Chandrawat & Partners

LIFE SCIENCE

A comprehensive guide

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Introduction

Life science is the study of microorganisms, plants, animals and human beings – including their physical structure, chemical processes, molecular interactions, physiological mechanisms, development, and evolution. While biology remains the epicenter of life sciences, technological advances in molecular biology and biotechnology have led to new specializations and interdisciplinary fields. New disciplines such as genomics and metabolomics technologies have revolutionized the course of this gigantic field.

Life science subjects may be basic or applied science. Basic science gains new knowledge and a better understanding of the natural world. The aim of applied science is to find solutions to practical problems using the findings from basic science. This field has gained immense popularity due to its continuous advancements. Biology, medicine and agriculture are the most obvious examples of the discipline. However, as science becomes ever more complex, it is more difficult to find clear definitions and boundaries.

Emerging Trends

For India, the success of the country's vaccine manufacturing capabilities during the Covid-19 pandemic has demonstrated the value of its entrepreneurial, innovative, and domestic talent-driven approach. The global market has also been positively impacted by the rise in opportunities and advancements in drug development and vaccine manufacturing. Furthermore, the success of messenger RiboNucleic Acid ("mRNA") vaccines and accelerated approval processes have led to a surge in vaccine-related revenues.

In addition to the growth in the vaccine market, both the consumption and exports of diagnostic and medical devices are expected to increase significantly in India. The expansion of biotech incubators and start-ups will also play a key role in driving the success of the Indian biotechnology industry.

Adaptation of new technology is a significant factor in tackling future challenges. Artificial Intelligence ("AI"), aided by machine learning ("ML") techniques such as Natural Language Processing ("NLP"), promises to enhance the capabilities of the life science industry manifold by extracting insights hidden in data rapidly and effectively.

The emerging technologies also bring chemists and computer scientists together – aiding medicinal chemists to identify the synthesis route. With the available resources and requirements, scientists quickly go from imagining what is possible to test what is probable.

Economic overview

India is among the top 12 destinations for biotechnology worldwide and 3rd largest destination for biotechnology in Asia Pacific. In 2022, India's biotechnology industry has crossed $80.12 billion, growing 14% from the previous year. The Indian BioEconomy has witnessed a manyfold increase in valuation in the past ten years, with COVID-19 giving the industry a much needed push. Today, India is poised as one of the leading destinations for bioinnovation and biomanufacturing, and hence is identified as a sunrise sector and a key part of India's vision of reaching a $5 trillion Economy by 2024. India's Biotechnology sector is categorised into BioPharmaceuticals, Bioagriculture, BioIT and BioServices.

Bio Agriculture: With nearly 55% of Indian terrain under agriculture and allied activities, India is one of largest producer of Bt-cotton and has the 5th Largest area of organic agriculture land globally.

Bioindustrial: The application of biotechnology to industrial processes is transforming manufacturing and waste disposal across the country.

Biopharmaceuticals: India is one of the biggest suppliers of low cost drugs and vaccines in the world. India also leads in biosimilars, with the most number of biosimilars approved in the domestic market.

Bio IT & Services: India offers a strong capability in contract manufacturing, research and clinical trials, and is home to the most US Food and Drug Administration ("FDA") approved plants globally outside of the US.

Valued at US$ 80.12 billion in 2022, the Indian biotechnology industry is targeted to reach US$ 150 billion by 2025 and US$ 300 billion by 2030.
The growth of the Indian biotechnology sector is fuelled by rising demand at both a domestic.

Government initiative

Finance Minister in union budget 2023 has announced the launch of a new programme to promote research in pharmaceuticals with a view to promoting the growth of the sector. Government also said facilities in select Indian Council of Medical Research ("ICMR") labs will be made available for research by public and private medical faculties.

Initiatives announced in the budget which could help the Healthcare industry include a plan to have Centres of excellence for Artificial Intelligence and introduction of multi-disciplinary courses for medical devices to upskill manpower for futuristic medical technologies and high-end manufacturing and research.

To boost research and development ("R&D") and innovation, the government has announced a new pharma program and further collaborations for public and private medical faculties and private R&D teams. While these are steps in the right direction, the much-hoped income tax benefits in the form of higher R&D linked weighted deductions, extension of sunset date for commencement of manufacturing to avail concessional tax regime by new manufacturing units or simplification of the patent box regime were not considered. Also missed was extension of customs exemption for specified goods used in pharmaceutical and biotechnology sector for R&D beyond 31 March 2023.

