Accredited Consultants
Private Limited

SEPT 2026 | Vol - 30

ACPL NEWSLETTER

A monthly Internal News Letter of ACPL

Dear Colleagues,

The true strength of any organisation lies not only in its expertise or achievements but in the values that guide its people. Among these, integrity and sincerity are the foundation of lasting success.

As a Regulatory Affairs organisation, we operate in an environment where trust, accuracy, and accountability are essential. Every document we prepare, every commitment we make, and every decision we take reflects not only our individual professionalism but also the reputation of our organisation. Our success depends on the confidence that clients and stakeholders place in us, and that confidence is earned through ethical conduct and genuine dedication.

Integrity means doing the right thing even when no one is watching. It is about being honest, transparent, and accountable in every aspect of our work. Sincerity is reflected in the commitment we bring to our responsibilities, the respect we show one another, and the pride we take in delivering quality outcomes. Together, these values create a culture of trust, collaboration, and excellence.

While knowledge and technical expertise are important, they alone cannot sustain an organisation. It is the collective commitment of individuals who work with honesty, responsibility, and purpose that drives meaningful progress. Every sincere effort, every ethical decision, and every act of teamwork strengthens the organisation and contributes to our shared goals.

As we continue our journey of growth, I encourage each one of you to uphold these values in your daily work. Let integrity guide your decisions and sincerity inspire your actions. By staying true to these principles, we will continue to build an organisation that is respected not only for its professional excellence but also for its unwavering ethical standards.

I sincerely thank each member of our team for your hard work, dedication, and commitment. Together, let us continue to grow with purpose, uphold the highest standards of professionalism, and create a legacy of excellence built on integrity and trust.

Warm regards,
C S Prasad

KNOWLEDGE CENTRE

Biological Products Licences and Approvals Process in India: A Complete Guide as per CDSCO Guidelines

Understanding the Regulatory Pathway for Biological Products

India has emerged as one of the world's leading biotechnology and vaccine manufacturing hubs. As innovation in biologics continues to expand, ensuring regulatory compliance has become increasingly important for manufacturers, importers, and research organizations.

The Central Drugs Standard Control Organisation (CDSCO), operating under the Ministry of Health and Family Welfare, serves as India's national regulatory authority for biological products. CDSCO oversees the licensing, clinical evaluation, manufacturing approvals, import permissions, and post-marketing surveillance of biological products to ensure their safety, quality, and efficacy before they reach patients.

What are Biological Products?

Biological products (biologics) are medicinal products derived from living organisms or biological processes. Unlike conventional small-molecule drugs, biologics are complex molecules requiring specialized manufacturing and stringent quality controls.

Examples include:

- Vaccines
- Recombinant DNA (r-DNA) products
- Monoclonal antibodies
- Blood and plasma-derived products
- Stem cell and cell-based therapies
- Gene therapy products
- Immunological products

Each category follows a specific regulatory pathway under the Drugs and Cosmetics Act, 1940, the Drugs Rules,
1945, and applicable CDSCO guidance documents.

Regulatory Authorities Involved

The approval process involves multiple regulatory bodies depending on the product type and development stage.

CDSCO

- Clinical trial approvals
- Marketing authorization
- Import permissions
- Post-approval changes
- Central licensing approvals

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State Licensing Authority (SLA)

- Manufacturing licences
- Site inspections
- Compliance with Good Manufacturing Practices (GMP)

Central Drugs Laboratory (CDL), Kasauli

- Batch testing and release for vaccines and selected

Biologicals

Institutional Ethics Committees and Subject Expert Committees (SECs)

- Ethical review
- Scientific evaluation of clinical studies

Certain recombinant and advanced biotechnology products may also require approvals from other competent authorities under India's biotechnology regulatory framework

Step-by-Step Biological Licensing and Approval Process.

1. Product Classification

The regulatory pathway begins with determining the biological product category, such as:

- Human vaccines
- Recombinant biologics
- Blood products
- Cell and gene therapies
- Similar biologics (biosimilars)

Correct classification determines documentation requirements and applicable regulations.

1. **Research and Development Approval**

Before manufacturing investigational material, developers must obtain the necessary permissions for research and analytical activities.

For biological products, CDSCO provides No Objection Certificates (NOCs) for manufacturing products intended for examination, testing, or analysis under the applicable provisions of the Drugs Rules.

3. Clinical Trial Approval

Before initiating human clinical trials, sponsors must submit:

- Clinical trial protocol
- Investigator's brochure
- Chemistry, Manufacturing and Controls (CMC) data
- Non-clinical safety studies
- Ethics Committee approvals
- Informed consent documents
- Risk management information

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CDSCO evaluates the submission for scientific validity and participant safety before granting clinical trial permission.

