



**ICICI Lombard**  
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**CORPORATE INDIA  
RISK INDEX**

2022

Intelligence partner

FROST & SULLIVAN



**SECTOR REPORT 2022**  
**BIOTECH & LIFESCIENCES**





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## Preface

Corporate India Risk Index is primarily an academic exercise to understand the level of risk that companies are facing and also assist in developing a successful risk aversion plan, CIRI is a first-of-its-kind risk measurement tool to gauge the level of a company's risk exposure and preparedness.

This Corporate risk comprises of various aspects of the business—spanning customer, competition, regulatory environment, business operations, technology finances, environmental factors etc. The impact of unprecedented events is significantly higher now.

This Index is a comprehensive framework that draws upon global risk management best practices and comprises of 32 risk elements across 6 broad dimensions. The Risk Index is based on the principles of Lean and Six Sigma that qualify business processes by measuring effectiveness and efficiency.

ICICI Lombard's Corporate India Risk Index provides a crucial tool for assessing and addressing risks, fostering resilience and adaptability in the ever-evolving global landscape. In the current climate of increasing macroeconomic uncertainties, it is essential for corporates to prioritize robust risk management. We believe that a proactive approach to risk management not only fortifies individual businesses but also contributes significantly to India's overall economic growth and stability.

## Executive Summary

India's Biotech and Life science sector grew 8% primarily due to price increases as volume remained like previous years. Central government's support of the PLI scheme with a concessional corporate tax rate of 15% for one year infused new energy to biotech startups in 2022. Despite geopolitical concerns, India continued to supply generic medicines to 200 countries.

India's association with QUAD association and Biotech Startup Expo in June 2022 is attributed to the increased global presence of the Indian Biotech and Life sciences industry.

The strengthening of the dollar against local currencies affected overseas sales for Indian generic medicines. The industry was hit with the highest inflation, and thus, the prices of generic medicines became more expensive. Recalls of generic drugs due to packaging error and quality issues, R&D costs skyrocketing, and poor performance in the stock market were also indicators of the Biotech industry.

Supply chain risk and raw chemical procurement was hindered  
Employee retention and the freebie to medical practitioners wer

# Introduction

ICICI Lombard Corporate India Risk Index is a one of its kind, unified, credible, standardized corporate Risk Index that spans over the country level, the industry level, and the company level. The index has a comprehensive sector coverage.

Aerospace and Defense, Agriculture and Food Processing, Automotive and Ancillary, BFSI, Biotech & Life sciences, Chemicals and Petrochemicals, Education Skill

Development, Energy, FMCG, Healthcare Delivery, Infra and Realty, IT/ITES, Manufacturing, Media and Gaming, Metals and Mining, New Age & Startup, Pharmaceuticals, Telecom and Communication Technology, Tourism and Hospitality, Transportation and Logistics.

The impact is identified across key business risk (internal and external) under the following ‘Strategic Risk Areas’, The ICICI Lombard Corporate India Risk Index Framework comprises of 32 risk elements across 6 broad dimensions.



## Market and Economic Risk

Corporate Risks arising due to market and economy related factors, such as internal or external political uncertainty, global slowdown, taxation-regulatory changes etc. Market and economy related risks are also identified as ‘Systematic Risks’, we have further classified the risks into below mentioned categories.

- **Inflation:** Inflation is the general increase in prices within the economy. The rising prices for businesses could result in bigger production spending and a fall in profitability. The companies should be attentive, acute, and responsive to changes in inflation to efficiently manage the prices of final products.
- **Taxation:** In a large democracy like India, complexity of multiple taxes (multiple taxes like GST, custom duties, central excise duty, etc.) is a major concern. The changing legislations, increased scrutiny by tax authorities and increasing public attention are together resulting in tax risks for organizations. There is, thus an increasing urgency for firms to manage their tax affairs efficiently to minimize tax risks.
- **Regulatory Risks:** Regulatory risk is the risk of changes in regulations and laws that might affect an industry or businesses. The regulatory changes can pertain to tariffs and trade policies, business laws pertaining to employment, minimum wage laws, financial regulation, Foreign Direct Investment etc.

- **Foreign Exchange Risk:** The exchange rate plays an important role for firms who export goods and import raw materials. The fluctuations in foreign exchange will have great impacts on the prices of traded goods. For example, if the currency depreciates (devaluation), the exporting firms will benefit. However, the firms importing raw materials will face higher costs on imports. The firms need to hedge their exposure to foreign exchange risks to insulate themselves from the impact from forex changes.
- **Geo-political Tension:** Geopolitical risk means the political and economic risks that are a potential threat to the financial and operational stability of companies.
- **Competitive risk:** Competitive risk is the risk associated with the fact that there are multiple companies competing in the market, each seeking to obtain the highest position and consumer ratings, to gain maximum benefits for themselves. The companies devise different strategies to garner a higher market share and acquire customers from competitors. Any failure in managing the competitive stand could lead to losses in business, thereby making marketing and competition a major risk in market.



## Technology Risk

Technology risks are also identified as information technology related risks which may arise due to failure of any installed hardware or software system, spam, viruses or any malicious attack. Also delay/over/under adoption of trending disruptive technologies can lead to technology related risks. We have classified the risks in below mentioned categories.

- **Innovation Risk / Obsolete Technology:** Innovation is the key to success in all the industries. Risk of redundancy and losing out to competition on account of poor R&D is a major concern.
- **Intellectual Property risk:** Dependence on trade secrets and unpatented proprietary know-how.
- **Disruptive Technologies:** These will fundamentally alter the financial prospects of the industry.

**Data Compromise:** Hardware failure refers to malfunctions within the electronic circuits or electromechanical components (disks, tapes) of a computer system; Software failure refers to an operating system crash. Such failures lead to stoppage of entire computer or operating systems creating substantial losses to business.

## Operational and Physical Risk

Risk of losses caused due to faulty or failed processes, systems or human resource related inefficiencies are classified as operational and physical risks. We have classified Operational & Physical risks in below mentioned categories.

