USFDA Inspections Rise: Indian Pharma at the Crossroads of Opportunity and Responsibility

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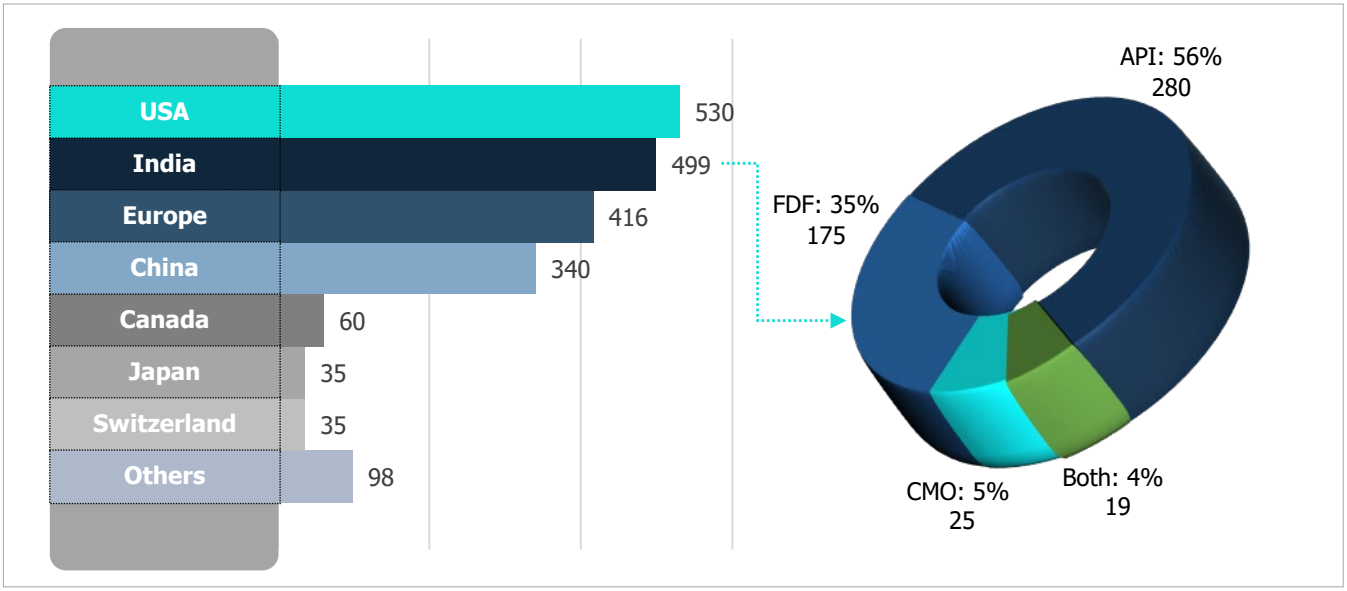
Synopsis

- The United States Food and Drug Administration (USFDA) remains a pivotal regulatory authority in safeguarding the quality and efficacy of pharmaceutical products in the US market. In recent years, Indian pharmaceutical companies have been subject to intensified scrutiny and regulatory oversight by the USFDA, which is in line with the growing presence of the Indian pharmaceutical sector in the US market.
- India has the second-highest USFDA-approved pharmaceutical manufacturing facilities worldwide, second only to the US. With the US being the largest pharmaceutical market in the world and India being one of the largest exporters of generic drugs, approximately 35% of India's pharmaceutical exports were to the US market in FY25.
- Post the pandemic-induced dip in inspections, there has been an increasing trend in USFDA inspections of Indian pharmaceutical manufacturing facilities. In calendar year 2024 (CY24), the USFDA conducted over 256 inspections of Indian pharmaceutical manufacturing sites, expecting further growth in inspection frequency in CY25.
- Despite more USFDA-approved facilities and increased inspections, OAI observations stayed around 7%, down from 15-20% between CY13 and CY17. This highlights improved compliance with cGMP by Indian pharma companies standards.
- Looking ahead, CareEdge Ratings expects the Indian pharmaceutical sector to maintain its growth trajectory, underpinned by consistent investments in research and development, regulatory compliance, and quality enhancement. The sector is well-positioned to effectively manage and navigate any potential escalation in regulatory scrutiny by the USFDA, reinforcing India's role as a vital supplier of quality drugs in the global pharmaceutical supply chain.

USFDA-approved Manufacturing Facilities

As per the USFDA, Generic Drug User Fee Amendments II, on an aggregate, there were 2013 facilities approved by it to produce a finished dosage form (FDF) of a human generic drug or an active pharmaceutical ingredient (API) contained in a human generic drug as of March 2025.