4. Manufacturing Licence

Manufacturers must establish facilities compliant with Good Manufacturing Practices (GMP). Following satisfactory inspection and regulatory review, manufacturing licences for biological products are issued by the State Licensing Authority, with applicable CDSCO approvals for centrally regulated biological products. Depending on the product category, licences such as Form 28-D or Form 28-E may apply.

5. Marketing Authorization

After successful completion of development, manufacturers submit a comprehensive dossier including:
Quality documentation
Manufacturing process validation
Analytical methods
Stability studies
Clinical efficacy data
Safety data
Risk management plans
Product labeling
CDSCO evaluates the complete dossier before granting marketing authorization.

6. Import Registration (Where Applicable)

Foreign manufacturers intending to market biological products in India must obtain:

- Registration Certificate
- Import Licence
- Test Licence (where applicable)

The submission includes manufacturing site information, quality systems, GMP certifications, and product-specific documentation.

7. Batch Release and Quality Testing

For vaccines and selected biological products, every production batch may undergo independent testing by designated laboratories such as the Central Drugs Laboratory before commercial distribution.
This additional oversight helps ensure consistent product quality and safety.

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8. Post-Approval Compliance

Regulatory responsibilities continue after product approval and include:

- Pharmacovigilance reporting
- Adverse event monitoring
- Post-approval change submissions
- Manufacturing change notifications
- Periodic safety updates
- GMP inspections

Significant manufacturing or quality changes generally require prior regulatory review and approval.

Documentation Commonly Required

A typical biological product application includes:

- Administrative forms
- Product Quality Documentation
- Manufacturing information
- GMP certificates
- Process validation reports
- Stability studies
- Non-clinical studies
- Clinical trial reports
- Risk Management Plan
- Product labels and package inserts
- Environmental and biosafety information where applicable

The exact documentation depends on the product category and development stage.

Special Considerations for Similar Biologics

India has established dedicated regulatory requirements for similar biologics (biosimilars).

Manufacturers must demonstrate:

- Analytical comparability
- Quality consistency
- Non-clinical comparability
- Clinical similarity
- Pharmacovigilance planning

The approval process emphasizes a comprehensive comparability exercise with the reference biological product rather than independent development from first principles.

Digital Submission through the SUGAM Portal

Most biological product applications are now submitted electronically through the CDSCO SUGAM portal. The platform supports applications for:

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- Clinical trials
- Manufacturing permissions
- Import licences
- Marketing authorization
- Post-approval changes
- Export permissions

Digital submission has improved transparency, tracking, and communication between applicants and regulators.

Common Challenges During Approval

Organizations often encounter challenges such as:

- Incomplete CMC documentation
- Insufficient comparability data
- GMP compliance deficiencies
- Manufacturing validation issues
- Delays in responding to regulatory queries
- Inadequate stability data

Early regulatory planning and adherence to CDSCO guidance can significantly reduce approval timelines.

India's regulatory framework for biological products is designed to balance innovation with patient safety. From early research permissions to manufacturing licences, clinical trials, marketing authorization, and ongoing post-marketing surveillance, every stage requires comprehensive documentation and compliance with CDSCO requirements.

For manufacturers and biotechnology companies, understanding the biological licensing pathway is essential for efficient product development and successful market entry. By following CDSCO guidance documents, maintaining robust quality systems, and preparing scientifically sound submissions, organizations can navigate the approval process more effectively while ensuring that safe, effective, and high-quality biological products reach patients.

Happiness grows when
you care for others.
Suffering grows when
everything is about you.

Regulatory Affairs Excellence

Common Mistakes to Avoid and Best Practices to Follow

Regulatory Affairs (RA) staff play a critical role in ensuring products comply with regulatory requirements throughout their lifecycle. Even small mistakes can lead to delays, product recalls, warning letters, or regulatory action. Below are some of the most common mistakes and the key precautions RA professions should take.

Common Mistakes in Regulatory Affairs

1. Incomplete or Incorrect Documentation
- Missing required documents.
- Incorrect product information or specifications.
- Inconsistent information across documents.
- Failure to maintain document version control.

Impact: Submission rejection, regulatory queries, or approval delays.

2. Missing Regulatory Deadlines
- Late submission of applications.
- Delayed renewal of licenses or registrations.
- Missing variation or amendment timelines.

Impact: License expiry, product supply interruptions, or penalties.

