Turning the Tide: How Indian Pharma Is Redefining USFDA Compliance

The United States Food and Drug Administration (USFDA) continues to play a critical role in ensuring the safety, efficacy, and quality of pharmaceutical products in the U.S. market. In recent years, Indian pharmaceutical companies have come under increased regulatory scrutiny, reflecting the sector's expanding global footprint and operational complexity.

Post-pandemic, USFDA inspection activity has picked up significantly. In calendar year 2024 (CY24), the USFDA conducted over 256 inspections at Indian pharmaceutical facilities, with inspection frequency expected to rise further in CY25. Encouragingly, the share of inspections resulting in Official Action Indicated (OAI) observations has remained low at around 7%, a marked improvement from the 15–20% OAI rates recorded between CY13 and CY17. This sustained reduction highlights Indian pharma's improved focus on cGMP compliance and quality standards.

D. Naveen Kumar and Pulkit Agarwal, CareEdge Ratings remains confident in the continued growth trajectory of the Indian pharmaceutical sector, supported by ongoing investments in R&D, regulatory adherence, and quality enhancement. The sector remains well-positioned to manage evolving regulatory expectations, strengthening India's position as a key player in the global pharmaceutical supply chain.

Inspections/ audit by USFDA:

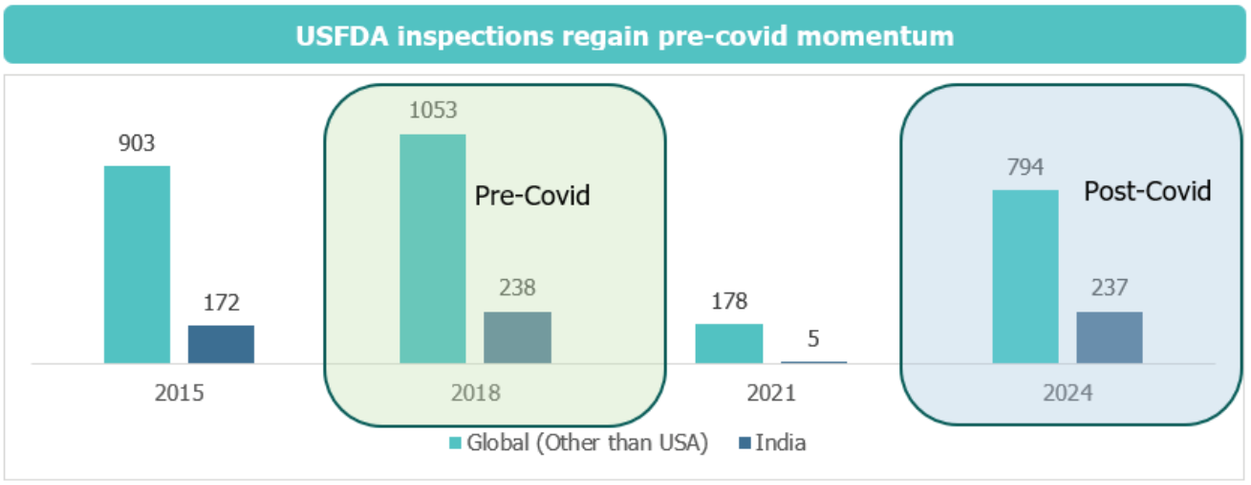
The chart depicts the trend of number of inspections carried out by the USFDA on the international facilities and Indian facilities over the past 10 years

The USFDA has significantly increased its global inspection activities, nearly reaching pre-Covid levels. While inspections outside the U.S. had sharply declined during the pandemic, they have now recovered substantially. In 2018, the USFDA conducted 1,053 inspections globally (excluding the U.S.), including 238 in India. However, pandemic-related restrictions saw this fall to just 178 globally and only 5 in India by 2021.

With the easing of travel restrictions and renewed regulatory focus, 2024 has seen a strong rebound. The USFDA carried out 794 inspections globally (excluding the U.S.), including 237 in India—almost matching pre-pandemic volumes.

The USFDA is also prioritizing inspections of facilities linked to high-priority drugs, complex generics, and injectables. This renewed focus bodes well for Indian pharma, enhancing regulatory visibility and potentially expediting product approvals. However, it also raises compliance expectations, reinforcing the need for stringent quality systems. The current trends align with the global emphasis on strengthening pharmaceutical supply chains and ensuring product safety in regulated markets.

USFDA action against India: Declining share of OAI observations indicates high compliance ratio



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

The frequency of OAI statuses issued by the USFDA on approved pharmaceutical facilities in India has seen a downward trend over time. This suggests a decline in regulatory and/or administrative actions suggested by the USFDA, resulting in accelerated pace of product filing and approvals.

Quality of Inspections: Improvement in Compliance

The classification of observations indicates a consistent reduction in the proportion of Official Action Indicated (OAI) outcomes for Indian sites. From a high of 44% OAI in 2021, the share declined to 7% in 2024, signifying improved preparedness and compliance by Indian facilities during regulatory audits. Favorable trends are also visible in the global context, with the USA and other key geographies like China and Canada maintaining or improving their inspection compliance metrics.

