



Phone : 040-27840844
Fax : 040-27840767
E-mail : andhrachamber@gmail.com
Web : www.andhrachamber.com

Andhra Chamber of Commerce

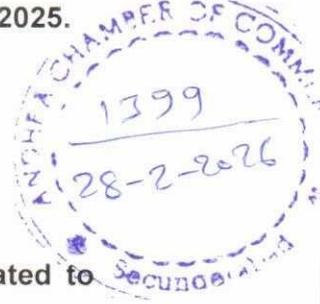
(INCORPORATED UNDER SECTION 8 OF THE COMPANIES ACT)

TELANGANA STATE CHAPTER

"T.G. Venkatesh Bhavan" 602 & 603, Cheney Trade Centre, VI Floor, 116, Park Lane, Secunderabad - 500 003. (T.S.)

The Secretary,
Health & Family Welfare,
Government of India,
New Delhi

December 12, 2025.



Dear Sir,

Subject: Submission Regarding Concerns and Recommendations Related to USFDA Inspection Practices in India

The Indian pharmaceutical industry remains fully committed to upholding the highest global standards of quality, safety, and regulatory compliance. As one of the world's largest suppliers of affordable and high-quality medicines, the industry continuously invests in digital systems, data integrity controls, advanced automation, and globally accepted GMP standards.

In this context, we wish to bring to the attention of the Government of India and CDSCO certain concerns arising during U.S. Food and Drug Administration (USFDA) inspections in India, along with practical recommendations to safeguard the integrity of audits and prevent potential misuse of the process.

1. Concerns Regarding Misuse of Whistleblower Encouragement and Resultant Blackmail

It has come to the industry's notice that certain USFDA personnel, during interactions with employees of Indian pharmaceutical manufacturing units, encourage staff to provide internal information on alleged non-compliances. While whistleblower protections are globally accepted, in some instances this encouragement has led to unintended consequences:

- Certain employees have begun misusing this opportunity by providing misleading or fabricated information with malicious intent.
- In a few cases, individuals have used this channel to blackmail or threaten company management for financial gain by claiming that they will report negative information to the regulator.



REGD.OFFICE: "Velagapudi Ramakrishna Bldg.", 23, Third Cross Street, West C.I.T. Nagar, Nandanam, P.B.No.3300, Chennai-600 035
Phone : 044-24315277 / 78, Fax : 044-24315279, Email: andhrachamber1@gmail.com

VISAKHAPATNAM OFFICE: D.No. 1E, 1st Floor, Sai Sadan Apartments, Near Diamond Park, Dwaraka Nagar, 3rd Lane, Visakhapatnam-530016(AP).
Phone : 0891-2792220, Fax : 0891-2792221, Email : andhrachamberofcommercevizag@gmail.com

VIJAYAWADA OFFICE : Siddhartha Hotel Management College Premises, Pinnameneni Poly Clinic Road, Technical Nagar, Vijayawada - 520 010 (A.P),PHONE : 0866-2472500, Fax : 0891-2792221 Email: andhrachambervijayawada@gmail.com

NELLORE OFFICE: No.24-2/395, Saraswathi nagar, Magunta Lay-out,Nellore-524 003 (A.P), Email: andhrachambernellore@gmail.com



Phone : 040-27840844
Fax : 040-27840767
E-mail : andhrachamber@gmail.com
Web : www.andhrachamber.com

Andhra Chamber of Commerce

(INCORPORATED UNDER SECTION 8 OF THE COMPANIES ACT)

TELANGANA STATE CHAPTER

"T.G. Venkatesh Bhavan" 602 & 603, Chenoy Trade Centre, VI Floor, 116, Park Lane, Secunderabad - 500 003. (T.S.)

- This poses a serious risk to both data integrity and the credibility of genuine regulatory processes.

The industry strongly believes that employee grievance mechanisms and compliance oversight must remain structured, verifiable, and transparent to prevent misuse.

2. Request for Greater Transparency and Coordination between USFDA and CDSCO

To ensure fairness, accuracy, and transparency during inspections, the industry respectfully proposes that:

1. USFDA should notify CDSCO in advance of any planned inspection of Indian manufacturing units.
 2. A representative from CDSCO should be present throughout the duration of the USFDA inspection as an official observer.
- This will ensure that both regulators have a consistent understanding of facts.
 - It will also help prevent misinterpretation or misuse of information.
3. A reasonable notice period of one week may be provided before the commencement of any USFDA inspection.
- This will ensure that appropriate senior personnel are available to provide accurate information and clarifications.
 - It will also support smoother and more efficient conduct of inspections.

