

INDEPENDENT INDUSTRY RESEARCH

THE ₹20 CRORE BLIND SPOT

*India's First Independent Study of Hidden Operational & Compliance Losses in
Pharmaceutical Manufacturing*

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Research Period: 2019 — 2024

Plants Visited: 50+

Professionals Met: 100+ (QA Heads, Plant Heads,
Regulatory Specialists, Consultants, US FDA
Auditors, CEOs & MDs)

Problem Areas Mapped: 200

Published: 2025

*“Every pharma plant has a P&L. Almost none has a complete picture of what is
actually leaving.”*

Researcher's Notes

“This is normal here.”

Five years ago, I walked into a pharmaceutical manufacturing plant and saw forty-seven pending deviations sitting in a spreadsheet. No owner assigned. No timeline. No corrective action. When I asked the QA manager about it, the response was simple: “This is normal here.”

That single sentence is what started this research.

Over the following five years, I visited more than 50 plants and met with over 100 professionals across the pharmaceutical industry — QA heads, plant heads, regulatory affairs specialists, independent consultants, US FDA auditors, and CEOs and MDs. The question I kept asking was simple: what does “normal” actually cost?

This report documents what I found — and what it is quietly costing Indian pharma manufacturers every year.

— Santosh Agrawal, Founder, BLINE Solution Pvt. Ltd.

Executive Summary

The average Indian pharmaceutical manufacturing plant with approximately ₹200 crore in annual revenue loses between ₹20 crore and ₹25 crore every year to hidden operational and compliance failures.

This loss rarely appears as a single line item in any profit and loss statement. Instead, it is distributed silently across eight to fifteen operational categories — batch failures, export delays, working-capital blockages, audit downtime, talent attrition, raw-material waste, rework costs, and regulatory penalties, among others.

This research identifies 200 specific problem areas across the plant floor, the quality function, and the leadership layer — each one mapped, categorized, and, where possible, quantified in financial terms.

Market Reality

Indian pharmaceutical manufacturing is a \$50 billion industry — the world's third largest by volume, and the largest generic drug supplier globally. Yet regulatory pressure on this industry is rising sharply:

- Schedule M was revised in 2023, raising the compliance bar for every domestic manufacturer.

- US FDA, EU GMP observations issued against Indian plants have risen approximately 40 percent over the past three years.
- WHO GMP compliance is now mandatory for access to 150+ export markets worldwide.

Every plant is required to comply. Most are not ready.

The Problem in Numbers

The average Indian pharma plant generates approximately ₹200 crore in annual revenue — and loses ₹20 crore to ₹25 crore of it annually to hidden operational and compliance failures. That is 10 to 20 percent of revenue disappearing silently, with no single line item to explain it.

No single system observed brought compliance, quality, and operations together as one intelligent, integrated pharma operating system. That is the gap this research identifies — and that is what BLINE was built to close.

Research Scope

This publication covers fifteen operational categories in which hidden losses were consistently observed across plants of varying size and export orientation:

- Category 1 — Batch & Production
- Category 2 — Audit & Compliance
- Category 3 — Materials & Warehouse
- Category 4 — People & Process
- Category 5 — Production Planning
- Category 6 — Export & Customer
- Category 7 — Quality & Testing
- Category 8 — IT & Data Integrity
- Category 9 — Finance & Hidden Cost
- Category 10 — Leadership
- Category 11 — Regulatory & Submissions
- Category 12 — Supply Chain & Vendors
- Category 13 — Engineering & Maintenance
- Category 14 — Environment, Health & Safety
- Category 15 — Advanced Quality

About the Researcher

Santosh Agrawal (MCA, BSc in Computer Science & Statics) is the founder of BLINE Solution Pvt. Ltd. — India's pharma intelligent operating system. His five-year independent research into pharma manufacturing operations spans more than 50 plant visits and over 100 conversations with QA professionals, plant heads, regulatory specialists, consultants, US FDA auditors, CEOs, and MDs across India.

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Santosh takes calls directly — no gatekeeping, no call centre. If any of these findings resonate with your plant, call without hesitation.

Access the Complete Research

This publication presents the headline findings of a five-year study. The complete dataset — all 200 documented problem areas, category-wise financial impact, and a personalized plant risk assessment — is available free of charge.

Complete the Plant Assessment Form on the last page of this document and mail it to info@blinesolution.com — we respond the same day.

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FREE PLANT ASSESSMENT FORM

Fill this form and email it to info@blinesolution.com — we respond the same day with your personalized report.

Section A — About You

Full Name

Designation / Role

Business Email Address

Phone Number (WhatsApp preferred)

Section B — About Your Company

Company Name

Company Headquarters City

Annual Turnover (Approximate)

- Below ₹50 Cr
 ₹50–100 Cr
 ₹100–250 Cr
 ₹250–500 Cr
 ₹500–1,000 Cr
 Above ₹1,000 Cr

Total Number of Employees

- Below 100
 100–250
 250–500
 500–1,000
 Above 1,000

Section C — Regulatory Profile

Regulatory standards currently followed (select all that apply)

- WHO GMP
 US FDA (21 CFR)
 EU GMP / Annex 11
 Schedule M (India)
 UK MHRA
 TGA (Australia)
 ANVISA (Brazil)
 Other

Export Markets (select all that apply)

- USA
 Europe
 UK
 Africa
 Southeast Asia
 Middle East
 Other
 Domestic Only

Section D — Quick Pulse Check (5 questions, 30 seconds)**1. Are your Batch Manufacturing Records currently paper-based?**

- Yes — fully paper Partially digital Fully digital

2. How do you currently manage Deviations and CAPA?

- Excel / Manual Basic software Integrated QMS

3. When was your last FDA / WHO / EU inspection?

- Never inspected Within 1 year 1–3 years ago
 More than 3 years ago Not applicable

4. How many batch failures occur per month, approximately?

- 0 1–2 3–5 More than 5 Not tracked

5. What is your current audit preparation time?

- Always ready 1–2 weeks 3–4 weeks More than 1 month

Section E — Consent

- I agree to receive my personalized Plant Risk Assessment Report by email within 24 hours.
 I understand this is independent research, not a sales pitch, and may receive one follow-up call from Santosh Agrawal's team to discuss my results.

Email this completed form to info@blinesolution.com — or call +91-9977975607 directly, no hesitation needed.