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सत्यमेव जयते
GOVERNMENT OF INDIA
MINISTRY OF SKILL DEVELOPMENT
& ENTREPRENEURSHIP

N·S·D·C
National
Skill Development
Corporation
Transforming the skill landscape

Human Resource and Skill Requirements in the Pharmaceuticals Sector

(2013-17, 2017-22)

cutting through complexity

This report is prepared by KPMG Advisory Services Pvt Ltd (KASPL).

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We would like to thank all NSDC's industry and training partners for their active participation. The success of the study has been possible through their collaborative efforts.

In addition, we convey our gratitude to all those who have, in some way or other, contributed towards the successful completion of this study.

Executive Summary

Industry Overview

The Indian pharma sector witnessed a robust growth over the last 5 years to reach USD 34.5 billion by 2014

Key Growth Drivers

- Increased budgetary allocation for healthcare spending, which is expected to have an overall positive impact on the sector. There has been a proposal to extend weighted deduction of 200 percent for R&D expenditure in an in-house facility for a further period of five years beyond 31 March 2012
- In the 2013–14 budget, the healthcare sector witnessed a 22 percent increase in allocation from INR30,702 crore allocated in 2012–13 to INR37,330 crore. Out of this, 56 percent is allocated to primary healthcare
- There has also been a 24.5 percent rise over RE in the new national health mission for training and education in the budget, INR1,650 crore have been allocated to set up six AIIMS- like institutes

India's Competitive Advantage

Favourable FDI policies	100 percent FDI was allowed in the pharma sector through automatic approval route in the new projects. The cumulative FDI in the drugs and pharmaceuticals sector from 2009–10 to December 2012 stood at US$4,243.34 million. Zero duty for technology upgrades in the pharmaceuticals sector through the Export Promotion Capital Goods (EPCG) Scheme
Strong domestic manufacturing sector	The country's strong local manufacturing sector offers advantage in the case of pharma. As a result, the leading domestic players have been able to or are trying to establish notable international presence
Labor abundance	India also has availability of low-cost skilled labor force in abundance
Greater public-private partnerships	Major multi-billion dollar initiative of the government with 50 percent public funding through a public-private partnership (PPP) model aims at harnessing India's innovation capability. The government aims to make India one of the top five pharmaceutical innovation hubs by 2020, targeting to achieve a global niche with one out of every 5–10 drugs discovered worldwide by 2020 originating from India

Leading industry players in the sector

Ranbaxy Labs. (CY12)	**Revenue from Exports 10,124.74**
Dr Reddy's Labs	**Revenue from Exports 9,741.20**
Sun Pharma.Inds	**Revenue from Exports 8,206.62**

- According to government estimates, the pharma exports are poised to reach US$25 billion in 2016

Sources: KPMG in India analysis

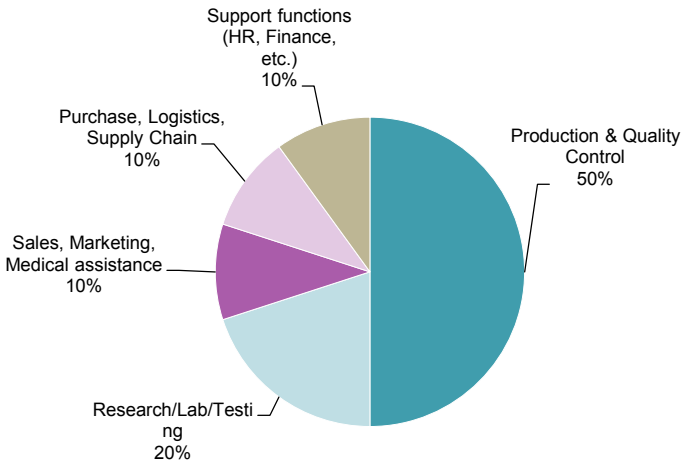
Demographic characteristics of workforce

The upward movement in the value chain is likely to create more demand for skilled labor

- A large percentage of the workforce in the sector is categorized under the informal/ un-organized bracket making it necessary to streamline job profiles and skill assessment for the people falling under these categories
- The workforce is expected to undergo gradual changes in its composition by in the next decade
- The managerial roles are expected to witness the steepest rise. This is indicative of the presently evolving status of the industry and the upward movement in the value chain
- Commerciality of the sector makes it a preferred employer for management graduates and accountants, while the production and research component makes it a preferred option for people with science and pharmacy backgrounds
- Colleges in India offer diplomas, undergraduate and post graduate degrees in pharmaceutical sciences
- Graduates in science also find employment in the pharmaceuticals sector
- The higher spectrum of R&D organizations requires candidates who have a doctorate or post doctorate degree
- Maximum number of employees (about 50 percent) in the pharma sector are engaged in the production and quality control division
- Ph.D/ M.Tech/ M.Sc account for only 5–8 percent of the workforce in the chemicals and pharmaceuticals segment, while a majority of the people employed in the sector have an educational background of 12th grade or below

Key Characteristics of Workforce

Percentage distribution of manpower in pharma industry



Qualifications of personnel employed in the chemicals & pharmaceuticals segment

Qualifications	Distribution
Ph. D / M.Tech / M.Sc etc.	5–8%
Graduate Engineers	15–25%
Diploma Engineers	10%
ITI and other vocational courses	15–20%
Graduates (BA/ B Sc./B.Com/ others)	15–25%
12th standard or below	20–25%

Sources: Industry Interactions; KPMG in India analysis

Incremental Human Resource Requirement (2013-22)

Current workforce of ~1.86 million (2013) is expected to increase 3.5 million by 2022

Human Resource Growth Trends in the Sector

Segment	Employment (in Million)			Employment Growth 2013-17	Employment Growth 2017-22	Employment Growth 2013-22
	2013	2017	2022	(In millions)	(In millions)	(In millions)
Manufacturing	0.69	0.89	1.15	0.20	0.25	0.45
R&D	0.07	0.09	0.11	0.02	0.02	0.04
Wholesale Sales	0.20	0.29	0.42	0.09	0.13	0.22
Pharma Retail	0.90	1.32	1.90	0.43	0.58	1.00
Total	**1.86**	**2.60**	**3.58**	**0.74**	**0.98**	**1.72**

Nearly one third of the workforce in the sector is categorized under the informal/ unorganized indicating the necessary to streamline job profiles to enhance productivity levels

Field force (medical representatives) form a significant portion of the employment pie under the sales function

As companies strategize to establish a footprint in rural areas and tier II and tier III cities, it is vital to establish credible distribution channels and a supply chain, which leads to a need for increased recruitment in these area

New areas/ trends in the sector

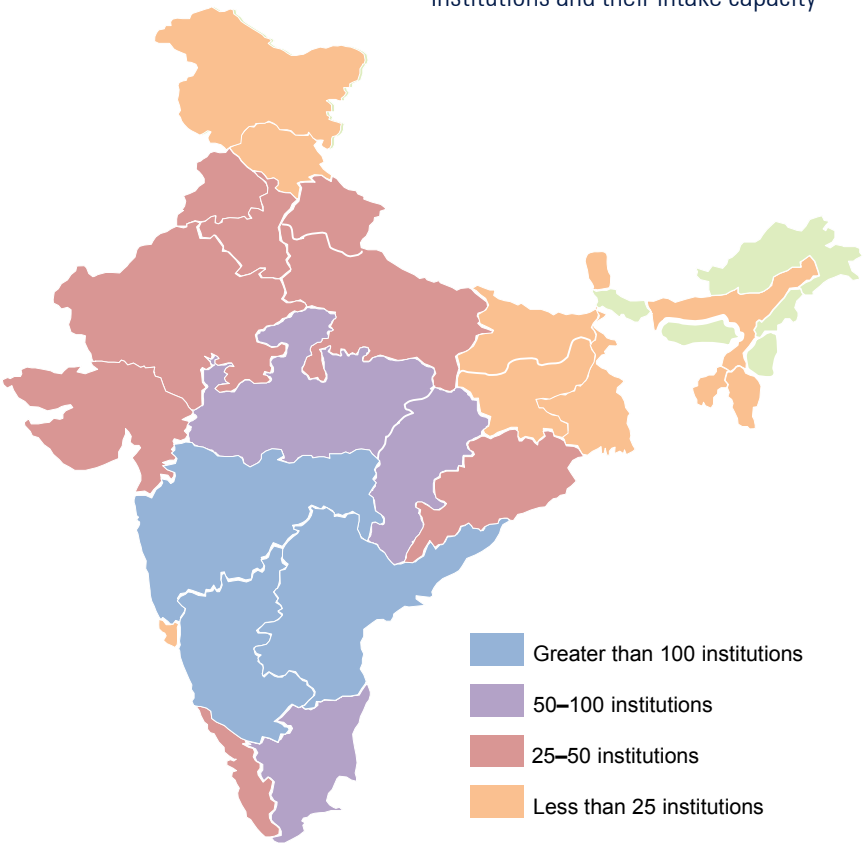
- Discovery of drug processes and not just pre-clinical trials
- Specialized manufacturing processes for specific streams
- Oncology, particularly in the field of biotechnology
- Sales an emerging function or skill in the industry

Job Roles	Representative Skill Gaps
Medical representative, territory manager	Workers possess the theoretical knowledge, but lack the training required to fit into the job. Disconnect between teaching and industry requirements. Lack of structured training programs for MRs
Area sales manager, regional/ zonal sales manager, National sales manager	Lack of technical skills and regular trainings to stay updated on current norms. Lack of people management skills
Product executive, product manager	Lack of candidates with both technical and market acumen, Lack of a structured training programs focused on pharma marketing
Production manager, head-production, head- R&D)	Lack of focus on research and hence lesser PhDs and Post-Doctoral fellows entering the industry. Lack of innovative ideas, focus on reverse engineering

Supply & Training Infrastructure

There is a visible disparity in the distribution of educational institutes that offer pharma education across the country

Institutions and their intake capacity



State/ UT	Total intake
Maharashtra	**10,240**
Karnataka	8,410
Andhra Pradesh	5,682
Madhya Pradesh	4,250
Tamil Nadu	3,390
Kerala	2,205
Uttar Pradesh	2,200
Rajasthan	2,069
Gujarat	2,025
Punjab	1,920
Haryana	1,745
Orissa	1,370

Challenges associated with training institutes

Lack of skills premium

- There is a lack of skills premium correlation to increasing wages, as the industry does not pay premium for pharmacy graduates in the sector

Standards in training

- Lack of coordination among regulatory bodies, leading to stagnation of curriculum

High Attrition

- Students lack patience and progression to higher job roles is slow in the industry, hence lot of them move to other industries

Lack of awareness

- Low awareness of emerging streams such as regulatory space, drug auditing and clinical pharmacy

Select recommendations & implications

Recommendation	Implications
Strong industry-academia linkage to figure out the industry needs and teach and train students accordingly	▪ Curriculum should be revised with inputs from industry people ▪ Incentivize them, with realization that they can save money spent on training, if students are trained in college only (as per the requirements)
Regulations should be formulated wherein pharma students are preferred for employment	▪ Government should formulate regulations which would promote employment for pharma students and provide opportunities at par with other stream students
Industry needs to be proactive and invest in training	▪ Industry needs to be proactive and design training process as per the requirements of job ▪ They need to work in liaison with educational institution for devising a comprehensive and successful training program
Incentivize and bring good quality teachers in the pharma sector	▪ More benefits should be given to teachers joining in, so that they stick with the profession and institute ▪ Incentives should be given on part of government's policy as well as institutes'
Up gradation infrastructure to impart industry-relevant training	▪ Improvising infrastructure would provide facilities for students to acquire better skill set ▪ Quality infrastructure, good curriculum, & good teachers would renown a college on national/international level
Coordination between various accrediting bodies to have coherent curriculum and rules	▪ Inputs from academia, industry, government bodies, advisory should be taken for holistic development of curriculum, which meets the market requirement
Promoting and investing in R&D	▪ Government needs to invest heavily to boost R&D in pharma sector ▪ Collaborations with international university/colleges would help in improvisation of the same
Awareness about emerging job roles has to be spread among students & customization of the curriculum accordingly	▪ A mobile application for updates on the vacancies in pharma sector in key towns and cities would be useful for the workers to locate jobs

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Abbreviations

APIs	Active Pharmaceutical Ingredients
AICTE	All India Council of Technical Education
ANDA	Abbreviated New Drug Application
ASSOCHAM	Associated Chambers of Commerce and Industry of India
CAGR	Compounded Average Growth Rate
CTO	Clinical Trial Organisation
CL	Compulsory Licensing
CPSU	Central Public Sector Undertaking
CMO	Contract Manufacturing Organisation
CRAMS	Contract Research and Manufacturing Services
CRO	Clinical Research Organisation
DMF	Drug Master File
EU	European Union
FDI	Foreign Direct Investment
FTA	Free Trade Agreement
FYP	Five Year Plan
GDP	Gross Domestic Product
IT	Information Technology
MIS	Management Information Office
MNC	Multi-national Company
MR	Medical Representative
NIC	National Industry Classification
NIPER	National Institute of Pharmaceutical Education and Research
PMO	Project Management Office
R&D	Research and Development
SME	Small and Medium Enterprise
VP	Vice President

Context and approach

Brief background	NSDC had conducted sector-wise skill gap studies for 19 high priority sectors in 2008–09 . ▪ KPMG has been engaged as a consultant to help evaluate the skill gap across 25 sectors and develop actionable recommendations for its stakeholders. ▪ Mandate includes sector and sub-sector level analysis, demand-supply projection, estimation of incremental man-power requirement between 2013-2017 and 2017-2022, identification of key-employment clusters, and SWOT analysis of each sector ▪ Study also aims to take qualitative insights from stakeholders on enablers and challenges for each sector, way forward in terms of specific policy level actionable recommendations,
Inclusions over the previous study	▪ Study led by industry – Sector Skill Councils and a panel of professionals from different sub-sectors were consulted for their inputs on industry trends, key takeaways in terms of skill requirement, qualitative insights to understand specific interventions required for each sector and to validate the quantitative results and recommendations ▪ 6 sectors were added to the list of NSDC priority sectors for studying the skill gaps Updated study also includes ▪ Identification of top 20 job-roles in each sector, case studies around good training practices, sub-sector level indicators and growth factors ▪ Study also includes understanding of existing training infrastructure, work-force characteristics and employment clusters, ▪ Macro economic factors, central and state governments policies and their envisaged impact ▪ Synchronisation of the sector wise demand from the district level skill gap studies ▪ Recommendations for key stakeholders - Industry, NSDC, Training organizations and Government ▪ Environment scans every year till 2015-16 including SWOT analysis for the sector