India has 2nd highest number of USFDA approved plants worldwide



Source: USFDA and compiled by CareEdge Ratings. Note: Both indicates FDF and API

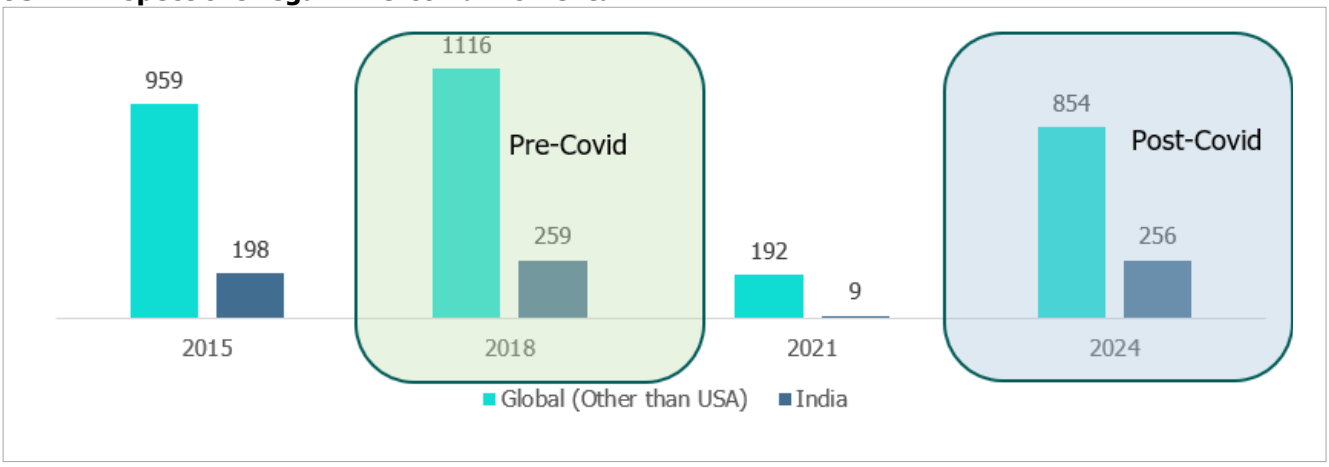
The chart highlights India's significant position in the global pharmaceutical manufacturing landscape.

The number of USFDA-approved manufacturing facilities in the US stood at 530. Outside the US, India has the highest number of USFDA-approved manufacturing plants globally, with 499 facilities. This underscores India's critical role in supplying quality pharmaceutical drugs to regulated markets, particularly the US. Notably, over 90% of India's USFDA-approved plants are involved in the production of API and FDF, accounting for 56% and 35% of the total plants, respectively. The Contract Manufacturing Organisations (CMOs) constitute 5%, while 3% of plants handle API and FDF, reflecting India's diverse and robust pharmaceutical manufacturing capabilities.

Inspections/ Audit by USFDA

The chart depicts the trend of the number of inspections carried out by the USFDA on various international facilities, including those in India, over the past 10 years.

USFDA inspections regain Pre-covid momentum



Source:USFDA; Complied by CareEdge Ratings
Note: The inspection data represens the audit by USFDA for drugs and biologics manufacturing facilities.

The USFDA has significantly increased its global inspection activity, reaching close to pre-COVID-19 levels. The number of inspections outside the USA, which had sharply declined during the pandemic, has recovered substantially. In 2018 (pre-COVID), the USFDA conducted **1,116** inspections globally (excluding the USA), with **259** in India. However, due to pandemic-induced restrictions, inspections dropped to just **192** globally and a mere **9** in India in 2021. With the easing of global travel restrictions and renewed regulatory focus, 2024 has seen a marked rebound. The USFDA has carried out **854** inspections globally (excluding the USA), with **256** inspections in India, almost matching the pre-COVID-19 numbers for India.

As per the latest developments, the USFDA has prioritised inspections of facilities linked to high-priority drugs and those involved in complex generics and injectables. While this intensifies the compliance pressures on Indian manufacturers to maintain stringent quality protocols, the current inspection trends align with the broader global emphasis on strengthening pharmaceutical supply chains and ensuring product safety in regulated markets. This may also aid in faster product approvals.

Stronger Compliance Speeds US Approvals

The frequency of OAI observations issued by the USFDA on its approved pharmaceutical facilities in India has decreased over time. This indicates improving compliance standards of Indian pharmaceutical manufacturing facilities, which has aided in the accelerated pace of product filing and approvals.

