Accredited Consultants
Private Limited

July 2026 | Vol - 29

ACPL NEWSLETTER

A monthly Internal News Letter of ACPL

Dear Colleagues,

It gives me immense pleasure to connect with you through this edition of ACPL Times, our monthly internal magazine that reflects our journey, achievements, learning, and shared experiences as one organization.

ACPL Times is not just a collection of updates; it is a platform created to encourage continuous learning and development among our employees. Through this initiative, we aim to provide valuable insights, enhance technical knowledge, share best practices, and encourage everyone to expand their skills in their respective fields. At the same time, the magazine also focuses on motivational thoughts, life lessons, and inspiring stories that help us grow not only as professionals but also as individuals.

In today's rapidly changing environment, continuous learning has become essential for personal and organizational success. The ability to adapt, acquire new knowledge, and apply innovative ideas helps us remain competitive and prepared for future challenges. I encourage each one of you to actively engage with the content of ACPL Times and use it as a source of knowledge, inspiration, and motivation.

I appreciate the efforts of the team behind ACPL Times for creating this valuable platform and bringing together meaningful content for our employees. I also encourage all colleagues to share their experiences, ideas, technical insights, and success stories so that this magazine continues to become a stronger medium for learning and collaboration.

Let us continue to develop a culture of excellence, innovation, and continuous improvement. Together, with the right knowledge, positive mindset, and commitment, we can achieve greater milestones and create a brighter future for our organization.

I wish all of you continued success, good health, and happiness.

Warm regards,
C S Prasad

KNOWLEDGE CENTRE

As per the Central Drugs Standard Control Organization (CDSCO), a biological (biologic) product is a medicinal product that is derived from living organisms or contains components obtained from living sources such as humans, animals, or microorganisms. Unlike conventional small-molecule drugs that are synthesized chemically, biologics are produced using biological processes and require stringent controls to ensure their quality, safety, and efficacy.

Definition of Biologicals
CDSCO describes biological products as medical products made from a variety of natural sources (human, animal, or microorganism). These products may be intended to:

- Treat diseases
- Prevent diseases
- Diagnose diseases

Examples include:

- Vaccines
- Blood and blood products
- Allergenic extracts
- Human cells and tissues for transplantation
- Gene therapy products
- Cell therapy products
- Diagnostic products such as blood donor screening tests for infectious diseases

Categories of biologicals regulated by CDSCO
CDSCO regulates several classes of biological products, including:

1. Human and veterinary vaccines
2. Recombinant DNA (r-DNA) products
3. Stem cell and cell-based biological products
4. Blood and blood products
5. Gene therapy products
6. Tissue-engineered products (where applicable)
7.

CDSCO guidelines governing biologicals
The principal regulatory guidance includes:

- CDSCO Guidance for Industry – Biologicals
- Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India (prepared jointly by CDSCO and the Department of Biotechnology)
- Guidance on post-approval changes (PAC) for biological products.

KNOWLEDGE CENTRE

Similar Biologics (Biosimilars)
According to the CDSCO–DBT guidelines:
A Similar Biologic is a biological product that is demonstrated to be similar in quality, safety, and efficacy to an already authorized Reference Biological Product through a comprehensive comparability exercise.
The regulatory pathway requires:

- Extensive analytical characterization
- Quality comparability studies
- Non-clinical studies (where required)
- Clinical studies to establish comparable safety, efficacy, and immunogenicity
- Post-marketing pharmacovigilance and risk management

Key characteristics of biological products
Biologicals generally:

- Are produced from living cells or organisms.
- Have complex molecular structures.
- Show inherent batch-to-batch variability.
- Require specialized manufacturing and quality control processes.
- Cannot be exactly duplicated like conventional generic drugs.

