

Cliorbit Launches Emergency Pharmacovigilance Services as Indian Pharma Companies

Leading PV Services Provider Offers Rapid Compliance Solutions as CDSCO Enforcement Wave Claims Hundreds of Manufacturing Licenses

Mumbai, Maharashtra Oct 11, 2025 ([Issuewire.com](https://www.issuewire.com)) - As India's pharmaceutical industry grapples with the most severe regulatory enforcement period in its history, Cliorbit, a premier pharmacovigilance services provider, today announced the launch of its Emergency Compliance Program designed to help pharmaceutical companies navigate the current regulatory crisis and avoid business-threatening penalties.

With **1,394 drug batches recalled in 2023-24** and **694 enforcement actions taken** against inspected manufacturing units, the Indian pharmaceutical landscape has become a regulatory battlefield where non-compliance equals business extinction. Recent data shows that **36% of inspected pharmaceutical units have been forced to shut down**, while over **4,300 MSME manufacturers face potential closure** by December 2025 for failing to meet mandatory Schedule M compliance requirements.

"We're witnessing an unprecedented regulatory crackdown that has already claimed hundreds of pharmaceutical licenses and threatens thousands more," said Kajal Gupta, Senior Partner of Cliorbit. Companies that were operating without robust pharmacovigilance systems are now facing immediate license suspensions, criminal prosecutions, and complete business shutdowns. Our Emergency Compliance Program is designed to be the lifeline these companies desperately need."

Crisis Reaches Critical Point as Enforcement Escalates

Recent enforcement actions have sent shockwaves through India's pharmaceutical sector:

- **Enforcement Directorate raids** on three Himachal Pradesh companies in June 2025, uncovering a psychotropic drug trafficking network involving **20 crore alprazolam tablets**
- **Maharashtra FDA seizures** worth over **Rs. 2 crores** from illegal manufacturing operations
- **Telangana DCA raids** recovering **Rs. 1.33 crore worth of fake antibiotics** destined for export
- **Multiple MSME clusters** in Baddi, Punjab, and other pharmaceutical hubs facing mass inspections and production shutdowns

The regulatory noose has tightened further with the government's proposal for **immediate license suspension** for any manufacturer whose drugs are classified as "Not of Standard Quality" (NSQ), eliminating appeals and second chances.

[Cliorbit's](#) **Leading PV Services Provider Offers Rapid Compliance Solutions as CDSCO Enforcement Wave Claims Hundreds of Manufacturing Licenses** **Emergency Response: 30-Day Compliance Guarantee**

Understanding the critical time pressure facing pharmaceutical companies, Cloribit has developed rapid-deployment pharmacovigilance systems that can be implemented within **30 days**:

Emergency Compliance Package Features:

- **Complete CDSCO-compliant pharmacovigilance system** setup
- **Automated PSUR preparation and submission** through Sugam Portal
- **Real-time ICSR processing** with guaranteed 15-day SAE reporting
- **AI-powered signal detection and management** systems
- **Audit preparation and regulatory representation**
- **24/7 crisis management support**

"Our clients don't have months to implement compliance systems – they have weeks," explained **[Technical Director Name]**, Head of Regulatory Affairs at Cloribit. "We've streamlined our processes to deliver bulletproof pharmacovigilance systems in record time, because we understand that delay equals disaster in today's enforcement environment."

Market Intelligence Drives Targeted Solutions

Cloribit's approach is informed by comprehensive analysis of recent enforcement patterns:

- **Companies recently flagged** with NSQ declarations are prioritized for emergency intervention
- **MSME manufacturers** in high-risk clusters receive specialized small-company packages
- **Export-oriented facilities** get enhanced international compliance support
- **Recently audited companies** receive immediate gap analysis and remediation

The company has identified specific pharmaceutical clusters in Himachal Pradesh, Maharashtra, Gujarat, and Telangana where enforcement actions have been concentrated, deploying dedicated teams to provide on-site support.

Technology-Powered Solutions for Regulatory Survival

Cloribit's pharmacovigilance platform leverages cutting-edge technology to ensure compliance:

- **Artificial Intelligence** for predictive safety signal detection
- **Natural Language Processing** for automated case processing
- **Real-time monitoring dashboards** providing instant compliance status

- **Automated regulatory reporting** eliminating human error and delays
- **Integration with global safety databases** for comprehensive monitoring

Industry Experts Warn of Continued Enforcement

Pharmaceutical industry analysts predict the regulatory crackdown will intensify as authorities implement zero-tolerance policies:

"The statistics are clear – **only 1,700 out of 6,000 MSME manufacturers** have submitted mandatory compliance plans, leaving over 4,300 companies at immediate risk of shutdown," noted **[Industry Expert Name]**, a leading pharmaceutical regulatory consultant. "Companies without professional pharmacovigilance systems are living on borrowed time."

The financial stakes are enormous, with seizures from recent raids totaling over **Rs. 15 crores**, while the broader market faces potential losses in the thousands of crores as non-compliant companies exit the market.

Immediate Availability for Crisis Intervention

Recognizing the urgency of the situation, Clorbit has established:

- **Emergency response hotline** for immediate consultation
- **48-hour compliance assessment** service
- **Mobile audit teams** for on-site rapid deployment
- **Legal liaison services** for companies under investigation

"Every day of delay increases the risk of regulatory action," warned Kajal Gupta of Clorbit. "We've seen companies receive license suspension notices within days of inspection. Our message to pharmaceutical manufa

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