



Sector: Biotech & Lifesciences



ICICI Lombard Corporate India Risk Index

Introduction

- ICICI Lombard Corporate India Risk Index is a one of its kind, unified, credible, standardised corporate Risk Index that spans over the country level, the industry level and the company level
- This is the 2nd Iteration of the Corporate India Risk Index which was started in 2021. This index maps the risks to a company on the basis of awareness, preparedness, probability and criticality.
- The Corporate India Risk Index for 2021 is based on published business performance reports, assessments, insights & collaborative inputs from key executives/ officials of 220 companies in India across 20 key sectors. It will help the companies understand the level of risk exposure and current level of risk management.

Comprehensive Sector Coverage

Aerospace & Defense **Chemicals & Petrochemicals** Infra & Realty New Age & Startup Agriculture & Food Processing* Education Skill Development* IT/ITES Pharmaceuticals Automotive & Ancillary Energy Manufacturing **Telecom & Communication*** BFSI FMCG Media & Gaming* **Tourism & Hospitality** Biotech & Life sciences* Healthcare Delivery Metals & Mining **Transportation & Logistics**

* New Sectors for ICICI Lombard Corporate India Risk Index 2021

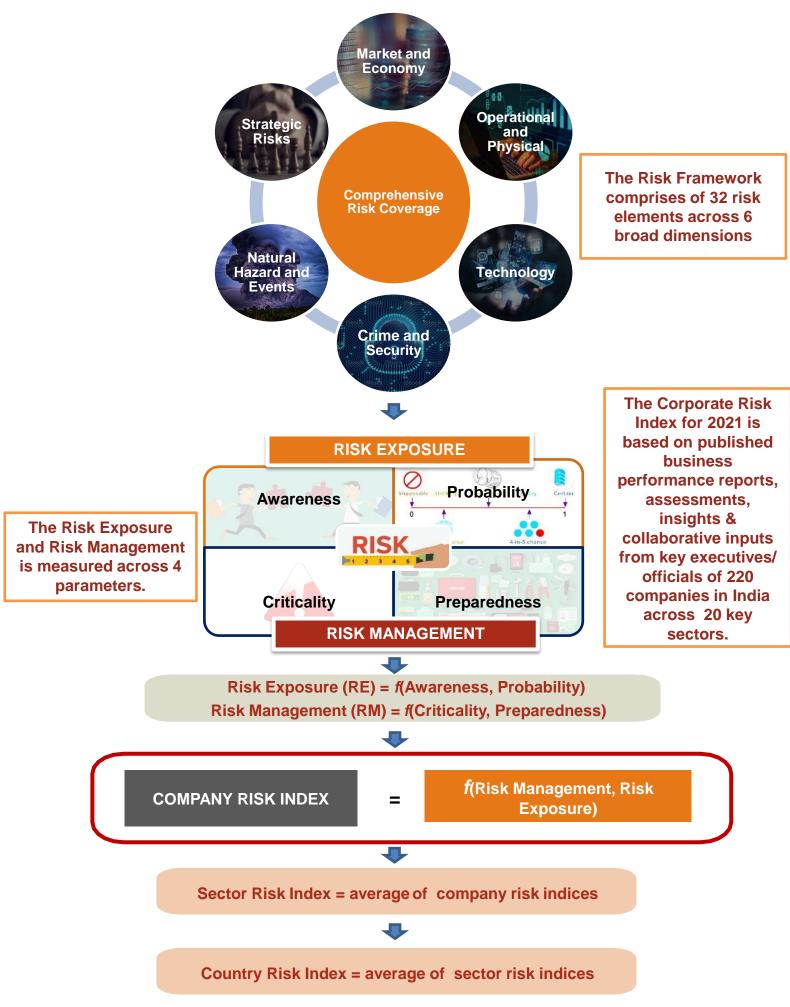
Risk Framework

The ICICI Lombard Corporate India Risk Index Framework comprises of 32 risk elements across 6 broad dimensions:





ICICI Lombard Corporate India Risk Index – Approach





ICICI Lombard Corporate India Risk Exposure – Scale

Score	< 40	40 - 50	50 - 60	60 - 80	> 80
Category	Very Low Risk Exposure	Low Risk Exposure	Moderate Risk Exposure	High Risk Exposure	Very High Risk Exposure
	Has minimal exposure to overall risks and thus probability of a risk incident is very less.	Has low exposure to overall risks and its risk exposure is within acceptable tolerable limits.	The corporate is able to balance the impact of moderate exposure to overall risks up to a certain extent.	The risk exposure and its impact is very high in the industry in which the corporate operates.	Unable to foresee risk incidents, the probability of these incidents and quantified business loss may be extremely high.

ICICI Lombard Corporate Risk Management – Scale

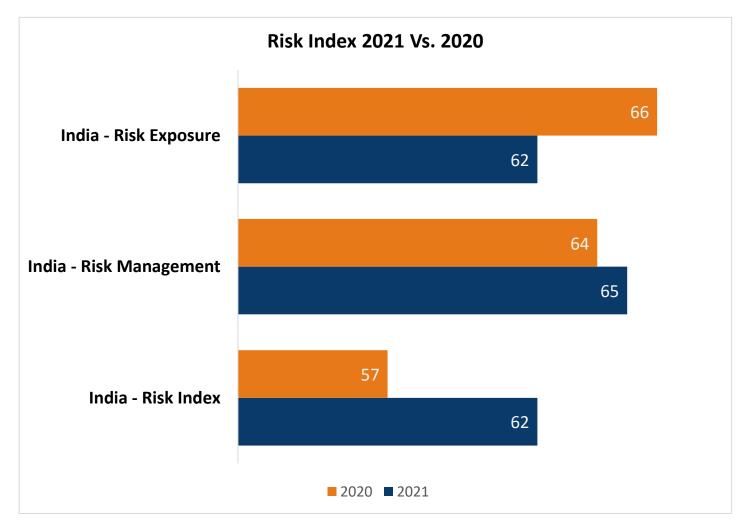
Score	< 40	40 - 50	50 – 70	70 - 80	> 80
Category	Poor Risk Management Unable to understand the concept of Risk management and reactive to overall risks that affect it.	Below Par Risk Management Use of inefficient or legacy risk management practices which is reactive to newer or unknown risks.	Acceptable Risk Management The corporate is prepared to handle known risks and the criticality of its risks are not severe.	Superior Risk Management Top class risk management practices with its ability to manage dynamic risks as well as unknown risks.	Exemplary Risk Management Over prepared in Risk management practices, proactive to emerging risks with high investment in risk mitigation practices

ICICI Lombard Corporate Risk Index – Scale

Score	< 40	40 - 55	55 <mark>– 65</mark>	<mark>65 - 75</mark>	> 75
Category	Ineffective The corporate has very high exposure or very poor risk management practices or both	Sub-optimal Not all risks are handled effectively. Risk management practices are likely dated or inefficient.	Optimal Most current risks are being handled effectively. Emerging risks associated with strategic initiatives need more diligence.	Superior Very effective and efficient risk management practices. Well positioned to handle current and future risks across dimensions.	Over- prepared High investment in risk mitigation practices. Likely over-investment in one or more risk dimensions. Difficult to justify ROI