For biological products, CDSCO oversees:

- Clinical trial approval
- Manufacturing and import licensing
- Marketing authorization
- Quality evaluation
- Post-approval changes
- Pharmacovigilance after commercialization

Under CDSCO, a biological is a medicinal product derived from living organisms or their components and includes products such as vaccines, recombinant proteins, blood products, cell and gene therapies, and similar biologics. These products are regulated under specialized CDSCO guidance because of their complexity and the need to demonstrate quality, safety, efficacy, and consistency throughout their lifecycle.
1. Clinical Trial Approval
Clinical trial approval is the regulatory authorization required before a biological product can be tested in humans. The objective is to ensure that participant safety, scientific validity, and ethical standards are maintained.
Requirements for approval
Before initiating clinical trials, the sponsor must submit a clinical trial application that includes:

- Preclinical data (pharmacology and toxicology)
- Chemistry, Manufacturing, and Controls (CMC) information

KNOWLEDGE CENTRE

- Clinical trial protocol
- Investigator's Brochure
- Informed consent documents
- Risk–benefit assessment
- Information on the manufacturing process and product characterization
- Information on the manufacturing process and product characterization

Additional considerations for biologicals

Since biologicals are produced from living cells, regulators require additional evidence regarding:

- Manufacturing consistency
- Product purity
- Stability
- Biological activity (potency)
- Immunogenicity risk
- Viral safety and sterility

Approval is granted only after the regulatory authority and an ethics committee determine that anticipated benefits justify the potential risks.

2. Manufacturing and Import Licensing

Manufacturing and import licensing ensures that biological products are consistently produced according to approved quality standards.

Manufacturing license

Manufacturers must demonstrate compliance with:

- Good Manufacturing Practice (GMP)
- Quality management systems
- Qualified manufacturing personnel
- Validated production processes
- Sterile manufacturing controls
- Environmental monitoring
- Batch release procedures

Facilities are inspected before licensing and periodically thereafter.

Import license

Imported biologicals require authorization confirming that:

- The product is approved in the exporting country (where applicable).
- Manufacturing facilities comply with GMP.
- The product maintains cold-chain integrity during transport.
- Product labeling complies with local regulatory requirements.
- Certificates of analysis accompany imported batches.

Because biologicals are sensitive to temperature, maintaining cold-chain conditions throughout transportation is essential to preserve product quality.

3. Marketing Authorization

Marketing authorization is the formal approval allowing a biological product to be sold after regulators determine that its benefits outweigh its risks.

KNOWLEDG CENTRE

Data required
A marketing authorization application generally includes:

- Quality (CMC) documentation
- Non-clinical studies
- Clinical trial results (Phases I–III)
- Manufacturing validation data
- Stability studies
- Risk Management Plan (RMP)
- Proposed labeling and prescribing information

Evaluation criteria
Regulators assess:

- Product quality
- Clinical efficacy
- Safety
- Immunogenicity
- Manufacturing consistency
- Benefit–risk balance

For biosimilars, comparative analytical, non-clinical, and clinical studies are required to demonstrate high similarity to the reference biologic rather than independent proof of efficacy.
4. Quality Evaluation
Quality evaluation is one of the most important aspects of biological regulation because biological products are inherently more variable than chemically synthesized drugs.
Critical quality attributes
Regulatory agencies evaluate:
Identity
Confirms that the product is the intended biological molecule.

Purity
Assesses impurities arising from manufacturing, including:

- Host-cell proteins
- Residual DNA
- Aggregates
- Process-related contaminants

Potency
Measures biological activity using validated laboratory assays.
Safety
Includes testing for:

- Sterility
- Endotoxins
- Adventitious viruses
- Mycoplasma contamination

Stability
Determines shelf life under recommended storage conditions.
Comparability
Whenever manufacturing changes occur, studies must demonstrate that product quality, safety, and efficacy remain unchanged.

KNOWLEDGE CENTRE

5. Post-Approval Changes
Biological manufacturing processes often evolve over time. Any significant changes after product approval require regulatory evaluation.
Examples include:

- New manufacturing sites
- Equipment upgrades
- Cell bank modifications
- Changes in raw materials
- Process optimization
- Scale-up of production
- Packaging changes
- Analytical method updates

Comparability studies
Manufacturers must perform comparability studies demonstrating that the modified product remains highly similar to the previously approved version with respect to:

- Structure
- Biological activity
- Purity
- Stability
- Immunogenicity
- Clinical performance (when necessary)

The extent of regulatory review depends on the significance of the proposed change.
6. Pharmacovigilance After Commercialization
Even after approval, continuous safety monitoring is required because some adverse effects may only become apparent when the product is used in large and diverse populations.