Number of inspections carried out by the USFDA

	2018	2019	2020	2021	2022	2023	2024
USA	1481	1421	800	791	959	937	963
India	259	333	180	9	85	228	256
China	132	131	19	14	8	40	142
Canada	61	85	33	1	29	48	57
Germany	66	77	36	35	52	47	27
Italy	70	74	15	5	58	52	25
Other Countries	528	510	229	128	246	413	347

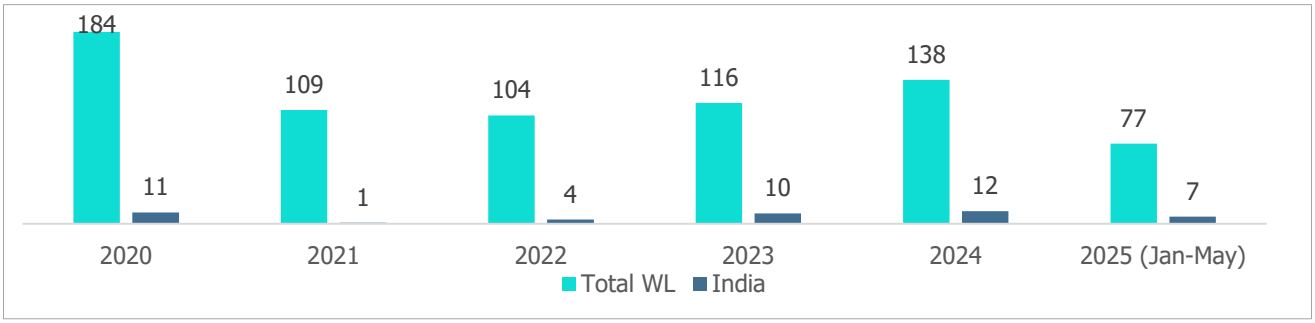
Source: USFDA; Compiled by CareEdge Ratings

Classification of inspection observations by the USFDA

Country (in No's.)		2018	2019	2020	2021	2022	2023	2024
USA	VAI+NAI	97%	96%	97%	93%	96%	97%	91%
	OAI	3%	4%	3%	7%	4%	3%	9%
India	VAI+NAI	92%	91%	91%	56%	86%	90%	93%
	OAI	8%	9%	9%	44%	14%	10%	7%
China	VAI+NAI	89%	84%	100%	82%	60%	90%	93%
	OAI	11%	16%	0%	18%	40%	10%	7%
Canada	VAI+NAI	90%	98%	86%	80%	88%	97%	93%
	OAI	10%	2%	14%	20%	12%	3%	7%
Germany	VAI+NAI	100%	99%	100%	100%	98%	100%	100%
	OAI	0%	1%	0%	0%	2%	0%	0%
Italy	VAI+NAI	99%	99%	100%	100%	100%	100%	88%
	OAI	1%	1%	0%	0%	0%	0%	12%

VAI: Voluntary Action Indicated NAI: No Action Indicated OAI: Official Action Indicated.
Note: The % for 2021 is an outlier, not very meaningful because of the abysmally low number of inspections done by the USFDA in that year due to travel-related restrictions arising from the COVID-19 pandemic.

Number of Warning Letters (WL) issued by the USFDA to Indian facilities



Source: USFDA; Compiled by CareEdge Ratings

The classification of observations indicates a consistent reduction in the proportion of Official Action Indicated (OAI) outcomes for Indian sites. From a high of 14% OAI in 2022, the share declined to 7% in 2024 (best in the 3 years before and the 3 years post the pandemic), signifying improved preparedness and compliance by Indian facilities during regulatory audits.

Indian Pharma Sector is Poised to Leverage Upcoming Opportunities

Amid the resurgence in inspections, the USFDA has strategically focused on facilities associated with priority review products, injectables, complex generics, and critical supply chain components. This aligns with global efforts to mitigate drug shortages and strengthen supply reliability post-pandemic. For India, which supplies around 40% of generic drugs to the US by volume, this presents both opportunities and challenges—opportunities to expand market share, and challenges in the form of continued regulatory scrutiny.

With recent USFDA guidance on data integrity, aseptic processing, and complex injectable production, Indian pharma companies are increasingly investing in compliance upgrades, automation, and digital quality management systems. Furthermore, the USFDA's heightened focus on CMOs is relevant for Indian players engaged in outsourcing and third-party manufacturing models.

In conclusion, the positive trajectory of USFDA inspections and declining warning letters for India reflects growing regulatory maturity in the Indian pharmaceutical ecosystem. However, sustained investments in compliance and proactive engagement with regulatory changes will remain essential for maintaining this momentum.