Several global regulatory systems already follow such cooperative frameworks, which help align expectations and ensure balanced evaluations.

3. Robust Digital Systems and Part 11 Compliance Across Indian Facilities

Today, almost all Indian pharmaceutical manufacturing units operate under 21 CFR Part 11—compliant electronic data management systems. These systems ensure:

REGD.OFFICE: "Velagapudi Ramakrishna Bldg.", 23, Third Cross Street, West C.I.T. Nagar, Nandanam, P.B.No.3368, Chennai-600 035
Phone : 044-24315277 / 78, Fax : 044-24315279, Email: andhrachamber1@gmail.com

VISAKHAPATNAM OFFICE: D.No. 1E, 1st Floor, Sai Sadan Apartments, Near Diamond Park, Dwaraka Nagar, 3rd Lane, Visakhapatnam-530016(AP).
Phone : 0891-2792220, Fax : 0891-2792221, Email : andhrachamberofcommercevizag@gmail.com

VIJAYAWADA OFFICE : Siddhartha Hotel Management College Premises, Pinnameneni Poly Clinic Road, Technical Nagar, Vijayawada – 520 010 (A.P),PHONE : 0866-2472500, Fax : 0891-2792221 Email: andhrachambervijayawada@gmail.com

NELLORE OFFICE: No.24-2/395, Saraswathi nagar, Magunta Lay-out,Nellore-524 003 (A.P), Email: andhrachambernellore@gmail.com



Phone : 040-27840844
Fax : 040-27840767
E-mail : andhrachamber@gmail.com
Web : www.andhrachamber.com

Andhra Chamber of Commerce

(INCORPORATED UNDER SECTION 8 OF THE COMPANIES ACT)

TELANGANA STATE CHAPTER

"T.G. Venkatesh Bhavan" 602 & 603, Cheney Trade Centre, VI Floor, 116, Park Lane, Secunderabad - 500 003. (T.S.)

- Full audit trails,
- Restricted access controls,
- Real-time data recording,
- Zero scope for data manipulation or bypassing.

Every action, entry, or modification is automatically captured and fully traceable. This digital governance framework significantly minimizes the possibility of human interference or intentional wrongdoing.

4. Indian Industry's Commitment to Quality and Compliance

Indian manufacturers consistently adhere to validated processes, advanced automation, and stringent quality systems. Every step—from raw material receipt to finished product release—is digitally monitored and governed by established SOPs and validation protocols.

There is no opportunity to deviate from approved processes without detection, given the integrated nature of equipment controls, data systems, and audit trails.

The industry remains deeply committed to providing high-quality medicines to global patients, supported by:

- thorough validation of equipment and processes,
- effective change control systems,
- robust deviation and CAPA mechanisms, and
- continuous training and GMP reinforcement.

5. Stability, Retention Samples, and Analytical Reliability

Indian pharmaceutical units follow globally harmonized procedures for product verification and lifecycle management, including:

- Maintenance of reference/retention samples for every commercial batch,
- Stability studies for all validation batches,
- Annual stability studies as per regulatory expectations,

REGD.OFFICE: "Velagapudi Ramakrishna Bldg.", 23, Third Cross Street, West C.I.T. Nagar, Nandanam, P.B.No.3368, Chennai-600 035
Phone : 044-24315277 / 78, Fax : 044-24315279, Email: andhrachamber1@gmail.com

VISAKHAPATNAM OFFICE: D.No. 1E, 1st Floor, Sai Sadan Apartments, Near Diamond Park, Dwaraka Nagar, 3rd Lane, Visakhapatnam-530016(AP).
Phone : 0891-2792220, Fax : 0891-2792221, Email : andhrachamberofcommercevizag@gmail.com

VIJAYAWADA OFFICE : Siddhartha Hotel Management College Premises, Pinnameneni Poly Clinic Road, Technical Nagar, Vijayawada – 520 010 (A.P),PHONE : 0866-2472500, Fax : 0891-2792221 Email: andhrachambervijayawada@gmail.com

NELLORE OFFICE: No.24-2/395, Saraswathi nagar, Magunta Lay-out, Nellore-524 003 (A.P), Email: andhrachambernellore@gmail.com



Phone : 040-27840844
Fax : 040-27840767
E-mail : andhrachamber@gmail.com
Web : www.andhrachamber.com

Andhra Chamber of Commerce

(INCORPORATED UNDER SECTION 8 OF THE COMPANIES ACT)

TELANGANA STATE CHAPTER

"T.G. Venkatesh Bhavan" 602 & 603, Cheney Trade Centre, VI Floor, 116, Park Lane, Secunderabad - 500 003. (T.S.)