Industry classification

Coverage as per NIC classification

Sector and subsectors as per NIC classification

Division 21: Manufacturing of pharmaceuticals, medicinal chemical and botanical products	
210: Manufacturing of pharmaceuticals, medicinal chemical and botanical products	
2100: Manufacturing of pharmaceuticals, medicinal chemical and botanical products	21001: Manufacture of medicinal substances used in the manufacture of pharmaceuticals: antibiotics, endocrine products, basic vitamins; opium derivatives; sulpha drugs; serums and plasmas; salicylic acid, its salts and esters; glycosides and vegetable alkaloids; chemically pure sugar etc.
	21002: Manufacture of allopathic pharmaceutical preparations
	21003: Manufacture of `ayurvedic' or `unani' pharmaceutical preparation
	21004: Manufacture of homoeopathic or biochemic pharmaceutical preparations
	21005: Manufacture of veterinary preparations
	21006: Manufacturing of medical impregnated wadding, gauze, bandages, dressings and surgical gut string
	21009: Manufacturing of other pharmaceutical and botanical products n.e.c. such as henna powder
Division 72: Scientific research and development	
721: Research and experimental development on natural sciences and engineering	
7210: Research and development for pharmaceuticals and biotech pharmaceuticals,	

Division 46: Wholesale trade, except of motor vehicles and motorcycles	
464: Wholesale of household goods	
4649: Wholesale of other household goods	46497: Wholesale of pharmaceutical and medical goods
Division 47: Retail trade, except of motor vehicles and motorcycles	
477: Retail sale of other goods in specialized stores	
4772: Retail sale of pharmaceutical and medical goods, cosmetic and toiletries in specialized stores	47721: Retail sale of pharmaceuticals, medical and orthopaedic goods and toiletries

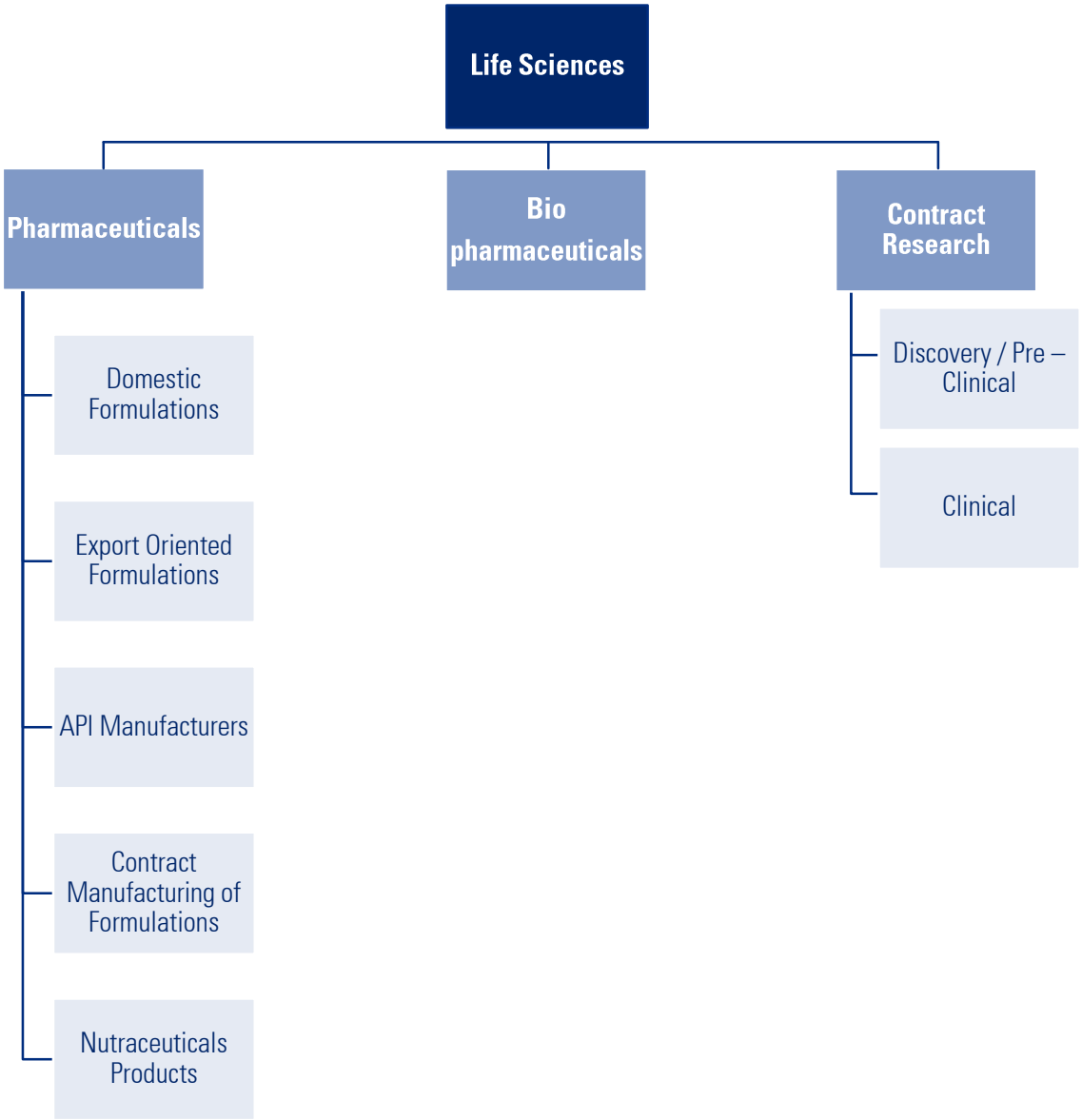
Sources: National Industrial Classification – Ministry of Statistics and Program Implementation

Industry overview

Major sub-sectors and sub-segments

Major sub-sectors and sub-segments

Pharmaceutical industry falls under the broader umbrella of Life Sciences. Pharmaceutical industry is further classified into five sub-segments - Domestic Formulation Companies, Export Oriented Formulation Companies, API Manufacturers, Contract Manufacturing of Formulations, Nutraceuticals Products. Apart from core sub segments, Pharmaceutical is affected by Biopharmaceuticals and Contract research.



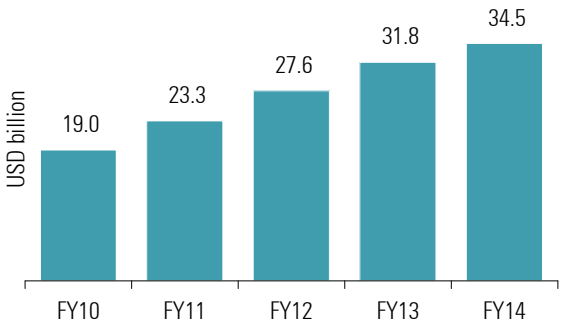
Sources: CRISIL Research

The Indian pharma sector witnessed a robust growth over the last 5 years to reach USD 34.5 billion by 2014

Indian pharmaceutical industry growth indicators

- Currently, the Indian pharmaceuticals sector ranks third globally in terms of volume sales and 10th, in terms of value
- The new health economy is a vibrant network of players across the spectrum. From drug discovery companies in biotechnology and pharmaceuticals to healthcare providers, there are a myriad of stakeholders in this sector. These stakeholders work in tandem with each other
- With the evolution of the sector, the boundaries between these sub-sectors are getting blurred. Biotechs are increasingly catering to phrama clients, while pharma companies now have biotech products in their fold. Understanding any one element necessitates understanding the entire spectrum
- Panacea Biotech and Biocon are investing in antibiotic research, while DRL and Wockhardt have s strong bio-similar pipeline
- The importance of the sector is reflected in the increased budgetary allocation for healthcare spending, which is expected to have an overall positive impact on the sector. There has been a proposal to extend weighted deduction of 200 percent for R&D expenditure in an in-house facility for a further period of five years beyond 31 March 2012
- In the 2013–14 budget, the healthcare sector witnessed a 22 percent increase in allocation from INR30,702 crore allocated in 2012–13 to INR37,330 crore. Out of this, 56 percent is allocated to primary healthcare
- There has also been a 24.5 percent rise over RE in the new national health mission for training and education in the budget, INR1,650 crore have been allocated to set up six AIIMS- like institutes
- INR1,069 crore has been allocated to the department of AYUSH, which is expected to contribute to the capacity-building of the healthcare and pharma sectors

The Indian Pharmaceutical & life-sciences sector has seen a robust growth over the last 5 years

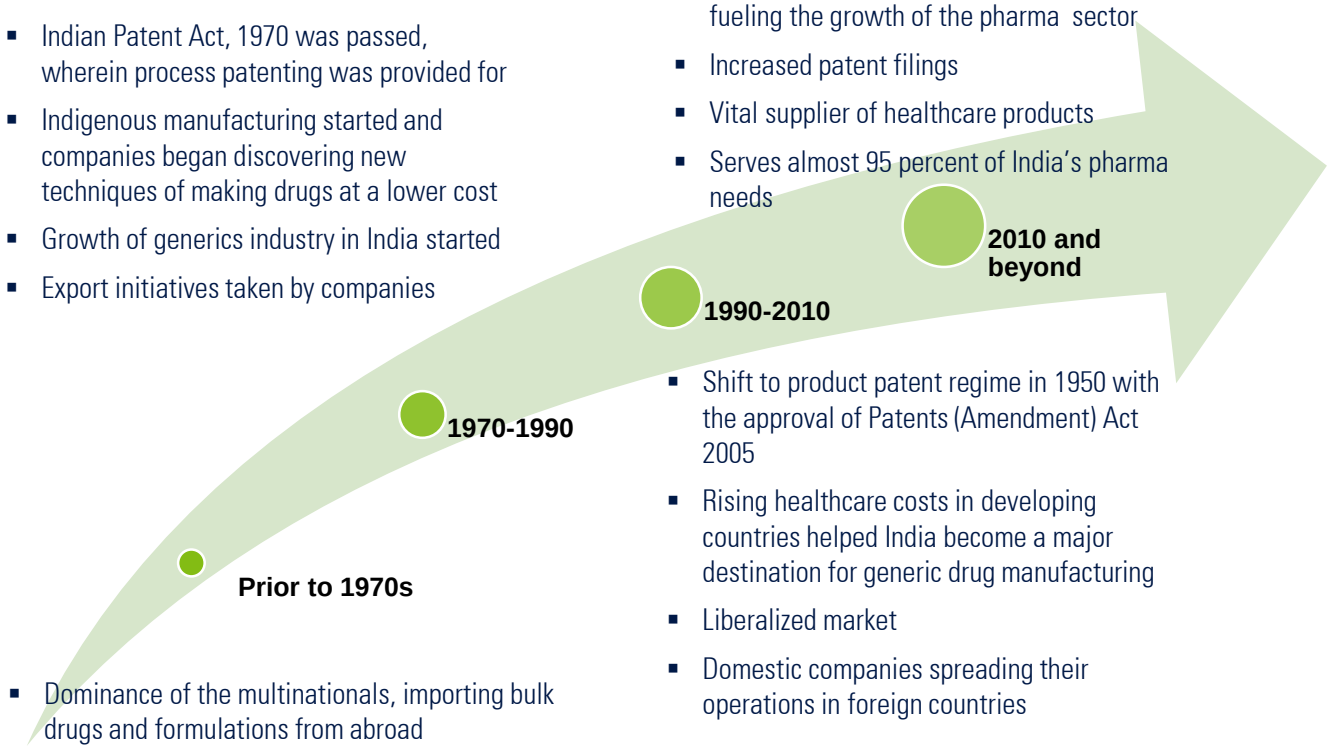


- Indian pharmaceuticals sector has increasingly demonstrated growth in mid-teens over the last few years- inherent nature makes it recession proof
- One of the few sectors where large number of Indian companies have been able to make a global impact
- India has inherent strengths vis-à-vis the sector- low cost manufacturing, relevant chemistry skills, large human resource base

Sources "Vision of India as pharma power house in 2020", IBEF December 2013, KPMG in India analysis

The Indian pharmaceuticals sector has evolved considerably since its inception

Evolution of the Indian pharmaceuticals sector



Prior to 1970s

- Dominance of the multinationals, importing bulk drugs and formulations from abroad
- Domestic manufacturers engaged in repacking formulations prepared by MNCs
- Setting up of Bengal Chemical and Pharmaceutical works in 1892 led to the production of modern medicine by indigenous units
- Establishment of Alembic Chemical, works in1907 and Bengal Immunity in 1919
- During this time, Patents Act of 1911 being followed
- Local firms legally prevented from manufacturing most of the new drugs during patent life of 16 years

1970-1990

- Indian Patent Act, 1970 was passed, wherein process patenting was provided for
- Indigenous manufacturing started and companies began discovering new techniques of making drugs at a lower cost
- Growth of generics industry in India started
- Export initiatives taken by companies

1990-2010

- Shift to product patent regime in 1950 with the approval of Patents (Amendment) Act 2005
- Rising healthcare costs in developing countries helped India become a major destination for generic drug manufacturing
- Liberalized market
- Domestic companies spreading their operations in foreign countries

2010 and beyond

- 2010 was the second successive year of strong growth
- Strong demand, improved healthcare spending and rising middle class income fueling the growth of the pharma sector
- Increased patent filings
- Vital supplier of healthcare products
- Serves almost 95 percent of India's pharma needs