Objectives
Post-marketing pharmacovigilance aims to:

- Detect rare adverse events
- Identify long-term safety concerns
- Monitor product effectiveness
- Detect manufacturing-related safety signals
- Evaluate medication errors and misuse

Pharmacovigilance activities
These include:

- Collection of adverse event reports
- Periodic Safety Update Reports (PSURs) or Periodic Benefit–Risk Evaluation Reports (PBRERs), depending on regulatory requirements
- Risk Management Plans (RMPs)
- Post-authorization safety studies (PASS)
- Post-marketing clinical studies
- Product traceability through batch numbers
- Signal detection and risk assessment

Every goal begins with believing it is possible.

Narcotics Compliance in India

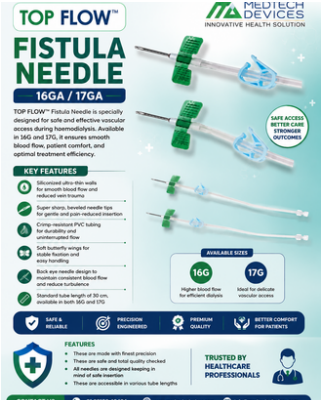
Narcotics compliance in India refers to the legal and regulatory requirements governing the manufacture, possession, transport, sale, import, export, prescription, and use of narcotic drugs, psychotropic substances, and controlled substances.

The primary legal framework includes:

- Narcotic Drugs and Psychotropic Substances Act, 1985 (NDPS Act): The principal law regulating narcotic drugs and psychotropic substances, with strict penalties for unlawful activities.
- Central Bureau of Narcotics (CBN): Issues licenses and oversees cultivation of certain narcotic crops, among other regulatory functions.
- Narcotics Control Bureau (NCB): Coordinates enforcement against illicit drug trafficking and NDPS violations.
- Central Drugs Standard Control Organisation (CDSCO): Regulates pharmaceuticals, including many medicines containing controlled substances.
- Drugs and Cosmetics Act, 1940 and related rules: Govern the manufacture, sale, and quality of pharmaceutical products.

Organizations dealing with controlled substances typically need to:

- Obtain the required licenses, registrations, or permits before manufacturing, importing, exporting, possessing, selling, or distributing regulated substances.
- Maintain accurate inventory, procurement, dispensing, and disposal records.



- Implement secure storage and access controls to prevent diversion or theft.
- Verify suppliers and customers where required by law.
- Submit periodic returns and comply with inspections by the relevant authorities.
- Report thefts, losses, or suspicious transactions when required.
- Ensure employees are trained on applicable legal obligations and standard operating procedures.

Narcotics compliance is particularly important for:

- Pharmaceutical manufacturers
- Hospitals and healthcare providers
- Pharmacies
- Research institutions
- Importers and exporters
- Chemical manufacturers handling controlled precursors
- Logistics providers transporting regulated substances

Narcotics Compliance in India

Consequences of non-compliance
Failure to comply with the NDPS Act and related regulations can result in:

- Criminal prosecution
- Imprisonment
- Significant fines
- Suspension or cancellation of licenses
- Seizure and confiscation of goods
- Reputational and commercial consequences

Compliance obligations vary depending on the specific substance involved, as different rules apply to narcotic drugs, psychotropic substances, essential narcotic drugs, and controlled precursor chemicals.

1. Pharmaceutical manufacturing
   - Licensing under the applicable drug laws
   - NDPS permissions for controlled substances
   - Raw material procurement controls
   - Batch records and inventory reconciliation
   - Secure storage and audits
2. Import and export
   - Import/export authorizations
   - Quantity approvals
   - Customs documentation
   - International treaty compliance
   - Shipment tracking and recordkeeping
3. Hospitals and healthcare providers
   - Procurement from authorized suppliers
   - Secure storage of essential narcotic drugs
   - Prescription and dispensing controls
   - Patient records
   - Stock registers and periodic reconciliation

4. Retail and wholesale pharmacies
   - Drug sale licenses
   - Prescription verification
   - Controlled drug registers
   - Storage and disposal procedures
   - Inspection readiness
5. Chemical manufacturers (controlled precursors)
   - Registration or licensing where applicable
   - Customer due diligence
   - Transaction monitoring
   - Record retention
   - Reporting of suspicious orders
6. Clinical research and laboratories
   - Ethics and regulatory approvals
   - Controlled substance licenses
   - Secure handling and storage
   - Usage logs
   - Disposal documentation

Don't blame people for disappointing you. Blame yourself for expecting too much from them.