- **Critical Infrastructure Failure / Machine Breakdown:** Industries with a heavy dependence on machinery consider any rise in machinery breakdowns a hindrance to their businesses operations. An untimely equipment breakdown can bring businesses to a standstill or be the root cause for fires and explosions. Mostly, human errors and deferred maintenances are the major reasons for such breakdowns. The companies should actively invest in timely maintenance of all machineries.
- **Business Continuity / Sustainability:** Non adoption of Business Continuity/ Sustainability Plans and Lack of Internal Control tools would result in: Failure of businesses, Brand Equity / Loss of reputation, Financial Loss, Business model Failure, Ineffective engagement/communication with stakeholders, Losses in productivity, Lack of opportunity monitoring.
- **Supply chain risk:** Raw Material unavailability and Heavy Dependence on Global Supply Chains / Supplier concentration risk. Unavailability of raw materials owing to disruption in the supply chain or heavy dependency on one source (company/country) which is unable to supply owing to some geo-political tensions, fires, or any other incidents. Transportation is one of the key activities for companies making it an important risk to mitigate. The loss of goods in transit and spillage is one of the major concerns as it accounts for a sizeable loss of revenue to companies.
- **Commodity Price Risk - Volatility in prices of raw materials:** The fluctuations in raw material prices creating a margin pressure / top-line pressure in the scenario of rising input costs.
- **Portfolio Risk:** Loss of key customers, Customer concentration - Key customers accounting for a larger share of revenue, Over-dependence on suppliers, Business Model Risk: Transformative changes in business model, Tail Risks: Ability to overcome or manage extreme worst-case scenarios.
- **Environmental Hazard Risk:** Any environmental hazard having the potential to affect the surrounding environment.
- **Workplace Accident:** Fire and Explosion Hazards, Containment Incidents, Workplace Injuries
- **Human Resource:** Key person risk: This risk occurs when a business or business unit becomes heavily reliant on a key individual. Talent acquisition and retention - The companies require a highly skilled labor force for R&D as well as continuous production. Accessing skilled resources and expertise on an on-going basis is one of the major challenges; moreover, retention of trained staff is imperative. Labor shortages, Union Strikes & Industrial Actions, Employee health, safety, and security (SHE/Sustainability risk).
- **Financial Risk:** Financial Reporting Risk: Material misstatement of Financial Statements, whether due to fraud or error. Interest rates and equity prices: Interest rate risk arising out of working capital borrowings at variable rates. Equity price fluctuations affect the Company's income or the value of its holdings of financial instruments. Liquidity Risk (Credit Risk / Receivables).
- **Breaches of law (local/ international):** Voluntary/ involuntary breaches of law can lead to costly lawsuits.





## Crime & Security Risk

Cybersecurity risks relate to the loss of confidentiality, integrity, or availability of information, data, or information (or control) systems and reflect the potential adverse impacts to organizational operations. These attacks can cause major financial losses, reputational harm, and a loss of client trust. Regarding cybersecurity, the BFSI industry in India has several difficulties, including difficult-to-secure legacy systems, a shortage of qualified cybersecurity personnel, and the requirement for ongoing system and network monitoring. There is a significant investment in cybersecurity tools like network monitoring, endpoint security, access control, and threat intelligence. Many organizations are also implementing cutting-edge technology like artificial intelligence and machine learning to strengthen their security posture. Around 7.4% of the attacks in the Asian region were targeted at India in 2022.

We have classified Crime & Security risks in below mentioned categories.

- **Cyber Crimes:** Data Theft, Spam, scams and phishing, Hacking, Malwares and Viruses, Piracy, Fraud, Corruption, Malicious attacks
- **Counterfeiting:** Counterfeiting of goods/services leads to loss of revenues, profits and ultimately affects the brand equity
- Threat to Women Security
- **Terrorism:** Un-lawful use of violence and intimidation, especially against civilians, in the pursuit of political aims.



## Natural Hazard Risk

A natural hazard is the threat of an event that will likely have a negative impact. A natural disaster is the negative impact following an actual occurrence of natural hazard if it significantly harms a community. Due to India's geographical structure, it is one of the most disaster-prone countries in the world. Natural hazards like floods, earthquakes, landslides, and cyclones are common risks faced by India. The situation has worsened due to rise in GHG emissions, loss of biodiversity, deforestation, and degradation of environment. From Surat Gas leak to landslides in the north and cyclones in Bay of Bengal, the year 2022 was no exception. Such natural disasters hamper the day-to-day operations of corporates, and it is important for them to understand that such risks cannot go unheeded. Over the years, Indian corporates have learnt to mitigate such risks by diversifying their supply chains, having multiple logistics partners, diversified geographical presence and multiple vendors.

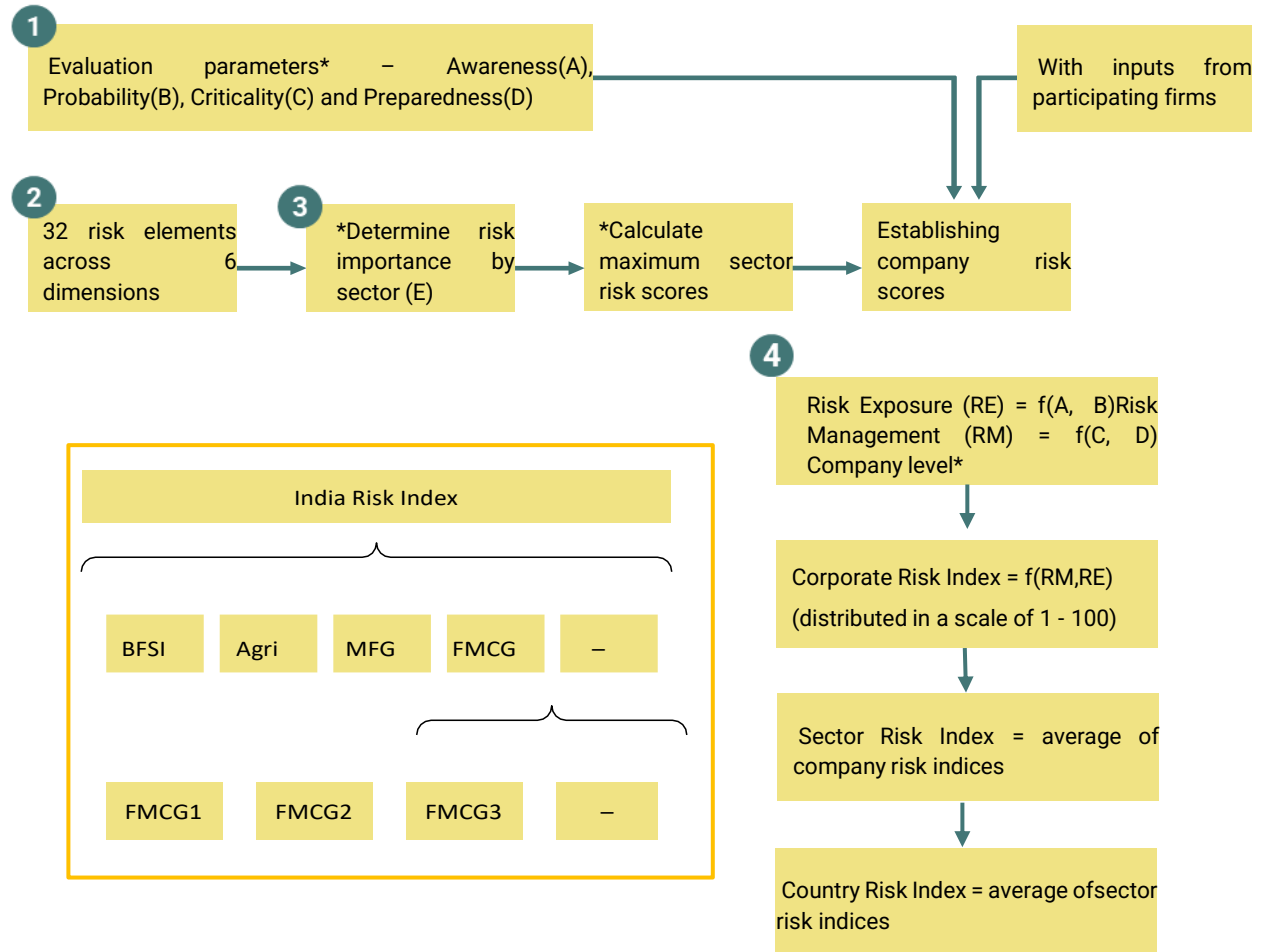
- **Pandemic and other global epidemic diseases:** Risk to business owing to disruptions caused by COVID-19 pandemic and similar another global epidemic.



