligently combines process data from multiple sources like batches, Enterprise Resource Planning (ERP), Manufacturing Execution System (MES), Laboratory Information Management System (LIMS), process equipment, and manual sources into a single, validated data source.

Bio4C ProcessPad Software works by breaking down the intricate working of biopharma processes into 3 simple steps: acquire, aggregate, and analyse data. The process starts by collecting and managing information from various paper-based records, spreadsheets, batch records, quality control data, external databases, historians, and streaming machine data in a single software environment. This unrefined information is then automatically assembled into an analysis-ready format while maintaining the relationships that exist between batches, unit operations, and parameters. The output received is then visualized using advanced analytical tools for bioprocess analysis and easy reporting. With this process, Bio4C ProcessPad Software ensures that the data input and reports remain accurate, complete, and contextual throughout the product life cycle.

As a specially curated solution for the BioPharma industry, Bio4C ProcessPad Software provides data integration, analysis and sharing across the manufacturing network and end-to-end data management throughout the process validation lifecycle that successful continued process verification (CPV) requires. At one end biomanufactrerss can reply on out of the box capabilities of the Bio4C ProcessPad Software such as end to end management of CPV, APQR, and other end Bio4C ProcessPad Software also provides advance analytics capabilities such as MVDA based Process Health Monitoring and prediction.

Conclusion

According to a report, the global big data analytics market size was valued at USD 307.51 billion in 2023. The market is projected to grow from USD 348.21 billion in 2024 to USD 924.39 billion by 2032, exhibiting a CAGR of 13.0% during the forecast period. Since the use of data is still in its early phase in the biopharma industry, this growth, if embraced early, can empower pharma companies to stay ahead and function in an informed manner. Leveraging software capabilities like Bio4C will enable better consolidation and collaboration among different internal and external stakeholders by breaking the silos that separate internal functions and achieving better collaboration among teams. ■

Author

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Leveraging the Potential of Generative AI to Deliver Enhanced Patient Outcomes

The past few years have seen widespread proliferation of artificial intelligence (AI) in multiple aspects of our everyday life. When we talk about offering quality healthcare, the life sciences industry, especially all major pharma companies, have adopted the latest in technological trends and efficiencies to fulfill the promise of delivering transformative outcomes for improved patient health.

Suman Giri, Vice President & Global Head of Commercial Data Science and Analytics Solutions, Pfizer emphasizes about how Life sciences organizations are investing in generative AI across various functions and strategies to accelerate the application of AI.

AI in the life sciences space

Life sciences organizations are investing in generative AI across various functions, including R&D, Manufacturing, Commercial, and Medical Affairs, as well as several other corporate functions. R&D focuses on drug discovery, molecular design, clinical development, and trial design, with estimated efficiency gains of 20-30%. Manufacturing leverages generative AI for quality management, achieving similar anticipated efficiency improvements. On the commercial side, applications such as content creation, personalization, faster review processes, marketing/sales, market access, and patient services offer revenue growth, cost savings, and improved efficiency.

Sometimes challenges can hinder progress

Challenges can be categorized into intrinsic and extrinsic factors. Intrinsic factors include data strategy, immature platform bets, integration issues with existing solutions, and governance. Extrinsic factors encompass talent acquisition and retention and inadequate change management strategies. Addressing these challenges is crucial for organizations to overcome the "failure to launch" syndrome and unlock the true potential of generative AI.

Actionable strategies to accelerate the application of AI

To advance and accelerate the application of AI in life sciences, companies must focus on three key strategies: data strategy, financial and partnership strategy, and talent and change management strategy.

- **Data Strategy:** Organizations must develop a comprehensive data strategy that includes handling unstructured data, implementing appropriate tagging mechanisms, and preparing for a multi-modal world. Compliance considerations should be integrated from day one to ensure data integrity and regulatory compliance.