Narcotics Compliance in India

Area	Typical Requirements
Governance	Compliance policies, SOPs, responsible personnel
Licensing	Obtain and renew all required approvals
Inventory	End-to-end tracking and reconciliation
Security	Restricted access, CCTV where appropriate, secure
Documentation	Purchase, receipt, issue, return, destruction records
Training	Periodic employee training on legal obligations
Audits	Internal audits and corrective actions
Incident Management	Reporting of theft, loss, or diversion where required

The future belongs to those who prepare while others hesitate.

CDSCO has been pursuing a combination of AI regulation, AI-enabled digitalization of regulatory processes, and collaborative AI innovation initiatives.

Initiative	Purpose	Status
AI regulation for medical devices	Regulatory framework for AI-enabled Software as Medical Device (SaMD)	Operational under Medical Devices Rules, 2017
Digital Drugs Regulatory System (DDRS)	Digital modernization of regulatory workflows with AI-ready architecture	Under implementation
SUGAM Portal modernization	Digital submission and workflow automation	Ongoing
IndiaAI × CDSCO Health Innovation Hackathon	Develop AI tools for regulatory review	Launched in 2026
Secure AI for Health Initiative (SAHI)	National framework for trustworthy healthcare AI	CDSCO participates as regulator
Automation of certificates and approvals	Rule-based digital automation	Ongoing
AI-ready documentation requirements	Standardized technical documentation for AI products	Operational

The future belongs to those who prepare while others hesitate.

CDSCO has been pursuing a combination of AI regulation

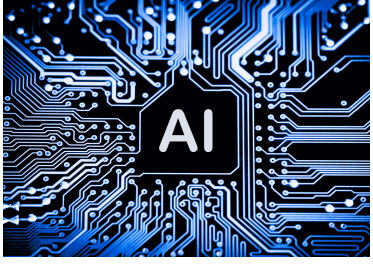
1. Regulatory framework for AI-enabled Medical Devices
This is CDSCO's most mature AI-related initiative. Rather than regulating AI separately, CDSCO regulates AI-enabled medical devices under the Medical Devices Rules, 2017.
Manufacturers of AI-based software intended for diagnosis, monitoring, screening, or treatment must submit:

- Essential Principles Checklist
- Software Verification & Validation
- Clinical Evaluation
- Risk Management
- Cybersecurity documentation
- Quality Management System documentation
- Clinical evidence demonstrating safety and performance

The regulatory requirements are based on device risk (Class A–D), not simply on whether AI is used.

2. AI-ready Digital Drugs Regulatory System (DDRS)
CDSCO has initiated procurement and implementation of the Digital Drugs Regulatory System (DDRS).
The objective is to replace fragmented regulatory systems with an integrated digital platform that can support:

- online submissions
- digital review workflows
- document management
- automated tracking
- future AI-assisted review



The DDRS tender indicates a long-term modernization of CDSCO's regulatory infrastructure.
3. Modernization of the SUGAM Portal
The existing SUGAM Portal continues to evolve through digital initiatives, including:

- online licensing
- online clinical trial applications
- medical device applications
- workflow digitization
- automated notifications
- improved user guidance (e.g., tooltips)
- online extensions and certificate generation

While these improvements are primarily digital rather than AI-based, they provide the foundation for future AI integration.
4. IndiaAI × CDSCO Health Innovation Acceleration Hackathon (2026)
One of the clearest AI implementation efforts is the IndiaAI × CDSCO Health Innovation Acceleration Hackathon.
The challenge focuses on developing AI tools to assist regulatory reviewers by automating repetitive tasks such as:

CDSCO has been pursuing a combination of AI regulation

- document summarization
- data anonymization
- NLP-based information extraction
- identification of missing submission data
- duplicate detection
- adverse event classification
- automated comparison of document versions
- structured regulatory report generation

The goal is to integrate these capabilities into CDSCO's SUGAM and Medical Device Online portals while keeping human reviewers responsible for regulatory decisions.