## Strategic risk

- Strategic risk is the risk that failed business decisions may pose to a company. Strategic risk is often a major factor in determining a company's worth, particularly observable if the company experiences a sharp decline in a short period of time. Several factors, such as unethical or unlawful activities, poor customer service, product recalls, data breaches, or unfavorable media coverage, can lead to strategic risk. An organization's reputation can be severely harmed by a single negative incident, such as a high-profile data breach or fraud scandal, resulting in a loss of clients, income, and market share.
- **Resource scarcity / Misutilization / Overall Utilization:** Difficulties in acquisition of land, water, fuel, or other resources for operations of business.
- **Public Sentiment:** Current events playing out in the public scene can change the public sentiment.
- **Delay in execution of projects:** Delays in execution of projects can surge in the capex.
- **Increased number of recalls and quality audits:** Impacts both the brand equity and increased operational expenses.
- **Failed / Hostile Mergers & Acquisitions:** High dependence on inorganic growth.

# Bottom-Up Risk Assessment Approach



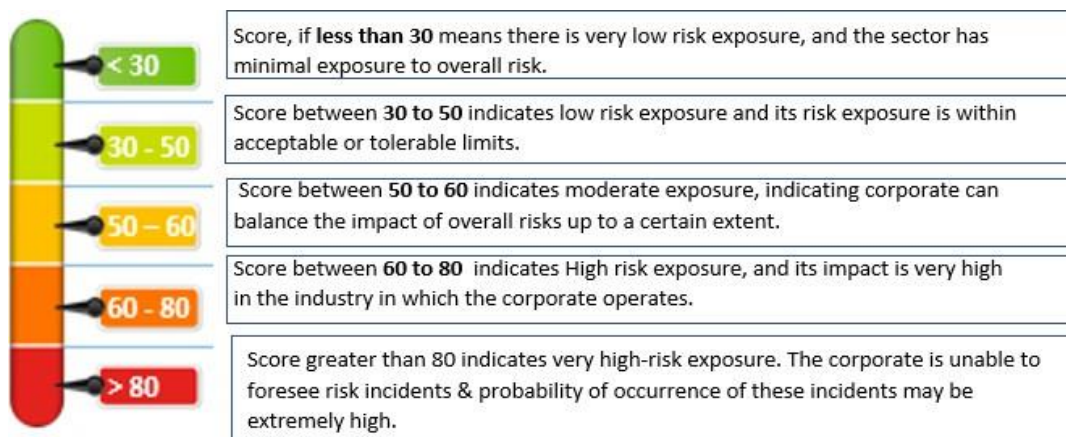
- 1. Evaluation Parameters\*:** The index maps the risks faced by any enterprise basis of Awareness, Probability, Criticality and Preparedness against the defined Risk elements. The evaluation Parameters are defined as: Awareness - Level of awareness of potential risk affecting the firm. - Likelihood of risk to affect the business goals of the firm adversely. Criticality - Level of impact of the identified risk on the success of business goals. Preparedness - Risk handling practices/ mechanisms already in place to handle the risk.
- 2. Determining Risk Importance\*:** Importance/Impact of individual risk element is established against individual sector based on the published corporate risk reports, in depth sector understanding by F&S team and SMEs.
- 3. Calculating Maximum Sector Risk Score:** Weighted Sum of all risk elements based on their importance to the respective sector.
- 4. Company Level\*:** All the Risk Index scores for companies in a sector are averaged to represent the sector; and sectors average to India. Risk Exposure is defined as the function of corporate’s Risk Awareness and Probability of risk occurrence. Risk Management is defined as the function of an enterprise risk preparedness and criticality risk impact assessment.

# Defining the Risk Scale

We have selected 20 sectors to understand the current stand of our country today in terms of risk. Risk for various sectors is measured on the risk exposure scale and risk management scale.

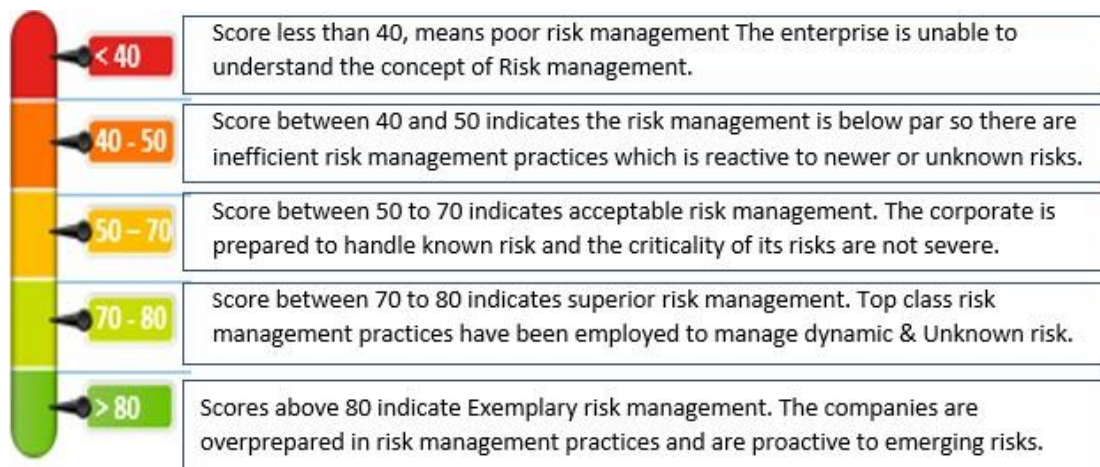
## A. ICICI Lombard Corporate Risk Exposure – Scale

**Risk Exposure:** The impact of any internal, external or strategic occurrence on the financial performance of an organization is defined as the corporate risk exposure. Risk has traditionally been seen as something to be avoided – with the belief that if behavior is risky, it’s not something a business should pursue. But the very nature of business is to take risks to attain growth. Risk can be a creator of value and can play a unique role in driving business performance. Let’s look at the risk exposure scale.



## B. ICICI Lombard Corporate Risk Management – Scale

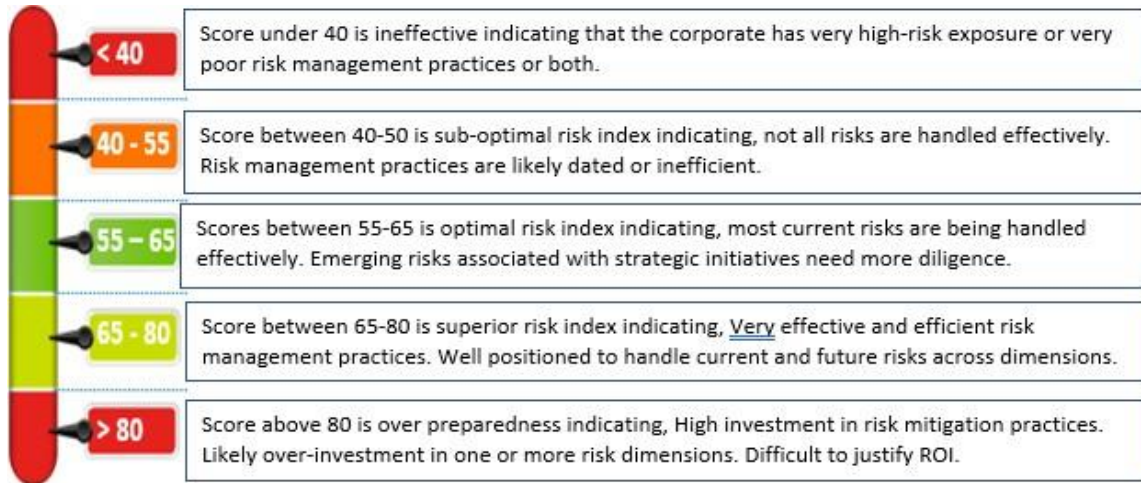
**Risk Management:** Identification, Evaluation and Prioritization of corporate risks followed by well-coordinated steps to minimize the occurrence of uncertainties in the foreseeable future is defined as the Corporate Risk Management. The risk management scale works in the opposite to that of the risk exposure scale. Let’s look at the risk management scale.