- **Financial and Partnership Strategy:** Companies should align AI use cases with their business strategy and evaluate the build vs. buy vs. partner options. This strategic approach helps identify areas where partnerships or acquisitions can accelerate progress and maximize value.

- **Talent and Change Management Strategy:** Equipping both technical and business teams with the necessary skills is crucial. Organizations should invest in training programs to enhance technical expertise and provide effective

expectation management for business teams. Change management strategies should be implemented to foster a culture of AI adoption and ensure smooth organizational transformation.

Despite the challenges, there is a growing sense of optimism in the industry. Compliance language is evolving, enabling organizations to navigate regulatory complexities more effectively. The build vs. buy vs. partner strategy is being refined, allowing companies to leverage external expertise and resources where needed.

In the life sciences and pharma industry, a clear focus on a few high-potential use cases has emerged, providing a roadmap for scaling AI applications. Last year, Pfizer launched its first ever dedicated commercial analytics centre in India, called the Analytics Gateway. The centre is aimed at accelerating data science and analytics solutions to meet the evolving patient needs and deliver stronger patient outcomes.

Shaping the future of healthcare

Generative AI holds immense promise for the life sciences industry, with the potential to revolutionize drug discovery, manufacturing, commercial operations, and patient services. By developing comprehensive data strategies, aligning AI initiatives with business goals, and with a mindset of continuous improvement, the life sciences industry can harness the power of generative AI to drive innovation, improve patient outcomes, and shape the future of healthcare. ■

Author

Suman Giri
Vice President & Global Head of Commercial Data Science and Analytics Solutions, Pfizer

Adverse Drug Reactions and Pharmacovigilance in India: Building on Opportunities

Adverse drug reactions (ADRs) are a significant public health concern worldwide, and India is no exception. With a vast population of over 1.3 billion people and a rapidly growing pharmaceutical industry, India faces unique challenges in ensuring drug safety. Pharmacovigilance, the science of detecting, assessing, and preventing ADRs, plays a crucial role in mitigating these risks. The Indian population's genetic diversity, combined with widespread use of polypharmacy and traditional medicines, increases the risk of ADRs.

Dr. Kausik Maiti, Executive Director,Safety Medical Sciences, Parexel India emphasizes about Adverse Drug Reactions and Pharmacovigilance in India. He also spoke about the Challenges facing Pharmacovigilance in India

Understanding Adverse Drug Reactions

Adverse Drug Reactions (ADRs) are unintended and potentially harmful responses to medications when used as prescribed for therapeutic purposes. These reactions can range from mild discomfort to severe, life-threatening conditions, and they represent a significant challenge in healthcare. The World Health Organization defines an ADR as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function."

The incidence and severity of ADRs can vary due to several factors. Patient-related factors such as age, genetics, underlying health conditions, and lifestyle habits play a significant role. Similarly, drug-related factors including type, dosage, frequency of administration, and method of delivery influence the likelihood and severity of ADRs. Understanding ADRs is crucial for healthcare professionals to ensure patient safety, optimize treatment outcomes, and contribute to the ongoing process of pharmacovigilance, which aims to detect, assess, understand, and prevent adverse effects related to medicinal products.

Pharmacovigilance in India: Current Status

India has made significant strides in pharmacovigilance in recent years. The Central Drugs Standard Control Organisation (CDSCO), New Delhi, under the aegis of Ministry of Health & Family Welfare, Government of India initiated a nation-wide pharmacovigilance programme in July 2010. The programme is coordinated by the Indian Pharmacopoeia Commission (IPC) and is supported by the Ministry of Health and Family Welfare. The mission of Pharmacovigilance Programme of India (PvPI) is to safeguard the health of the Indian population by ensuring that the benefit of use of medicine outweighs the risks associated with its use.