ICICI Lombard Corporate India Risk Index

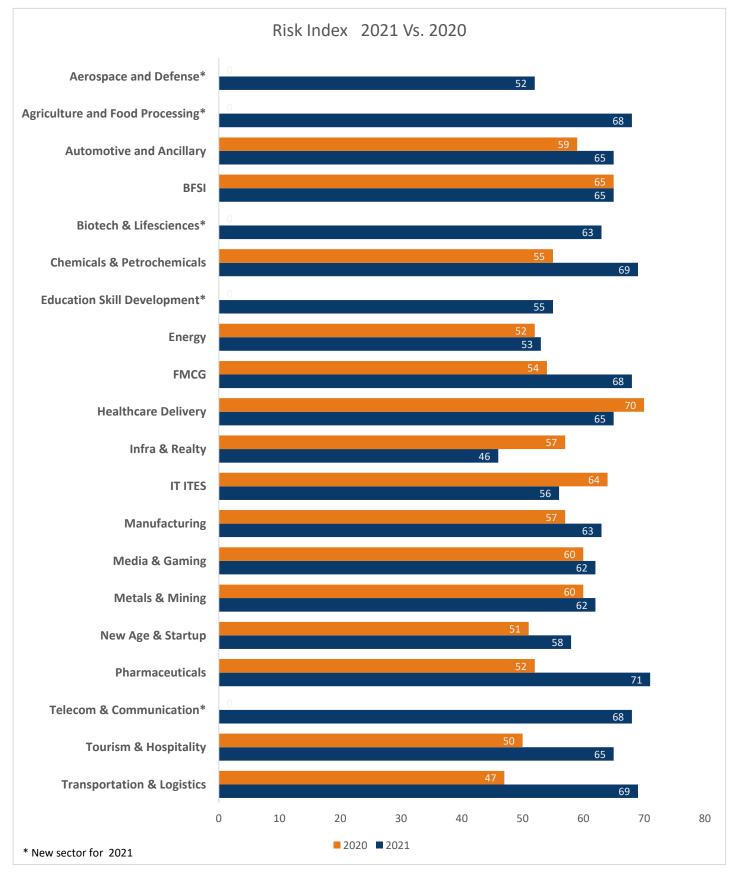


India Risk Index(Optimal Risk Handling)

- As the pandemic and pandemic related constraints eased up, Sectors showed varied recovery as risk related to Resource Scarcity, Delay in Execution of projects due to pandemic and Financial Risks due to tax relaxation pacified
- The overall Risk Index for India improved from 57 to 62 in 2020-2021, however sectors like Infra & Realty, Metals & Mining and New Age & Startup the risk Index decreased which was primarily due to the increased Strategic Related Risks, Crime & Security Risks, Financial Risks, Inflation and Technology Risks
- Sectors like Transportation & Logistics, BFSI, Chemicals & Petrochemicals and Tourism & Hospitality showcased significant improvement in the Risk Index, because the risk exposure lessened across all the risk dimensions.
- It was also observed that the Risk Exposure came down for the Large Businesses(67 vs. 64), Medium Businesses(65 vs. 61) and Small businesses (64 vs. 63) for 2020 vs. 2021.
- With the reduced impact of the pandemic and innovative initiatives by business leaders over the supply-chain, sectors like **Manufacturing**, **Automotive**, **FMCG and Chemicals & Petrochemicals** improved on the **Risk Index**.



ICICI Lombard Corporate India Risk Index – Sector Comparison



Observations:

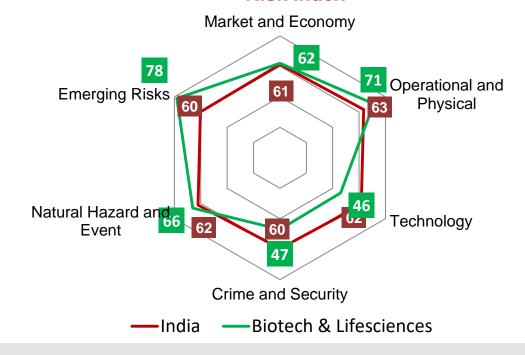
Automotive & Ancillary, FMCG, Manufacturing and Pharmaceuticals sector have been managing their Risk in a defined, methodical and strategic manner, with continuous monitoring and containment of Risks. Transportation & Logistics, Metals & Mining, Healthcare Delivery and Biotech & Life Sciences sectors need to improve their Risk management capabilities in order to have an overall acceptable Risk measure.