Key takeaways

- While generics remain the mainstay of the Indian market, players have diversified their portfolios to include more complex formulations
- Indian firms are upgrading infrastructure to meet global compliance norms
- Few Indian companies have strong R&D pipelines, indicating a positive growth in terms of value proposition

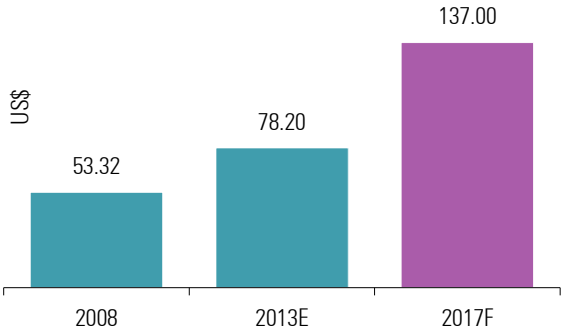
Source: KPMG in India analysis

Growth drivers in indian pharmaceutical industry

Rising per capita expenditure on healthcare in India to boost pharma sector growth

(US$)	2008	2013E	2017F
China	158.60	376.00	618.00
India	53.32	78.20	137.00
Japan	3,237.60	3,787.00	4,225.00
UK	3,969.50	3,836.00	4,575.00
US	7,979.80	9,565.00	11,159.00

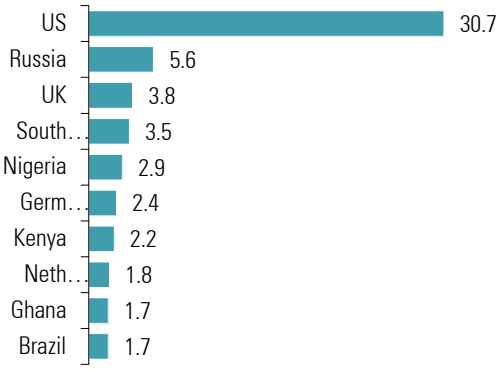
Projection of per capita expense on healthcare in India (in US$ billion)



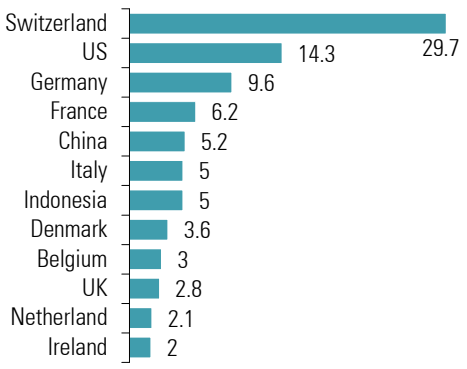
- Although the per capita expenditure on healthcare in India is significantly lower than countries such as the US, the UK, China and Japan, the country has been witnessing a rise in expenditure in recent times
- The per capita expenditure on healthcare is expected to reach US$137 in 2017 in India
- Rising per capita healthcare expenditure is expected to provide an impetus to the Indian pharma sector

The Indian pharmaceuticals sector is primarily fuelled by exports

Main export markets in value terms (%) (2012)



Main import markets in value terms (%) (2012):



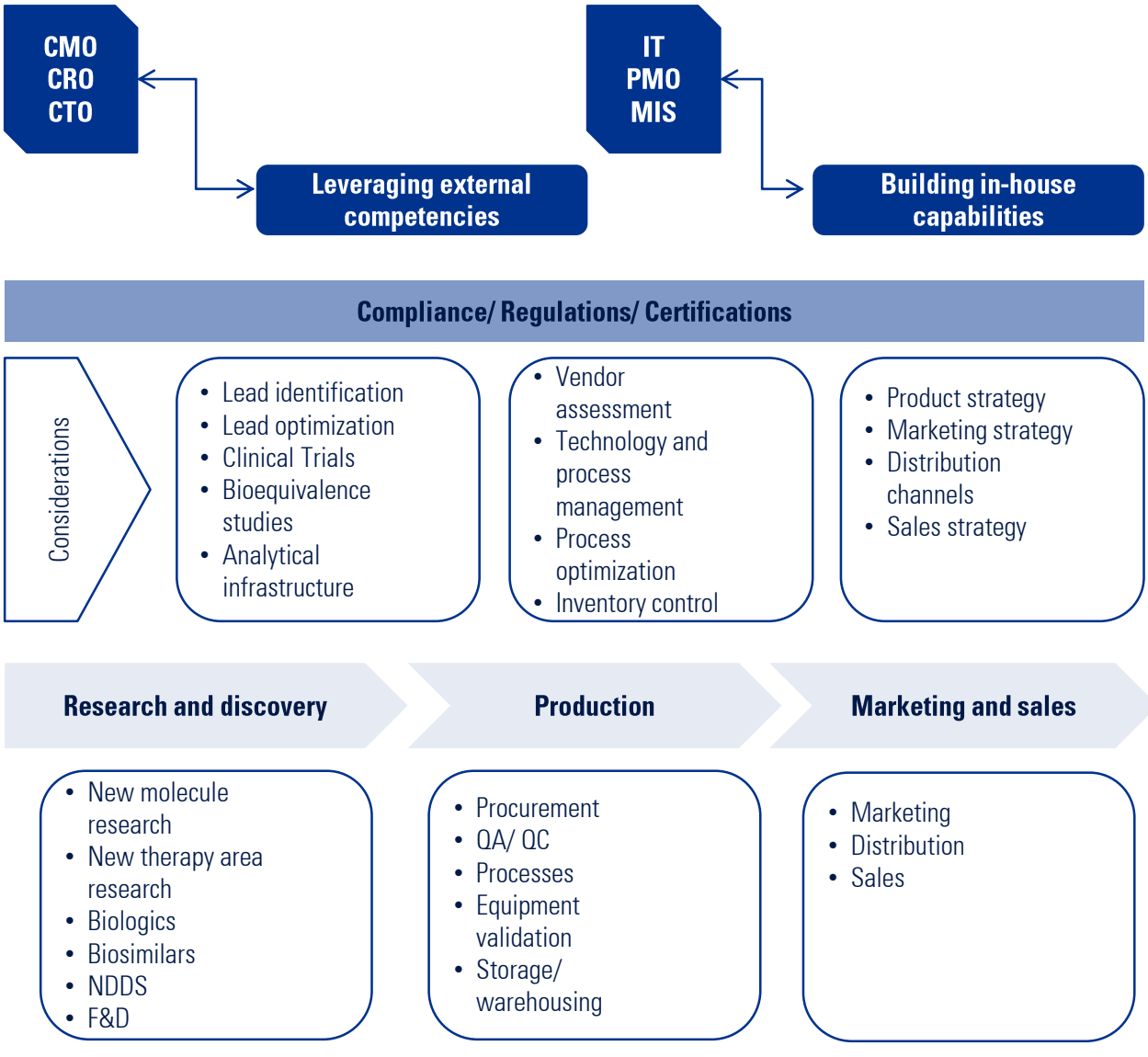
- Indian drugs are exported to more than 200 countries in the world, particularly to the US
- Approximately 80 percent of the formulations produced are consumed indigenously, while a majority of the bulk drugs manufactured are exported
- In terms of value, the US is the largest export market for India, with 30.7 percent share, while Brazil accounts for the lowest share, with 1.7 percent
- In contrast, India imports a majority of the pharma ingredients/ products from Switzerland (29.7 percent) and the least from Ireland (2 percent)
- In 2012, APIs and drug intermediaries worth US$4.6 billion (~INR25,000 crore) were imported by India, compared with US$2.9 billion in 2011

Sources: : Emerging Markets Insight- September 2013; Centre for WTO studies

Skill requirements vary across the value chain, ranging from R&D to sales

Value chain – pharmaceuticals

The value chain of the pharmaceuticals sector essentially comprises R&D, production and marketing and sales. All the stakeholders interplay within the boundaries of these key processes



Key:

CTO: Clinical Trial Organization

CMO: Contract Manufacturing Organization

CRO: Clinical Research Organization

IT: Information Technology

PMO: Project Management Office

MIS: Management Information Office

Sources: KPMG in India analysis

While the sector is highly fragmented, few key players hold maximum market share

Leading industry players

INR crores (2013)	Revenue from India	Revenue from Exports	Companies with maximum focus on exports
Ranbaxy Labs. (CY12)	2,334.99	10,124.74	
Dr Reddy's Labs	1,752.10	9,741.20	
Sun Pharma.Inds.	3,202.09	8,206.62	
Lupin	2,604.43	7,036.87	
Cipla	3,619.44	3,487.21	
Cadila Health.	4,040.20	2,317.50	
Wockhardt	1,101.61	4,619.06	
Torrent Pharma	1,268.65	1,784.88	
Jubilant Life	1,333.36	3,827.60	
Glenmark	1,742.90	3,269.44	

300–400 organized players

Organized players dominate formulations market

MNCs in Indian pharma market account for a 26–28% share (as of March 2013)

- The export segment accounts for a major share of the total revenue
- According to government estimates, the pharma exports are poised to reach US$25 billion in 2016

Sources: Annual Reports of respective companies; CRISIL research

The Indian pharmaceuticals sector is posing a tough competition for the global pharmaceuticals sector

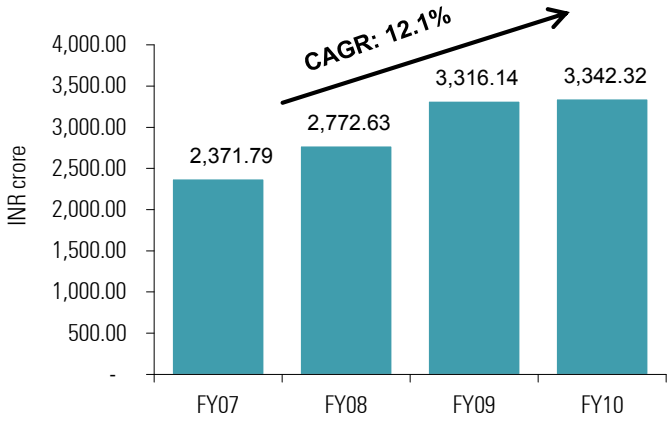
Advantages offered by the pharmaceuticals sector

India accounts for about 10 percent of the global pharmaceutical production. The country accounts for over 60,000 generic brands across 60 therapeutic categories and manufactures more than 500 different APIs

The Indian pharmaceuticals sector offers the following advantages over other countries:

Growing modernization and reforms	The Indian pharmaceuticals sector has an immense growth potential, which is highly dependent on modernization and reforms
Strong domestic manufacturing sector	The country's strong local manufacturing sector offers advantage in the case of pharma. As a result, the leading domestic players have been able to or trying to establish notable international presence
Labor abundance	India also has availability of low-cost skilled labor force in abundance
Low R&D costs	The efficiency of Indian pharma companies is further enhanced by low cost of production and R&D
Favorable policy support	Favorable policy support has helped reduce the approval time for new facilities to boost investments. India has 119 manufacturing sites approved by the USFDA, highest in any country outside of US

Growth in R&D expenditure of domestic companies



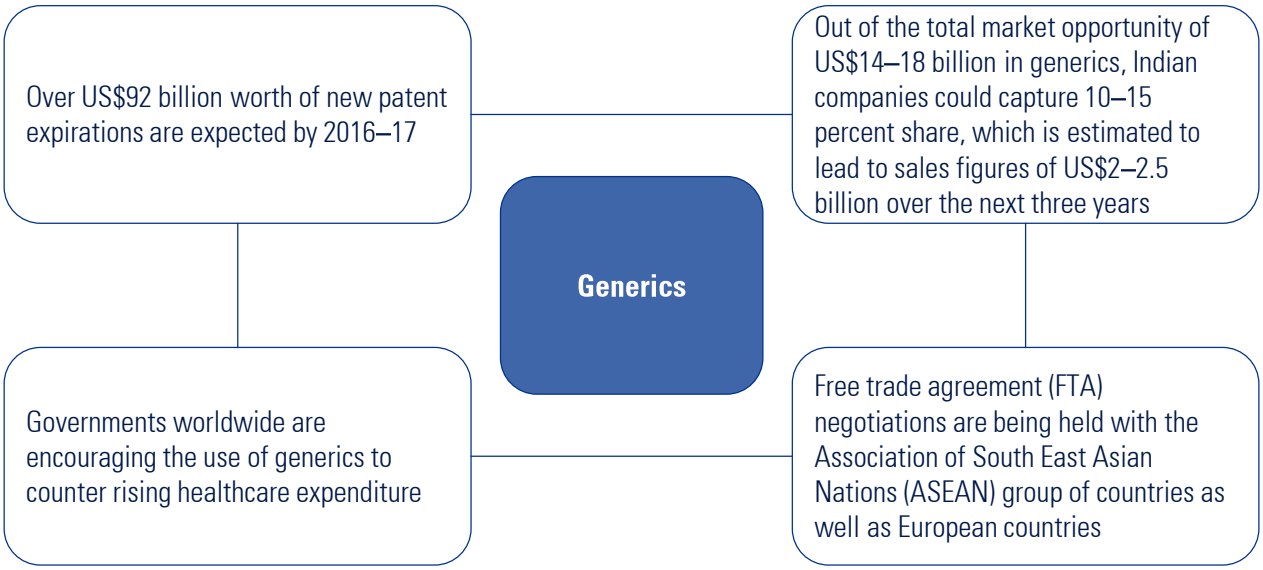
- Incremental innovation is a reality and Indian firms have moved from vanilla generics to products that are technology intensive and difficult to manufacture
- Zydus launched India's first NCE in 2013, proving India's metal in end-to-end innovation
- Indian companies have focused their R&D pipelines in the field of diabetes, oncology and some infectious diseases

Sources: KPMG in India analysis; Department of Pharmaceuticals Annual Report 2011-12; IBEF August 2013

Indian pharma players can leverage their existing strengths to capture a larger share of the global market

Growth drivers of the sector

The pharmaceuticals sector presents diverse and lucrative opportunities for both domestic and foreign multinational companies



