The background features a complex pattern of blue hexagons and circuit-like lines. The hexagons vary in opacity and color, ranging from light blue to dark blue. Some hexagons are solid, while others are outlines. The circuit lines are thin and white, connecting various points across the top and middle sections of the page. The overall aesthetic is clean, modern, and scientific.

Telangana Life Sciences: Vision 2030

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Foreword

Every advancement in the study of life sciences has the potential to change our world for the better. It could translate into a more sustainable environment, a more robust economy, and the need of the hour—better healthcare solutions for patients who need them.

Telangana has done well over the last few years to establish itself as a premier life-science hub in India through availability of skilled manpower, strong technical capabilities, favourable policies, and high quality infrastructure.

To give a further boost and the required thought leadership, our state government has constituted a Life Sciences Advisory Committee to set stretched aspirations to build a state-of-the-art life sciences grid, which is expected to double the growth of the sector and create lakhs of new jobs.

These developments demonstrate that the life sciences sector in Telangana is at a critical juncture; it now needs a strong push to develop into the premier life sciences hub of not just India, but also Asia and the World.

This report, "Telangana Life Sciences: Vision 2030", seeks to build on these aspirations by offering a comprehensive take on the landscape of the life sciences industry in Telangana, defining a vision for the industry, identifying potential challenges and outlining the way forward for the next decade.

I am certain that the rich insights shared in this report will propel the life sciences industry and our state of Telangana to greater heights.

Kallam Satish Reddy

Chairman, Life-Sciences Advisory Committee

Chairman, Dr. Reddy's Laboratories, and President Indian Pharmaceutical Alliance

Executive Summary

The life sciences industry in India has been witnessing unprecedented growth post India's independence, the opening of the economy and the global therapeutic revolution. The industry in Telangana too is primed to achieve healthy growth, well on its way to achieve its vision of "becoming one of the top life sciences clusters in Asia" by 2030.

LANDSCAPE OF THE INDUSTRY IN INDIA AND TELANGANA

The Indian pharmaceuticals sector is responsible for around 3.6 percent of global pharmaceuticals by value¹. India ranks 3rd worldwide for production by volume and 10th by value. Of the total Indian life sciences industry revenues of around USD 43 billion in 2020², Telangana accounted for USD 12.8 billion or nearly 30 percent of this revenues³. The state even leads in life sciences-related exports in India⁴. Further, the life sciences industry and the state of Telangana have had a symbiotic relationship over the years, paving the road to growth for one another.

VALUE PROPOSITION OF TELANGANA STATE

The Telangana Life Sciences sector is endowed with several assets and tail winds. The clusters have proximity to several renowned research institutes, and leading education institutes, and is already a home to ~800⁵ large Indian and Global pharma companies. Telangana created the country's first systematically developed life sciences R&D cluster – in the form of Genome Valley, which currently houses around 200 companies and has prepared Genome Valley 2.0 masterplan for its expansion. Strategic partnerships include the ones with Department of Biotechnology for B-Hub and with United State Pharmacopeia on a skilling programme focused on data and quality standards, with Centre for Cellular and Molecular Biology (CCMB) for developing an institution focussed on curative therapies.

¹ <https://www.investindia.gov.in/sector/pharmaceuticals#:~:text=India%20is%20a%20prominent%20and,%2010th%20by%20value.>

² Annual Report, Department of Pharma

³ Annual Reports, Team analysis

⁴ <https://economictimes.indiatimes.com/news/science/telangana-aims-to-double-size-of-life-sciences-sector-to-100-bn/articleshow/63034969.cms>

⁵ <https://www.moneycontrol.com/news/business/companies/indian-pharma-aims-to-corner-7-of-global-market-by-2030-report-4120651.html>

The largest initiative of the state under the Life Sciences Grid – Hyderabad Pharma City, has completed the planning stage. In Medical Devices Park, ~ 25 companies are already setting up their manufacturing and R&D units.

Public-private partnerships have culminated in initiatives like T-Hub, RICH, Life Sciences Infrastructure Fund and such, which have made Hyderabad one of the hottest start-up ecosystems in the country. The state boasts huge native & acquired tech-talent pool, and is home to offices of the world-leading tech companies. Further, the state tops the charts in terms of ease of doing business, and ranks highly in quality of living too.

THE VISION FOR 2030

The Telangana life sciences industry's vision for 2030 is “to become one of the top life sciences clusters in Asia by leading innovation-driven and tech-enabled growth, and leveraging latent domestic demand”. This vision was formulated after detailed discussions with thought leaders from the industry, investors, academia, advisors, the state government and other non-governmental entities. To make this vision a reality, the state must attain USD 50 billion in cluster revenues, become Asia's pre-eminent innovation destination and follow the “Telangana for Telangana first” motto.

CHALLENGES TO THE INDUSTRY

To unlock growth and achieve its vision by 2030, the Telangana life sciences industry will have to overcome a few key challenges such as global patent cliffs, pricing pressures, quality issues, changing market dynamics and local headwinds.

Moreover, the sector must watch out for challenges such as lower focus on fundamental academic research, speeding up of the aspirational Hyderabad Pharma City, and scope for improvement in clarity and ease of regulations, employability gap and growing dependence on external markets. In fact, some these challenges to the industry could be opportunities for Telangana life sciences cluster.

THE WAY FORWARD

To overcome these key challenges and to unlock the next level of growth, the life sciences industry in Telangana would have to make certain key interventions, as formulated and discussed with the various stakeholder of the cluster.

These interventions are cut across three themes.

Giving a fillip to pure-play innovation:

- Scaling up infrastructure to help start-ups graduate to the commercialization stage
- Augmenting current sources of funding for existing and emerging innovations
- Establishing technology sharing and transfer linkages within and between industry and academia
- Floating grant-backed missions against critical diseases to serve the local population
- Spearheading the state's position as the leading clinical trials destination in India

Building a world class life sciences eco-system:

- Developing a world-class Pharma City that is conducive to breeding an integrated healthcare ecosystem (beyond just an industrial estate)
- Boosting the equipment manufacturing industry on back of the sector growth
- Attracting leading MNCs as anchor tenants (across manufacturing, offshore operations & analytics, and med-tech & digital)

Putting in place the enablers for sustainable growth:

- Creating training and finishing programs to bridge talent-employability gap
- Simplifying the regulatory framework that governs the local life sciences sector
- Improving ease of running operations seamlessly for existing industry
- Floating financial incentives to foster fresh investments, regularly undertaking policy changes, and further strengthening the investment promotion body with life sciences focus

By focusing on these strategic interventions and collaborating with key stakeholders such as industry players, academia, the central government and investors, Telangana could be well poised to achieve its vision for 2030, emerging as a forerunner in the life sciences cluster in Asia and the world.

Preface

Telangana's origins as a life sciences industry started way back in the 1980s with the setup of Indian Drugs & Pharmaceuticals Limited (IDPL). The last 25 years have seen this industry transform from being home to just local entrepreneurs to welcoming global MNCs, life sciences companies, research institutes and quality talent into its fold. It is no wonder that today, Telangana is famously called the "Vaccine Hub of the World"⁶.

As we work towards maintaining this momentum of growth, now would be the right time to think about how the industry transformed, critical elements in its ecosystem that helped spur growth and what it would take for the industry to realize its vision for growth by 2030.

Every year in India, 5 lakh children die due to vaccine-preventable diseases and another 89 lakh children remain at risk, because they are either unimmunized or partially immunized against vaccine-preventable diseases⁷. This is a gap that India & Telangana must close at the earliest with renewed focus on vaccine development & delivery. COVID-19 has further reinforced the importance of a strong ecosystem of research & development, clinical trials & manufacturing capabilities for vaccines for restoring & maintaining the physical & economic wealth of nations.

This knowledge paper titled 'Telangana Life Sciences: Vision 2030' emphasizes the need to focus on innovation and technology to make Telangana rank amongst the pre-eminent life sciences clusters in Asia. For this to happen, the industry, academia and government must walk together to achieve the singular goal of establishing Telangana's relevance in the global life sciences industry and to serve as a torchbearer of bleeding-edge technology and innovation.

We would like to express our gratitude to the multitude of thought leaders from the life sciences industry, academia, investors, legal advisors, the state government and various non-governmental entities who lent their invaluable insights towards creating this document.

⁶ <https://telanganatoday.com/telangana-is-now-a-vaccine-hub-says-ktr>

⁷ National Health Portal - Intensified Mission Indradhanush 2.0, Ministry of Health & Family Welfare

Life Sciences Industry Landscape in Telangana

Life Sciences Industry Landscape in Telangana

With the opening of the Indian economy in the 1990s and the discovery of huge opportunities in foreign markets, especially the US, the Indian life sciences sector began its journey of unparalleled growth. The growth was significantly facilitated by expertise in process engineering, low cost manufacturing, spurt in demand of domestic and generics markets and several other factors.

Overall reasons for the growth of the life sciences sector in India

Several factors led to the growth of the life sciences industry in India. These include:

Expertise in reverse engineering, process engineering and low-cost manufacturing

In 1970, the Indian Patents Act was enacted for process patents in the fields of drugs, medicines and food. Further, citing necessary reasons, the compulsory licensing of drugs was allowed. The intention behind this was to ensure the low-cost availability of medicines and to curb foul-play by monopolies. This fuelled the rise of many indigenous entities that specialized in reverse engineering, process engineering and cost-effective manufacturing, leading to a massive growth in low-cost, high-quality drug production in India.

Spurt in demand

The rapid growth of the Indian life sciences industry was boosted by a massive increase in domestic and international demand owing to several factors such as:

- **Huge domestic population**

Although India's age dependency ratio decreased from 51.6 percent in 2015 to 49.2 percent in 2019⁸, India's old age dependency ratio increased from 8.5 percent in 2015 to 9.5 percent in 2019⁹. This, coupled with a 4.27 percent overall increase in the population during the same period¹⁰, spelled huge growth in the domestic demand for better healthcare.

⁸ <https://data.worldbank.org/indicator/SP.POP.DPND?locations=IN>

⁹ <https://data.worldbank.org/indicator/SP.POP.DPND.OL?locations=IN>

¹⁰ <https://data.worldbank.org/indicator/SP.POP.TOTL?locations=IN>

- Increased access to better domestic healthcare facilities

India's GDP (current price) grew from approximately USD 2100 billion in 2015 to USD 2870 billion in 2019¹¹. This translated into an increase in the availability of better domestic healthcare facilities, with India's healthcare expenditure per capita from USD 57.83 to USD 82.5¹².

- Growth in exports and many blockbuster drugs going off patents

Over the years, a rise in exports, especially to the US, served as the biggest contributor towards the growth of the Indian pharmaceuticals sector. This happened due to an increase in the number of innovator drugs going off-patents in the early 2000s. Generic drugs constituted only 27 percent of drug costs in the US despite being responsible for 87 percent of prescriptions. Further, generics helped the US trim down its drug costs by around USD 1.46 trillion from 2006–2015¹³.

- Growth in medical tourism

The country's medical tourism industry is purported to grow from USD 3 billion in 2015 to USD 7–8 billion by 2020¹⁴. The presence of multiple low-cost and accredited facilities are the primary reasons for India's attractiveness as a centre for medical tourism, especially for natives from Afghanistan, Bangladesh, Africa, and GCC and CIS regions¹⁵.

- Increased attractiveness for allied services like clinical trials

India, by virtue of its huge population, provides a large pool of patients. The country also has a huge base of doctors, assistants and professionals with top-notch scientific and analytical skills—a boon for quality clinical research. Moreover, some of the regulations governing clinical trials such as the minimum number of trials, minimum number of hospital beds, accreditations to institutional ethics committees, compensations on severity of damages and approval processes were recently refined to accelerate the growth of clinical research in India¹⁶.