3. Poor Knowledge of Current Regulations
Using outdated regulatory guidelines.
Ignoring updates from regulatory authorities.
Applying requirements from the wrong market.
Impact: Non-compliance and delayed approvals.

4. Incorrect Product Classification
Wrong classification of drugs, medical devices, cosmetics, or food products.
Incorrect risk classification.
Impact: Wrong submission pathway and possible rejection.

5. Data Integrity Issues
Typographical errors.
Copy-paste mistakes.
Missing signatures or dates.
Incorrect calculations or stability data.
Impact: Regulatory observations and loss of credibility.

Regulatory Affairs Excellence

6. Lack of Cross-Functional Communication
- Poor coordination with:
  - Quality Assurance (QA)
  - Quality Control (QC)
  - Manufacturing
  - R&D
  - Supply Chain
  - Marketing

Impact: Incorrect submissions and compliance gaps.

7. Failure to Assess Regulatory Impact
- Implementing manufacturing or formulation changes without regulatory assessment.
- Not filing required variations before implementation.

Impact: Major compliance violations.

8. Poor Change Control Management
- Not reviewing changes through the change control process.
- Missing regulatory impact assessments.

Impact: Unauthorized product changes.

9. Inadequate Submission Review
- Formatting errors.
- Missing attachments.
- Incorrect forms.
- Wrong dossier structure.

Impact: Refusal-to-file or deficiency letters.

10. Incomplete Labeling Review
- Incorrect claims.
- Missing mandatory warnings.
- Outdated artwork.
- Incorrect storage conditions.

Impact: Product recall or regulatory action.

11. Weak Record Keeping
- Poor archival practices.
- Missing submission history.
- Difficulty retrieving previous approvals.

Impact: Audit findings.

12. Poor Audit Readiness
- Missing supporting evidence.
- Incomplete training records.
- Unavailable standard operating procedures (SOPs).

Impact: Regulatory observations during inspections.

Regulatory Affairs Excellence

Important Things Regulatory Affairs Staff Should Take Care Of

✔️ **Stay Updated**
- Monitor regulatory authority updates.
- Review revised guidelines regularly.
- Subscribe to official regulatory notifications.

✔️ **Maintain Document Accuracy**
- Double-check every document before submission.
- Ensure consistency across all files.
- Use current approved templates.

✔️ **Follow SOPs**
- Adhere strictly to internal procedures.
- Avoid shortcuts.
- Document any deviations appropriately.

✔️ **Maintain Regulatory Calendar**
Track:
- License renewals
- Product renewals
- Submission deadlines
- Annual reports
- Commitments
- Inspection dates

✔️ **Verify Technical Data**
Confirm:
- Batch records
- Stability data
- Validation reports
- Specifications
- Certificates of Analysis (CoAs)

✔️ **Review Labels Carefully**
Check:
- Product name
- Strength
- Dosage form
- Manufacturing details
- Expiry date format
- Storage conditions
- Mandatory warnings
- Barcode/QR code (if applicable)

✔️ **Ensure Data Integrity**
Follow principles such as:
- Attributable
- Legible
- Contemporaneous
- Original
- Accurate
- Complete
- Consistent
- Enduring
- Available

Regulatory Affairs Excellence

✔️ Maintain Good Communication
Regularly coordinate with:

- QA
- QC
- Production
- R&D
- Packaging
- Marketing
- Supply Chain

✔️ Perform Independent Reviews
Before submission:

- Conduct a detailed checklist review.
- Arrange peer review where possible.
- Confirm all annexures and supporting documents are included.

✔️ Maintain Inspection Readiness
Ensure:

- Documents are readily accessible.
- Training records are current.
- SOPs are up to date.
- Regulatory files are organized.

Best Practices for Regulatory Affairs Professionals

- Use standardized submission checklists.
- Maintain a regulatory intelligence tracker.
- Keep a submission history log.
- Archive correspondence with regulatory authorities.
- Track all commitments and follow-up actions.
- Participate in regular compliance training.
- Conduct periodic self-audits.
- Review change controls for regulatory impact before implementation.
- Document every regulatory decision with supporting rationale.

Quick Pre-Submission Checklist
Before any regulatory submission, verify:

- ✅ All required documents are included.
- ✅ Information is accurate and consistent.
- ✅ Current regulatory requirements have been followed.
- ✅ Forms are complete and signed.
- ✅ Supporting data is verified.
- ✅ Labels and artwork are approved.
- ✅ Submission format meets authority requirements.
- ✅ Internal approvals have been obtained.
- ✅ Deadlines are met.
- ✅ A final quality review has been completed.