Indian Pharma Well-Positioned to Capitalize on Emerging Opportunities

With the resurgence of USFDA inspections, there is a strategic focus on facilities linked to priority review products, injectables, complex generics, and critical supply chain elements. This approach aligns with global efforts to address drug shortages and enhance supply chain resilience post-pandemic. For India—currently supplying nearly 40% of generic drugs to the U.S.—this presents a dual scenario: opportunities to strengthen its global position, alongside the challenge of navigating heightened regulatory scrutiny.

In response to evolving regulatory expectations, particularly around data integrity, aseptic processing, and complex injectable manufacturing, Indian pharmaceutical companies are stepping up investments in compliance upgrades, automation, and digital quality systems. Additionally, the increased

Number of inspections carried out by USFDA

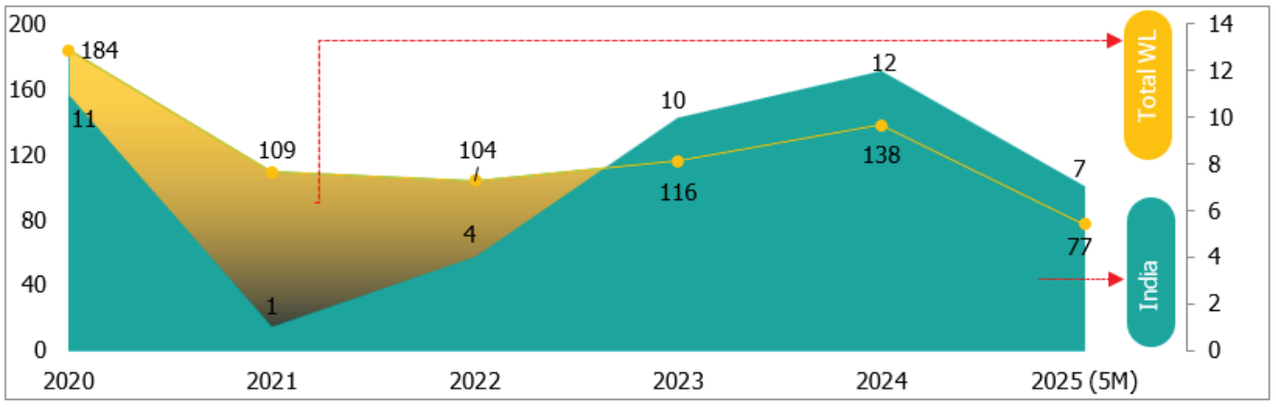
	2018	2019	2020	2021	2022	2023	2024
USA	3503	3330	1269	2157	3555	2625	963
India	286	346	103	20	108	220	256
China	123	127	4	17	5	58	142
Canada	52	87	21	5	42	63	57
Germany	72	74	43	34	58	39	27
Italy	81	73	7	18	58	36	25

Source: USFDA; Compiled by CareEdge Ratings

Classification of observations made by USFDA								
Country		**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

Number of Warning letters (WL) issued by USFDA to India



Source: USFDA; Compiled by CareEdge Ratings

attention on contract manufacturing organizations (CMOs) by the USFDA has direct implications for Indian firms engaged in third-party and outsourcing models.

Overall, the positive trend in inspection outcomes and a decline in warning letters reflect the growing regulatory maturity of the Indian pharmaceutical sector. However, sustaining this progress will require continued investment in compliance and proactive alignment with evolving regulatory standards.

Nature of USFDA Observations for Indian Pharma Companies:

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

An analysis of observations made by USFDA in its Warning Letters (WLs) issued to Indian pharmaceutical companies between 2022 and May 2025 reveals that quality lapses and documentation deficiencies remain key areas of concern. Of the 33 WLs issued during this period, the primary reasons were Failure to Maintain Quality and Purity (24%), Lack of Data Documentation Discipline (21%), and Poor Hygiene (21%). While data integrity concerns, once a major issue, accounted for only 6%, compliance lapses (15%) and inadequate deviation investigations (9%) were also notable contributors.

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

A significant trend is that most recent WLs have been issued to small and mid-sized companies, many of which face resource constraints in meeting evolving cGMP standards. Challenges around documentation, quality assurance, and procedural discipline continue to expose gaps in compliance.

With the USFDA intensifying its focus on data integrity, risk-based quality management, and environmental monitoring—particularly for sterile facilities and complex generics—larger Indian pharma players have largely strengthened compliance. However, smaller firms will need to increase investments in systems, automation, and workforce training to mitigate regulatory risks.

The shifting regulatory environment highlights that compliance is no longer just a regulatory requirement but a strategic imperative for sustaining growth in global markets.

Conclusion

The resurgence of USFDA inspections to near pre-pandemic levels, coupled with a decline in adverse regulatory actions against Indian pharmaceutical facilities, highlights the sector's increasing regulatory maturity. India's role as a major supplier of generics to the U.S. has been further strengthened by consistent advancements in compliance systems, quality assurance, and operational discipline.

With the USFDA sharpening its focus on high-value segments such as complex generics, injectables, and critical supply chain components, Indian pharmaceutical companies are well-positioned to leverage emerging global opportunities. However, sustained investments in technology, talent, and proactive regulatory engagement will be critical. Going forward, regulatory compliance will not just be an obligation—but a strategic pillar for growth, competitiveness, and long-term sustainability in global markets. ■

Authors

D. Naveen Kumar
Associate Director
CARE Ratings Ltd

Pulkit Agarwal
Director
CARE Ratings Ltd