¹¹ <https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?locations=IN>

¹² Economic Intelligence Unit Data

¹³ <https://www.gphaonline.org/gpha-media/press/generic-drugs-continue-to-deliver-billions-in-savings-to-the-u-s-healthcare-system-new-report-finds/#>

¹⁴ [http://www.grantthornton.in/news-centre/medical-tourism-in-india-to-touch-us\\$-8-billion-by-2020-grant-thornton/](http://www.grantthornton.in/news-centre/medical-tourism-in-india-to-touch-us$-8-billion-by-2020-grant-thornton/)

¹⁵ <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/indian-medical-tourism-industry-to-touch-8-billion-by-2020-grant-thornton/articleshow/49615898.cms>

¹⁶ <https://health.economictimes.indiatimes.com/news/pharma/govt-plans-regulatory-pathway-to-assist-pharma-companies/46091175>

Other reasons that sustained growth

Apart from these factors that have boosted the growth of the Indian life sciences industry, there are a few additional reasons that have helped sustain this growth:

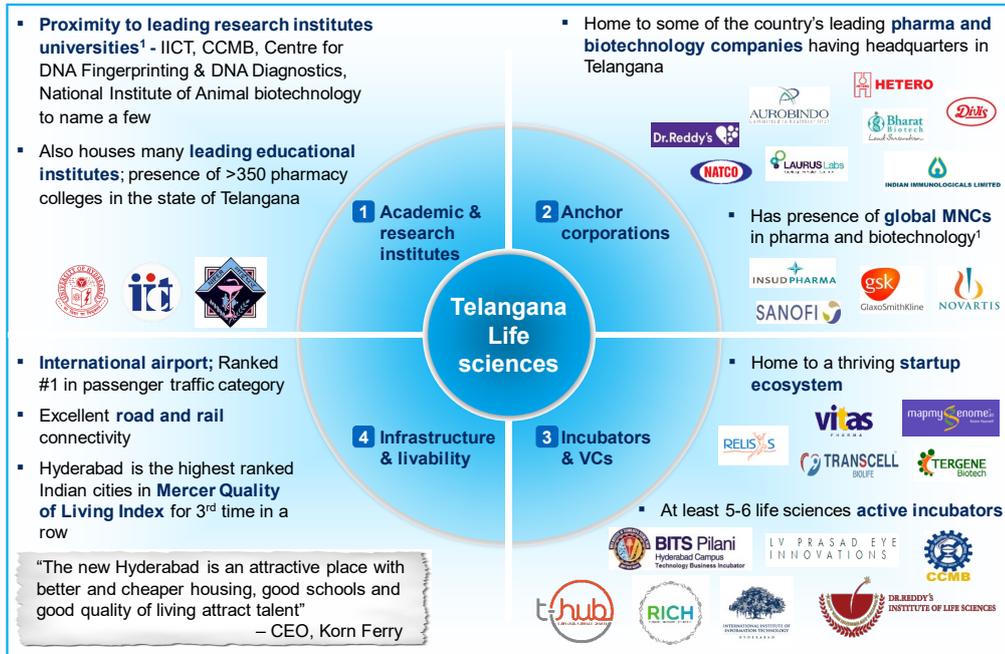
- Increased government expenditure in the healthcare space
- Increased private expenditure on healthcare
- Extensive knowledge base of regulatory know-how across markets
- Availability of a huge low-cost and skilled talent pool

Evolution of the Telangana life sciences industry

Telangana served as a cornerstone in scripting the Indian life sciences success narrative (Exhibit 1). A centre of prominence even during the pre-independence era of India, Telangana has been home to some of the oldest research institutes in the country such as the National Institute of Nutrition (1918) and the Indian Institute of Chemical Technology (1944), along with several pioneering bodies such as the Centre for Cellular and Molecular Biology (CCMB) and the International Crops Research Institute for Semi-Arid Tropics (ICRISAT). Further, with the establishment of industrial infrastructure, the rise of several Indian pharmaceutical giants and the growth of Hyderabad's IT industry in the 1990s, Telangana became home to prominent forums such as Pharmexcil, the Federation of Asian Biotech Associations (FABA), BioAsia and NIPER.

EXHIBIT 1

Telangana provides a strong life sciences eco-system

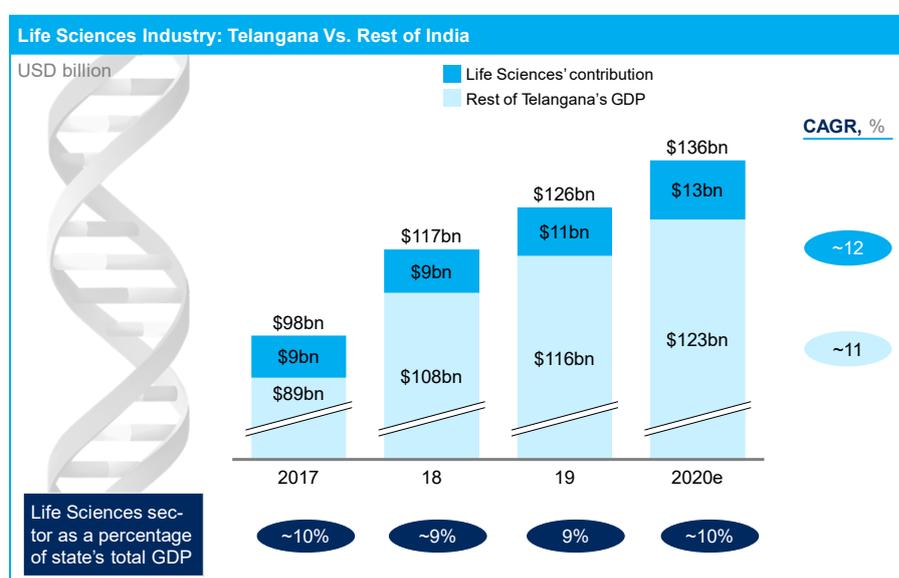


Contribution to the state's economy

Telangana's Gross State Domestic Product (GSDP) grew from USD 88.2 billion in 2016 to USD 136.28 billion in 2020, with a CAGR of more than 13 percent¹⁷. The state's life sciences sector was a key component behind unlocking this growth, growing from USD 9 billion to USD 13 billion in the same period, and clocking a CAGR of approximately 12 percent (Exhibit 2)¹⁸. Life sciences exports constituted around 60% of the state's merchandise exports(Exhibit 3), signalling healthy demand¹⁹.

EXHIBIT 2

Telangana's Life Sciences sector contributes ~10% to the state's GDP



SOURCE: Annual industry analysis

SOURCE: Company websites, annual reports, Capital One IQ, Hoovers

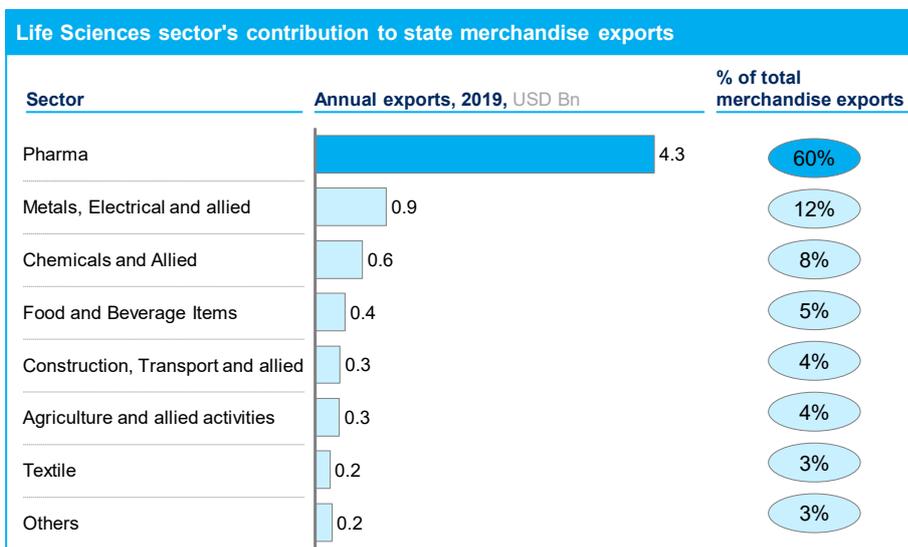
¹⁷ <https://www.ibef.org/states/telangana-infographic>

¹⁸ Company websites, annual reports, Capital One IQ, Hoovers

¹⁹ "Export strategy yields growth in Bangaru Telangana", The Hans India, October 17, 2015, Department for Promotion of Industry and Internal Trade (DPIIT)

EXHIBIT 3

Telangana's life sciences sector accounts for ~60% of the state's merchandise exports



Telangana's strong position in India's life sciences industry

The Indian pharmaceuticals sector is responsible for around 3.6 percent of the global pharmaceuticals sector by value²⁰. Out of the total revenue of approximately USD 43 billion generated by the Indian life sciences industry in 2020²¹, **Telangana accounted for USD 12.8 billion or nearly 30 percent** (Exhibit 4).

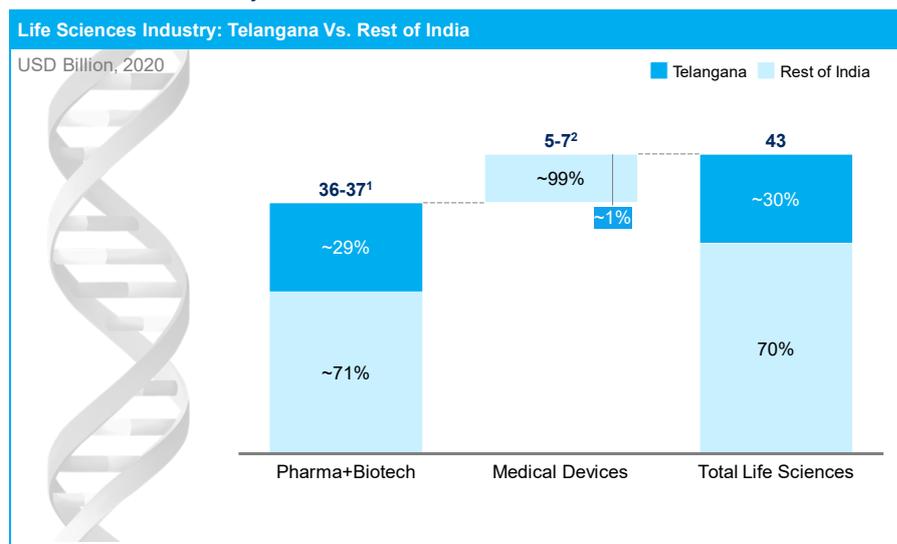
²⁰ <https://www.investindia.gov.in/sector/pharmaceuticals#:~:text=India%20is%20a%20prominent%20and,an d%2010th%20by%20value.>
<https://www.moneycontrol.com/news/business/companies/indian-pharma-aims-to-corner-7-of-global-market-by-2030-report-4120651.html>

²¹ Department of Pharma annual report

Even under an exports lens, Telangana is **amongst the biggest contributors towards pharmaceutical exports** from India, i.e., roughly USD 3.5 billion in 2019²².

EXHIBIT 4

Telangana constitutes around ~30% of India's total Life Sciences industry



¹ Economic Times, India Brand Equity Foundation Pharmaceuticals report, Make in India – Biotechnology
² Emergo research report, Make in India – Medical devices

SOURCE: Experts interviews, Team analysis, Press search

SOURCE: Expert interviews, IBEF: Pharmaceuticals (November 2017), IBEF: Biotechnology (July 2017), DIPP: Pharmaceuticals Sector Achievement Report (January 2017), Company websites, annual reports, Capital One IQ, Hoovers, Make in India – Biotechnology, Department of Pharma Annual Report FY20

The state also enjoys an assortment of endowments due to a rich academic heritage along with a **huge talent pool that spans from bio-sciences to information technology**. Moreover, Telangana has **the first-of-its-kind life sciences infrastructure in India in the Genome Valley, Hyderabad Pharma City and Med Tech Park** (Exhibit 5). Further, it is **one of the most cost-effective manufacturing destinations in India**.

Dubbed as the "Vaccine Hub of the World", Hyderabad has some of the country's leading vaccine producers, including Bharat Biotech, Biological E, Indian Immunologicals, Shantha Biotechnics (subsidiary of Sanofi) & VINS Bioproducts who own hundreds of patents and are critical suppliers for India's UIP as well as

²² <https://www.ibef.org/archives/state/telangana-reports/industrial-dev-economic-growth-july-2019>

exporters to ~100 countries. Telangana contributes to over 33% (See Exhibit 7) of India's vaccine exports.