Rise in domestic demand	Increase in the awareness levels, rising per capita income, growing urbanization resulting in changing lifestyles and increasing literacy rates are the key drivers of the Indian pharmaceuticals sector
Emerging segment's demand	Emerging segments such as contract research and development, bio-pharma, clinical trials, bio-generics and medical tourism are expected to drive the overall growth of the sector
Growth in healthcare financing products	With greater penetration of health insurance due to the development of the Indian financial industry, there has been a rise in healthcare spending
Government reforms and initiatives	Proactive role played by the government to boost growth and investment in the sector and 100 percent FDI allowed under the automatic route in the drugs and pharmaceuticals sector are driving the growth of the sector

Source: KPMG in India analysis

India's cost efficiency aided by low manufacturing, installation costs and manpower costs is providing competitive advantages…

- Both India and China offer cost advantages over developed, Western countries in R&D and manufacturing
- Manufacturing costs in India of the USFDA approved plants is only 35–40 percent of the manufacturing costs in developed countries such as the US
- China has the ability to produce pharma products at 25–30 percent less than costs incurred in developed countries

Salaries paid to the pharma sector employees in India vis-à-vis other low middle income countries indicate availability of cheap labor

Country	Year	Number of employees	Wages and salaries paid (US$)
Colombia	2005	16,344	12,36,09,820
Ecuador	2008	2,856	2,94,88,000
Ethiopia	2009	1,437	11,67,480
Georgia	2009	2,373	89,00,552
India	**2008**	**3,78,413**	**1,40,77,93,200**
Indonesia	2009	58,875	18,68,79,218
Iran	2008	20,207	15,09,59,215
Jordan	2009	5,215	6,85,53,433
Kyrgyzstan	2009	343	3,51,038

Country	Year	Number of employees	Wages and salaries paid (US$)
Lebanon	2007	699	72,99,000
Malaysia	2008	9,894	6,56,01,860
Pakistan	2006	36,336	14,29,91,304
Philippines	2006	15,436	13,59,73,500
Russia	2009	70,923	50,15,86,800
Sri Lanka	2006	11,654	1,50,27,048
Thailand	2006	27,080	7,69,14,290
Ukraine	2009	19,295	7,81,69,316
Uruguay	2007	3,102	5,22,83,171

Source: KPMG in India analysis; The Pharmaceutical Industry and Global Health, Facts and Figures 2012 - International Federation of Pharmaceutical Manufacturers & Associations

The sector has witnessed increasing government support

Favorable FDI policies

- 100 percent FDI was allowed in the pharma sector through automatic approval route in the new projects
- The cumulative FDI in the drugs and pharmaceuticals sector from 2009–10 to December 2012 stood at US$4,243.34 million
- Zero duty for technology upgrades in the pharmaceuticals sector through the Export Promotion Capital Goods (EPCG) Scheme

Vision documents for greater focus

- In order to make India one of the leading destinations for end-to-end drug discovery and innovation, the Department of Pharmaceuticals prepared a "Pharma Vision 2020" document

Greater public-private partnerships

- Major multi-billion dollar initiative of the government with 50 percent public funding through a public-private partnership (PPP) model aims at harnessing India's innovation capability
- The government aims to make India one of the top five pharmaceutical innovation hubs by 2020, targeting to achieve a global niche with one out of every 5–10 drugs discovered worldwide by 2020 originating from India

Tax incentives

- Tax-breaks are provided to the pharmaceuticals sector
- Weighted tax deduction at 150 percent are offered for the R&D expenditure
- Steps are being taken to streamline procedures covering development of new drug molecules and clinical research

New schemes launched

- Two schemes, particularly targeted at drugs and pharma research were launched — New Millennium Indian Technology Leadership Initiative and the Drugs and Pharmaceuticals Research Programme
- The government plans to set up a Pharmacopeial Commission to support ayurveda, yoga and naturopathy, unani, siddha and homoeopathy (AYUSH) through guidelines laid down in the review of the 11th Five Year Plan

State governments' initiatives

- Interest in the revival of the sector in the northern region has been expressed
- In December 2011, the Uttar Pradesh state cabinet approved a proposal for the revival of the Uttar Pradesh Drugs and Pharmaceuticals Company Limited (UPDPL) in a phased manner
- Excise free zones in north India offer incentivization for SMEs and big ticket pharma companies to set up drug manufacturing units in the region

Source: KPMG in India analysis

The 12th Five Year Plan's key objectives and recommendations show increased focus on the pharma sector to achieve higher growth

Key objectives

- Growth of the sector to reach US$60 billion in 2017 (CAGR of 18 percent)
- By the end of 12th FYP, achieve a five percent share of the global pharma industry
- Reach an industry size of US$100 billion by 2020
- Value of exports to be approximately INR1,30,000 crore by the end of 12th FYP
- Employ 1.5 million people in the sector by 2015, 1.898 million by 2018 and 2.464 million by 2022
- To have an internationally competitive domestic R&D sector
- To have a universal access to quality medicine at affordable prices
- To improve the share of domestic companies in medical device manufacturing
- Make all the CPSUs self-sustaining by 2020

Government – strategy and recommendations

- Build the private sector capacity to meet WHO–GMP standards and other international manufacturing standards
- Help the sector develop competence in advanced areas of drug manufacturing such as dedicated research facility in bulk drugs, improving processes of manufacturing generics and new APIs
- Develop coordination between relevant ministries/departments and stakeholders and tackle non-tariff barriers through counter measures and during signing of FTAs
- Develop competencies for 2D Bar-coding for SMEs
- Develop capacity of Central Drug Standards and Control Organisation to ensure timely clearance for new drug trials, pharmaco-vigilance, and assistance to the willing industry members to shore up their technical capacities for better regulatory, compliances and adequate number of labor inspectors
- Develop ecosystem to take advantage of the opportunities in clinical research and development of clinical research centers for high-risk trials such as Phase-I
- Strengthen the NIPERs to boost patent filing from these institutes
- Improve industry–academia linkages by creating a strong platform for incentivizing innovation in producing safe, affordable medicine, arranging public–private partnerships with industry and leading academic partners
- Review the regulatory system, including expanding tax deduction (to cover activities such as international patenting costs, regulatory consultants, outsourced R&D services and patent litigation expenses) and reducing approval timelines

Source: 12th Five Year Plan Planning Commission

The challenges and concerns of the pharma sector require careful deliberation by players as they contemplate strategies in the pursuit of growth

Pricing policy

- The Drugs Price Control Order (DPCO) 2013, which replaced the DPCO of 1995, seeks to reduce the prices of 348 drugs that are deemed to be essential medicines, leading to an erosion of INR1,600 crores from the sector's top line

Compulsory licensing (CL)

- The recent CL issuance judgments passed by the Supreme Court of India have deterred MNC investments in the country
- The ruling against Bayer for the manufacturing of onco drug Nexavar was the first CL judgment passed
- The Supreme Court cited that Bayer's drug was very highly priced and affordable by only 2 percent of the country's patients, thereby not meeting the 'reasonable public criteria' requirement
- While it can be argued that benefits of invention must reach those who need it, the ruling in favor of a generic manufacturer is likely to have significant repercussions on new chemical entity (NCE)/new molecule launches in India

Non-trade barriers from US/ Europe

- Various non-trade barriers existing in the US and the EU, which are primary export destinations for Indian pharmaceutical companies, have affected the growth of the sector
- Generic Drug User Fee Amendments (GDUFA): On 9 July 2012, the US Government passed the GDUFA 2012. This policy, which is being considered a historic first, has been drafted in a bid to accelerate the review of applications for generic drugs. In effect, the policy is expected to facilitate the accessibility of safe and efficacious drugs to the larger population in a shorter time frame and at a lower cost to the industry. However, the GDUFA may affect the margins of a number of large and mid-size pharmaceutical companies that will have to pay the proposed fee for selling their products in the US. The fee for the re-inspection of FDA-approved facilities and on Drug Master Files (DMFs) is a further burden that these companies will have to bear
- EU quality protocols: The new quality guidelines imposed by the European Medicines Agency (EMA) for drugs being exported to Europe have created further compliance issues for Indian manufacturers exporting drugs to EU countries

Source: KPMG in India analysis

SWOT Analysis

Strengths	▪ Increased disposable income and healthcare spending due to higher GDP growth rate ▪ Robust local manufacturing sector, with leading domestic players establishing notable international presence ▪ Low-cost but skilled English-speaking labor force ▪ Long established trade patterns with Western Europe and the US ▪ Rapid market approval ▪ Low cost of innovation, manufacturing and operations
Weaknesses	▪ Among the least developed pharma markets in Asia, with extremely low per-capita consumption ▪ Unclear and biased government drug pricing and reimbursement policy ▪ Underdeveloped healthcare infrastructure ▪ Uneven healthcare coverage across states ▪ Lack of comprehensive drug reimbursement ▪ Future margins would be lowered with movement away from original drug research ▪ Many multinationals already selling their products at reduced prices ▪ Data protection issues discouraging innovation
Opportunities	▪ Robust generic and over-the-counter drug market growth, with the latter benefitting from expected liberalization of sales channels ▪ Large and increasing population, boosting pharmaceutical and medical demand ▪ Underdeveloped market for chronic illnesses and diagnostic drugs ▪ The recognition of pharmaceutical patents from January 2005 ▪ Increasing global and Asian demand for generic drugs ▪ Ongoing FTA negotiations with the ASEAN group of countries ▪ Increased demand for India-produced APIs ▪ Rising research and development activity by domestic firms ▪ Global expansion of larger local companies ▪ Increased public funding for disease-eradication programs ▪ Political changes in the US to promote the use of Indian generic drugs
Threats	▪ Failure to properly enforce WTO-compliant patent legislation for drugs ▪ Considerable counterfeit drug industry ▪ Failure on part of the government to revise its unclear and discriminatory pricing and reimbursement policy ▪ Need for overhaul of healthcare delivery structures, which hamper better access to medicines ▪ Government plans of imposing further price controls on essential medicines ▪ India's patent laws threatened by litigation ▪ Manufacturing problems posing a threat to Indian generic drug exports, especially to the US ▪ Stiff competition being faced from other low-cost countries such as China and Israel ▪ Entry of foreign players in the Indian market

Sources: KPMG in India analysis

Sub-sectoral overview

Domestic formulations segment is driven by the improving healthcare infrastructure and rising awareness in the country

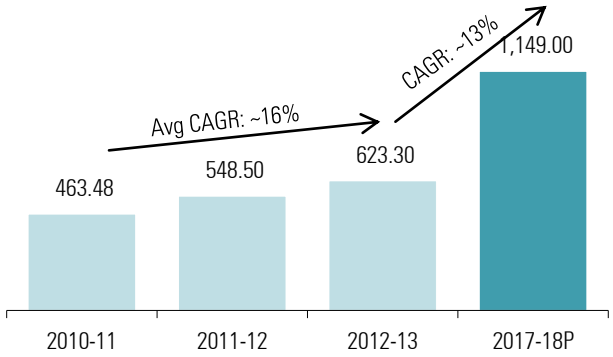
Key facts

- The domestic formulations market stood at an estimated US$11.41 billion (INR623.3 billion) in 2012–13, registering a growth of t 12 percent y-o-y
- The growth rate was recorded at 15.5 percent in 2011–12
- The decline is attributed to the reduction in the number of patients with chronic diseases such as diabetes, the switch to generic drugs and lesser number of product approvals
- In 2012–13, sales of anti-diabetic, cardiovascular and neuro /CNS therapeutic drugs recorded the fastest growth
- Between 2012–13 and 2017–18, domestic formulation sales are expected to grow at a CAGR of 12–14 percent

Growth drivers

Raise in the number of drug launches	Industry has witnessed higher number of drug launches catering to lifestyle-related ailments during the recent years
Changing life-style	Higher stress levels, changing lifestyle of the working population and unhealthy eating habits are leading to higher incidence of lifestyle-related ailments such as obesity and diabetes
Increase in health awareness	Improving literacy rates, media awareness and exposure, the Indian population is becoming increasingly health conscious and adopting preventive measures
Increase in disposable income	Growth in disposable income levels in India is translating into greater spending on healthcare services, giving a boost to the domestic formulations market

Domestic formulations market size (INR billion) (2007–08 to 2017–18)



Note:
INR1= US$0.0183 (2012-13); INR1= US$0.0207 (2011-12); INR1= US$0.0218 (2010-11);

Source: CRISIL research; KPMG in India analysis

Indian companies have diverse product portfolios, which require diverse specialized skills

Therapeutic split and its past and future CAGR

INR billion	2012-13E	% share	CAGR	
			Past 5 years	Next 5 years
Cardiovascular system/ CVS	76.3	12	17	12–14
Respiratory	51.3	8	12	11–13
Vitamins/ Minerals/ Nutrients	50.1	8	14	11–13
Anti-diabetic	42.5	7	22	13–15
Neuro/ CNS	35.1	6	15	13–15
Dermatology	34.8	6	15	11–13
Gynecological	34.5	6	14	11–13
Anti-infectives	100.2	16	12	7–9
Gastro-intestinal	67.1	11	14	9–11
Pain/ Analgesics	50.5	8	12	8–10
Others	80.9	13	14	11–13
Total	**623.3**	**100**	**14**	**10–12**

Skill variations and requirements

R&D

- Strong analytical skills
- Efficient organizational skills
- Attention to details
- Efficiency in multi-tasking
- Ability to work in a challenging and fast-paced environment
- Ability to innovate

Production

- Efficiency in working with equipment
- Technology-friendly
- Attention to detail
- Strong analytical skills
- Efficient organizational skills
- Focus on quality

Distribution

- Appropriate product and industry knowledge
- Strong communication and marketing skills
- Working knowledge of computer
- Goal oriented
- Ability to work with targets

Source: CRISIL research; KPMG in India analysis

India's value proposition in generics remains strong despite competition from China