India Risk Profile Vs. Sector Risk Profile

Risk Profile	2021 Risk Exposure	2021 Risk Management	2021 Risk Index	2020 Risk Index
India	62	65	62	57
Biotech & Lifesciences Sector	57	60	63	NA

India Risk Index Vs. Biotech & Life sciences Sector Risk Index



The Indian Biotech & Lifesciences sector's Risk Exposure score is 57 mainly due to its high exposure to Natural Hazards and Technology risks.

Despite the developments in the Biotech industry, this sector faces some serious hurdles. The main challenges for this sector are a lack of continuous sustained investment in R&D, Regulatory hurdles, ethical research and low R&D Productivity. External factors such as sluggish economic conditions, higher production costs, and the overall regulatory environment, all of which have a direct impact on business performance. On the positive front,

- The biotechnology business in India is seeing rapid growth and has proven to be highly imaginative.
- India is one of the world's top 12 biotechnology destinations, and the third-largest in Asia-Pacific.

The overall Risk Management score is 60, indicating an acceptable Risk Management in this sector.

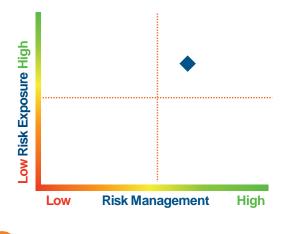
Companies must however improve their overall Risks pertaining to Natural Hazards, Crime and security and strategic risks Given the increase in skilled work force and greater acceptance of advanced biotech technology, India has become a hotspot for biotech industries.

• Players in the industry are attempting to reduce costs in order to gain a competitive advantage. This includes optimizing input resources, operating efficiency for handling assets owned by the company, lowering overhead costs, and stabilizing newly formed operation units.



Risk Dimension Analysis: Market and Economy

Risk Exposure Score: 58 Risk Management Score: 61



Rapid growth and high competitive risks.

- The country comprises 3% of the worldwide biotechnology industry. Multiple waves of the COVID-19 pandemic had a significant positive impact on the necessity for the development of India's biotech businesses.
- The New Drugs and Clinical Trials Rules were created to create a streamlined legal framework for the biopharmaceutical sector in order to reduce costs, approval timeframes, and bureaucratic red tape.
- Pricing restrictions by the government and tightening other regulations, like environment and labor laws in India may lead to increased costs for adherence.

Given the interruptions in supply chains and global trade wars India should capitalize on opportunities such as Laboratory reagents and Enzymes. Additional fiscal incentives, such as tax cuts and special incentives under the Department of Biotechnology's (DBT) Atal Jai Anusandhan Biotech Mission to grow downstream facilities, would increase industry production and development.

Risk Dimension Analysis: Technology

Recommendation:

Risk Exposure Score: 66 Risk Management Score: 65



Need for technological modernization of the sector's facilities

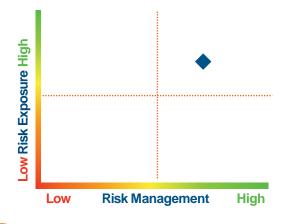
- To optimize manufacturing, the Biotech industry is implementing technologies such as artificial intelligence (AI), data analytics, and automation.
- As a result, there has been an increase in consumer Biotech or Biotech products aimed directly at consumers rather than biopharma or healthcare enterprises.
- Genetic engineering has progressed to the point where it is now commonly used in clinical practice. It enables precision medicine, a method that lets clinicians to determine which treatment and prevention efforts will be effective for a specific population of patients.

Big data and analytics solutions should be the emphasis of biotech enterprises. With the ever-expanding "omics" technologies and the integration of sensors and Internet of Things (IoT) devices, there is an unprecedented scope for usage in BioTechnology. This can help drive innovation. It can also assist biopharma companies in achieving a higher success rate for ethical clinical trials.