### C. ICICI Lombard Corporate Risk Index – Scale

**Risk Index:** Risk Index is a measurement tool to gauge the level of Risk Exposure against Risk Preparedness. The score intends to give companies/Sector/Country access to an extensive and quantifiable metrics of risk management.

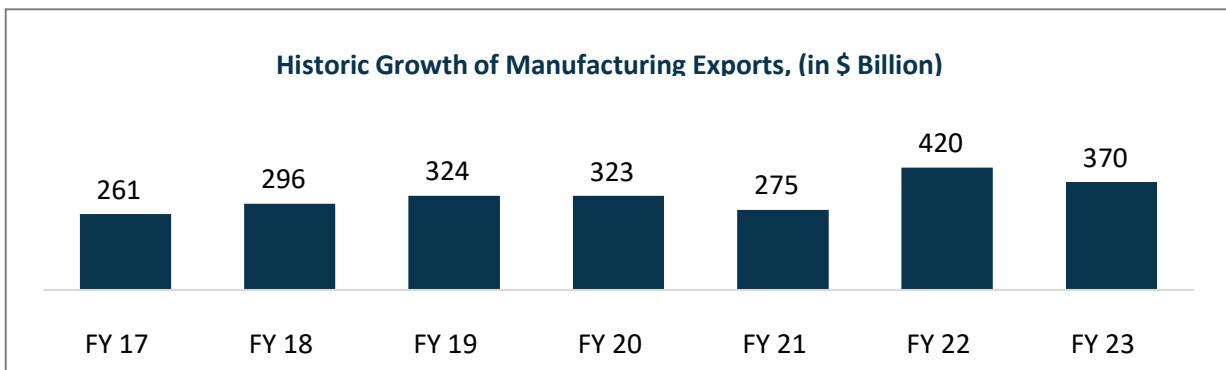
Let’s look at the risk Index scale.



# India - Emerging Superpower with Optimized Corporate Risk Handling

Manufacturing sector contribution to India’s GDP in 2022 stands at 17% and is expected to grow to 25% by 2025, the expected growth is attributed to various favorable schemes initiated by Government of India like ‘Make in India’, ‘Digital India’, Improved Road Infrastructure, implementation of modern technologies of manufacturing resulting in optimized and effective production, Also the pandemic has made business realize that they cannot just rely on a single manufacturing hub; hence notion of “China+1” is making the world realize the significance of India. China is in a trade war with the USA, which is positively shaping the role India will play in the global arena.

The below chart showcases the gradual increase in India’s manufacturing exports.



**Figure 1: India’s Growth of manufacturing exports. (Source: Redseer)**

Indian manufacturing sector is also focusing on electronics manufacturing like mobile phones, industrial electronics consumer electronics, etc. due to government initiatives the production has doubled since 2015.

Aerospace and defense sector in India have evolved significantly, Govt. of India have identified A&D as area of focus due to the belligerent neighborhood, steps like Make in India (Atmanirbhar Bharat) is helping the overall defense sector, however India still remains the largest importer of arms and ammunition, favorable policies and ease in regulations is helping the drone industry in India and many new start-ups and big players are entering in this space.

Urbanization is another phenomenon evolving in India and it is estimated that by 2030 more than 400 million people will be living in cities, due to this megatrend huge push towards realty and infra sector is observed which is also the growth of ancillary industries like metals, cement, water availability, sanitation, mobility etc., the government along with the private sector is working on multiple initiatives to manage the huge inflow.

India has observed a steady adoption towards EVs in recent years, though India adoption still remains very low in comparison to Europe, Canada, China, however all big auto players are coming with new lines of EVs, and significant strategic investment have been made. The adoption is primarily due to lower running

costs, lower maintenance, zero tailpipe emissions, tax and financial benefits by the government, convenience of charging.

BFSI sector in India is showcasing a significant robustness in the time of global crisis, there is a growing demand for financial services as there is a gradual rise in income across income brackets, with a rapid increase in mobile penetration and internet availability more than 2100 fintech companies have emerged in India, the traditional banks are also adopting the digital technologies at a required pace, investment on making the systems secured from cyber threats is utmost priority. Policy support by the government in the union budget 2021-22 is taking up shape and is helping the BFSI sector in 2022 and coming years, like government approval of 100% FDI for insurance intermediaries have increased the FDI limit to 74% from 49%.

Healthcare sector is also continuously growing healthcare has become the one of the India's largest employers, employing around 4.7 million people, though in 2021-22 India only spends 2.1% of its GDP in healthcare, in the union budget 2022-23, US\$ 11.28 billion was allocated to the Ministry of Health and Family Welfare (MoHFW). there is still huge room for improvement in the overall healthcare system in India. Efforts towards having well trained medical professionals in India is top priority. There were exemplary development in the vaccine manufacturing by India, Bharat Biotech Covaxin and Oxford AstraZeneca's Covishield manufactured by SII, helped India get a protection shield against Covid. There is a plan by the government of India to infuse US \$ 6 billion to boost the healthcare infrastructure in India.

The IT/ITes sector is a key engine for fueling India's economic growth and contributing to 7.5% of India's GDP in 2021-22, the Big four IT firms in India have recruited over 1 million employees, As the world is moving towards era of digital economy Indian IT-sector will be contributing significantly towards this journey, the rollout of 5G communication technologies and adoption of new age technologies across industries; like AI, Robotics, Internet of Things will further increase the size of Indian IT sector.

Indian enterprises are also concerned about the risks emerging out of the growing economy and the globalization India is heading towards, its observed that Indian enterprises are taking significant steps towards risk management and keeping budget allocated to implement best in class risk mitigation practices.