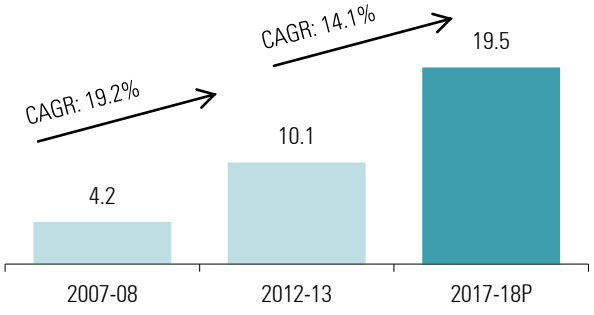
Key insights

- The formulation exports from India, to both regulated and semi-regulated markets, doubled from US$4.2 billion in 2007–08 to US$10.1 billion in 2012–13 (CAGR: 19.2 percent)
- Exports to the US accounted for a majority of the growth in formulations in 2012–13. It continued to register strong growth (22 percent year-on-year) in during the year
- Between 2012–13 and 2017–18, India's formulation exports are expected to grow at a CAGR of 13–15 percent
- Sales of generics, due to large number of patent expirations, is expected to grow at a CAGR of 6–8 percent over the next five years

Growth drivers

Patent expiries	India can benefit from a large number of expected patent expiries. Major drugs such as Nexium, Gleevec and Namenda are set to open up for competition in the generics market over the next five years
Rise in the number of ANDA approvals	The number of ANDA approvals received by the country is on a rise. India bagged more than 40 percent of total ANDA approvals in 2013
Expansion strategy of small and medium Indian companies	There has been a growth in the number of small and medium Indian formulation companies entering the US and Europe. Demand from these countries is also on a rise
Growing demand from semi-regulated markets	India has been able to develop strong alliances with global players to aid exports to semi-regulated markets. Semi-regulated markets such as Brazil and Russia are branded generics markets with high healthcare expenditure. Indian companies are also partnering with MNCs in these markets to utilize the marketing and distribution network of these MNCs in such markets

Formulations exports market size (US$ billion) (2007–08 to 2017–18)



Source: CRISIL research; USFDA; KPMG in India Analysis

India holds an important place in the global API industry

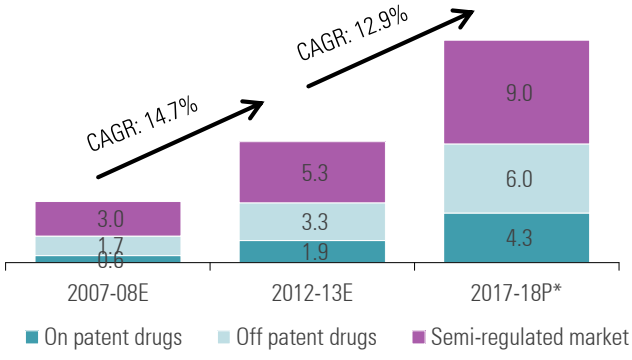
Key insights

- Indian bulk drug manufacturers primarily focus on export of APIs, to regulated and semi-regulated markets
- Investment in the bulk drugs segment is expected to rise in the coming years, as the sector grows strongly
- Between 2012–13 and 2017–18, bulk drug exports, largely driven by exports of primary off-patent drugs, are expected to grow strongly at a CAGR of 11–13 percent
- Between 2007–08 and 2012–13, bulk drugs exports grew at a CAGR of 18 percent, to reach an estimated US$10.5 billion

Growth drivers

Cost advantage	Due to the easy availability of skilled labor and cheap raw materials, cost of manufacturing bulk drugs in India is comparatively lower than that in developed markets of US/ Europe
Maximum DMF filings	In comparison to competitor countries such as China, Japan and Italy, India has filed the most number of DMFs to date, indicating India's conformity to the required quality standards for exporting to the regulated markets
Process chemistry skills	Excellent process chemistry skills makes Indian bulk drug manufacturers preferred choice for global innovators
Skilled personnel availability	Skilled personnel with high managerial and technical abilities are available in India at much lower costs compared with Europe and the US
Low infrastructure costs	India provides a considerable cost advantage vis-à-vis other countries in terms of setting up of manufacturing plants and operation costs

Bulk drug exports – review and outlook (US$ billion)



Source: CRISIL research; KPMG in India analysis

Sub-sectoral overview – Pharmaceuticals/ Contract Manufacturing

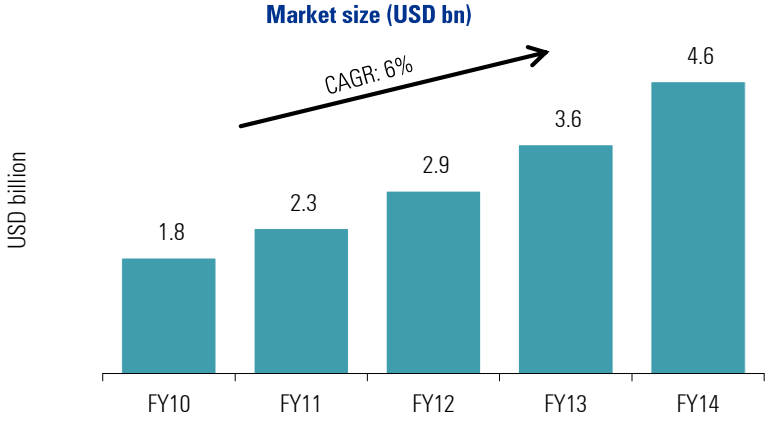
India offers cost advantage, compliant facilities and large talent pool to propel contract manufacturing

Key insights

- India has the capability (manpower, infrastructure) to manufacture APIs, intermediates and formulations in compliant plants
- Patent expiries, rising cost of U.S. Pharma companies and low infrastructure cost in India will further boost the contract manufacturing sector
- Key Players - Divi's Laboratories, Dishman Pharma, Aurobindo Pharma

Growth drivers

Patent expiries	India can take advantage of large pipeline of expected patent expiries. Major drugs such as Nexium, Gleevec and Namenda are set to open up for competition in the generics market over the next five years
Rising costs for US pharma companies	With the introduction of the Patient Protection and Affordable Healthcare Act, cost of US pharma companies has gone up. R&D expenditure is on a rise with decreasing productivity, increasing salaries, leading to outsourcing to manufacturing
Stricter USFDA norms	The USFDA is taking longer to provide approvals and is mandating additional clinical trials/studies before granting approvals. This is leading to delays and higher costs for firms. The process is outsourced to manufacturing to streamline the drug research process
Preference to Indian companies	Increasingly Indian companies are being preferred because of the product mix offered, which caters to high-end research services, and biologics and complex technology services
Low infrastructure costs	India provides a considerable cost advantage vis-à-vis other countries in terms of setting up of manufacturing plants and their operation costs



Source: CRISIL research, CARE research; KPMG in India analysis

Dietary supplements forms nearly two-third of the Nutraceuticals market and is primarily driven by the pharma sector

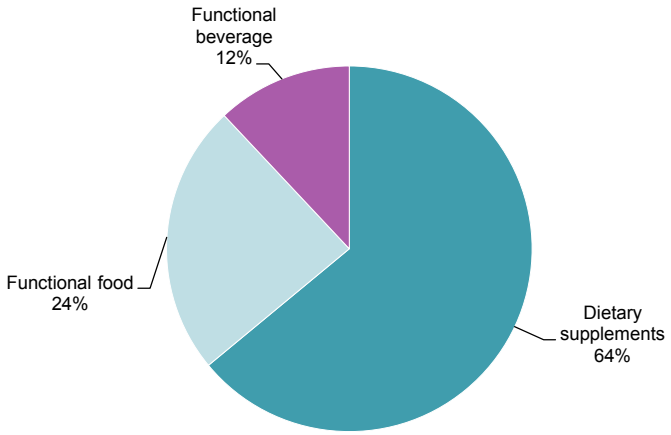
Key insights

- India contributes to a mere 2 percent in the total global market for Nutraceuticals. With greater presence in the urban areas, the segment remains underpenetrated or unexploited in other parts of the country
- In the form of vitamin and mineral supplements, the dietary supplements segment is primarily driven by the pharma sector
- Key players in the Nutraceuticals segment are Dabur India, Abbott India, Dr. Reddy's Laboratories, Ranbaxy Laboratories, Himalaya Drug, Yakult Danone, HerbalifeInternational India, Amway India Enterprises
- Pharma companies are increasingly seen entering the segment to supplement their therapeutic products with Nutraceuticals products. For instance, recognizing the shift in consumer preferences, Aurobindo Pharma added Nutraceuticals products to its portfolio. West-Coast Pharmaceutical Works and GRAF Laboratories, two Gujarat based pharma companies, recently announced plans of entering the Nutraceuticals segment

Growth drivers

Rising health consciousness	Significant increase in health consciousness is evident from flooding of new products in the market, specialized e-retail sites like Healthkart and fitness chains across the country. The consumer base is increasing continuously
Increasing disposable incomes and thereby healthcare spending	With the increase in disposable income and increasing health consciousness as a driver, the per capita spending on healthcare services and products is bound to happen in future
Increasing and aging population	India's with its huge young population is bound to be one of the larger markets in coming years, especially with growing working class relying heavily on Nutraceuticals for essential like vitamins

Nutraceuticals - market segments (2012)

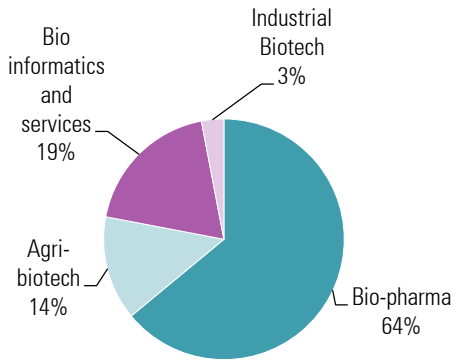


Source: CRISIL research, CARE research; KPMG in India analysis

The Indian Biotech market has demonstrated a robust growth trajectory

Segment	Revenue (2012–13)	Revenue (2012–13)	Revenue (2011–12)	Revenue (2011–12)	% change (for INR crore values)
	INR crore	US$ billion	INR crore	US$ billion	
Bio-Pharma	14,923	2.73	12,679	2.62	17.69
Bio-Services	4,329	0.79	3,749	0.78	15.47
Bio-Agri	3,210	0.59	3,050	0.63	5.25
Bio-Industrial	772	0.14	696	0.14	10.92
Bio-Informatics	290	0.05	266	0.06	9.02
Total	23,524	4.30	20,441	4.23	15.08

Percentage of companies involved in each biotech segment in India



- In 2012–13, the Indian biotech market grew 15.08 percent, to US$4.3 billion
- The BioPharma, clinical trials and contract research sectors accounted for 82 percent of market share in FY13
- India is among the top 12 biotech markets globally. It ranks second in Asia, after China
- India is known to be the largest global producer of recombinant Hepatitis B vaccines
- The Indian biotech sector is estimated to increase to US$11.6 billion by FY17
- Exports account for 52 percent of the BioPharma sector as total domestic sales amounted to US$2.11 billion (INR11,512 crore) in 2012–13
- Bio-pharma accounted for the largest share (of 65 percent) of the overall exports, while Bio-services accounted for 32 percent of export share
- The biotech sector, which is said to be at an inflection point, aims to garner US$100 billion revenues in 2025

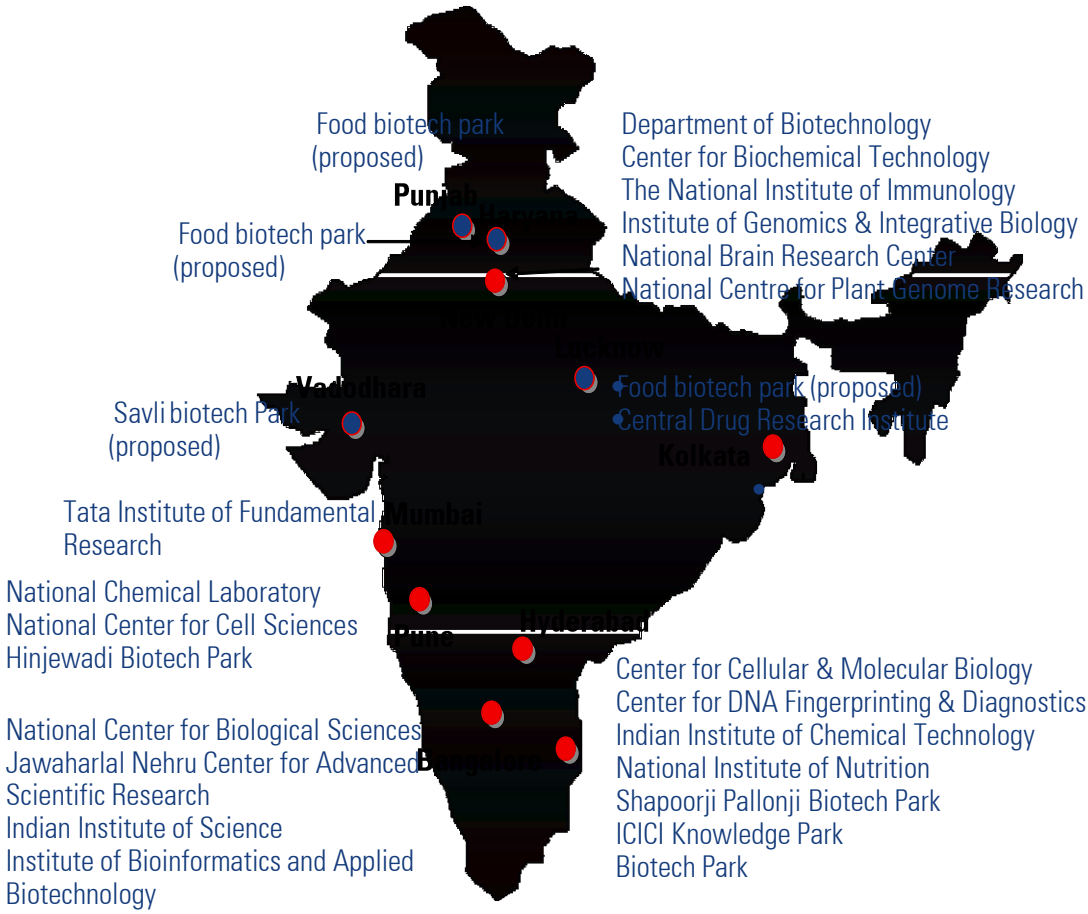
~500 biotech companies in India ⇨ **40,000 biotech students graduate per annum** ⇨ **Supply demand ratio of 25:1**