Risk Dimension Analysis: Operational and Physical

Risk Exposure Score: 62 Risk Management Score: 68



Expansion of operations, with improving operational costs with scale

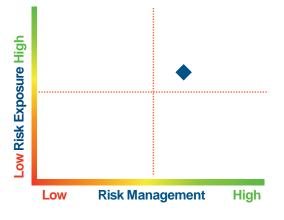
- India has a significant reservoir of scientific human resources, including scientists and engineers. As a result, India has a big pool of young and highly skilled workers.
- Clinical trials in India are governed by the Central Drug Standard Control Organization, which has decreased approval times to 30-60 days, allowing for market expansion.
- The government intends to implement productionlink incentive system with 10-20% output incentives to create an end-to-end manufacturing ecosystem through the growth of clusters.

Recommendation:

Companies should continuously review research to ensure that R&D costs do not turn into sunk costs. Also, supply chain disruptions can be avoided by diversifying suppliers and manufacturing partners and periodic material requirement planning. Companies should also ensure Biosafety hazard protocols are adhered to at the highest possible levels to ensure we have another of pandemic

Risk Dimension Analysis: Crime and Security

Risk Exposure Score: 67 Risk Management Score: 65



Recommendation:

Increased risk of Cyber attacks across the world

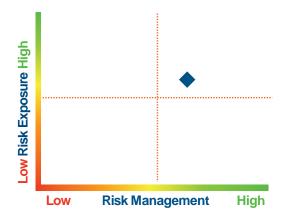
- Biotech sector has a robust risk management framework to identify, monitor and minimize security risks.
- Data breaches, in addition to ransomware attacks, are the other main cyberthreat to Biotech businesses. These two attacks are frequently combined.
- Bioterrorism poses a security risk. A dizzying array of biological toxins and infectious organisms could be utilized to assault animals, humans, and plants. The most likely biothreats to humans involve all branches of the microbial world, including bacteria, viruses, and toxins.
- Measures like safety assessment, audit capacity and regular monitoring are undertaken to ensure safety within the sector

Through Vulnerability Analysis (VA) and predictive analytics, firms can employ novel ways to strike facilities/systems encompass Information security, Physical security, Cyber security and well-established Security policies and procedures.



Risk Dimension Analysis: Natural Hazard and Event

Risk Exposure Score: 54 Risk Management Score: 58



Balancing the impacts of the pandemic has become an overarching management principle

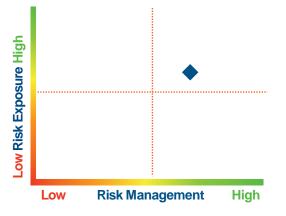
- The Biotech industry has suffered no big losses in recent years and has been mostly spared by natural calamities in India. However, the COVID-19 pandemic has highlighted the importance of adequate risk management in order to avoid excessive pressures from life-saving medications.
- To ensure the availability of commodities across the economy, the biotech industries are focusing on managing volumes or manufacturing locations to match altering demand and changing supply routes.

Recommendation:

The companies could mandate all of its units to undertake rigorous testing of probability of Natural hazards, Physical hazards, Bio-hazards, Electrical hazards, etc. Insurance of high value Bio Technology equipment's can also help reduce significant financial risk.

Risk Dimension Analysis: Strategic Risk

Risk Exposure Score: 24 Risk Management Score: 27



High project risk, risk related to volatility in commodity prices and supply chain disruptions.

- The industry is constantly expanding with a huge capital expenditures involved; Delay in project execution pose a substantial financial risk.
- If key risks are not mitigated, biotech firms may face a loss of consumer trust, reputational harm, a loss of competitive advantage, claims and legal disputes, regulatory noncompliance issues, investigations, fines and penalties, securities class actions and shareholder derivative lawsuits, and even bankruptcy.

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Recommendation:

The biotech industry's methodologies have a lot of opportunity for improvement. Biotech firms could use innovative models such as Fully Integrated Pharma Companies (FIPCO). A key component of achieving this model is the use of an M&A strategy to aid biotech firms in becoming long-term with long-term goals and vision.





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