5. Participation in the Secure AI for Health Initiative (SAHI)

Under the Ministry of Health and Family Welfare, the Secure AI for Health Initiative (SAHI) provides governance principles for trustworthy healthcare AI. CDSCO's role includes:

- regulatory oversight of AI-enabled medical devices
- defining evidence requirements
- ensuring safety and effectiveness
- supporting integration with national digital health infrastructure

The initiative emphasizes secure, evidence-based deployment rather than unrestricted use of AI.

6. Digital automation of regulatory processes

CDSCO has progressively automated several regulatory functions, including:

- auto-generated Market Standing Certificates
- auto-generated Non-Conviction Certificates
- online application processing
- electronic workflows
- digital communications with applicants

Although these are not AI systems, they reduce manual administrative work and create structured data that could support AI applications in the future.

7. AI-ready regulatory documentation

For AI-enabled medical devices, CDSCO requires manufacturers to provide documentation covering:

- software lifecycle
- algorithm validation
- clinical performance
- risk management
- verification and validation
- quality systems

This aligns AI products with the same evidence-based regulatory expectations applied to other higher-risk medical devices.

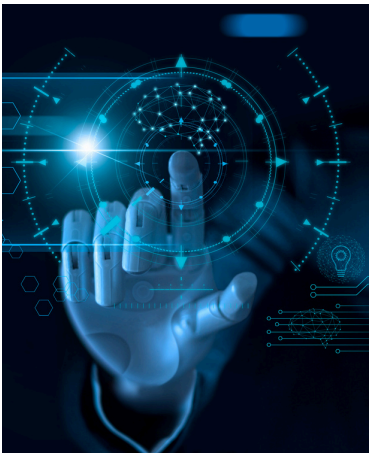
Areas where AI is expected to be implemented

Based on CDSCO's modernization programs and hackathon objectives, AI is expected to support regulatory affairs through:

CDSCO has been pursuing a combination of AI regulation

- Automated dossier screening
- Completeness checks
- NLP-based document summarization
- Duplicate detection
- Clinical trial document review
- Adverse event classification
- Regulatory intelligence
- Metadata extraction
- Workflow prioritization
- Decision-support dashboards (with human oversight)
- These are planned or exploratory capabilities rather than broadly deployed production systems.

Falling down is an Accident.
Staying down is a Choice.



The Bridge Builder

When Arjun became the operations head of a growing manufacturing company, he inherited a team known for delivering projects quickly. Deadlines were met, production numbers looked impressive, and customers were generally satisfied.
Yet there was a hidden problem.
Every department worked in isolation. Engineering blamed production for delays. Production blamed procurement for late materials. Procurement blamed sales for unrealistic promises. Although each team performed well individually, the organization struggled whenever projects became more complex.
At a leadership conference, Arjun listened to an architect describe the construction of a massive bridge.
The architect explained that the strength of a bridge depends not only on the quality of its pillars but also on the connections between them. Even the strongest pillars are useless if they are not securely linked. The connections distribute pressure, create stability, and allow the entire structure to carry heavy loads.
The idea stayed with him.
Arjun realized his company had built strong departments but weak connections.
Instead of introducing more performance targets, he focused on improving collaboration. Weekly cross-functional meetings replaced isolated reporting sessions. Teams began sharing information earlier, solving problems together instead of assigning blame. Employees spent time learning how other departments operated and what challenges they faced.

At first, the changes seemed to slow things down. Meetings took longer, and employees wondered whether all the discussions were necessary.
But over time, misunderstandings decreased. Decisions became faster because people already understood one another's priorities. Problems were identified before they became crises. Customers noticed smoother deliveries and more consistent service.
Within eighteen months, the company reduced project delays by nearly half, improved customer retention, and won several major contracts that required seamless coordination across departments.
During the annual leadership meeting, Arjun shared the lesson that had changed his perspective:
"Organizations don't fail because people work hard. They fail when hardworking people work apart instead of together."
Everyone understood.
The company's greatest improvement had not come from hiring more people or demanding longer hours.