- Use of validated and verified analytical methods that ensure accurate and reliable results.

These systems provide multiple layers of assurance that no product can be released without meeting stringent regulatory and scientific standards.

6. Appeal to Prevent Misuse of Employee Testimony and Blackmail

The industry respectfully submits that unstructured or informal solicitation of internal information from staff may:

- Create fear, confusion, and opportunities for malicious intent,
- Encourage certain individuals to misuse regulatory processes for personal gain,
- Undermine genuine compliance culture by introducing distrust within organizations.

Given that all data is electronically secured and protected, and cannot be altered due to audit trails, there is no need to incentivize staff to provide information outside formal and verifiable channels.

The industry reiterates that it fully welcomes regulatory oversight, encourages transparent inspections, and remains accountable for resolving any genuine non-conformances raised by inspectors.

However, to maintain fairness and credibility, information flows must be structured, validated, and free from potential misuse or coercion.

Conclusion

The Indian pharmaceutical industry respectfully requests the Government of India and CDSCO to engage with USFDA on the above points and establish a more collaborative, transparent, and balanced inspection framework.

Such cooperation will:

- Strengthen regulatory trust,
- Protect the integrity of inspection processes,
- Prevent misuse of audit-related interactions, and
- Ensure continued availability of high-quality Indian medicines to global patients.

REGD.OFFICE: "Velagapudi Ramakrishna Bldg.", 23, Third Cross Street, West C.I.T. Nagar, Nandanam, P.B.No.3368, Chennai-600 035
Phone : 044-24315277 / 78, Fax : 044-24315279, Email: andhrachamber1@gmail.com

VISAKHAPATNAM OFFICE: D.No. 1E, 1st Floor, Sai Sadan Apartments, Near Diamond Park, Dwaraka Nagar, 3rd Lane, Visakhapatnam-530016(AP).
Phone : 0891-2792220, Fax : 0891-2792221, Email : andhrachamberofcommercevizag@gmail.com

VIJAYAWADA OFFICE : Siddhartha Hotel Management College Premises, Pinnameneni Poly Clinic Road, Technical Nagar, Vijayawada – 520 010 (A.P.),PHONE : 0866-2472500, Fax : 0891-2792221 Email: andhrachambervijayawada@gmail.com

NELLORE OFFICE: No.24-2/395, Saraswathi nagar, Magunta Lay-out,Nellore-524 003 (A.P), Email: andhrachambernellore@gmail.com



Phone : 040-27840844
Fax : 040-27840767
E-mail : andhrachamber@gmail.com
Web : www.andhrachamber.com

Andhra Chamber of Commerce

(INCORPORATED UNDER SECTION 8 OF THE COMPANIES ACT)

TELANGANA STATE CHAPTER

"T.G. Venkatesh Bhavan" 602 & 603, Chenoy Trade Centre, VI Floor, 116, Park Lane, Secunderabad - 500 003. (T.S.)

We remain committed to working closely with CDSCO and all international regulators in the spirit of quality, compliance, and global public health.

We request an early action in this regard.

Thanking you,

Yours sincerely,

Dr. J.A.S.Giri
Senior Vice President &
Chairman, Telangana Chapter
Andhra Chamber of Commerce.

REGD.OFFICE: "Velagapudi Ramakrishna Bldg.", 23, Third Cross Street, West C.I.T. Nagar, Nandanam, P.B.No.3368, Chennai-600 035
Phone : 044-24315277 / 78, Fax : 044-24315279, Email: andhrachamber1@gmail.com

VISAKHAPATNAM OFFICE: D.No. 1E, 1st Floor, Sai Sadan Apartments, Near Diamond Park, Dwaraka Nagar, 3rd Lane, Visakhapatnam-530016(AP).
Phone : 0891-2792220 , Fax :0891-2792221, Email : andhrachamberofcommercevizag@gmail.com

VIJAYAWADA OFFICE : Siddhartha Hotel Management College Premises, Pinnameneni Poly Clinic Road, Technical Nagar, Vijayawada – 520 010 (A.P),PHONE : 0866-2472500, Fax : 0891-2792221 Email: andhrachambervijayawada@gmail.com

NELLORE OFFICE: No.24-2/395, Saraswathi nagar, Magunta Lay-out,Nellore-524 003 (A.P), Email: andhrachambernellore@gmail.com