The PvPI has achieved several milestones, including:

- Establishment of 250 Adverse Drug Monitoring centres across the country
- Creation of a national database of ADRs, collaboration with WHO
- Development of guidelines for ADR reporting and management
- Conducting training programmes for healthcare professionals

Despite these achievements, challenges persist. ADR reporting rates remain low, and there is a need for increased awareness and training among healthcare professionals. In India, the magnitude of this issue is stark. Between April 2020 and March 2021, over 52,000 ADRs were reported, with more than 28% classified as serious events. However, these numbers likely represent only the tip of the iceberg due to significant underreporting.

Moreover, in the context of India, where traditional medicine systems coexist with modern pharmaceuticals, the scope of pharmacovigilance extends beyond conventional drugs to include herbal and traditional remedies.

Contributory Factors for this trend

In an era where access to health information is more convenient than ever, people turn towards online sources or non-professional recommendations for medications and treatment advice. On the parallel, self-medication with over-the-counter (OTC) medicines is becoming an increasingly popular and perilous practice. Furthermore, the trend extends more than this, the trend of sharing prescriptions and medications among friends and family or using leftover drugs aggravates the risk of adverse effects. Despite the desire to save time and money, self-medication can be far more harmful than anticipated.

Compounding the issue, some pharmacists in India contribute to the problem by prescribing medications without proper medical oversight. It is crucial to address these issues through widespread public awareness and innovation in healthcare to ensure safe and effective treatment practices.

The crucial role of pharmacists

In many countries, pharmacists play a crucial role in medication safety, acting as a final checkpoint before drugs reach patients. However, in India, their role is often diminished, with doctors frequently dispensing medications directly. Elevating the role of pharmacists in the medication use process could significantly enhance drug safety. Their expertise in drug interactions, dosing, and potential adverse effects complements that of physicians and can provide an additional layer of safety for patients.

Challenges in Pharmacovigilance in India

India's unique demographics and healthcare ecosystem present several formidable challenges. One of the most significant challenges facing pharmacovigilance in India is severe underreporting. The country's adverse drug reaction (ADR) reporting rate stands at a mere 1%, significantly lower than the global average of 5%. This stark disparity underscores an urgent need for heightened awareness and active participation from both healthcare providers and patients in reporting adverse events.

Another challenge is the vast genetic diversity of India's population. Genetic variations can profoundly influence how individuals respond to medications, making standardized approaches to drug safety challenging. This genetic diversity introduces a layer of complexity in predicting and managing ADRs.

Furthermore, resource constraints in many healthcare facilities, particularly in rural and semi-urban areas, hamper the implementation of robust pharmacovigilance practices. Inadequate infrastructure and a shortage of trained personnel limit the ability of these facilities to effectively monitor and report ADRs

To address these challenges, it is imperative to enhance ADR reporting rates, and strengthen pharmacovigilance infrastructure across the country. By doing so, India can improve drug safety and protect the health of its population.

Importance of Patient Engagement in Pharmacovigilance

The role of patients in reporting and preventing adverse drug reactions (ADRs) is increasingly recognized as a critical element of pharmacovigilance. Patient engagement and empowerment can greatly enhance medication safety, leading to improved health outcomes and a more robust healthcare system.

Patients play a vital role as independent reporters of ADRs, providing first-hand accounts of their experiences with medications. Their direct reporting can complement the information gathered from healthcare professionals, resulting in a more comprehensive understanding of drug safety. Furthermore, patient involvement in ADR reporting can enhance the detection of adverse reactions, especially for widely prescribed drugs or those used by specific populations. Patient-reported data can provide valuable insights. When patients report adverse events, they are not just sharing their experiences; they are contributing to the safety of future patients. Accurate and timely reporting of adverse events is crucial for identifying potential safety risks and taking appropriate action.

On the other hand, several barriers can impede effective patient reporting of ADRs. A significant challenge is the lack of awareness; many patients may not know they

have the right to report ADRs or may be unaware of how to do so.

Additionally, patients may face difficulties in distinguishing between symptoms of their underlying conditions and ADRs, leading to underreporting and missed opportunities for detecting potential signals. Limited access to user-friendly reporting systems can also be a barrier. If existing reporting processes are perceived as cumbersome or time-consuming, patients may be discouraged from participating.