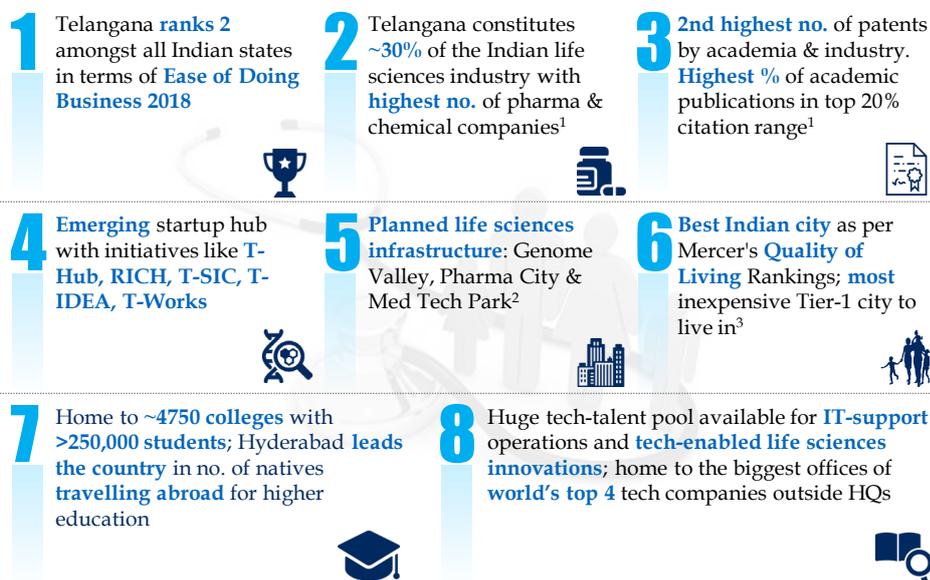
Telangana has been home to several major vaccine innovations including the first completely indigenous vaccines for rotavirus and Japanese encephalitis which also received WHO pre-qualification, and the world's first typhoid conjugate vaccine. Telangana is also home to one of only three producers of the oral non-live cholera vaccine²³.

Telangana has also been a prominent presence in development of COVID-19 vaccines. Hyderabad based Bharat Biotech developed the first Indian COVID-19 vaccine candidate to be given approval for human testing and has also been recognised by the WHO in its repository of vaccines under clinical trials. Several other vaccine majors like Biological E, Indian Immunological are in preclinical stages of COVID-19 vaccine research making Telangana one of the foremost centres of COVID clinical research in India²⁴.

²³ <https://www.cdc.gov/cholera/vaccines.html>

²⁴ <https://www.healthcareradius.in/clinical/26706-indias-role-in-covid-19-vaccine>

Telangana poised to lead life sciences growth in the country



¹ IKP-BIRAC Report; ² Pharma City & Med Tech Park are planned; ³ Press search
SOURCE: Team analysis, Press search

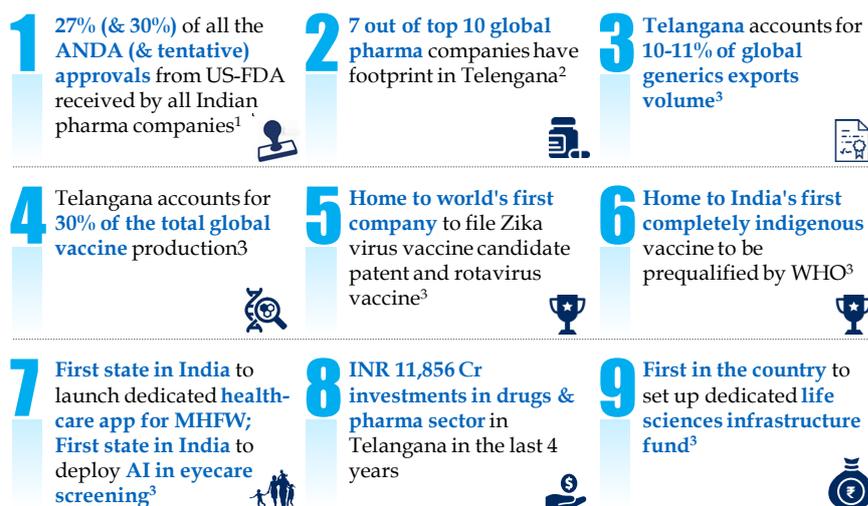
SOURCE

- <https://www.thehindu.com/business/telangana-leads-state-wise-ease-of-doing-business-ranking/article20005271.ece>
<https://www.businessinsider.in/business/news/next-ranking-of-states-for-ease-of-doing-business-likely-to-be-released-in-mar/articleshow/73136764.cms>
- Exhibit-4, Company websites, annual reports, Capital One IQ, Hoovers
- IKP-BIRAC: Mapping Regional Innovation Ecosystems, 2016, 2017
- <https://www.t-hub.co/>, <http://rich.telangana.gov.in/>, <http://www.thehansindia.com/posts/index/Indian-Business/2017-09-29/Telangana-govt-looks-to-cure-sick-MSMEs-in-a-big-way/330034>, <https://www.tgnns.com/goir-telangana-gov-in/t-idea-telangana-state-industrial-development-and-entrepreneur-advancement-incentive-scheme-2014/2014/11/29/attachment/1-25/>, <http://it.telangana.gov.in/sectors/t-works/>
- <http://genomevalley.co/>, <https://www.thehindu.com/news/cities/Hyderabad/pharma-city-to-come-up-on-19000-acres/article23337233.ece>, <https://www.thehindu.com/todays-paper/tp-national/tp-telangana/biggest-medical-devices-park-in-country-inaugurated/article19097575.ece>
- <https://timesofindia.indiatimes.com/city/hyderabad/hyderabad-best-city-to-live-in-india-survey/articleshow/63389408.cms>
<https://housing.com/news/hyderabad-affordable-metro-country/>
- http://mhrd.gov.in/sites/upload_files/mhrd/files/statistics/AISHE2015-16.pdf,
- Google, Microsoft, Apple, Amazon

Telangana is also poised to lead healthcare and life sciences growth in India in the coming years (Exhibit 6).

EXHIBIT 6

Telangana leading the life sciences growth story in the country



1 IKP-BIRAC Report; 2. Pharma City & Med Tech Park are planned; 3. Press search
SOURCE: Team analysis, Press search

SOURCE:

- [1. http://www.mondaq.com/india/x/674750/Life+Sciences+Biotechnology/Indian+Pharmaceutical+Companies+Abbreviated+New+Drug+Application+Approvals+2017](http://www.mondaq.com/india/x/674750/Life+Sciences+Biotechnology/Indian+Pharmaceutical+Companies+Abbreviated+New+Drug+Application+Approvals+2017)
- [2. https://www.business-standard.com/article/companies/j-j-s-largest-india-plant-to-be-operational-by-2018-11612200032_1.html](https://www.business-standard.com/article/companies/j-j-s-largest-india-plant-to-be-operational-by-2018-11612200032_1.html)
- [3. https://thewire.in/economy/pharmaceutical-drugs-exports-india](https://thewire.in/economy/pharmaceutical-drugs-exports-india); <http://www.hitex.co.in/images/img189.pdf>
- [4. https://timesofindia.indiatimes.com/city/hyderabad/hyd-produces-one-third-of-global-vaccine-output-ktr/articleshow/77157589.cms](https://timesofindia.indiatimes.com/city/hyderabad/hyd-produces-one-third-of-global-vaccine-output-ktr/articleshow/77157589.cms)
- [5. https://www.firstpost.com/world/made-in-india-hyderabad-scientists-claim-worlds-first-zika-vaccine-2610166.html](https://www.firstpost.com/world/made-in-india-hyderabad-scientists-claim-worlds-first-zika-vaccine-2610166.html)
- [6. https://www.thebetterindia.com/129080/rotovac-indias-first-completely-indigenous-vaccine-who-pre-qualification/](https://www.thebetterindia.com/129080/rotovac-indias-first-completely-indigenous-vaccine-who-pre-qualification/)
- [7. https://www.mahindracomviva.com/telangana-government-launches-indias-first-dedicated-healthcare-app-ministry-health-family-welfare-powered-mahindra-comviva.html](https://www.mahindracomviva.com/telangana-government-launches-indias-first-dedicated-healthcare-app-ministry-health-family-welfare-powered-mahindra-comviva.html);
<https://www.outlookindia.com/newscroll/telangana-to-use-ms-cloudbased-analytics-for-health-plan/1115582>
8. Government of Telangana
- [9. https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/telangana-teams-up-with-cerestra-to-set-up-indias-first-life-sciences-infra-fund/articleshow/57005228.cms](https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/telangana-teams-up-with-cerestra-to-set-up-indias-first-life-sciences-infra-fund/articleshow/57005228.cms)

Competencies across the value chain

As per analysts, India consistently led the world in the number of US FDA approved manufacturing sites out of the US. India currently has 665²⁵ US FDA approved sites out of the total 563 plants outside the US. Interestingly, within India, erstwhile Andhra Pradesh had led the country in the number of approved

²⁵ <https://www.investindia.gov.in/sector/biotechnology>

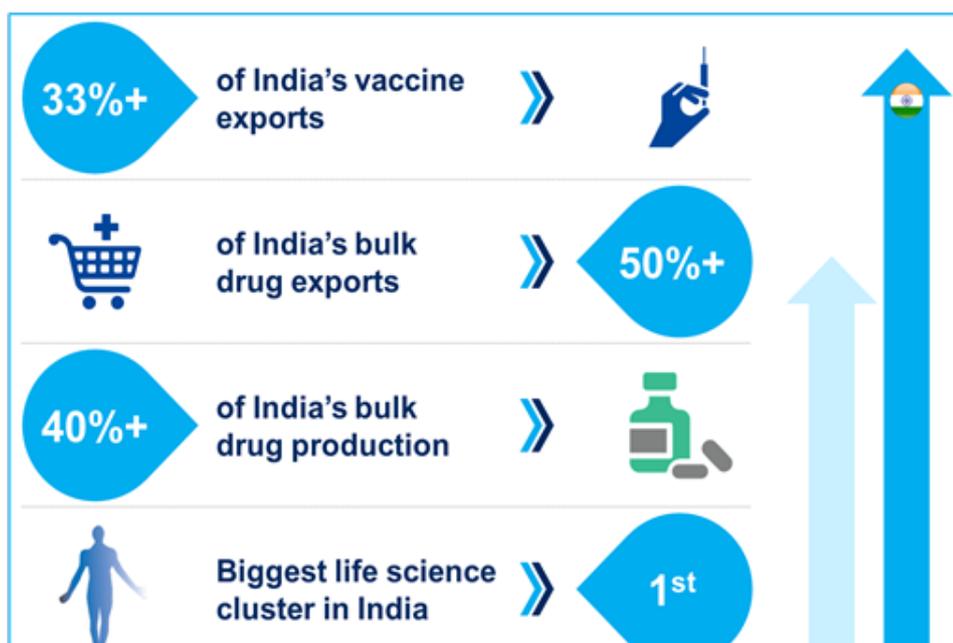
plants (66 out of 276).²⁶ Currently, Telangana is amongst the top 3 states in India with the most number of plants.

Spearheading access and affordability

The Indian pharmaceuticals sector has been the flagbearer of drug access and affordability worldwide. The country leads the supply of generic medicines globally, with a 20 percent volume share²⁷. In India, Telangana serves as the production hub for bulk drugs and API formulations (Exhibit 7), thus aiding not only exports, but also in meeting the domestic demand for affordable medication.

EXHIBIT 7

Telangana's contribution to drug access, both in India and globally



SOURCE: Press information Bureau; "Affordable Efficacious Medicines – All Roads Leads to India" report by IDMA; "Vaccines Market in India" reported by Netherlands Office of Science and Technology, HITEX Report 2019

²⁶ US FDA Database (2014)

²⁷ <https://www.investindia.gov.in/sector/pharmaceuticals#:~:text=India%20is%20a%20prominent%20and,%20global%20demand%20for%20vaccines.>

Structure of the state's life sciences industry

The life sciences industry in Telangana comprises three segments—pharmaceuticals, biotechnology and medical devices (see Exhibit 8):

Pharmaceuticals

Telangana's pharmaceuticals industry currently stands at around USD 12 billion. Further, Hyderabad accounts for 40 percent of India's total bulk drug production and 50 percent of total bulk drug exports, with exports contributing towards approximately USD 500 million out of the state's USD 1.6 billion bulk drugs industry. The state, along with Andhra Pradesh, is home to more than 2,500 pharmaceutical companies, with more than 200 API manufacturing units in the state²⁸.

Biotechnology

The USD 11 billion Indian biotechnology industry registered a 20 percent CAGR over the last decade. Based on the area of application, the sector can be classified into three segments—bio-pharma and bio-services bio-agri, bio-industry and bio-informatics, with first two segments accounting for more than 80 percent of the total Indian biotechnology market²⁹.