# India Showcasing an Optimized Risk Handling



**Figure 2: Corporate India Risk Index 2022**

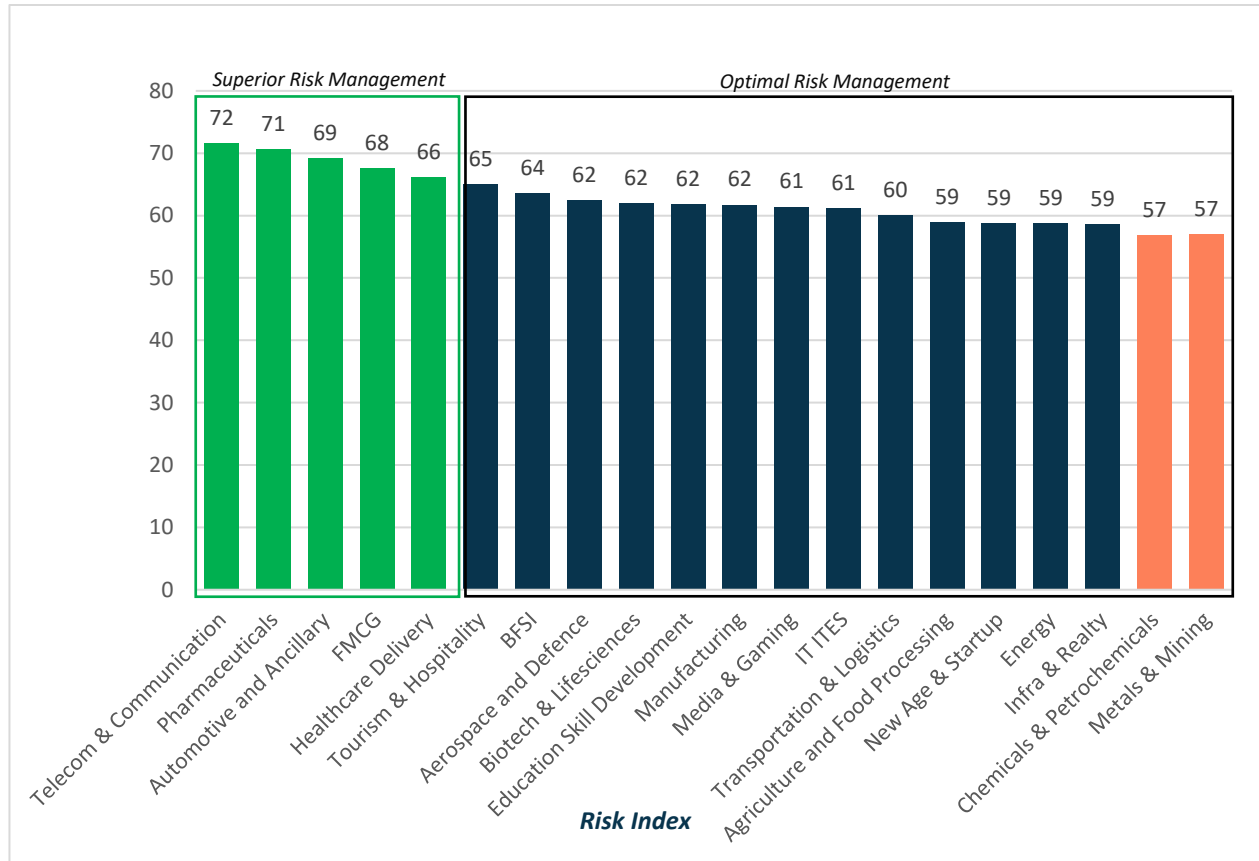
Corporate Risk Index Score of 63 implies that Indian enterprises are handling the risk in an optimal way but still there is scope of improvement to get into superior risk handling territory, Indian enterprises have a well-defined risk management practice in place for inherent risks, however risk management can be improved further as a potential buffer against potential risk events arising from market & economy, operational and technology related Risk events, openness towards adoption of technology and having a well-defined risk management team was observed across enterprises in India.

Sectorial categorization across above stated five categories, it was found that risk management is getting a paramount importance in the growth strategy of every organization and all the organization fell either into 'Superior Risk Management' or 'Optimal Risk Management' category.

From a risk exposure front the intensity of impact due to market and economy related risks increased due to the heightened inflation, global recession, and geopolitical tensions though from a regulation point the sector specific policies by the government helped the industries. Some of the inherent risks exposure due to the operational aspect did not see a significant change as compared to previous year, however companies are adopting diversification, technologically enabling the supply chain, and creating better hedging against financial related risks, whose results will be seen in coming years.



Below is a broader categorization of sectors in terms of risk index:



**Figure 3: Corporate India Risk Index 2022 Sector Score**

### Superior Risk Index

Superior risk handling was found in five industrial sectors: Telecom & Communication, Pharmaceuticals, Automotive & Ancillary, FMCG, Healthcare Delivery.

### Optimal Risk Index

Optimal risk handling was found in 15 industrial sectors: Tourism & Hospitality, BFSI, Aerospace & Defence, Biotech & Lifesciences, Education Skill Development, Manufacturing, Media and Gaming, IT & ITES, Transportation & Logistics, Agriculture and Food Processing, New Age & Startup, Energy, Infrastructure & Realty, Chemicals & Petrochemicals, Metals & Mining.

# Biotech & Lifesciences Insights 2022

According to the market research firm AWACS, Indian Biotech and Lifesciences sector grew by 8% YOY to 1.8 Lakh Crore Rupees in 2022, primarily attributed to price increase as the volume sold remains similar to the previous years. India's Biotechnology sector is categorized into Biopharmaceuticals, Bio Agriculture, Bio-IT and BioServices.

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

**Bio Agriculture:** With nearly 55% of Indian terrain under agriculture and allied activities, India is one of largest producer of BT-Cotton and has the 5th Largest Area of Organic Agriculture Land Globally.

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

According to Union Minister Jitendra Singh, India's Bio-economy has grown eight times in the last eight years to 80 billion USD by 2022. A total of 1128 startups in Biotech were registered in 2021. There are around 5300 biotech startups in India as of Dec 31, 2022. The investment in Biotech firms increased from 10 crores INR in 2014 to 4500 crores INR in 2022, creating over 25000 highly skilled jobs. Also, the number of biotech incubators rose from 6 in 2014 to 75 in 2022.

In 2022, Despite geopolitical concerns, India continued to supply medicines to over 200 countries, living up to its reputation as the world's pharmacy. The biotech industry crossed 1 billion USD in Research and Development spend due to the Covid economy, which was 320 million USD in 2020. The sale of antibiotics declined by 5% in 2022, and volume decreased by 1%.

Prime Minister Narendra Modi inaugurated the Biotech Startup Expo on June 9, 2022, in Pragati Maidan, New Delhi. Around 5000 participants from 20+ countries visited in 2 days.

Pfizer announced a partnership with MPP, an organization supported by the UN, to grant voluntary, royalty-free licenses for producing generic Paxlovid in 95 middle- and low-income nations, including India. India's drug regulator approved the antiviral medication Paxlovid on Thursday for restricted emergency use against Covid-19 amid rising infections in the country.

India's Kotak Mahindra Group, asset management arm, announced in February 2023 it would invest 10.70 billion rupees (\$129 million) in Biocon Ltd to help it fund its acquisition of Viartis Inc's biosimilars business. R&D Spends are declining and is now at 6% of revenues. Many top player's R&D initiatives have not delivered the required results.

Currently, majority of biotech products are in either of 5 percent, 12 percent and 18 percent tax bracket. The industry has constantly demanded to rationalize these and bring more products in the five or 12 percent bracket. To aid demand, the current budget and future policy changes may require lowering of GST rates for different drugs; could even be for a short term.

While the initial outlay in the Product Linked Incentive (PLI) schemes are encouraging, a lot more needs to be done, especially in the Active Pharma Ingredient (API) space. The industry needs to be encouraged further by extending the PLI schemes for several critical APIs as there is a dire need for several API players to backward integrate.