Quiz on Biologicals (Answers in the subsequent pages)

1. Which organization is responsible for regulating biological products in India?
2. Which Act primarily governs biological products in India?
3. A biosimilar is:
4. Which schedule of the Drugs and Cosmetics Rules covers requirements for manufacturing biological products under GMP?
5. Which guideline provides the regulatory pathway for biosimilars in India?
6. Which document describes the manufacturing process of a biological product?
7. Pharmacovigilance for biologicals mainly focuses on:
8. Which clinical phase primarily evaluates efficacy?
9. A monoclonal antibody is classified as:
10. The purpose of comparability studies is to:
11. Which quality attribute is especially critical for biological products?
12. Biological products are mainly produced using:
13. Which laboratory is India's National Control Laboratory for many biological products?
14. Which quality system is essential for manufacturing biologicals?
15. Which regulatory principle is especially important for biological products?

The quiet moments often teach
the loudest lessons.

Pharma Regulatory Institute (PRI)

participated in the JOB FAIR organized by the College of Pharmacy, Shree Guru Gobind Singh Tricentenary (SGT) University, Gurugram, on 5th June 2026. The response was highly encouraging, with a large number of students expressing keen interest in the job oriented DRA and PV courses being offered. The College presented mementos to the team members as a token of appreciation for participating in the fair.

The Strongest foundation is built on honest effort.

Answers for the Quiz on Biological.

1. CDSCO
2. Drugs and Cosmetics Act, 1940
3. A biological product highly similar to an approved reference biological product
4. Schedule M
5. Guidelines on Similar Biologicals
6. Chemistry, Manufacturing and Controls (CMC)
7. Adverse events following administration
8. Phase III
9. Biological product
10. Demonstrate similarity after manufacturing changes.
11. Molecular structure and biological activity
12. Living cells or Organisms
13. CDL, Kasauli
14. Good Manufacturing Practices (GMP)
15. Risk-based lifecycle management

Min of Health & Family Welfare/CDSCO Regulatory Updates

- CDSCO issued a circular dated 6th July 2026 Inviting comments on consideration of the proposal regarding Issue of use of brand name extensions by the pharmaceutical firms
- CDSCO issued a Notification dated 2nd July 2026 G.S.R. 561(E)_Notification for consideration of Navi Mumbai International Airport (NMIA) as authorized Airport for Drug Import, under the provision of Rule 43A of Drugs Rules 1945.
- CDSCO issued a Notification dated 8th July 2026 - 607(E)_Notification regarding restriction of sale of drug products containing alcohol content under Drugs Rules 1945.
- CDSCO issued a Circular on 23rd July 26 onVigilance on imported cosmetics products sold in the domestic market without valid lmport Registration certificate.
- CDSCO issued a Circular on 22nd July 26 on Clarification regarding submission of applications under Rule 4 of the Drugs and Cosmetics (Compounding of Offences) Rules, 2025..
- CDSCO issued a public notice on 24th July 26 on Regulatory Alert regarding Cancellation of Registration Certificates of Ethics Committees under the New Drugs and Clinical Trials Rules, 2019
- CDSCO issued a public notice on 21st July 26 on Guidance document on Medical Device Software under MDR-2017

THANK YOU FOR READING

Please connect any exceptional achievements, new initiatives , specific information related to ACPL Group of companies or any other individual contributions like Poems, Stories ,Jokes etc to hr@acplgroupindia.co.in for incorporating the same in the upcoming editions of ACPL times.

PLEASE LIKE AND SUBSCRIBE OUR SOCIAL MEDIA CHANNELS

https://www.facebook.com/accreditedconsultantsprivatelimited
https://www.linkedin.com/company/accredited-consultants-pvt-ltd
https://www.instagram.com/accreditedconsultantspvtltd
https://www.youtube.com/@accreditedconsultantspvtltd
https://x.com/accreditedltd