Bio-pharmaceuticals include all the therapeutic and preventive drugs that are derived from materials found in living organisms, while bio-services include allied activities like clinical trials, contract research and manufacturing. Henceforth, we would be referring to these two segments whenever we cite the biotechnology sector unless specified otherwise.

Hyderabad, Bangalore & Mumbai-Pune cluster are the foremost clinical research clusters in India, and Hyderabad has emerged as the preferred destination. With a vibrant innovation mega cluster in the Genome Valley that is home to top Indian & multinational CROs & CMOs including Dr.Reddy's Laboratories, Sai Life Sciences, Syngene, SYNEOS Health(erstwhile INC Research and inVentiv Health), Parexel International, VIMTA and many more.

Telangana's biotechnology market currently stands at around USD 0.8 billion. The state is home to more than 25 biotechnology companies, including some of the most prominent Indian bio-pharmaceutical manufacturers and leading clinical trial companies³⁰.

²⁸ HITEX Research Report: Pharma Industry in Hyderabad Region (<http://hitex.co.in/about/industryreport.html>)

²⁹ https://www.investindia.gov.in/sector/biotechnology&utm_term=

³⁰ Company websites, annual reports, Capital One IQ, Hoovers

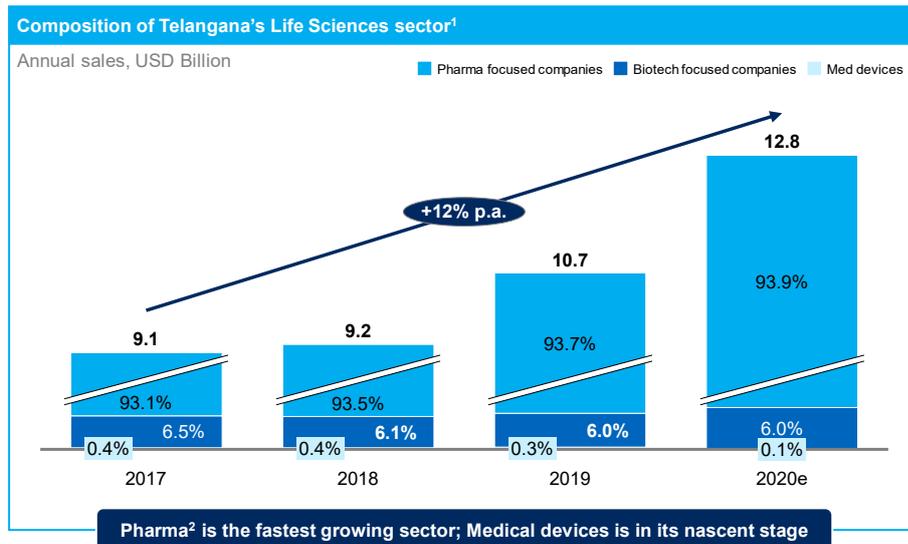
Medical devices

The medical devices industry in India is still at a nascent stage. However, it is expected to grow at a healthy rate over the next five years. This growth could be driven by the rapid rise of the urban poor and the middle class, an increasing government focus, a growth in infrastructure, and an increase in health insurance coverage and medical tourism.

Telangana's medical devices market in the last 2-3 years has taken off and is making rapid strides by attracting investments in R&D. Medical Devices Park, launched in 2017, has become one of the leading destinations for top medical devices companies in the Country. Spread across 276 Acres in Sultanpur village of Sangareddy district, the park offers dedicated ecosystem for Medtech innovation and manufacturing. About 25 companies are in the process of establishing their R&D and manufacturing units including Sahajanand Medical Technologies (SMT), Promea Therapeutics Private Limited, Arka Medical Devices, Virchow Biotech Private Limited, among others. Recently, Medtronic has committed to expanding the existing R&D centre with INR 1200 Cr investment³¹.

EXHIBIT 8

Telangana life sciences is a ~\$13 Bn industry by revenues growing at 12%; pharmaceutical companies constitute 94%



¹ Based on the analysis of top 80 life sciences companies in Telangana

² Biotech sector deemed to constitute bio-pharmaceuticals (therapeutic & preventive) & bio-services (clinical trials, CROs, CMOs)

SOURCE: Team analysis, Expert interviews, IBEF, FICCI report, Press search

³¹ <https://www.livemint.com/companies/news/hyderabad-to-host-medtronic-s-largest-global-r-d-centre-outside-us-11597214022048.html>

Telangana Life Sciences: Vision 2030



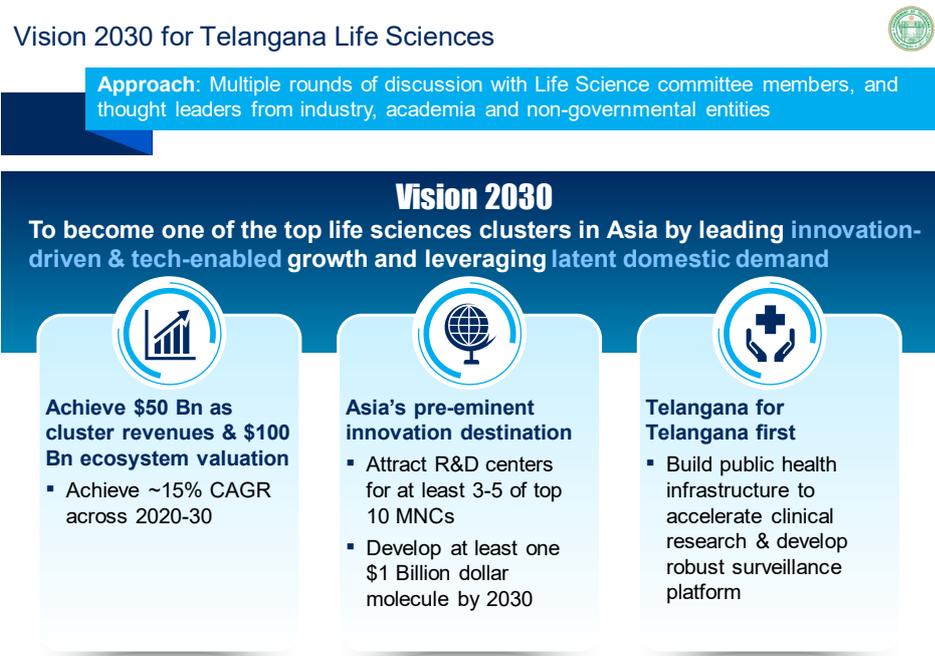
Telangana Life Sciences: Vision 2030

Numerous rounds of discussion with thought leaders from the life sciences industry, academia, investors, legal advisors, the state government and non-governmental entities led to the formulation of the 2030 vision statement for Telangana's life sciences sector.

VISION 2030: To become one of the top life sciences clusters in Asia by leading innovation-driven and tech-enabled growth, and leveraging latent domestic demand.

This vision entails a three-pronged ambition-setting approach, with a categorical focus on goals (Exhibit 9).

EXHIBIT 9



SOURCE: Team analysis, stakeholder interviews

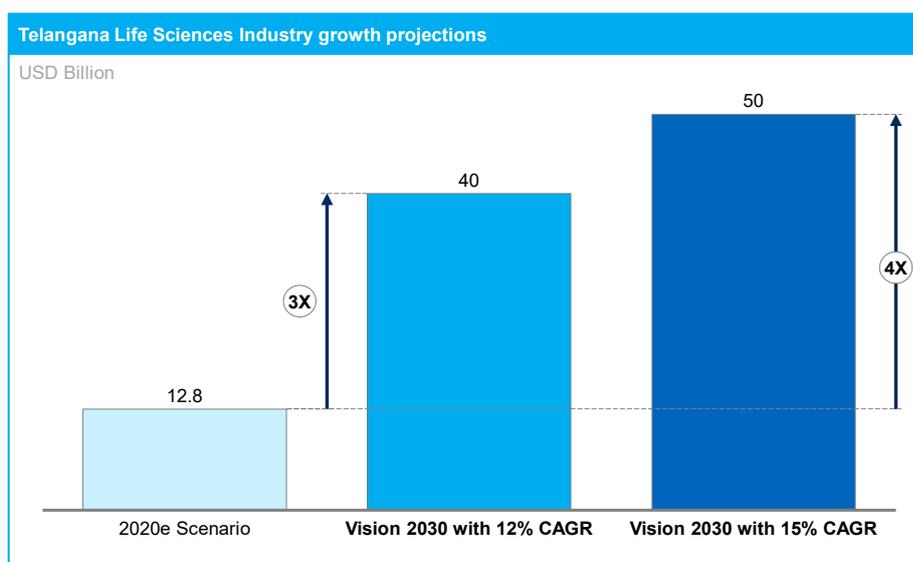
SOURCE: Interviews with industry, academia, government & investors

Achieve USD 50 billion in cluster revenues

The current growth rate of Telangana's life sciences industry, if continued till 2030, could lead to a 3x increase in current size. However, to realize the vision of USD 50 billion in cluster revenues (and USD 100 billion ecosystem valuation), the sector would need to boost its current growth level of around 12 percent per annum to around 15 percent per annum³² (Exhibit 10).

EXHIBIT 10

Telangana Life Sciences industry shall become 3x with the current CAGR, shall need 15% CAGR to become 4X



SOURCE: Expert interviews, company websites, annual reports, Capital One IQ, Hoovers

Become Asia's pre-eminent innovation destination

Besides being a life sciences manufacturing hub, the industry in Telangana would have to garner international relevance as a pre-eminent innovation hub.

For example, China did this by launching 19 NMEs (Class 1.1 new drugs) in the domestic market between 2006 and 2015. Likewise, Telangana could look at attracting not just manufacturing facilities, but also the R&D wings of leading pharmaceutical, biopharmaceutical and medical devices companies. In the same stead, the sector could also aim to realize the commercialization of at least one billion-dollar molecule or drug internationally to showcase the state's innovative prowess.

³² Expert interviews, company websites, annual reports, Capital One IQ, Hoovers

Telangana for Telangana first

India suffers from a huge disease burden, leading the number of deaths globally due to numerous communicable (TB, hepatitis, dengue, etc.), neo-natal and non-communicable diseases (cancer, diabetes, hypertension, etc.)³³. Telangana, as one of the frontrunners of the life sciences industry in India, has a significant opportunity to lead by example in meeting the latent healthcare needs of the domestic population. A concerted effort in capturing public health data through adequate data collection and management norms could help in understanding the extensive morbidity and mortality profiles of people in the country. Further, a commitment to boost clinical research in the state via infrastructure upgrades and training programs could help establish pre-eminence as the leading clinical research destination in India.

³³ http://www.who.int/healthinfo/global_burden_disease/en/

Challenges to the industry



Challenges to the industry

While the life sciences industry in India is all set to ride the next wave of growth, it is imperative for it to overcome a few key challenges such as patent cliffs, pricing pressures, quality issues, import dependence, changing market dynamics and local headwinds.

Import dependence for KSMs and intermediaries

A couple of decades earlier, India was self-reliant on Intermediates and Key Starting materials for API manufacturing. Over time significant part of this raw materials supply chain moved to other countries which have been able to set-up large scale facilities (e.g., China)³⁴. However due to changes in the global market dynamics the costs of import have not been sustainable and there has been supply risk of these raw materials. This calls for a concerted effort towards the development of India's self-reliance in such key intermediaries and starting materials. Telangana State Life Sciences cluster could play a significant role in this.

Pricing pressure

The generics industry has been subject to increasing pricing pressure due to various factors, such as:

- Domestic competition

India is home to more than 10,000 pharmaceutical companies, with more than 75 percent of them engaged in the manufacture of formulation drugs³⁵. As such, the industry is heavily fragmented, resulting in a significant overlap in target markets for individual entities and an erosion in generics pricing.

- International competition

The cost of establishing an FDA-approved plant in India is lower than in developed countries by 50 percent, while production costs are lower by 40–70 percent and labour costs are lower by around 60–70 percent³⁶. However, there are other emerging economies that offer a similar degree of cost savings

- Buyers' leverage

³⁴ <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/taking-steps-to-reduce-dependence-on-api-imports-government/articleshow/57790774.cms>

³⁵ <http://www.nppaindia.nic.in/Directory-NPPA.pdf>

³⁶ <https://www.drugdevelopment-technology.com/contractors/regulatory-affairs/pharmaceutical-developmentgroup/pressreleases/pressindia-pharmaceutical-industry/>

Volume-driven buyers' leverage has added to the continually downward pricing pressure on generics.