Addressing these barriers through targeted education and improved reporting mechanisms can enhance patient engagement and contribute to a more effective pharmacovigilance system.

Strengthening Pharmacovigilance in India and navigating the challenges

To improve drug safety in India and address existing challenges, several key strategies are essential. Enhancing ADR reporting mechanisms is critical; simplifying and expanding reporting channels and mediums, through user-friendly mobile apps and helplines, can boost participation from healthcare professionals and patients alike.

Education and training also play a crucial role. Increasing awareness about pharmacovigilance among healthcare providers through targeted training programs is vital, and integrating this knowledge into medical and pharmacy curricula will help instill a culture of vigilance from the beginning of their careers.

Additionally, leveraging technology can significantly advance pharmacovigilance efforts. Implementing advanced tools like artificial intelligence and machine learning can enhance signal detection and data analysis, improving both efficiency and effectiveness. Finally, fostering collaboration among healthcare providers, pharmaceutical companies, research organizations, and regulatory bodies is necessary to create a comprehensive and responsive pharmacovigilance system.

Some examples of technology & scientific advancement that can be implemented in India contributing to improved patient safety, include:

- Artificial intelligence (AI) and machine learning: AI can process and analyse large amounts of data, identify potential safety signals, and automate case processing
- Natural language processing (NLP): NLP can interpret human language and extract data from unstructured sources like medical records and social media
- Big data analytics: Pharmacovigilance teams can use big data analytics to manage large amounts of data from various sources
- Wearable devices and remote monitoring: These devices are being used to monitor select patients regularly to help with pharmacovigilance
- National Digital Health Mission: This initiative aims to create a unified health database, which could significantly enhance ADR tracking and analysis.
- Pharmacogenomics Research: Investigating the genetic basis of ADRs in the Indian population could lead to more personalized and safer medication practices.
- Blockchain Technology: Implementing blockchain for secure and transparent ADR reporting and data management could enhance the integrity and efficiency of the pharmacovigilance system.

India's Path to Enhanced Drug Safety and Global Leadership

As India continues to grow as a global pharmaceutical powerhouse, the importance of robust pharmacovigilance cannot be overstated. By addressing the challenges of underreporting, enhancing regulatory frameworks, and fostering a culture of safety awareness among healthcare providers and patients, India can significantly reduce the burden of adverse drug reactions. This not only protects public health but also strengthens the reputation and reliability of India's pharmaceutical industry on the global stage.

The path to improved drug safety is complex, requiring sustained effort and collaboration across multiple sectors. However, with concerted action and a commitment to continuous improvement, India can build a pharmacovigilance ecosystem that effectively safeguards patient health and sets a standard for other developing nations to follow. ■

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- Laboratory Chemicals
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- Water Treatment Chemicals
- Catalysts
- Electronic Chemicals
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- SCALE@ CHEMTECH World Expo 2024: 60+ GLOBAL CLIMATE TECH STARTUPS FROM 20 COUNTRIES; 40 TECHNICAL PRESENTATIONS
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Bio Pharma World Expo 2024

NAVIGATING THE PATH TO LEADERSHIP IN BIOPHARMA EXCELLENCE

(L to R) Guest of Honour Dr Krishna Ella , Executive Chairman, Bharat Biotech International Ltd, Prof (Dr) Samir Kulkarni , Head, Department of Biological Sciences & Biotechnology, Coordinator, DBT – ICT Centre, Dr Rajesh Gokhale, Secretary , DBT, Ministry of Science & Technology, Govt. of India & Chief Guest, Mr Suresh Prabhu Former Union Minister, Govt. of India & Chief Patron & Brand Ambassador, ChemTECH World Expo 2024

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Dr Rajesh Gokhale
Secretary, DBT, Ministry of Science & Technology, Govt. of India

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