# Biotech & Lifesciences Sector Risk Index 2022 Vs 2021



**Figure 4: Detailed Comparative Analysis 2021 Vs. 2022**

## Biotech and Lifesciences Sector Risk Index 2022 Vs 2021

India Risk Index (Optimal Risk Handling): The overall Risk Index for Biotech and Lifesciences slightly improved to 63 from 62 in 2021, this was driven by minor decrease in the Market & Economy Risk, Natural Hazard and Strategic risks. There was no significant change in the Operations and Physical Risk, as Biotech sector has recovered from the pandemic situation better than other sectors. There was a significant improvement in Technology Risk, Crime Risk due to the increased incidents of counterfeit vaccinations and other similar problems.

## Biotech and Lifesciences Sector Risk Management 2022

There was an improvement in the India Risk Management, it slightly improved to 60 from 63 in 2022. Factors like support from the government in the form of PLIs, concession of corporate taxes, FDI policies, and decreased foreign exchange volatility attributed to the improved risk management score.

## Biotech and Lifesciences Sector Risk Exposure 2022 Vs 2021

Indian Biotech and Lifesciences Sector Risk Exposure went up from 57 to 61 in 2022 due to heighten geopolitical tensions, global slowdown in GDP growth resulting in reduced industrial activities, all-time low rupee valuation and high CPI inflation. Financial risks and geo-political tensions arising due to the Russia-Ukraine tensions, increased cost of R&D, Delay in approval of biotech products majorly increased the Risk exposure score.

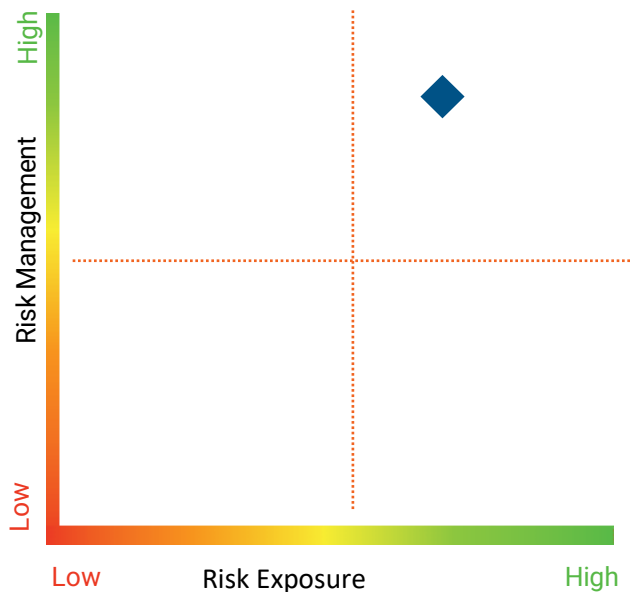
# Key Highlights



## Risk Dimension Analysis: Market and Economy

**Risk Exposure Score: 63**

**Risk Management Score: 61**



### Inflation

- During December 2022, India saw the highest inflation rates in 40 -years due to Russia-Ukraine war crisis.
- The operating profit margin (OPM) of top biotech companies stood at around 20 percent average in Q1 FY 2022 and 18 percent in Q4 FY 2022. This signals the sector is trapped with cost inflation and pricing pressures.
- The outlook for the Indian biotech industry remains still stable, led by expectations of continued steady revenue growth and comfortable margins.

### Taxation

- Indian govt announced concessional corporate tax rate of 15% for one year to newly incorporated manufacturing companies and companies could avail it along with the production linked incentive (PLI) scheme. So this will boost the capital-intensive biotech and life sciences industry startups.

### Regulatory Risks

- 100% FDI is allowed under the automatic route for greenfield pharma.
- 100% FDI is allowed under the government route for brownfield pharma. Up to 74% FDI is under automatic route and beyond 74% is under the government approval route.
- India's regulation of biotech products is not transparent and of global standard. Recently Approvals for Bharat Biotech's Covaxin, Delhi University's GM mustard and the recent issues with throat syrups and eye drops raise serious concerns of using biotechnology made products in India.
- The Union Health Ministry has released a draft of The Drugs, Medical Devices and Cosmetics Bill, 2022. Once implemented, the current Drugs and Cosmetics Act, 1940 (hereinafter referred as "D&C Act"), of the pre independence era, will be repealed. The Draft Bill completely misses on provisions

for recalling of drugs, cosmetics or medical devices if found to be in violation of the provisions of law. However, the draft Bill provides a mechanism towards regulating online sale or distribution of medical devices, which will be a welcome move for the industry.

- India's funding in 2022 for biotechnology sector is critically low, as the entire Ministry of Science and Technology receives only 0.05% of India's GDP as funding from the Central Government.

#### **Foreign Exchange Rates**

- Besides the sanctions resulting from Russia-Ukraine war, the strengthening of dollar against local currency also resulted in decline in Biotech exports. Countries like Nigeria (one of the top 5 markets of Indian Biotech and pharma exports) decreased the imports due to continuous depreciation of Nigerian Naira against USD.

#### **Geopolitical Risk**

- A consequence of COVID-19 on global supply chains has renewed interest in countries to near critical supply chains that feed into health products such as vaccines, pharmaceuticals, etc.
- Media reported regulatory approval for COVAXIN was rushed due to political pressure. Bharath Biotech and Union Ministry reported that the claims were misleading and fallacious.

#### **Competitive Risk**

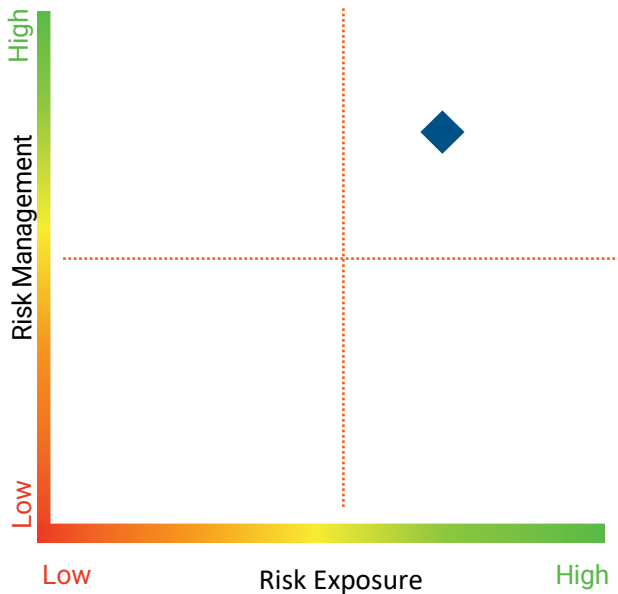
- Major players in Biotech are investing huge in R&D developments and planning initiatives in several domains, creating new patents, increasing drug development budget creating better competitive advantage among them.



# Risk Dimension Analysis: Technology

**Risk Exposure Score: 65**

**Risk Management Score: 65**



## Innovation Risk

- With exponential adaptation of latest trends in technology like AI, ML, innovation may be outdated more quickly than planned by the organizations. This might cause impact in investing in newer initiatives.

## Intellectual Property Risk

- The QUAD, known as “Quadrilateral Security Dialogue QSD”, is a strategic forum including 4 nations India, US, Japan, and Australia.
- The QUAD plans to provide countries with support to vaccine readiness and delivery, vaccine procurement, preparedness of healthcare professionals, community engagement, and immunization capacity. To Intellectual Property Policy will be needed to foster the innovation ecosystem of QUAD.