Quality issues

Globally, the generics industry has been subject to stringent US FDA norms, with many domestic generics companies facing alerts and warning letters. Since India has the highest number of FDA-approved plants outside the US³⁷, the industry could stand to experience more discomfort if these quality-related issues are not solved soon. Some of these issues include:

- More stringent norms

The frequency of FDA inspections has increased from around once in two–three years to once–twice a year. Also, the FDA has decreased prior intimation time for plant inspections to as little as 24 hours from 25–30 days earlier³⁸.

- Evolving standards

Regulatory bodies' norms on Good Manufacturing Practices (GMP) are evolving, making it imperative for companies to keep up with the pace. Further, given the changing nature of the industry's product portfolio, it is also important for the domestic regulatory body to address the differences in the requirements of different product categories (e.g., NMEs, biologics) to enable players to launch products in a timely and effective manner.

³⁷ <http://www.livemint.com/Industry/FsuFVKI1dNC30O4TyWeOGO/Fading-glory-Indian-pharma-industry-in-uncharted-terrain.html>

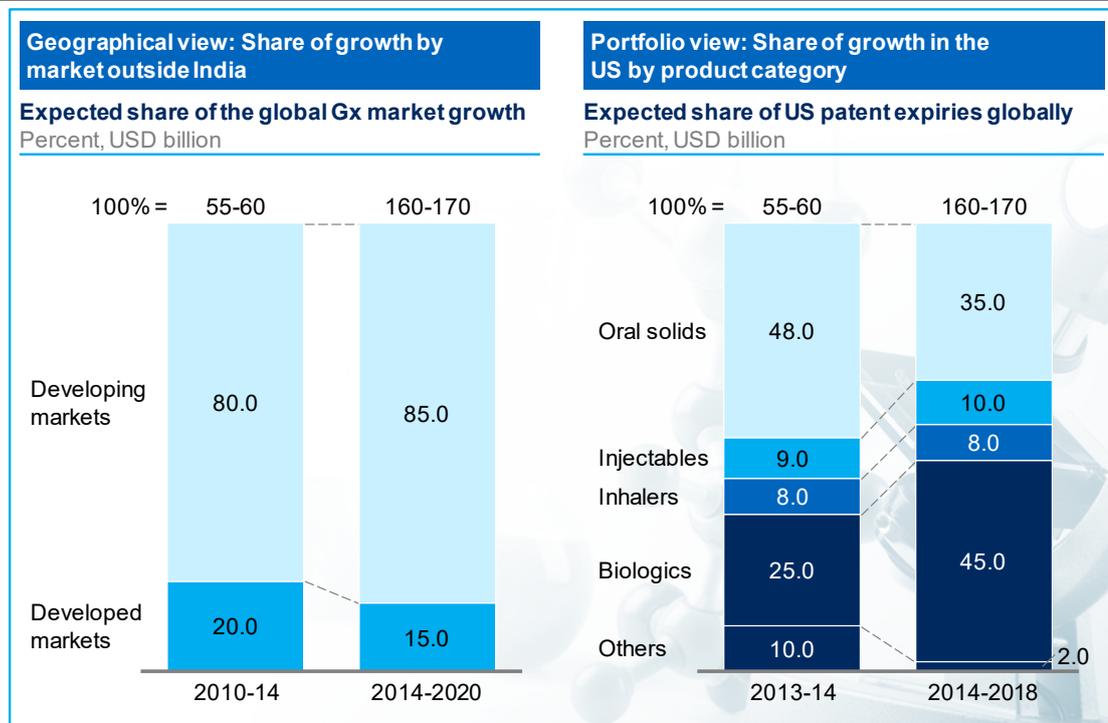
³⁸ <http://www.livemint.com/Industry/FsuFVKI1dNC30O4TyWeOGO/Fading-glory-Indian-pharma-industry-in-uncharted-terrain.html>

Other factors

As per a CRISIL report, the value of blockbuster drugs going off-patent has decreased from USD 48 billion in 2012 to around USD 20 billion in 2016³⁹. Thus, there is a significant pressure on generics producers to find additional revenues streams.

Further, the sources of growth in the global generics industry are undergoing a fundamental shift in geographies and portfolios (Exhibit 11), transitioning into areas where the Indian industry does not have a very strong presence today. This may impact the industry's ability to tap into these opportunities at the same scale⁴⁰.

EXHIBIT 11



SOURCE: Team analysis, Press search, IKP-BIRAC report, FICCI

SOURCE: FICCI Indian life sciences: Vision 2030; Expanding global relevance and driving domestic access, 2015

Also, emerging markets beyond BRIC countries may now account for around 25 percent of the growth⁴¹. Given India's nascent presence in these markets and strong local competition, the industry may need to make strong efforts to drive meaningful contribution from these markets.

³⁹ <http://www.livemint.com/Industry/pyVSAW1ntd4qbnoxaNUizJ/Indian-generic-exports-to-decline-1012-in-next-5-years-CR.html>

⁴⁰ FICCI Indian life sciences: Vision 2030; Expanding global relevance and driving domestic access, 2015

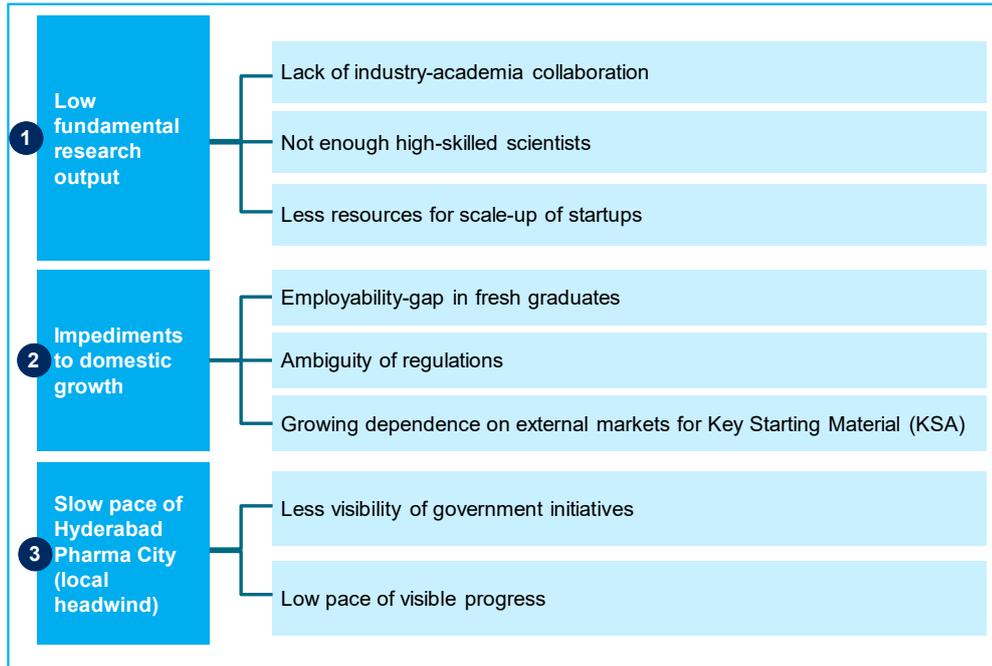
⁴¹ FICCI Indian life sciences: Vision 2030; Expanding global relevance and driving domestic access, 2015

Headwinds

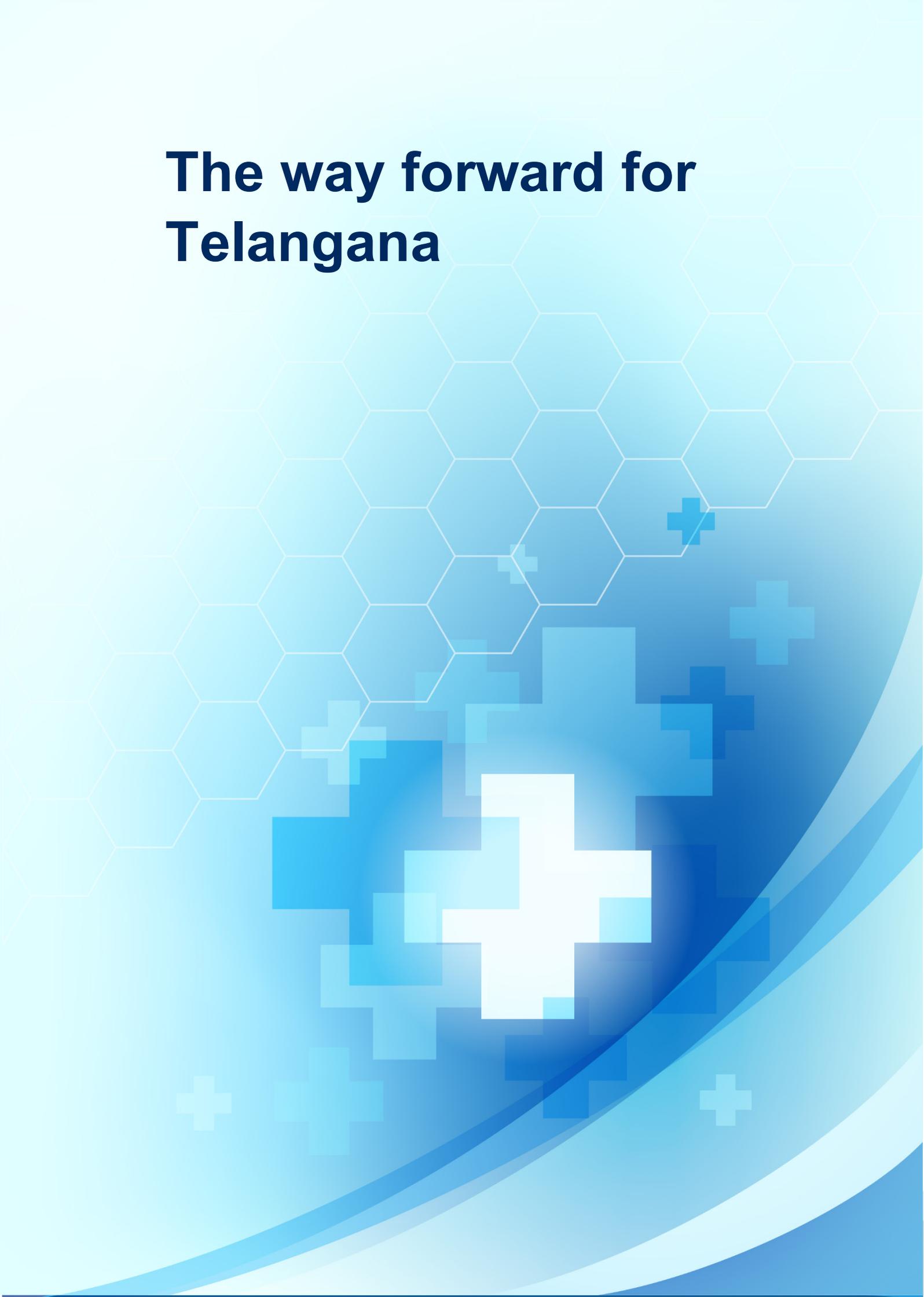
Life sciences sector across the country is also affected by headwinds as voiced by the industry, academia and investors (Exhibit 12). It is important for the sector to convert these challenges into opportunities to make growth sustainable and Telangana could lead the way for the country.

EXHIBIT 12

Headwinds affecting life sciences industry



The way forward for Telangana



The way forward for Telangana

Given current market dynamics, the ecosystem in Telangana and the aspirations that stem from the 2030 life sciences vision, the state could consider the following interventions across three themes (i) Giving a fillip to pure-play innovation, (ii) Building a world class life sciences eco-system, (iii) Putting in place the enablers for sustainable growth.

The initiatives under each of the themes are listed as below and explained in detail subsequently.