Even the existing supply of students has issues with the quality of training

Source: KPMG Analysis

The biotechnology clusters are concentrated in the south

Main biotech clusters in India



Region	Revenue (US$ billion)		
	2010–11	2011–12	% share 2011–12
North	0.42	0.36	9.47
South	1.54	1.72	45.27
West	1.52	1.72	45.27
Total	3.48	3.80	100

- Bangalore accounts for 50 percent of the total revenue in the national biotechnology sector
- During 11th Five Year Plan, six new institutions in different fields of biotechnology were started in India

Source: KPMG Analysis

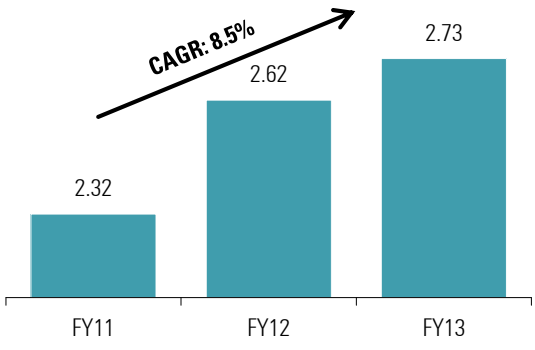
Sales from Bio products are expected to outpace conventional drug sales

Biopharmaceuticals – top 4 companies and their revenues

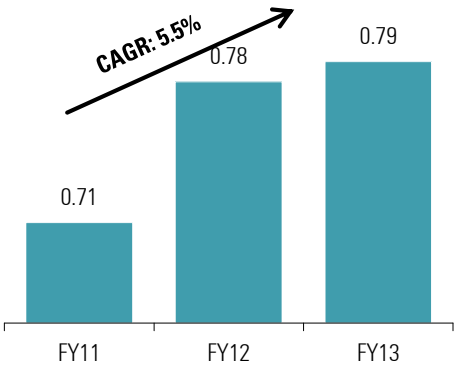
Company	Revenue (INR crore)			Revenue (US$ billion)	
	2012–13	2011–12	% change	2012–13	2011–12
Serum Institute of India	2,374.00	1,708.00	38.99	0.43	0.35
Biocon	1,871.00	1,676.40	11.61	0.34	0.35
NovoNordisk	712.00	647.28	10.00	0.13	0.13
Syngene International	557.00	410.00	35.85	0.10	0.08

- Top three companies account for 24.38 percent of the bio-pharma market, while top 20 companies account for 47.37 percent share of the total biotech sector of US$4.30 billion
- Over the past five years, the bio-pharma sector grew at a CAGR of 13.61 percent
- Bio-pharma includes biotechnologically engineered products, such as human insulin, plasma proteins and monoclonal antibodies

Bio-pharma market size (US$ billion)



Bio-services market size (US$ billion)



Employment potential in the sector

Serum Institute of India Ltd. has over 3,000 qualified scientists and professional employees

Biocon, Syngene and Clinigene together provide employment to more than 7,100 qualified personnel, ranging from biologists, chemists, medical practitioners, pharmacologists, engineers, finance/legal/marketing analysts, Human Resource generalists to general administrators

Source: Biospectrum, Serum Institute of India Ltd. company website; Biocon company website;

Sub-sectoral overview – Contract Research

Indian CRO segment comprises of a large number of players operating across the development value chain

CRO value chain

Drug Discovery Process	Pre-Clinical Study	Clinical Study
Disease Study/Target discovery, Target validation, Lead discovery, Lead testing, Lead optimization	In-vivo, In-vitro animal toxicity studies Filing of IND with FDA	Phase I – IV

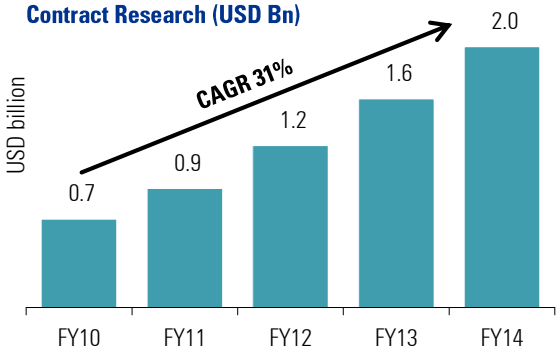
Companies

Drug Discovery Process	Pre-Clinical Study	Clinical Study
▪ AMRI ▪ EVOTEC ▪ Sai Life	▪ Divis Lab. ▪ Suven Life Sciences ▪ Sai Life ▪ AMRI	▪ Lambda ▪ Accutest ▪ Lotus Labs ▪ Karmic Life sciences*

▪ Syngene GVK Biosciences

India's drug discovery and pre-clinical industry has seen a robust growth over the years

- The drug discovery and pre-clinical market is estimated at about USD 2 billion in FY14
- The industry has more than doubled in the last 5 years
- Indian CROs are driving this growth through strategic alliances, portfolio and geographic expansion



Regulatory & Ethical Issues

- Ethical issues prompted the intervention of the courts: of the 162 approvals granted by the Drug Controller General of India until August 31, 2013, 157 trials were cleared in 2012, after a nod from just the New Drug Advisory Committees (NDACs). The Supreme court thus, suspended those 157 trials
- To tighten the regulation of clinical trials in India, the government has mandated that the ethics committees, which clear clinical trials, will have to be accredited in addition to being registered
- Regulations of clinical trials has also impacted the capacity of Indian players to conduct BE-BA studies

Source: KPMG in India analysis

Geographical clusters

Geographical clusters

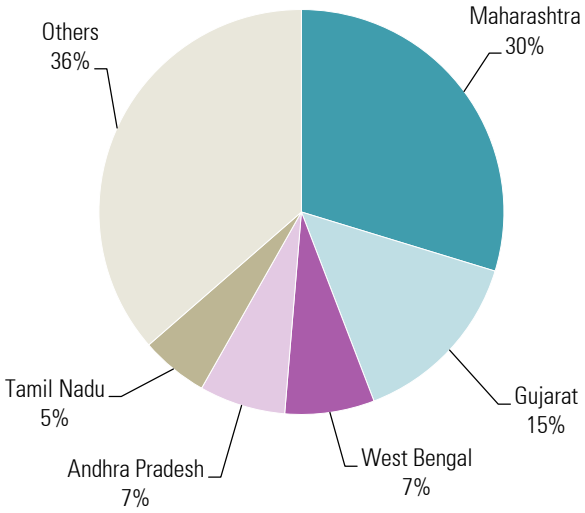
Majority of pharma companies are concentrated in the western and southern parts of the country

In India, pharmaceutical manufacturing units are primarily concentrated in Maharashtra and Gujarat. The two states collectively account for about 44 percent of the total number of pharmaceutical manufacturing units in the country

Geographical distribution of pharmaceutical companies in India

State	Number of manufacturing units		Total
	Formulation	Bulk drugs	
Maharashtra	1,928	1,211	3,139
Gujarat	1,129	397	1,526
West Bengal	694	62	756
Andhra Pradesh	528	199	727
Tamil Nadu	472	98	570
Others	3,423	422	3,845
Total	**8,174**	**2,389**	**10,563**

State-wise distribution of pharmaceutical companies



- The data clearly suggests the skewed concentration of the pharmaceutical units across the country
- Maharashtra remains an attractive destination for pharma companies due to better infrastructure facilities, conducive industrial atmosphere, enhanced support from small-scale companies and skills in chemistry
- The Maharashtra government promotes the "Centers of Excellence" which are expected to cover all aspects of cutting-edge R&D in emerging areas of life sciences and technology
- Gujarat has been very proactive in encouraging new investments in the state. It employs approximately 52,000 people in the pharma sector
- Himachal Pradesh, Jammu & Kashmir, Uttaranchal, Sikkim and Jharkhand — the 5 tax-free states — are seen as attractive investment destinations for pharma companies

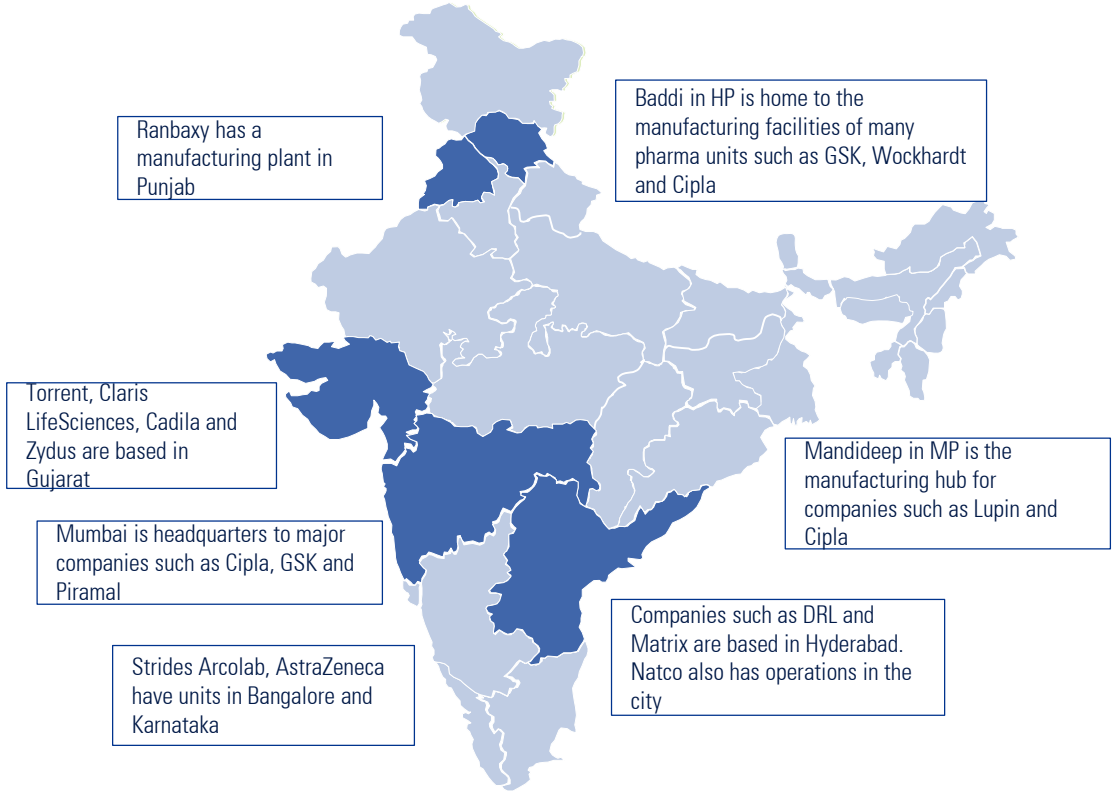
Sources: Department of Pharmaceuticals; KPMG in India analysis, ASSOCHAM

Geographical clusters

While the sector is fairly established in the south and west, the north is witnessing increasing activity recently

- The pharma sector in Himachal Pradesh (HP) and Uttarakhand is considered to be among the fastest growing in India
- The growth in these areas can be attributed to the incentives announced by the state governments in their Industrial Policy, 2004
- The HP government also launched initiatives to focus on developing new technologies in the areas of biotechnology for agriculture, animal husbandry and healthcare
- The chemical and allied MSME employment in HP in 2010 stood at about 9,376
- Haridwar, Roorkee, Dehradun and Rudrapur are reportedly the main hubs of pharmaceutical firms in Uttarakhand with ~200 pharma manufacturing units
- Baddi and some other pockets in HP have over 300 units
- Alembic, Dr. Reddy Lab, Alkem, Mankind, Torrent, Lupin, Cadila, Indswift Lab, Unichem, Morepen, Klitch, Ranbaxy, Nector, Surya, Cachet, Indchemie, Galpha are some of the major companies to have established their units in these areas
- The investment in the region is reported to be worth an estimated INR30 billion in recent years
- The development has also resulted in employment for thousands across the region

Key pharmaceutical ventures across India



Clusters have been highlighted in the map above based on the number and size of pharma units located across the country

Sources: KPMG in India analysis, IBEF August 2013

Geographical clusters

The northeastern states have announced initiatives to boost the growth of the pharma sector in the region

- Under the North East Industrial and Investment Promotion Policy (NEIIPP), 2007, the governments of the Northeastern states provide tax benefits to investors
- Excise duty exemption on finished products, income tax exemption and capital investment subsidy on investment in plant and machinery are some of the incentives being offered by the governments
- Sikkim has witnessed movement of many pharma companies into the state, due to the abundance of natural resources, as well as the monetary benefits offered by the government
- Education, bioinformatics and infrastructure projects have been initiated in the Northeastern states to provide support to R&D in pharma, biotech and allied activities
- As of 2011, 14 major companies, such as Cipla, Sun Pharma, Alkem and Zydus Cadila, had made investments in this region

Some initiatives undertaken under DBT support programs

Infrastructure

- A biotechnology incubator for entrepreneurship development in Assam
- Established regional research center of IBSD in Sikkim
- Women's biotechnology park
- Bioresources Centre at NEHU, Shillong
- Modern infectious disease detection laboratory/infrastructure in 11 medical schools
- A rural bio-resource complex targeting 1,500 households from 15 villages spread over 5 clusters
- Establishment of biotech hubs and state nodal centers

Bioinformatics

- Establishment of North Eastern Bioinformatics Network (NEBINet)
- Online information access facility for schools
- Creation of e-Journal access facility
- NER-DeLCON- e-Journals access to NER institutions

Education

- Program support in the areas of biotechnology to Indian Institute of Technology (IIT), Guwahati
- Program support to clinical research network in NER
- Network program on developing drugs from medicinal plants of NER
- Network on management of classical swine fever in piggeries in NER
- Launching of special fellowship/associateship
- DNA Clubs (DBT's Natural Resources Awareness Clubs) for NER
- Exclusive biotechnology overseas associateship for NER scientists
- Establishment of North Eastern Bioinformatics Network (NEBINet)
- Online information access facility for schools
- Creation of e-Journal access facility
- NER-DeLCON- e-Journals access to NER institutions