## Disruptive Technology

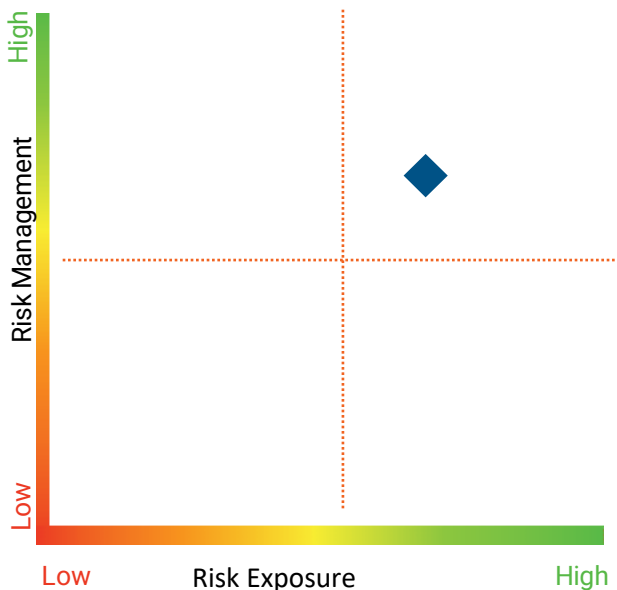
- According to industry experts, Artificial Intelligence (AI) continues to be among most desired technology. Biotech companies have deployed AI to streamline a variety of operational processes via enhanced automation.
- Synthetic Biology (bio-fabricated electronic film, cell engineering for therapy, automated coronavirus testing using sequencing) techniques are being intensively adapted by Biotech majors and investing in these technologies.



# Risk Dimension Analysis: Operational and Physical

**Risk Exposure Score: 62**

**Risk Management Score: 68**



## Supply Chain Risk

- A consequence of COVID-19 on global supply chains has renewed interest in countries to near critical supply chains that feed into health products such as vaccines, pharmaceuticals, etc

## Workplace Accident

- Although there is no direct major incidents of workplace accidents, there has been an increasing situation of burnout situation in R&D, where employees work more than 12 hours a day and gets affected with mental and physical wellness.

## Human Resource

- Indian biotech industry is emerging with high-quality, knowledge-driven, skilled employees.
- With constant layoffs, corporate mergers and acquisitions, and rise in compensation standards, many firms in biotech have adopted an outsourcing business model.
- Employee retention and motivation, and competitive compensation are one of the major challenges for HR department in Biotech companies in 2022.

## Financial Risk

- Unlike Pharma industry, Biotech industries saw decline in stocks after January 2022. Investments in biotech stocks are usually cyclical.
- Companies like Pfizer and Moderna are preparing for acquisitions in biotech startup ecosystem in India and interested in new innovations like RNA vaccines, CRISPR gene editing and precision medicines.

## Breaches of law (local/ international)

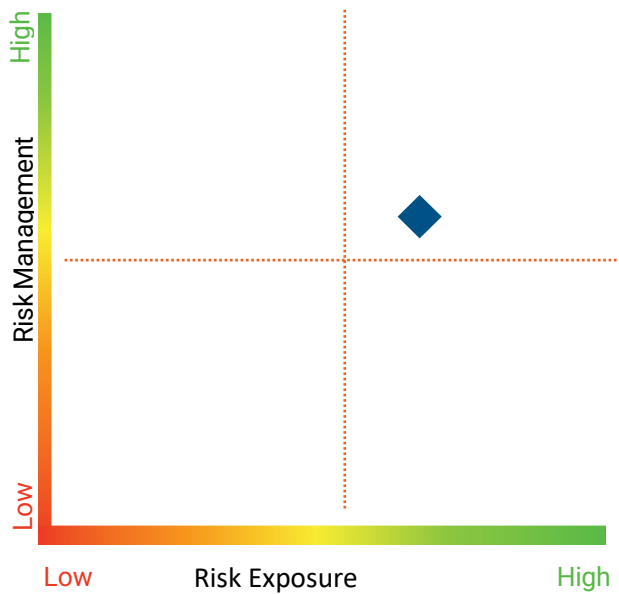
- There were few incidents reported where major biotech and pharma players were reported gifting freebies such as hospitality, conference fees, gold coins, LCD TVs, laptops etc to medical practitioners for creating awareness about their products



## Risk Dimension Analysis: Crime and Security

**Risk Exposure Score: 68**

**Risk Management Score: 66**



### Cyber-crimes

- Although there was no major data breaches or cyber attacks in biotech firms, reliance on BIG data and AI technologies has more exposure to such situations in upcoming years.

### Counterfeiting

- Fake vaccination dosages were found out in certain parts of the country and necessary actions are taken by the Government of India

### Bio-Terrorism

- Bioterrorism, in form of viruses, bacteria and antibodies are severe threat to world economy.

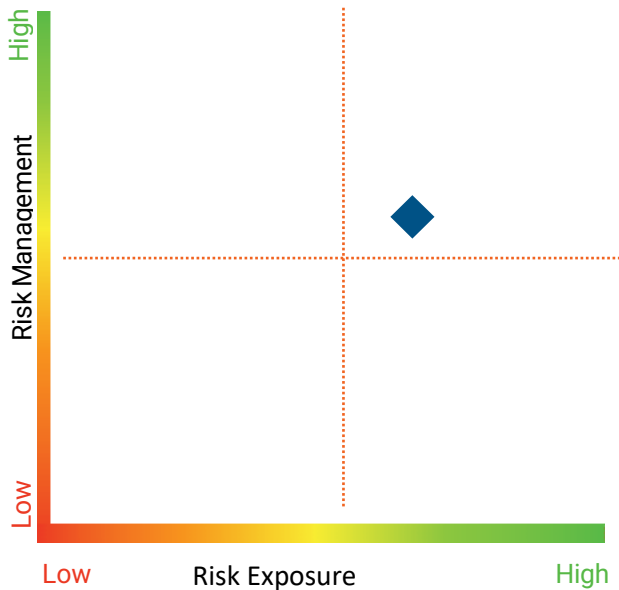
- Neutralizing human monoclonal antibodies is being used in trial in few countries which has the capacity of human-to-human respiratory route transfer and cause adverse effects on normal metabolism.



## Risk Dimension Analysis: Natural Hazard and Event

**Risk Exposure Score: 54**

**Risk Management Score: 60**



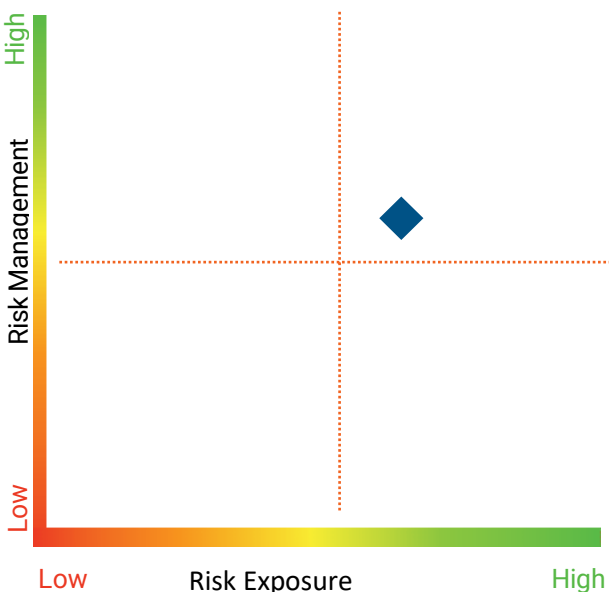
### Natural Hazards & Pandemic and other global epidemic diseases:

- According to the Centre for Science and Environment, the first 9 months of 2022 witnessed a disaster every day, claiming 2755 lives. In 2022, India recorded the wettest January and warmest ever in 121 years.
- Although Biotech sector has no major direct influence in natural hazards, the employee efficiency is affected due to the natural calamities and manufacturing capacity is greatly reduced by pandemic situation.