Nature of USFDA Observations for Indian Pharma Companies

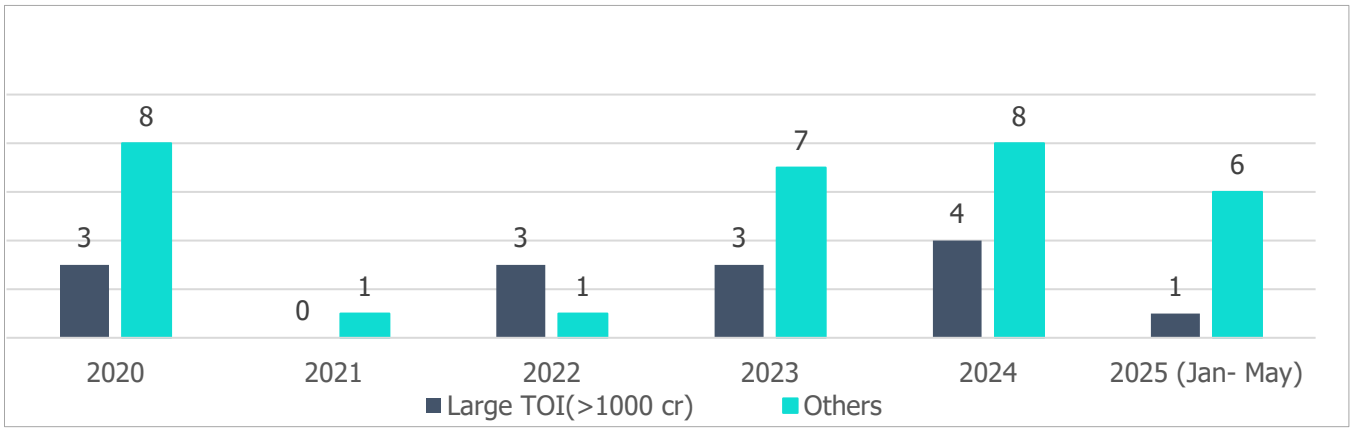
Based on the observations provided by the USFDA in its warning letters to Indian pharma companies during CY2022 to 5M2025, CareEdge Ratings has categorised them into various categories.

Classification of Observations	2022	2023	2024	5M2025	Total	% Share
Data Manipulation/Data Integrity	-	-	-	2	2	6%
Lack of data documentation discipline	1	1	4	1	7	21%
Failure to Maintain Quality and Purity	1	4	2	1	8	24%
Inadequate investigation of critical deviations or a failure	0	2	1	-	3	9%
Lack of procedural awareness	0	1	-	-	1	3%
Lack of hygiene	1	1	4	1	7	21%
Compliance	1	1	1	2	5	15%
Grand Total	4	10	12	7	33	100%

Source: USFDA and compiled by CareEdge Ratings

An analysis of Warning Letters (WLs) issued by the USFDA to Indian pharmaceutical companies over the past few years highlights that quality lapses and documentation issues remain key areas of concern. Between 2022 and May 2025, a total of 33 Warning Letters were issued, with Failure to Maintain Quality and Purity (24%) emerging as the single largest cause, followed closely by Lack of Data Documentation Discipline (21%) and Lack of Hygiene (21%). While data integrity concerns, which had been a major issue in earlier years, constituted only 6% of total observations during this period, compliance-related lapses (15%) and inadequate investigations of deviations (9%) also contributed to the regulatory observations.

Number of WL received by Indian Pharma cos by Turnover



Source: USFDA and compiled by CareEdge Ratings

It can be inferred from the above chart that most of the recent Warning Letters have been issued to smaller to mid-sized pharmaceutical companies, many of which face resource constraints in fully aligning with evolving current Good Manufacturing Practices (cGMP) expectations. These companies often struggle with building strong documentation frameworks, quality assurance systems, and procedural discipline, which are increasingly critical focus areas for regulators.

The USFDA has intensified its focus on data integrity, risk-based quality management, and environmental monitoring, particularly for facilities engaged in sterile manufacturing and complex generics. Larger Indian pharmaceutical players have generally improved their compliance standards. Still, smaller entities must invest in systems, automation, and workforce training to avoid regulatory headwinds and safeguard their market position in regulated markets like the US.

The evolving inspection landscape underscores that regulatory compliance is no longer just a cost but a strategic necessity for sustaining growth in international markets.

CareEdge Ratings' View

"The resurgence of USFDA inspections to pre-pandemic levels and the concurrent decline in major adverse regulatory actions against Indian pharmaceutical facilities underscore the growing regulatory maturity of the Indian pharmaceutical sector. India's position as a key supplier of generics to the US market has been reinforced by sustained improvements in compliance frameworks, quality control systems, and operational discipline," says D. Naveen Kumar, Associate Director, CareEdge Ratings.

"As the USFDA intensifies focus on high-value product categories—such as complex generics, injectables, and critical supply components—Indian pharma companies are well-positioned to capitalise on emerging global opportunities, provided they continue to invest in technology, talent, and regulatory engagement. Moving forward, compliance will not merely be a regulatory requirement, but a core driver of growth and sustainability in the global pharmaceutical ecosystem," says Pulkit Agarwal, Director, CareEdge Ratings.

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