Government Rule, Laws and Compliance

India has a federal form of government and the regulatory framework is divided between national and state authorities. The Drugs and Cosmetics Act 1940 ("DCA") and the Drugs and Cosmetic Rules 1945 ("DCR") regulate the manufacture, sale, import, export and clinical research of drugs and cosmetics. The Central Drugs Standard Control Organization ("CDSCO") under the Ministry of Health and Family Welfare regulates pharmaceutical products through the Drug Controller General of India ("DCGI"). The DCGI registers all imported drugs, new drugs and drugs in selected categories. It also has responsibility for clinical trials and quality standards. The state licensing authorities ("SLAs"), which are currently 35 in number, register all other products, accredit manufacturing plants and conduct the bulk of quality monitoring and inspections.

In addition to the DCA and the DCR, the other pieces of legislation that regulate the approval mechanism of drugs, cosmetics and food include the Pharmacy Act 1948, the Drugs and Magic Remedies (Objectionable Advertisement) Act 1954 (the DMR Act), the Narcotic Drugs and Psychotropic Substances Act 1985, and the Drugs (Prices Control) Order 1995 (under the Essential Commodities Act).

In India, clinical trials are regulated through various mechanisms, including the Drugs and Cosmetics Act 1940 and Rules 1945, Schedule Y regulations for conducting clinical research issued by the CDSCO, and guidelines for interpreting the regulations, such as the Indian Council of Medical Research guidelines and the Indian Good Clinical Practice ("GCP") Guidelines. While not legally binding, these guidelines for conducting clinical trials have been accepted by the industry in India. The prerequisites for conducting clinical trials in India are permission from the DCGI, ethics committee approval and mandatory registration of the trials.

Schedule Y of the DCR 1945 prescribes post-approval controls Periodic safety update report ("PSUR"), which require marketing authorisation holders to submit a report every six months for the first two years after drug approval is granted. For the subsequent two years, the PSUR report must be submitted annually. Post-market surveillance includes procedures for the distribution of records, complaint handling, adverse incident reporting, product recall and taking of corrective measures. Schedule Y also requires the applicant to inform the licensing authority if the marketing of the new drug is delayed after having obtained marketing approval. In the event that the applicant and manufacturer fail to launch the product in the market within a period of six months from obtaining a licence from the CDSCO, the licence would be treated as cancelled.

Dispute resolution

Healthcare is a potential sector that should be acquainted with the Alternative dispute resolution ("ADR") mechanisms as there has been a great increase in the medical litigation in India as compared to the previous year. A survey was carried out by the National Law School of India University ("NLSIU"), which clearly stated that there has been a 400% increase in medical litigation due to consumer awareness. That being the scenario, there can be expected a higher rise in medical litigation in the coming years, and a definite rise in this pandemic. Thus, India should adapt itself to the ADR mechanisms and help eradicate the medical disputes in a faster and easier manner.

There is a need to have proper clauses and provisions in the agreements signed by the health-care users and healthcare facility providers on admission in order to promote the need of addressing the healthcare disputes through ADR mechanisms. Clauses such as mandatory negotiation, mediation, or arbitration shall be included in the agreements in case any kind of dispute arises between the parties. Guidelines that are just, fair, and uphold the conscience of the parties to the dispute should also be issued to govern the ADR mechanism's process.

How we can help ?

- Our team of professionals can conduct comprehensive market research to help businesses understand their target audience, industry trends and potential competitors.

- Our experts can help set clear objectives, outline actionable steps and identify opportunities for growth and expansion.

- Our team can conduct risk assessments to identify potential threats and vulnerabilities within a business. They can then recommend risk mitigation strategies to safeguard against adverse events.

- Our team can investigate and identify any licenses, permissions or registrations required for the client's specific area or industry. The business assists with the application process and ensures that the organization complies with all legal criteria.

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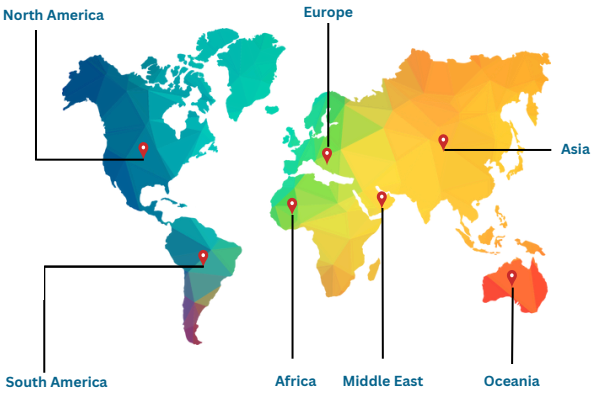

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