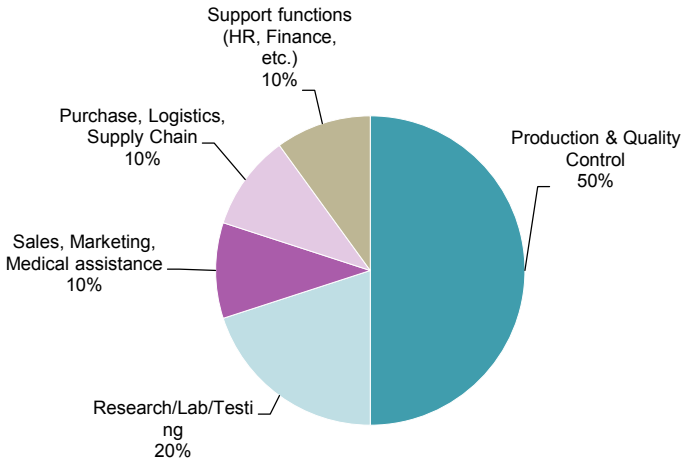
Sources: "Northeast India poised to be major pharma hub", BioSpectrum, KPMG Analysis

Demographic characteristics of workforce

The upward movement in the value chain is likely to create more demand for skilled labor

- A large percentage of the workforce in the sector is categorized under the informal/ un-organized bracket making it necessary to streamline job profiles and skill assessment for the people falling under these categories
- The workforce is expected to undergo gradual changes in its composition by in the next decade
- The managerial roles are expected to witness the steepest rise. This is indicative of the presently evolving status of the industry and the upward movement in the value chain
- Commerciality of the sector makes it a preferred employer for management graduates and accountants, while the production and research component makes it a preferred option for people with science and pharmacy backgrounds
- Colleges in India offer diplomas, undergraduate and post graduate degrees in pharmaceutical sciences
- Graduates in science also find employment in the pharmaceuticals sector
- The higher spectrum of R&D organizations requires candidates who have a doctorate or post doctorate degree

Percentage distribution of manpower in pharma industry



Qualifications of personnel employed in the chemicals & pharmaceuticals segment

Qualifications	Distribution
Ph. D / M.Tech / M.Sc etc.	5–8%
Graduate Engineers	15–25%
Diploma Engineers	10%
ITI and other vocational courses	15–20%
Graduates (BA/ B Sc./B.Com/ others)	15–25%
12th standard or below	20–25%

- Maximum number of employees (about 50 percent) in the pharma sector are engaged in the production and quality control division
- Ph.D/ M.Tech/ M.Sc account for only 5–8 percent of the workforce in the chemicals and pharmaceuticals segment, while a majority of the people employed in the sector have an educational background of 12th grade or below

Sources: Department of Pharmaceuticals, KPMG Analysis

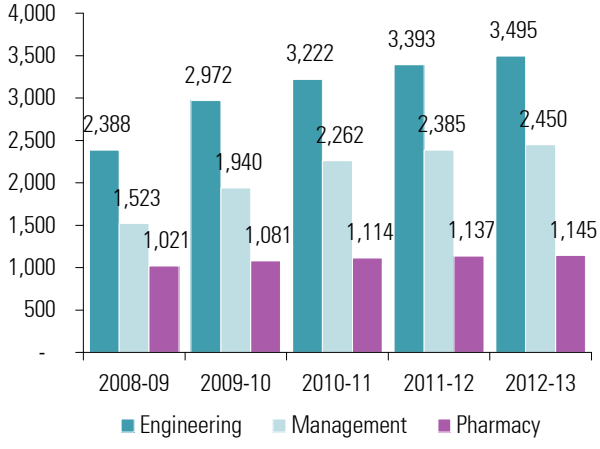
The pharma sector employees require varied skills to cater to different aspects of the diverse value chain

Demographic and workforce profile

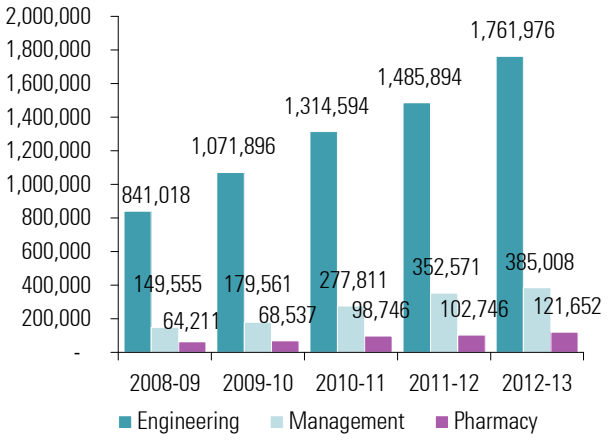
- The pharmaceuticals sector employs personnel from various backgrounds
- Commerciability of the sector makes it a preferred employer for management graduates and accountants, while the production and research component makes it a preferred option for people with science and pharmacy backgrounds
- Colleges in India offer diplomas, undergraduate and post graduate degrees in pharmaceutical sciences
- Graduates in science also find employment in the pharmaceuticals sector
- The higher spectrum of R&D organizations requires candidates who have a doctorate or post doctorate degree
- The pharmaceuticals sector has various allied fields such as healthcare, medical technology and biotechnology, which generate massive employment across the country
- The Indian pharma sector has been successful in creating rich talent pool of researchers, scientists, doctors and project managers

R&D	Production	Marketing and sales
Diploma holders, graduates, post graduates, doctorates and post doctorates in pharma and science	Diploma holders and graduates in pharma and science	Graduates from all disciplines, MBAs and CA's

Growth of technical institutes in India



Growth of intake in technical institutes



- The growth of industries in India after independence demanded the need for qualified professionals in fields such as business management and pharmacy
- Courses in pharmacy had a modest beginning. They started with short programs and moved toward higher quality programs of longer durations

Sources: All India Council for Technical Education; KPMG in India analysis

Incremental human resource requirement (2013-17, 2017-22) and skill gaps

Incremental human resource requirement (2013-17, 2017-22) and skill gaps

Current workforce of ~1.86 million (2013) is expected to increase 3.5 million by 2022

The pharma sector is expected to create a significant number of indirect employment opportunities with aggressive hiring at the entry level. Industry has witnessed. Hiring by major pharma companies has grown by about 24 per cent in 2013-14 so far, higher than in recent years indicating the high level of employment growth in the sector. Industry is estimated to employ over 1.8 million across the value chain. Manufacturing along with Pharma Retail account for maximum share of employment in the sector. Overall employment in the industry is expected to reach over 3.5 million by 2022.

Segment	Employment (in Million)			Employment Growth 2013-17	Employment Growth 2017-22	Employment Growth 2013-22
	2013	2017	2022	(In millions)	(In millions)	(In millions)
Manufacturing	0.69	0.89	1.15	0.20	0.25	0.45
R&D	0.07	0.09	0.11	0.02	0.02	0.04
Wholesale Sales	0.20	0.29	0.42	0.09	0.13	0.22
Pharma Retail	0.90	1.32	1.90	0.43	0.58	1.00
Total	**1.86**	**2.60**	**3.58**	**0.74**	**0.98**	**1.72**

Key Characteristics:

- The sector is expected to generate employment driven by the increasing healthcare awareness witnessed by the country
- Nearly one third of the workforce in the sector is categorized under the informal/ unorganized indicating the necessary to streamline job profiles to enhance productivity levels
- Field force (medical representatives) form a significant portion of the employment pie under the sales function
- With companies deploying more and more patient access programs, the sector has been hiring aggressively at the entry level to sustain growth
- While skillsets needed in R&D are well-defined, the manufacturing and sales function employs people from diverse backgrounds, creating the need for a technical training program
- As companies strategize to establish a footprint in rural areas and tier II and tier III cities, it is vital to establish credible distribution channels and a supply chain, which leads to a need for increased recruitment in these area
- Besides the direct employment generation, the sector is also expected to generate a significant number of indirect jobs

Source: Primary Interactions, KPMG Analysis

Critical skills

Changing skill set requirements		
	Skills required	**Skill gap**
SALES		
Need supervision (Medical representative, territory manager)	Detailed understanding of various pharma sector offerings and processes Knowledge of various third-party offerings with an attitude to sell Awareness of regulatory norms Understand physicians' needs and suggest suitable offerings Patience and perseverance Good oral and written communication skills Ability to work with targets	▪ Few undergraduate hires for regular procedural work ▪ Aspirational gap between the candidates' perception of work profile and the reality of their work ▪ Workers possess the theoretical knowledge, but lack the training required to fit into the job ▪ Disconnect between teaching and industry requirements ▪ Lack of structured training programs for MRs
Work independently (Area sales manager, regional/ zonal sales manager, National sales manager)	Ability to recruit, train and manage people Setting up sales targets for individual executives and helping achieve those targets along with retention and development of field force Development of area managers and medical representatives Clear and concise communication	▪ Aspirational gap between the candidates' perception of work profile and the reality of their work ▪ Lack of technical skills and regular trainings to stay updated on current norms ▪ Lack of people management skills
Manage a team (General manager/ Director- sales, VP-sales/ marketing)	Quick decision-making ability Analytical bent of mind Ability to handle new product planning, market research, strategy and sales responsibility Developing sales strategies, establishing system-driven national sales set-up Media interactions Developing road-map for business and market plans, and provide leadership to all the divisions	▪ Aspirational gap between the candidates' perception of work profile and the reality of their work ▪ Lack of initiative to take up tasks outside their role, leading to low level of innovation ▪ Lack of replacements in case attrition increases, up skilling required

Source: Primary interviews; KPMG in India analysis

Critical skills

Changing skill set requirements		
	Skills required	**Skill gap**
MARKETING		
Need supervision (Product executive, product manager)	Analytical bent of mind to study competitors' initiatives, develop pricing/ marketing strategies	▪ Aspirational gap between the candidates' perception of work profile and the reality of their work ▪ Lack of candidates with both technical and market acumen ▪ Lack of a structured training programs focused on pharma marketing
	Know-how on branding, product positioning and market perception	
	Good oral and written communication skills	
	Ability to understand market trends and demand fluctuations	
	Providing training to the field force on new developments related to competitor products	
Work independently (Senior product manager, group product manager, marketing manager)	Leading the team of product managers and motivating them	▪ Aspirational gap between the candidates' perception of work profile and the reality of their work ▪ Lack of people management skills ▪ Lack of a structured training program focused on pharma marketing
	Possessing detailed knowledge of pharma company portfolios/ marketing protocols and standardized marketing procedures	
	Having analytical bent of mind to develop product/ brand promotion strategies	
	Efficient management skills to assist with sales goals involving branding, communications, product and service development and customer relations	
Manage a team (General manager-marketing, vice president-marketing)	Quick decision-making ability	▪ Aspirational gap between the candidates' perception of work profile and the reality of their work ▪ Lack of initiative to take up tasks outside their roles ▪ Lack of replacement in case of rise in attrition, up skilling required ▪ Lack of training modules focusing on leadership, motivation and conflict management
	Analytical bent of mind	
	Efficient communication skills — visiting major clients and regional managers across the country	
	Organizational skills & Recruiting marketing staff	
	Ability to handle new product planning, market research, strategy and sales responsibility	
	Developing sales strategies, establishing system driven national sales set-up	
	Should possess in-depth knowledge and good understanding of the dynamics in the sector, as well as sub-sectors	

Source: Primary interviews; KPMG in India analysis

Critical skills

Changing skill set requirements		
	Skills required	**Skill gap**
MEDICAL SERVICES		
Need supervision (Medical advisor/ manager- medical services)	Required amount of medical, clinical and scientific knowledge to provide advisory expertise to all divisions	▪ Aspirational gap between the candidates' perception of work profile and the reality of their work
	Provide guidance to project managers on medical and scientific aspects	
	Good oral and written communication skills	
	Awareness of regulatory norms to comply with	
Work independently (Senior manager/ Deputy general manager- medical services)	Strong networking abilities and communication skills	▪ Aspirational gap between the candidates' perception of work profile and the reality of their work ▪ Lack of people management skills
	Thorough technical knowledge and data analysis skills	
	High level of accountability and ensuring continuation of stakeholder confidence	
Manage a team (Head- Medical Affairs/ General Manager- Medical Services, Medical Director)	Efficient management skills — managing medical staff, budgets and procedures	▪ Lack of candidates with both technical and management profiles
	Awareness of regulatory norms to comply with to formulate policies and procedures to deliver accredited medical services in order to meet all the required medical standards	
	Analytical bent of mind to develop clinical trial programs to support product registration and marketing	
TECHNICAL OPERATIONS		
Work independently (Manager- formulation development)	Exposure to patent and compliance norms to develop product, from conceptualization to the filing and commercialization	▪ Lack of compliance awareness training ▪ Lack of structured training modules with focus on Six Sigma and cost control ▪ Lack of candidates with know-how of statistical tools and other R&D adjacencies
	Ensuring cost efficiency	
	Ensuring seamless transition between conceptualization and marketing of the product	
	Knowledge of market trends relating to changing consumer demand and competition	
	Ability to work within targeted time limits	

Source: Primary interviews; KPMG in India analysis

Critical skills

Changing skill set requirements		
TECHNICAL OPERATIONS		
Manage a team (Production manager, head-production, head-R&D)	Effective management of production lines of the organization	▪ Lack of focus on research and hence lesser PhDs and Post-Doctoral fellows entering the industry ▪ Lack of innovative ideas, focus on reverse engineering
	Superior technical skills	
	Patience and perseverance	
	Efficient management skills to head the entire R&D and production department	
	Innovation skills to work on product development strategies and new drug discoveries	

Source: Primary interviews; KPMG in India analysis

Primary insights indicate the need for more external training programs, industry-academia collaboration and skill development