## Risk Dimension Analysis: Strategic Risk

**Risk Exposure Score: 54**

**Risk Management Score: 56**



### Increased number of recalls and quality audits:

- Biotech Indian Pharma Company Lupin Recalls skin medicine in USA over poor quality.
- Bharat Biotech announced voluntary product recall of ChiroRaba Vaccine - a rabies vaccines with specific batch number due to theft of its multiple vials.
- Dr.Reddy's Lab recalls 4000 bottles of generic drug in US due to packaging error.
- So, biotech industry is affected by various environmental factors in 2022 causing recalls in huge numbers.

### **Resource scarcity / Misutilization / Overall Utilization**

- Supply shortages for generic manufacturing biotech companies as most of the source materials are sourced from China and drug supply independence is required for further growth.

### **Delay in execution of projects**

- Specific projects planned in biotech, like TITAN biotech plans were affected by lockdown and financial crisis in post-COVID situation.
- R&D turned to be more expensive than 2021 due to supply-chain shortage and competitive compensations offered by other players in the biotech sector

### **Failed / Hostile Mergers & Acquisitions**

- Medley-Cipla deal called off over valuation mismatch issues.
- Hyderabad based Aurobindo Pharma – Blackstone deal scrapped in Feb 2022 due to market volatility and valuation mismatch.

# ICICI LOMBARD: Key Solution Offerings



## Property

- a. Businesses are always prone to risks and fire eruption and fire insurance provides a comprehensive protection against damages caused due to fire explosion and other risks. Besides fire related perils, it also protect damages caused due to any natural calamity, bursting of water tanks, theft etc. The built in covers include alterations or extensions, stocks on floater basis, temporary removal of stock, cover for specific contents, start-up expenses, professional fees, costs for removal of debris etc
- b. **Solutions**
  - i. **Property Loss Prevention exercise** - We have developed the methodology of Property Value Added Services for corporate customers which focuses on technical engagement with detail risk visit, followed by benchmarking of the risk (Industry Risk Profiling).
  - ii. **Fire Hydrant IoT** - Fire hydrant online monitoring devices use IoT to monitor fire hydrants and assure their availability in emergencies. We've helped multiple corporate customers maintain and monitor this important fire safety component in real time.



## Marine

- a. We offer specially curated plans for covering the risk of theft, malicious damage, shortage, and non-delivery of goods, damages during loading and unloading, and mishandling of goods/cargo
- b. Marine Cargo insurance primarily covers loss during transit caused due to fire, explosion, hijacks, accidents, collisions, and overturning
- c. **Solutions**
  - i. **GPS Device Tracking:** With the help of our advance GPS devices we can have bird eye view on the consignment and vehicle from anywhere in the world. OurSAAS allows us to track and get the visibility of the vehicle on the basis of our requirements which is fully customizable



## Liability

### a. Comprehensive general liability:

- i. This policy is important for every small and medium sized businesses to protect the insured entity against claims arising out of legal liability where they are held responsible for third party bodily injury or property damage due to insured's business, premises or products. It should be taken by every new business as it covers all risk a business may face.

### b. Cyber - With cyber risk steadily increasing, security/ data breaches affect millions of records a year. Cyber Risk insurance coverage is designed to help an organization mitigate its risk exposure by offsetting costs involved with recovery after a cyber-related security breach or similar event.

### c. Solutions

- i. **Simulated phishing tests** - Simulated real looking phishing tests and record employee behavior to phishing attacks along with training collateral in form of co-brandable posters, infographics and videos
- ii. **Cyber maturity assessments** - Assess the security posture of your organization and identify the potential risks with our assessment based on ISO 27001 Control measures for Information security
- iii. **D&O** - The need of Directors & Officers Insurance is more than ever before. Any breach or non-performance in the duties can result in claims against directors, officers and employees by reason of wrongful act and need to incur various expenses like defense costs, damages or compensation and other incidental costs. This can affect company's growth and performance.



## Group Health

- a. Employees are the backbone of an organization and the most valued asset. Our Group health insurance product is designed to offer health coverage to suit employees of all business types ranging from small & medium enterprises to large organizations.

### b. Solutions:

- i. **IL Take Care** - AI enabled mobile app for employees
- ii. **Health assistance services** - Health Assistance is a dedicated medical care service that assists you in all your health related queries for identifying specialist/hospital/fixing an appointment with doctors/nutritionist /facilitating 2nd opinion
- iii. **Tele Consultation** – Hello Doctor
- iv. The insured is eligible to avail unlimited General Physician consultations for routine health issues over the phone by a qualified doctor
- v. **Diagnostics & pharmacy services** – Book a lab test or home delivery of medicines



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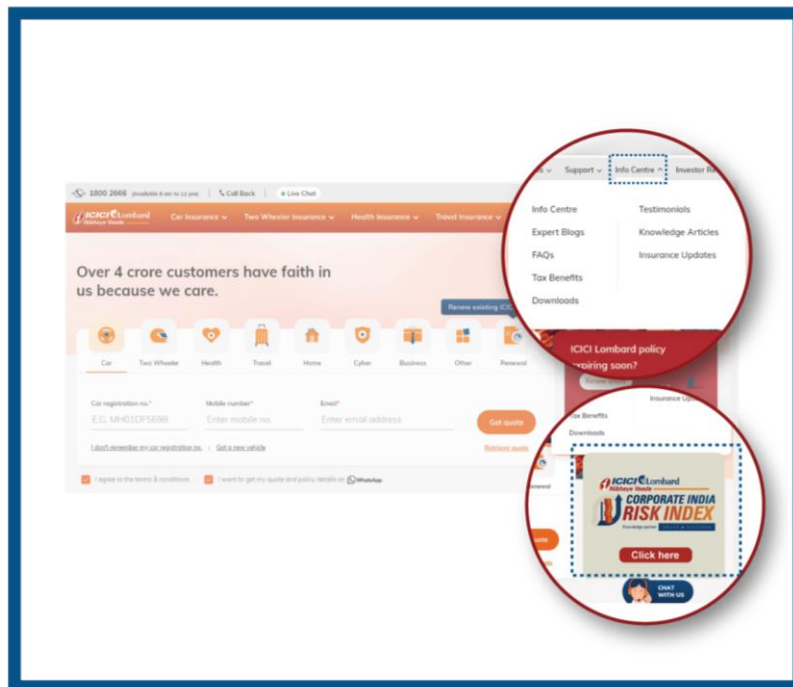






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