

A photograph of a modern, brightly lit office hallway with white walls, a drop ceiling with recessed lights, and a reception desk in the background. The hallway is clean and professional.

Privaan Health is an ISO 9001:2025 certified life sciences consulting organization specializing in GMP and regulatory compliance. With a global presence and extensive experience in GMP audits, we provide pharmaceutical companies with the expertise to meet and exceed industry standards. We proudly serve over 70 clients across Asia, Europe, and North America.

Our GMP Services

We offer a full range of GMP audit and compliance services including:

- Vendor/Supplier Qualification Audits
- Gap Audits (including CSV)
- Pre-Inspection Audits
- Data Integrity & QMS Audits
- GMP Compliance & Upgradation



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What is Schedule M?

Schedule M, part of the Drugs and Cosmetics Act in India, sets the GMP compliance requirements specifically for pharmaceutical manufacturing in India. It serves as a comprehensive guide to ensure that pharmaceutical companies meet the necessary standards for producing safe, effective, and high-quality products.

Key elements of Schedule M include:

- Premises: Specifications for the cleanliness, design, and maintenance of manufacturing facilities.
- Equipment: Guidelines on the proper installation, calibration, and maintenance of manufacturing equipment.
- Personnel: Requirements for qualified and trained staff to handle manufacturing operations.
- Documentation: Strict documentation practices to ensure traceability and accountability.
- Quality Control: Robust quality control systems for testing raw materials, in-process materials, and finished products.

By complying with Schedule M, manufacturers can ensure their facilities meet the necessary standards to obtain and maintain market authorization in India.

WHAT IS A THIRD-PARTY GAP ANALYSIS?

A Third-Party Gap Analysis is an independent, expert evaluation of a pharmaceutical company's adherence to Good Manufacturing Practices (GMP), particularly as outlined in Schedule M. This analysis involves an impartial review of your company's systems, processes, and documentation to identify areas where compliance may be lacking.

The goal is to pinpoint gaps that could prevent full adherence to GMP regulations, allowing companies to address issues before they become major problems.

KEY BENEFITS OF THIRD-PARTY GAP ANALYSIS

01.

Objectivity & Expertise

- Independent auditors with in-depth knowledge and extensive experience across pharmaceutical sectors such as formulations, sterile manufacturing, and biopharmaceuticals, having conducted over 150 GMP audits.

02.

Risk Mitigation

- By identifying potential compliance gaps early, a third-party gap analysis helps mitigate the risk of regulatory issues, product recalls, or costly penalties.
- Proactive Approach: Catching these issues early allows for timely corrective actions, reducing the chance of future disruptions.

03.

Enhanced Compliance

- A third-party gap analysis ensures that your company is fully compliant with Schedule M and GMP standards.
- This compliance helps protect your reputation, avoid legal penalties, and stay in good standing with regulators.

04.

Actionable Recommendations

- The analysis provides you with clear, actionable recommendations to address compliance gaps.
- These recommendations can improve product quality, operational efficiency, and overall business processes.

Latest Update: Why Third-Party Gap Analysis is More Important Than Ever

Recent updates to **Schedule M** have highlighted the **importance of third-party gap analysis** in maintaining GMP compliance. As per the latest notification, pharmaceutical companies are now required to undergo independent gap assessments to ensure alignment with the **most recent regulatory changes**.

This update emphasizes that a **third-party gap analysis** is not just a best practice it is now an essential part of staying compliant and avoiding any potential regulatory issues or disruptions in manufacturing operations.

HOW WE CAN HELP

At **Privaan Health**, we specialize in providing comprehensive **GMP audits** and **Gap Analysis** as per Schedule M compliance services. Our expert team helps pharmaceutical companies ensure they meet the rigorous standards required by both **GMP** and **Schedule M**, enabling them to maintain compliance and achieve regulatory success.

The Gap Analysis Process

1. Initial Assessment

- A thorough review of your current GMP compliance levels.

2. Identification of Gaps

- Pinpointing any discrepancies or deficiencies in your systems, processes or documentation.

3. Corrective Actions

- Proposing solutions to address identified gaps, ensuring compliance with Schedule M.

4. Compliance Confirmation

- Ensuring all corrective actions are implemented, leading to full regulatory compliance.

CALL TO ACTION

Don't wait until it's too late. Contact us today for a free consultation or audit assessment, and ensure your business is always aligned with **GMP standards** and **Schedule M compliance**.



+91-7069102121



bd@privaanhealth.com



Privaan Health