UNDERSTANDING THE TIMELINE OF KEY EVENTS IN REVISED SCHEDULE M IMPLEMENTATION

PULSE

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28 DEC

2023

The Government of India notifies the Revised Schedule M under the Drugs and Cosmetics Act, bringing India's Good Manufacturing Practices (GMP) in line with global standards.

28 JUNE

2024

Large pharmaceutical manufacturers (turnover above ₹250 crore) were required to comply with the Revised Schedule M standards by this date.

The original compliance deadline for small and medium-sized pharmaceutical manufacturers (turnover ₹250 crore or less) was set for this date.

11 FEB 2025

The Ministry of Health & Family Welfare announces a deadline extension for small and medium-sized pharma manufacturers, granting them until December 31, 2025, to fully comply with the Revised Schedule M*

There is no blanket extension. Only if you apply before May 11th, there is an extension up to year-end.

11 MAY

2025

*Manufacturers must submit Form A to the Central License Approving Authority outlining their upgradation plan. Failure to submit within this timeframe may lead to penalties, including potential factory closures.

The final deadline for all pharmaceutical manufacturers (irrespective of turnover) to achieve full compliance with the Revised Schedule M*.

There is no blanket extension. Only if you apply before May 11th, there is extension upto year end. If you dont apply, it means you have complied.

SPECIAL NOTE

- ***There is no blanket extension.***
- ***Only if you apply before 11th May, there is an extension upto year end.***
- ***If you don't apply, it means you have complied.***

SIGNIFICANCE OF THESE MILESTONES

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1.

The extension provides much-needed time for infrastructure upgrades, personnel training, and financial planning for smaller firms.

2.

Strict government monitoring is expected, with non-compliant firms facing penalties, including possible shutdowns.

WHAT TO DO NOW?

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WHAT TO DO NOW?

✅ ***Submit Your Upgrade Plan (Form A)*** **by May 11, 2025 to *avoid penalties, including possible factory closures.***

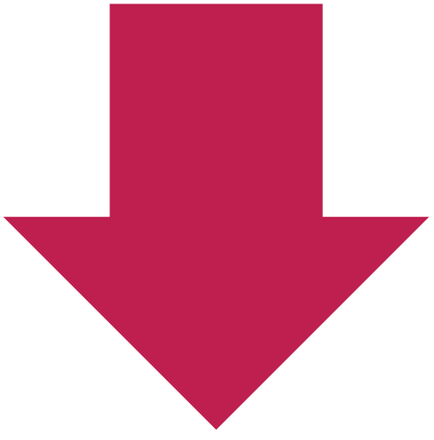
✅ ***Conduct a Gap Analysis*** ***to identify compliance shortfalls and create an actionable roadmap.***

WHAT TO DO NOW?

✅ ***Upgrade Infrastructure & Train Teams*** ***to meet the enhanced GMP requirements before inspections begin.***

✅ ***Stay Ahead of Regulatory Scrutiny*** ***— authorities are actively conducting risk-based inspections and shutting down non-compliant units.***

FROM WHERE CAN I LEARN GAP ANALYSIS & IMPLEMENTATION PLAN?



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SESSION 17:

Hands-on Workshop

"Gap Analysis & Implementation Plan"

AS PER

REVISED SCHEDULE M

16th March (Sunday) | 10:30 AM - 1:30 PM

BOOK NOW