Giving a fillip to pure-play innovation

- Establish scale-up infrastructure to aid start-ups in graduating to the commercialization stage
- Augment current sources of funding for existing and emerging innovations
- Establish technology sharing and transfer linkages within and between industry and academia
- Float grants-backed missions against critical diseases to serve the local population
- Spearhead the state's position as the leading clinical trials destination in India

Building a world class life sciences eco-system

- Plan the development of a world-class Pharma City to make it conducive to breed an integrated healthcare ecosystem
- Boost the equipment manufacturing industry
- Attract leading MNCs as anchor tenants

Putting in place the enablers for sustainable growth

- Create training and finishing programs to bridge the state's talent-employability gap
- Improving ease of running operations seamlessly for existing industry
- Ensure the seamless operation of the domestic industry
- Float financial incentives to foster fresh investments
- Create an investment promotion body for the State's life sciences sector

Establish scale-up infrastructure to aid start-ups in graduating to the commercialization stage

Hyderabad is home to many upcoming life sciences start-ups, ranging from pure-play innovative drug discovery to genomics. While these entrepreneurs and scientists are keen on pushing innovation frontiers, they have minimal financial resources and little-to-no knowledge of manufacturing know-how.

To establish the city's pre-eminence as the leading life sciences innovation hub in India and Asia, it is important to develop a local ecosystem that helps accelerate the journey from the product development stage to the commercialization stage. While the incubators present in the city are capable of supporting the initial phase of start-ups, they are not prepared to help them take their products to the market.

Feedback from stakeholders suggests that the government could play an important role here by identifying missing cogs and facilitating complementary expertise to foster the growth of local start-ups and attract entrepreneurs from other states. This could be done by:

- While Government of Telangana is undertaking initiatives such as Biopharma Hub (B-Hub) and Diagnostic Hub (D-Hub), more of such initiatives could be undertaken by the Government for the life sciences start-ups. This could be done by establishing state-of-the-art labs, testing equipment and pilot plants to aid in prototype manufacturing and ramping-up production for clinical trials.
- Identifying the critical services required for conducting clinical trials and investing towards developing self-sufficiency in these capabilities. One example of a critical clinical trial service is intravenous formulation capacity for new compounds.
- Supporting the critical ancillary industries necessary to catalyse manufacturing activity in the state. Examples include manufacturing of reagents, chemicals, point-of-care test kits, etc.
- Creating an extensive repository of GMP-certified manufacturers and traders that deal in clinical-grade materials in the state. This information should be publicly available so it can be used as a ready reckoner.
- Designing training-cum-excellence programs for basic and advanced manufacturing practices for entrepreneurs, in conjunction with incubators.
- Spreading awareness amongst universities, colleges and start-up hubs about lab equipment and infrastructure availability at publicly-funded academic institutes in the state.

Augment current sources of funding for existing and emerging innovations

The state government has made conscious efforts to spur innovation locally. A few examples of these efforts include the Life Sciences Infrastructure Fund (in partnership with a PE)⁴², the Telangana Industrial Health Clinic (for growth of MSMEs and revival of sick units)⁴³ and the RICH-vetted Research-to-Market Fund to support market-driven ideas (in partnership with private investors)⁴⁴.

However, the availability of funding in Hyderabad is still lesser when compared to other innovation hubs like Bengaluru, which has the largest number of life sciences companies to have raised funds via seed, angel, VC or private investors⁴⁵. Hence, to boost the confidence of the entrepreneur community, the process of funding needs to be made transparent and time-disciplined. State support much also be extended to diffuse awareness on the availability of grants amongst young students, existing start-ups and innovation circles.

To address these issues, various stakeholders have advised the following potential steps to the government:

- Establishing a corpus with private partnerships for performing start-ups by pledging public seed investments for next-level, big-ticket rounds. A comprehensive incentive package could be provided to private investors for partial shielding against any downfall.
- Attaining buy-in from private investors/VCs by outsourcing the process of vetting proposals, ascertaining valuations and identifying winners. Investors with a demonstrated record of investment expertise in life sciences space could be given preference. Also, the inclusion of a government representative on the board of such a fund should be encouraged for monitoring purposes.
- Evaluating performance and sharing reports for state-sponsored life sciences funds, including the criteria for the awarding of the fund and complete timelines, i.e., from the receipt of applications to funds disbursal.
- Promoting programs that spread awareness about government-backed schemes via notifications, messages and mailers to universities and colleges.

⁴² <https://www.financialexpress.com/economy/in-a-first-in-india-telangana-plans-rs1000-crore-life-sciences-infrastructure-fund/714912/>

⁴³ <http://tihcl.telangana.gov.in/>

⁴⁴ <https://www.thehindubusinessline.com/news/national/hyderabadbased-rampd-institutes-join-hands-to-set-up-fund/article9559255.ece>

⁴⁵ IKP-BIRAC: Mapping Regional Innovation Ecosystems, 2016, 2017

Establish technology sharing and transfer linkages within and between industry and academia

Some of the biggest life sciences companies in the world were formed due to coalitions between the industry and academia. For example, Biogen⁴⁶ and Genentech⁴⁷ are examples of such alliances. There is a potential opportunity for closer coordination between these two groups in Hyderabad as well.

The city has some of the best entities in India, both in the academic and industrial space. Hyderabad's life sciences institutes lead the country in publications and patents. The state industry itself is amongst the biggest contributors to India's life sciences' GDP and industrial research output⁴⁸.

The government could consider regularly triggering and fostering a self-sustaining collaborative spirit in Telangana's academic and industrial circles by:

- Instituting the Telangana Council for Research, Science and Technology (T-CREST), which will involve the industry and academia, to outline the state's life sciences sector vision (long-term and short-term goals) and identify priority areas.
- Establishing formal Technology Transfer Offices for universities and colleges. Further, institutes which cannot sustain individual offices can be collectively catered to via a regional office.
- Designing training modules for the employees of Technology Transfer Offices with a focus on marketing and valuation mechanisms that are specific to the life sciences industry.
- Promoting the induction of faculty from eminent foreign universities to the state's academic institutes, and encouraging and incentivizing partnerships with foreign universities that lead in innovation in the treatment of India- and Telangana-specific critical diseases.
- Creating an extensive catalogue to record the research and innovation in academia and industry in the state, and forming a common portal that will be available to entrepreneurs, industry and academia to form a complimentary expertise.
- Incorporating awards to recognize the research and innovation achievements of the state's academia and industry.

⁴⁶ https://www.biogen.com/en_us/history-overview.html

⁴⁷ <https://www.gene.com/media/company-information/chronology>

⁴⁸ Expert interviews, IBEF: Pharmaceuticals (November 2017), IBEF: Biotechnology (July 2017), DIPP: Pharmaceuticals Sector Achievement Report (January 2017), Company websites, annual reports, Capital One IQ, Hoovers

Float grants-backed missions for drug & vaccine development for critical diseases to serve the local population

Case Study: The program ‘Cancer Moonshot’ was initiated by the former US President Barack Obama in January 2016 to accelerate cancer research. Congress in 2016 authorized USD 1.8 billion in funding over seven years. Further, an initial USD 300 million was appropriated in FY 2017 to fund Moonshot initiatives⁴⁹.

Similarly, driven by the Vision 2030 spirit of ‘Telangana for Telangana First’, the state government could spur innovation growth and meet the unmet medical needs of the masses by floating dedicated grants-backed missions against critical diseases. The government could consider floating grants for research against critical epidemics. This may require the following interventions:

- Identification of the top five critical communicable and non-communicable diseases that are plaguing the state.
- Creation of five disease-grants for innovative cures and solutions for priority diseases.
- Evaluation criteria to award points to industry and academia cohorts, and collaborations with foreign leading universities, companies and start-ups.
- Launch of an extensive public healthcare surveillance initiative driven by data collection and digitization to aid innovation.

Disease surveillance

There is a need to design a comprehensive and integrated surveillance program to target critical communicable as well as increasingly emerging non-communicable diseases to first, assess the disease burden, detect trends and duly allocate resources; second, pre-empt, contain and control threats to public health; and finally, establish the latent unmet need for healthcare facilities, thereby, making a case for investment in R&D and manufacturing for MNCs and domestic players. Further, the following could be considered:

- Data collection
 - Floating of an integrated, multi-tiered disease surveillance program, starting with prioritization of diseases to include non-communicable diseases owing to changing lifestyles.
 - Mandating mortality and morbidity recording for critical diseases that have been identified across public and private institutions.

⁴⁹ <https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative>

- Strengthening public laboratory infrastructure with referral lab networks and mentorship programs.
- Adoption of electronics record-keeping mechanisms, online portals and mobile-applications for submission of various forms and records.
- Data management and assimilation
 - District-wise capability building for epidemiologists, microbiologists, data managers, lab technicians and attendants.
 - Pattern identification amongst age groups, genders, regions, education levels, occupation categories, lifestyle parameters and more.
 - Periodic epidemiological (and compliance) reports to be circulated across all healthcare centres, and cascaded review meetings involving State, District and block-level teams.

Spearhead the state's position as the leading clinical research destination in India

It takes years for a positive talent-capital-talent virtuous cycle to develop, culminating into a world-class cluster, especially in the case of life sciences. At present, India's clusters are still too young and have miles to go before catching up with the world's leading clusters such as Boston and San Francisco⁵⁰.

However, there is a characteristic trait of the Indian demography that accords it a unique importance in the world's life sciences ecosystem, especially in the conduct of clinical trials. The country is home to more than a sixth of the world's population⁵¹ and also faces a huge disease burden—India witnessed the highest number of deaths globally in 2015 due to several diseases⁵², including but not limited to, the following:

- Communicable diseases: Tuberculosis, diarrheal diseases, encephalitis, hepatitis and dengue
- Neonatal conditions
- Non-communicable diseases: Cancer (mouth, breast, cervix, ovary, testicular), diabetes, epilepsy, sclerosis, hypertensive heart disease, digestive and musculoskeletal

Apart from this huge disease footprint, there are some other factors which make India a significant prospective clinical trials destination. India is home to a

⁵⁰ Life Sciences Cluster Report (JLL, 2014), <https://www.cuttingedgeinfo.com/2018/life-science-hotspots/>

⁵¹ www.worldometers.info/world-population/

⁵² http://www.who.int/healthinfo/global_burden_disease/en/

hugely diverse gene pool⁵³. Further, while some of the advanced treatments are prohibitively expensive for the common and the poor, the costs of conducting clinical trials in India is far lower than in developed countries. The country is also home to a large and a low-cost pool of doctors, support staff and data management experts who have good proficiency in the English language.

While clinical research was on an uptick in India a decade ago, lack of regulatory clarity & operational challenges have depressed the sector. To ensure Telangana emerges as a foremost cluster for clinical research in India & the world, with focus on not just clinical trials but other growing sectors like pharmacovigilance as well, the following interventions along the complete research ecosystem could be considered:

Building an environment conducive for clinical research

- Encouraging greater emphasis on clinical research training in medical curricula and supporting educational institutions in developing quality education and training programs for research professionals and clinicians.
- Developing robust accreditation programs for research operators and ethics committees
- Increasing awareness of clinical research & its benefits for patients & healthcare in the country

Addressing key issues to render the state's environment conducive to conducting extensive clinical trials

While private hospitals are already operating on thin margins and the amount of time and resources needed for conducting a world-class clinical trial program would not be particularly attractive for them, the government could consider stepping in. The state could first identify and designate public hospitals that could be established as pre-eminent clinical trial venues in the state. Also, the following interventions could be considered:

- Investing in the upgradation of target hospitals to conduct internationally relevant trials, with a key focus on:
 - State-of-the-art infrastructural facilities
 - Best-in-class hygiene and sanitation standards
 - World-class data management and protection mechanisms

⁵³ <https://www.theguardian.com/commentisfree/2009/sep/26/india-genetics-genes-science>, <http://www.thehindu.com/sci-tech/science/Study-throws-light-on-genetic-diversity-of-Indian-population/article16883266.ece>

- Nonpartisan ‘ethical committees’ governed by a conscientiously drafted ‘code of conduct’
- Positive and negative reinforcements to encourage hospitals and doctors to engage in clinical trials. This could include:
 - Hospitals: Increased share of clinical trials in ratings criteria and additional funding to conduct these trials.
 - Doctors: Long-term tenures for doctors participating in clinical trials and additional variable compensation for such participation.
- Recruitment, training programs and certifications for human capital, including lead doctors, nurses, support and emergency staff, and data handling specialists.
- Establishment of a strong review and grievance redressal system. This includes:
 - Availability of direct complaint and escalation helplines for patients.
 - Failsafe checks like surprise visits to hospital premises, random survey of participating patients, etc.
- Initiatives to approach and coordinate with leading MNCs that work in the area of drug discovery for diseases of critical importance to India to conduct clinical trials in partnership with Telangana-based hospitals.