Primary growth drivers

- **Bulk drugs**
  - Generics, API, Bulk drugs to be the major drivers of growth in the next decade
  - Only a few players in the market, resulting in high potential to increase capacities of scale due to already existing customer base
- **Potential for growth**
  - Primarily export driven growth, major patents expected to expire in the near future
  - With drug manufacturers disclosing their DMF with the FDA, foreign formulators have the potential to source products from Indian factories

Workforce-related input

- **Skill gaps in the sector**
  - Lack of training for pharmacists
  - Need for enforcement, such as in the case of Maharashtra and Goa governments
  - Non-pharmacists provided only training, they do not have any qualifications due to lower salaries
  - Manufacturing roles are de-skilled, higher secondary graduates are hired and trained
- **Impact of technology on workforce**
  - Any intervention of technology is not expected to affect the proportion of workforce employed in the manufacturing segment. It will never decrease beyond 33 percent
- **Preferred form of training**
  - External training is given preference over in-house training, as it reduces the time spent by new joiners on the induction training

Need for industry – academia dialog

- **Industry – academia imbalance**
  - Disconnect between the school curriculum and industry requirements
  - Only theoretical knowledge imparted, without focus on job training
  - Curriculum is outdated, making autonomous institutions comparatively more flexible to adapt to latest external changes in the industry. It needs to be changed to target the retail segment
  - Focus on innovation required by educational institutions

Miscellaneous

- **New areas/ trends in the sector**
  - Discovery of drug processes and not just pre-clinical trials
  - Differentiated drugs evolving in the next 2–3 years
  - Increased focus on patient compliance
  - Specialized manufacturing processes for specific streams
  - Oncology, particularly in the field of biotechnology
  - Sales an emerging function or skill in the industry

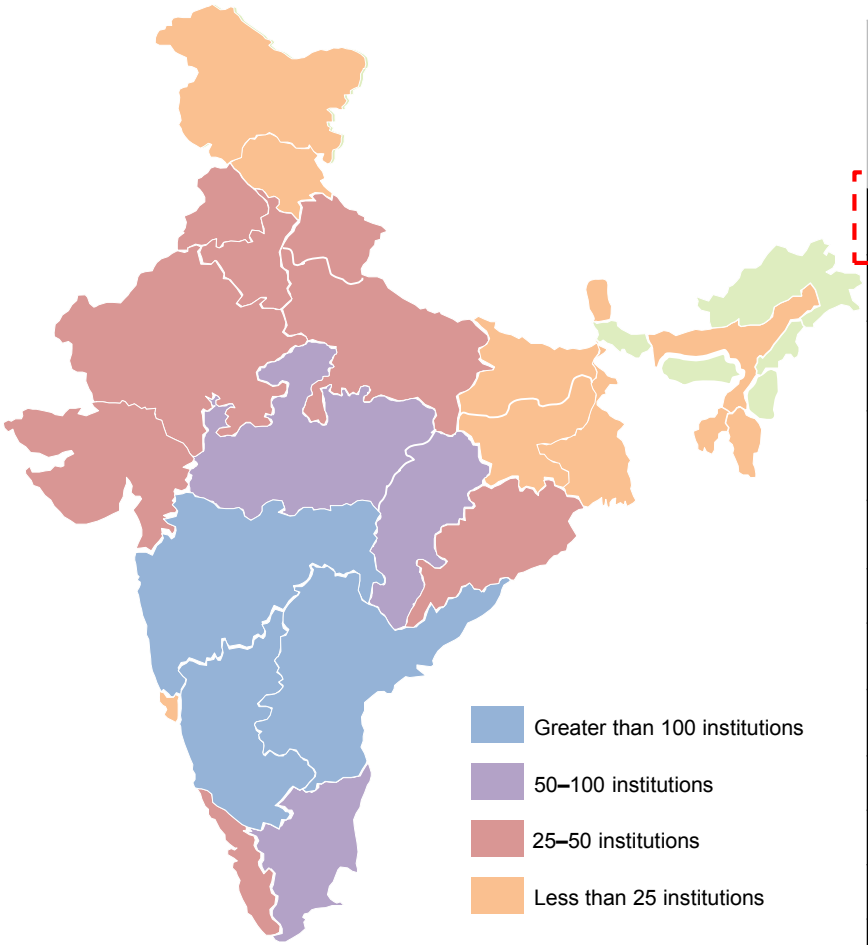
Source: Primary interviews; KPMG in India analysis

Training infrastructure

Training infrastructure

There is a visible disparity in the distribution of educational institutes that offer pharma education across the country

- The skewness in the distribution of the number of pharma units across the country is reflected in the pattern is similar for education institutes
- The map below indicates the distribution of AICTE-approved pharmacy institutions across the country



Total intake in important clusters

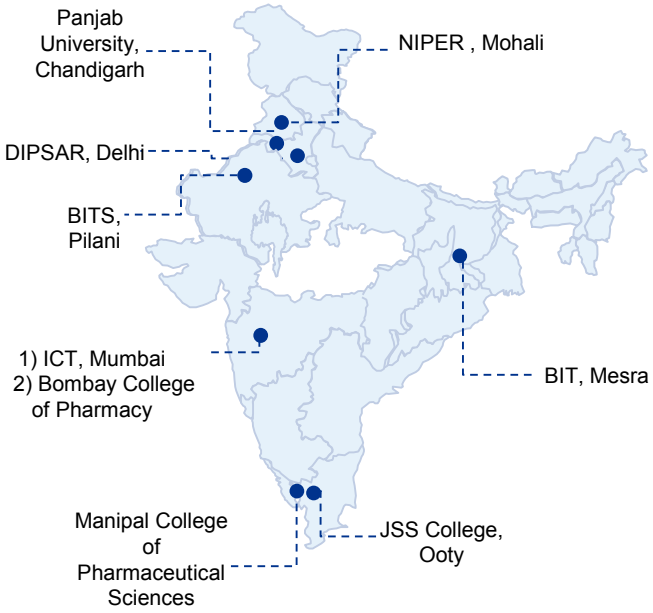
State/ UT	Total intake
Maharashtra	**10,240**
Karnataka	8,410
Andhra Pradesh	5,682
Madhya Pradesh	4,250
Tamil Nadu	3,390
Kerala	2,205
Uttar Pradesh	2,200
Rajasthan	2,069
Gujarat	2,025
Punjab	1,920
Haryana	1,745
Orissa	1,370

- Maharashtra accounts for the largest number of AICTE-approved pharmacy institutes, followed by Karnataka and Andhra Pradesh
- Northeastern states such as Arunachal Pradesh, Meghalaya and Manipur still do not have any AICTE-approved pharmacy institutes offering either diploma or degree courses

Source: All India Council of Technical Education

Leading pharmacy colleges in India need to focus on revising their curriculum to make the education relevant to the sector

Employers preference for supply sources: pharmacy institutes



National Institute of Pharmaceutical Education and Research (NIPER), Mohali

- NIPER offers masters and doctoral programs in various fields of pharmaceutical sciences
- The preferred courses are Pharmaceutics, Quality Assurance, Pharmacology and Medicinal Chemistry
- NIPER hosts several research facilities, including the National Bio, Availability Center and National Toxicology Center
- The Department of Pharmaceuticals has planned an investment of INR3,000 crore to set up 10 more National Institute of Pharmaceutical Education and Research (NIPER) over the next five years

Institute of Chemical Technology, Mumbai

- The Institute of Chemical Technology (ICT), formerly the University Department of Chemical Technology (UDCT) focuses on training and research in various branches of chemical engineering, chemical technology and pharmacy

Issues and challenges

- There is a demand for pharmaceutical professionals across levels and sub-segments
- There is a lack of skills premium correlation to increasing wages, as the industry does not pay premium for pharmacy graduates in the sector
- The pharmacy courses and the industry needs are totally divorced from each other
- The curriculum is outdated
- Reluctance of students to work in areas such as community pharmacy vis-à-vis marketing, which is a popular field
- Low awareness of emerging streams such as regulatory space, drug auditing and clinical pharmacy
- There is a mismatch between the aspirations of students and the industry package
- Lack of practical training
- Lack of coordination among regulatory bodies, leading to stagnation of curriculum
- Rapid technological changes render the training imparted to students irrelevant
- Students lack patience and progression to higher job roles is slow in the industry, hence lot of them move to other industries
- There is a perception problem associated with working in community pharmacy hence most people only want to join the industry which skews the demand-supply ratio across jobs roles

Source: Primary interviews; KPMG in India analysis; Respective company websites,

Qualifications in biotechnology, chemistry, biosciences and pharmaceutical management are also relevant to the pharma sector

Some select institutes offering courses relevant to the pharmaceuticals sector in India

	List of pharmaceuticals research centers and institutions in India
Chemistry (graduate and post graduate courses in biochemistry, organic chemistry and inorganic chemistry)	▪ Loyola college, Chennai ▪ St Stephens, Delhi ▪ Miranda House, Delhi ▪ Christ University, Bangalore ▪ St Xavier's college, Mumbai ▪ Fergusson College, Pune ▪ Hansraj College, Delhi ▪ Hindu College, Delhi ▪ Ramjas College, Delhi
Biotechnology (engineering courses in biotechnology)	▪ Indian Institute of Technology Kharagpur (IIT KGP), Kharagapur ▪ Indian Institute of Technology Roorkee (IIT Roorkee), Roorkee ▪ Indian Institute of Technology (IIT Guwahati), Guwahati ▪ National Institute of Technology, Warangall ▪ Netaji Subhas Institute of Technology, Delhi ▪ PSG College of Technology, Coimbatore ▪ Thapar University, Patiala ▪ Manipal Institute of Technology, Karnataka ▪ Vellore Institute of Technology (VIT),Vellore ▪ BMS College of Engineering, Bangalore ▪ National Institute of Technology, Durgapur ▪ Chaitanya Bharathi Institute of Technology, Hyderabad
Management in pharmaceuticals (MBA in pharmaceutical administration)	▪ Indian Institute of Pharmaceutical Marketing (IIPM), Lucknow ▪ ASM's Institute of International Business & Research (IIBR), Pimpri, Pune ▪ SVKMs NMIMS (Narsee Monjee Institute of Management Studies ▪ SIES College of Management Studies, Navi Mumbai, Mumbai ▪ Lovely Professional University, Jalandhar ▪ Tilak Maharashtra Vidyapeeth, Gultekadi, Pune ▪ Jamia Hamdard University, Hamdard Nagar, Delhi ▪ Panjab University (PU), Chandigarh ▪ Mahatma Jyoti Rao Phoole University, Jaipur

Source: KPMG in India analysis

Recommendations for stakeholders

Recommendations for stakeholders

Skill sets required in pharma sector aren't tuned with curriculum

- Industry requirements is lacking synchronization with curriculum
- Lack of practical knowledge/required skill set is evident in new employees
- Industry people aren't concerned about the curriculum

Recommendation 1: Strong industry-academia linkage to figure out the industry needs and teach and train students accordingly

- Curriculum should be revised with inputs from industry people
- Incentivize them, with realization that they can save money spent on training, if students are trained in college only (as per the requirements)

Industry prefer general stream students over pharma students

- Students are reluctant to join pharma sector as they aren't preferred for placements
- Lucrative streams are available for making money as compared to the pharma sector

Recommendation 2: Regulations should be formulated wherein pharma students are preferred for employment

- Government should formulate regulations which would promote employment for pharma students and provide opportunities at par with other stream students

Enhancing the productivity of trainees and employees

- Employees lack productivity due to poorly designed training process
- It's better to mitigate losses of poor skill set by investment in training.

Recommendation 3: Industry needs to be proactive and invest in training

- Industry needs to be proactive and design training process as per the requirements of job
- They need to work in liaison with educational institution for devising a comprehensive and successful training program

Source: KPMG in India analysis

Quality of teachers not up to the mark

- Framing a good curriculum without good teachers on bench is useless
- Teaching as a profession is on a decline these days, getting good teachers on board is difficult
- Retaining them is also an issue, lucrative offers available from different sources

Recommendation 4: Incentivize and bring good quality teachers in the pharma sector

- More benefits should be given to teachers joining in, so that they stick with the profession and institute
- Incentives should be given on part of government's policy as well as institutes'

Setting up infrastructure to provide training and impart required skill set

- Institutes lack proper infrastructure for training students
- Lack of proper channelization of investment is pertinent
- Institutes can collaborate with industry for funding infrastructure

Recommendation 5: Up gradation infrastructure to impart industry-relevant training

- Improvising infrastructure would provide facilities for students to acquire better skill set
- Quality infrastructure, good curriculum, & good teachers would renown a college on national/international level

Liaison between various bodies framing curriculum

- Coherent curriculum is of utmost importance to develop a good skill set among students
- Poor curriculum results in lesser of demand of pharma students for employment in industry

Recommendation 6: Coordination between various accrediting bodies to have coherent curriculum and rules

- Inputs from academia, industry, government bodies, advisory should be taken for holistic development of curriculum, which meets the market requirement

Source: KPMG in India analysis

Sub standard level of Research & Development

- R&D has always been an issue with all the sectors prevailing in India
- Dire state of R&D is prevailing in pharma sector
- Lack of investment and professionals interested in R&D

Recommendation 7: Promoting and investing in R&D

- Government needs to invest heavily to boost R&D in pharma sector
- Collaborations with international university/colleges would help in improvisation of the same

Information lag amongst students about emerging job roles

- Students are poorly informed on part of emerging job roles in the sector
- Communication gap is prevailing between employers and employees as the channel for recruitment is very narrow

Recommendation 8: Awareness about emerging job roles has to be spread among students & customization of the curriculum accordingly

- A mobile application for updates on the vacancies in pharma sector in key towns and cities would be useful for the workers to locate jobs

Source: KPMG in India analysis

GOVERNMENT OF INDIA
MINISTRY OF SKILL DEVELOPMENT
& ENTREPRENEURSHIP

N·S·D·C
National
Skill Development
Corporation

Transforming the skill landscape

National Skill Development Corporation
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Email: skillgapstudies@nsdcindia.org
Web: www.nsdcindia.org