Facilitating support to firms for approval of new drugs & vaccines

- Telangana can liaise with the Ministry of Health and Family Welfare to streamline the regulatory environment for clinical trials by
 - Empowering the CDSCO office in Hyderabad with decision making authority
 - Expansion of vaccine testing facilities by enabling setup of additional CDSCO approved lab infrastructure in Telangana
 - Increasing regulatory capacity by enabling expansion of training facilities

Plan the development of a world-class Pharma City to make it conducive to breed an integrated healthcare ecosystem

The Hyderabad Pharma City planned by the Telangana state government holds the potential to turn into a world-class life sciences centre. It includes several aspects such as:

Economic master plan

The Pharma City would cater everything related to pharma—from research to manufacturing and ancillary services. To realize this vision, the government, in addition to the disbursal of land, could create an economic master plan to allocate and divide the available land into industrial zones, residential areas, social amenities and physical infrastructure, and realize the phased monetization of real and commercial estates.

Comprehensive life sciences centre

A phased development plan would be required to tap into the entire life sciences spectrum such as API manufacturing units, formulation manufacturing units, generics and innovator R&D hubs, clinical trials and research destinations, big data, analytics and bio-informatics hubs, dedicated biotech and med-tech clusters, and centres for BPOs and support staff. This could be complemented by the establishment of transparent and merit-based allocation schemes for the disbursal of lands and resources.

To attract greenfield investments in the state, there may be a need for establishing a plug-and-play environment. This could entail creating a network of utilities, including water-lines, fuel-lines, steam-lines, HVAC-lines, a reliable 24X7 power source, common effluent treatment plants and more. Additionally, common supporting infrastructure such as warehousing spaces, cold storage facilities, logistics hubs, common labs and high-end testing equipment would have to be established.

Further, ring-fencing options might be considered for this mega project. Specific financial incentives, including tax breaks and low-cost capital could be offered to encourage newcomers. Jurisdictional privileges could help in boosting the confidence of investors. Also, establishing local offices, including but not limited to drug control, customs, and ‘connect-with-central-government’ could also help facilitate and streamline approval and compliance processes.

Moreover, to establish the ascendancy of the Hyderabad cluster as a leading innovation hub, a special high-technology complex could be considered with pilot investments and partnerships with world-leading universities. Aimed to become a one-of-its-kind centre in India, the venue could be home to research efforts that are dedicated to high-end and next-generation innovations such as carbon

neutral manufacturing, miniature manufacturing models, 3-D printing-aided manufacturing and more.

Public-private partnerships

An ambitious project of the magnitude of Telangana's Hyderabad Pharma City could take up a sizeable amount in the government budget if it is the sole body responsible for funding and execution. As such, forming fruitful public-private partnerships could facilitate the funding needed for the project, while helping in a more equitable allocation of risk. Further, this could also help in increasing the efficiency of project management and execution, and discovering new sources of funding. Many mega-projects across the world, driven by PPP-based models, have proven to be successful in the past.

Environment-friendly practices

The state government could set an example for the industry by adopting eco-friendly practices. To create a future-ready ecosystem, the government could explore setting parity with globally best emission standards for the Pharma City. This could include investing in infrastructure and technologies that support best-in-class and pro-environment manufacturing practices such as zero discharge facilities to control expelled fluid waste, solid waste recycling and upcycling facilities, and gaseous emission control techniques. Further, the industry could be nudged to invest in best practices by incentivizing and/or subsidizing private investments in cutting-edge technologies.

Live-work-play ecosystem with best-in-class social infrastructure

To boost the attractiveness of the Pharma City as a leading pharma hub, the liveability quotient of the region has to be high. This in turn merits detailed planning to include, among others, adequate lifestyle-focused components. To start off, the Pharma City's development plan could reflect its aspiration to meet world-class liveability standards and quality.

Further, the City's civic and social infrastructure needs categorical planning, with a focus on open and green spaces, greater trip sharing in public transport, and an emphasis on healthcare, education and research facilities.

Availability of and accessibility to quality social infrastructure will play a critical role in enhancing the livability standards. In that context, high-quality hospitals with adequate beds-to-population ratios, pre/junior/high schools and research and vocational training centres for freshers could help boost the liveability of the area. The plan could also include SMART elements like public wi-fi, charging stations, etc.

Governance

A project of the size of the upcoming Pharma City may need to focus on delivery and not just process check-ins. There may be a need to catalyse action across key stakeholders to drive decisions by being objective and task oriented. The state government could consider creating and adhering to institutional and development policy frameworks. A comprehensive Project Management Office (PMO) could be created, with a task force of Direct Responsible Individuals (DRI) who own different workstreams. To make governance successful, it would be important to keep the development process time-bound and transparent to the public.

Progress

Year 2019-20 has been an eventful year in the planning of this world's largest cluster, with many milestones including

- Completion of the master-planning, infrastructure planning, etc.
- Recognizing the importance of the project, Department for Promotion of Industry and Internal Trade (DPIIT), Government of India (GoI) has granted the status of National Investment and Manufacturing zone (NIMZ).
- Amendment to Environmental Clearance was issued by MoEF&CC, GoI and CFE was accorded to project by TSPCB.
- External road development and widening work are in progress.

Boost the manufacturing of API and intermediaries (ensure higher self-reliance)

There is an imminent need to develop India's self-sufficiency in key intermediaries and KSMs since a significant proportion is still imported, primarily owing to cost advantages⁵⁴. Telangana, with its capital Hyderabad already the pharmaceutical hub of India, could take some initiatives to develop a strong API industry, especially given the government's commitment to the flagship Pharma City, and could help de-risk India's external dependence for sourcing these materials. This could be done by:

- Carving out a dedicated cluster for manufacturing API/intermediaries in the upcoming Pharma City by:
 - Providing a dedicated expanse of land for API manufacturing via governmental subsidy or in exchange for equity.
 - Assuring essential amenities like CETP, power, water, steam, utilities, ready-to-use lab facilities and ready-to-drop-reactor manufacturing facilities.
 - Transparently allocating resources among small, medium and large producers.
- Apart from land and infrastructure provisions, domestic producers may need some assistance to establish competitiveness by:
 - Fiscally rejuvenating public manufacturers.
 - Providing incentives for setting up large plants—cheaper coal, electricity and IT hardware package incentives.
 - Offering cheap soft loans and long-term capex loans to manufacturers.
 - Assuring minimum procurement volumes to the cluster.
- In addition, Hyderabad based CSIR- IICT has been partnering with API manufacturers to develop cost-effective processes that could lead to minimal dependency on exports for key raw materials⁵⁵. This will enable Hyderabad based API companies to leverage financial incentives under the Production Linked Incentive (PLI) Scheme of GoI⁵⁶. The highlights of the scheme are:
 - Total project overlay of INR 6,950

⁵⁴ <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/taking-steps-to-reduce-dependence-on-api-imports-government/articleshow/57790774.cms>

⁵⁵ <https://pib.gov.in/PressReleasePage.aspx?PRID=1618136>

⁵⁶ <https://pharmaceuticals.gov.in/sites/default/files/Gazettee%20notification%20of%20bulk%20drug%20schemes.pdf>

- Financial incentive under the scheme shall be provided on sales of 41 identified products for six (06) years at the rates given below:
 - For fermentation based products, incentive for FY 2023-24 to FY 2026-27 would be 20%, incentive for 2027-28 would be 15% and incentive for 2028-29 would be 5%
 - For chemical synthesis based products, incentive for FY 2022-23 to FY 2027-28 would be 10%
- Further, industry-academia collaborations could be leveraged to help accelerate the development of API industry. This could include:
 - Dedicated merit-based screening and training programs that focus on essential finishing skills.
 - Grants to universities that collaborate with the industry on research projects.

Boost the equipment manufacturing industry

The current size of the life sciences industry in Telangana is around USD 12 billion⁵⁷. As per the vision statement, the state is expected to aspire to hit the USD 50 billion mark by 2030. Such a leap in industry size requires growth in the life sciences research and manufacturing equipment production activity as well. Hence, there exists an immense opportunity for Telangana to develop into a dominant destination for equipment manufacturing.

Telangana is already home to some of the leading engineering colleges in India. The government has already committed to make the state a hub for aerospace and defense activities ranging from R&D to manufacturing and incubation⁵⁸. The country's first aerospace and precision engineering SEZ is being planned just outside Hyderabad⁵⁹. Further, the city is one of the cornerstones of India's huge tech talent. To leverage such an extensive ecosystem, leading international and domestic life sciences equipment manufacturing companies could be targeted to set foot in Telangana via organic growth or partnerships.

Further, attractive technology-transfer transaction offers could be scripted for leading global players. Fresh incentive packages could be devised to accord low-cost factors of production to potential participants. A life sciences-exclusive 'T-

⁵⁷ Expert interviews, company websites, annual reports, Capital One IQ, Hoovers

⁵⁸ https://www.business-standard.com/article/news-ians/hyderabad-becoming-aerospace-and-defence-industry-hub-117081300343_1.html

⁵⁹ <http://www.thehindu.com/todays-paper/tp-national/aerospace-sez-set-to-take-off/article5307270.ece>

Works' could be supported by the state government to ignite sector-specific hardware innovation in Telangana.

Attract leading MNCs as anchor tenants

Telangana's life sciences industry has been growing at a CAGR of around 10% pa⁶⁰. The ambitious vision requires a growth at a CAGR of around 18% across 2017-2030. The state could consider expanding its occupancy mix to include attracting some of the leading international players to fuel the state's industrial growth to realize its vision. Below mentioned are few case studies and respective learnings to attract marquee global players as anchor tenants to Hyderabad cluster.

Model 1: Global centre for off-shore activities⁶¹

Case Study: Novartis has one of its five global service operations centres in Hyderabad, the other four being in Kuala Lumpur, Prague, Dublin and Mexico. Hyderabad was chosen as a destination from an initial list of 23 cities. The centre today hosts a multitude of activities, including but not limited to financial reporting, medical communication, scientific support and data management. Further, it supports global clinical trials with data management, bio-statistics and analyses, and data collection, dossier preparation and regulatory filings for approvals. Thus, Hyderabad, with its ample talent and infrastructure, is evidently an easy choice for setting up such activities in India.

As such, to leverage the huge IT/technology pool in Hyderabad, Telangana could pitch to leading players to have their global off-shoring centres in the state to undertake activities like financial reporting, regulatory support, external communication, data management, analytics, etc.

Model 2: Pre-eminent manufacturing hub⁶²

Case Study: Mylan entered India in 2007 with the acquisition of Hyderabad-based Matrix laboratories. The international company has a total workforce of 30,000, almost half of whom are based out of India. Mylan has 25 manufacturing facilities in India, including nine API centres, eight OSDs and eight injectables. Out of these, Telangana is home to one OSD and four API manufacturing centres. Further, Hyderabad houses one of Mylan's three global R&D centres of excellence, with extensive experience of working with health authorities from

⁶⁰ Company websites, annual reports, Capital One IQ, Hoovers

⁶¹ Expert interviews, <https://www.livemint.com/Companies/Sbtc0JDn0HWdniBcJPxV3H/Hyderabad-is-one-of-Novartiss-core-centres-says-MD-Vasant.html>

⁶² Expert interviews, <http://www.mylan.in/en/company/mylan-in-india>

multiple countries. The centre possesses ‘round-the-clock’ research, development, and clinical and regulatory capabilities.

Similarly, intensive global manufacturing players could be pitched to, citing the extensive ecosystem that renders Hyderabad the perfect city to have a production footprint in India. Further, tailor-made incentive packages could help tilt the scales in the state’s favour.

Model 3: High-end technology haven

Case Study: Global technology behemoths have been rapidly investing in the life sciences space. Examples include Alphabet in Verily for insights from healthcare data to create holistic solutions⁶³, Senosis for personal health monitoring⁶⁴, Apple in Beddit for sleep-tracking devices⁶⁵, Gliipmse for a personal health-data platform⁶⁶, Health Gorilla for a secure clinical network⁶⁷, Microsoft in Healthcare NeXT for an initiative that combines research, AI and industry expertise⁶⁸, and Intel⁶⁹ and IBM⁷⁰ in enterprise solutions for healthcare.

Hence, to establish Telangana’s life sciences cluster as one the most exciting innovation hubs in Asia, the state could attract research teams from various prestigious technology giants to have presence in the cluster. Hyderabad already boasts the presence of offices of Google⁷¹, Amazon, Microsoft, Apple⁷², Oracle⁷³ and more. Likewise, promotion campaigns could be crafted to target upcoming high-end innovations in the life sciences space such as AI, digital imaging, 3D printing, tele-health, cybersecurity, data-aided clinical research, and more.

⁶³ <http://fortune.com/2015/12/08/google-alphabet-verily/>

⁶⁴ <https://www.theverge.com/2017/8/15/16148212/google-acquires-start-up-senosis-health-patel-shwetak>

⁶⁵ <https://techcrunch.com/2017/05/09/apple-acquires-sleep-tracking-company-beddit/>

⁶⁶ <http://fortune.com/2016/08/22/apple-acquires-gliimpse/>

⁶⁷ <https://www.cnbc.com/2017/06/19/apple-working-with-start-up-health-gorilla-on-iphone-ehr-plan.html>

⁶⁸ <https://blogs.microsoft.com/blog/2018/02/28/microsofts-focus-transforming-healthcare-intelligent-health-ai-cloud/>

⁶⁹ <https://www.intel.com/content/www/us/en/healthcare-it/solutions/documents/healthcare-intel-across-healthcare-paper.html>

⁷⁰ <https://www.ibm.com/industries/healthcare>

⁷¹ <https://careers.google.com/locations/hyderabad/>

⁷² <https://economictimes.indiatimes.com/industry/services/property/-/cstruction/global-biggies-lap-up-big-ticket-office-spaces-in-hyderabad/articleshow/62455462.cms>

⁷³ <https://www.oracle.com/in/corporate/contact/index.html>

Create training and finishing programs to bridge the state's talent-employability gap

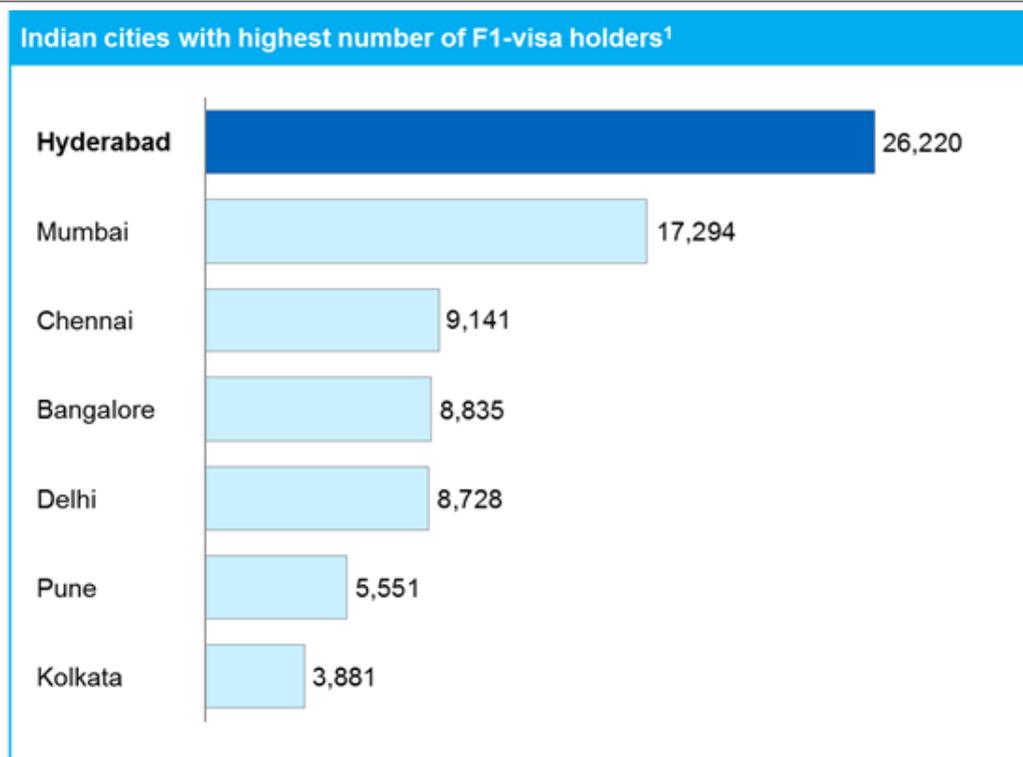
The talent pool for Telangana's life sciences sector could be roughly categorized into three segments, each with its unique set of issues.

Scientists working at knowledge frontiers and driving innovation in the sector

Telangana does not boast of a sizeable and continual influx of fresh knowledge-rich human capital that is capable of leading innovation-based endeavours. Scientists chiefly migrate from one organization to another, resulting in net zero addition to talent pool.

However, Hyderabad (and Secunderabad) have a unique advantage due to their highly-skilled population. Among the leading cities in India, Hyderabad has the highest number of students who have travelled abroad for higher education⁷⁴ (Exhibit 13). Hence, on the return of this talent pool to India, it could be easier to attract them to work in the Hyderabad cluster itself.

EXHIBIT 13



1. Brookings Institution (2008-2012)

SOURCE: <https://timesofindia.indiatimes.com/home/education/news/Hyderabad-sends-more-students-to-US-than-Delhi-Mumbai/articleshow/41314839.cms>

⁷⁴ <https://timesofindia.indiatimes.com/home/education/news/Hyderabad-sends-more-students-to-US-than-Delhi-Mumbai/articleshow/41314839.cms>

The biggest challenge is to attract such (and non-native) talent back to India. Although talent migration is a function of availability of opportunities, the state government could contribute to kick-start a self-sustaining virtuous cyclical process by:

- Conceptualizing the ‘Telangana Calling’ program to invite eminent faculties and corporate leaders who work abroad/in other states to work in Telangana, and provide them prestigious designations and financial incentives
- Actively reaching out to native talent to associate with local academia as guests/visiting faculties.
- Floating government-sponsored, disease-specific missions to invite natives to return and collaborate with local academia.
- Partnering with leading universities abroad for student and faculty exchange programs.
- Sponsoring world-class training/higher education programs for bright kids with a rider to come back to work in Hyderabad cluster after they complete their training/education.

Biologists, chemists, QA/IT/regulatory/data specialists required for industrial functioning

Telangana is home to several pharmaceutical colleges, generating an immense talent pool for the industry. However, there exists a lack of finishing skills amongst graduates and post-graduates, resulting in a talent-employability gap.

Case Study: The BCIL industrial training program, sponsored by the Government of India’s Department of Biotechnology, pays stipends to trainees and bench fees to trainer companies, thereby creating a talent pool that is actively looked for by the industry⁷⁵.

Likewise, the state government could consider playing a pivotal role to address this gap by:

- Creating a certification-based training-cum-excellence program, wherein the unemployed are prioritized. To do this, it is important to:
 - Have a meritocratic screening process to select candidates.
 - Provide stipends instead of charging fees or heavily subsidize such fees.
- Consulting with industry to identify areas of focus (for instance, quality assurance, microbiology, etc.), designing the curricula in consensus with

⁷⁵ http://bcil.nic.in/biotech_industrial-training.htm

sector experts and facilitating a hands-on training component for these trainees.

- Instituting incentives for potential employers to hire these trained/certified graduates.
- Pitching to leading life sciences companies to spend their CSR funds partly on this skilling initiative.

Attracting budding talent

Apart from graduates, there is an urgent need to promote the life sciences sector amongst undergraduates and aspiring freshers who are increasingly interested in IT. These candidates need to be made aware of the massive developments happening in the life sciences space across the globe, and more importantly, the emerging opportunities in the local industry.

The state government could take an active role in spreading awareness on these developments and opportunities among budding talent by:

- Orchestrating career counselling sessions and guest lectures at leading colleges in the state, and inviting people to share their local success stories.
- Promoting a spirit of innovation from early on by instituting innovation scholarships for high school students and undergraduates, and providing access to public labs for consultations and experimentations.

Simplify the regulatory framework that governs the local life sciences sector

Feedback from key stakeholders suggests that there are several issues on which the life sciences industry seeks the government's intervention. These include lack of awareness on the exhaustive regulations that govern start-ups, the existence of counterproductive rules that are aggravated by untenable enforcement practices and ambiguity around some of the current rules.

The state could consider the following actions to regulate reforms in the industry:

Content creation

- Designating a task force for comprehensive appraisals and to revise existing regulations governing life sciences by:
 - Ensuring such a task force comprises a diverse range of stakeholders, experienced nominees from the pharma, bio-pharma and medical devices industries, and academia.
 - Making exceptions in regulations as necessary for pharmaceuticals/biopharma/medical devices companies.

- Improving the overall ease of doing business by creating relevant regulations for ancillary and emerging industries, especially in the medical devices segment.
- Setting up a periodic reviewal mechanism for incumbent frameworks.
- Identifying department-wise issues that impact the awarding of licenses to establish new companies by:
 - Conducting periodic surveys in the industry involving start-ups and existing companies to identify the pain points that need urgent intervention.

Awareness and information dissemination

- Considering building a single-stop repository and legal advisory to guide emerging start-ups, and provide an exhaustive check-list of regulations and mandatory compliance requirements. This could be done by:
 - Instituting a 24X7 online and call helpline for entrepreneurs/industry/academia for regulatory support and monitoring.
 - Establish government-sponsored councils to advise start-ups and existing companies on exhaustive compliances.
- Spreading regulatory awareness amongst future life sciences graduates via updated regulatory courses and internship programs with leading domestic companies/MNCs in India.

Improving ease of running operations seamlessly for existing industry

Along with unwavering focus on the growth of the life sciences sector in Telangana, it is equally important to ensure the seamless continuity of the operations of the existing industry. Some of India's leading life sciences players have their manufacturing footprint in Hyderabad, already making the city a pre-eminent cluster in India. This in turn calls for mediation to catch the pulse of the industry and to recognize their pain points.

Over the years, Hyderabad has expanded, riding on the increasing industrial and academic growth of the city. As a result, manufacturing premises which once used to be on the outskirts of the city, now find themselves in the vicinity of residential areas. As important as it is to safeguard the population from exposure to any forms of pollution, it is also important to not forcefully displace the industry as it could lead to operational disruption and monetary loss for the companies. Further, it could erode the confidence of potential greenfield investors.

Hence, in view of this conundrum, the government could look at installing common infrastructure to reduce the pollution load on life sciences companies. Along with using public funds, existing companies could be asked to pitch in to form a corpus that is dedicated to designing measures that aim at reducing the pollution load within standard limits.

Besides making it easier for new companies to inaugurate their facilities in the state, the process of expansion of existing companies could also be made time-bound, transparent and seamless. Further, the state could look into a variety of ways for making frequently recurring processes such as compliance reports, import requisitions, etc., easier for applicants through speedy clearance practices.

Float financial incentives to foster fresh investments

Telangana could do well to ensure that within India, its financial offerings are at par with, if not better than, the rest of the states. Some parameters that companies could consider while making investment decisions are subsidies, reimbursements on stamp duties, transfer duties, land conversion charges, patent and trademark registration charges, utilities cost, interest subsidies, seed capital assistance and tax breaks.

Host leading life sciences events and foster networking

The 17th Edition of BioAsia - Asia's largest Biotechnology and Life-sciences forum that was hosted by the Telangana government in 2020 witnessed a record number of 2,000 partnership meetings held during the three-day global summit leading to key strategic collaborations.

To cement the state's position as a leading life sciences hub, Telangana government could consider earmarking annual budget to host leading life sciences events and conferences. Events such as these will not only aid-in promoting Telangana as one of the most attractive destinations for investments, but also support in providing a networking platform for the existing companies. Beyond knowledge sharing and updating the players of the latest trends, these select world-class events can play an instrumental role in facilitating partnerships within the ecosystem.

Strengthen the existing investment promotion body for the State's life sciences sector

To attract private investments from Indian and foreign entities, the Telangana government could consider further strengthening investment promotion agency. This body could choose an appropriate industry mascot that would act as a signatory to the state's success in the life sciences sector, and would help with

pitching to investors via roadshows, exhibitions, summits, conferences, etc. Demonstration days could be organized to connect the state's entrepreneurs to leading investors in the country/worldwide. In addition to the investment facilitation and execution, the promotion agency could play a critical role in providing aftercare support. Whenever required, it could offer help on manpower, infrastructure and service requirements.

□ □ □

Opportunities are rife in Telangana's life sciences industry to unlock its next phase of growth. It could realize its 2030 vision provided all stakeholders such as industry, academia, government and investors collaborate with the common goal of emerging as the pre-eminent cluster in Asia, while leveraging technology and talent.