By following disciplined documentation practices, staying current with regulations, and maintaining strong cross-functional communication, Regulatory Affairs staff can minimize compliance risks and improve the likelihood of timely regulatory approvals.

Climb your knowledge daily and success will meet you at the top.

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The Broken Fence

A farmer owned a large piece of land on the edge of a village. One day, he noticed that a section of the fence separating his fields from the road had fallen down.
He mentioned it to his workers.
“The fence is broken,” he said. “Someone should fix it before the animals wander in.”
The workers nodded.
“I’ll tell the maintenance team,” one said.
“I thought the village office was responsible for that side,” another replied.
“It’s been like this for weeks,” someone added. “I’m sure someone has already reported it.”
Days passed.
The broken section remained open.
One evening, a young farm assistant was walking past the area and noticed a group of cows had entered the field through the gap. They had damaged several rows of crops.
He looked at the fallen fence, found some spare wooden posts and wire in the storage shed, and repaired the opening before finishing his shift.
The next morning, the farmer inspected the field.
“Who fixed the fence?” he asked.
“I did,” the assistant replied. “It was only a small repair.”
The farmer looked at the damaged crops nearby and then at the repaired fence.
“For weeks, we talked about a broken fence,” he said. “We discussed whose responsibility it was, who should approve it, and when someone would come.”
He paused.
“But the fence did not need a meeting. It needed someone to pick up a hammer.”
The story soon became a lesson across the farm.
Whenever people noticed a problem, they stopped asking:
“Who is supposed to fix this?”
Instead, they started asking:
“Is this something I can help solve?”
Message
Many problems grow because people wait for the perfect person, perfect process, or perfect permission. Sometimes leadership is simply noticing what needs to be done and taking the first responsible step.
A small repair today can prevent a much bigger problem tomorrow.

Quiz on Biologicals (Answers in the subsequent pages)

1. The major regulation governing new drugs and clinical trials in India is:
2. r-DNA products are regulated as:
3. Which form is associated with a licence for manufacture of vaccines under the CLAA scheme?
4. Biosimilars are products that are:
5. Which document provides detailed quality, safety, and efficacy information for a biological product submission?
6. Stem cell and cell-based products are regulated under:
7. The main purpose of Good Manufacturing Practices (GMP) is to ensure:
8. The apex committee responsible for reviewing proposals involving genetically engineered organisms is:
9. IBSC stands for:
10. Which guidelines specifically address approval of biosimilar products in India?
11. The reference product used for comparison in a biosimilar application is called:
12. Biological products are generally more complex than chemical drugs because they:
13. Pharmacovigilance of biological products mainly involves:
14. Which regulatory submission section describes manufacturing process and controls?
15. Good Manufacturing Practice requirements for biological products focus on:
16. A monoclonal antibody is classified as:
17. The purpose of stability studies for biological products is to determine:
18. The primary purpose of clinical trials for biological products is to evaluate:

Make it a habit to respect people without knowing their qualifications, title or position.

Moments of Insight

Excellence Is a Habit

Excellence is rarely the result of one extraordinary effort. More often, it is built through ordinary actions performed consistently—meeting commitments, respecting deadlines, supporting colleagues, and paying attention to details.

Success is not an event; it is a habit that quietly shapes every achievement.

The little things we do every day become the big things we are known for.

Listening: The Most Underrated Skill

In a world where everyone wants to be heard, those who truly listen stand out.

Listening is more than waiting for a turn to speak. It is understanding perspectives, building trust, and discovering ideas that might otherwise be missed.

Sometimes, the best contribution to a conversation is not another opinion—it is genuine attention.

One who has control over the mind is a person of steady wisdom - Bhagavad Gita

Answers for the Quiz on Biological.

1. Answers for the Quiz on Biological Products Regulation
2. New Drugs and Clinical Trials Rules (NDCTR), 2019
3. Biological drugs
4. Form 28-D
5. Highly similar to an already approved biological product
6. CMC dossier
7. Biological product regulations
8. Consistent quality and safety
9. GEAC (Genetic Engineering Appraisal Committee)
10. Institutional Biosafety Committee
11. 10. CDSCO-DBT Guidelines for Similar Biologics
12. 11. Comparator product
13. 12. Are produced using living systems
14. 13. Monitoring adverse events after marketing
15. 14. CMC (Chemistry, Manufacturing and Controls) section
16. 15. Identity, purity, potency, and safety
17. 16. Biological therapeutic product
18. 17. Product shelf life and storage conditions
19. 18. Safety and efficacy

Min of Health & Family Welfare/CDSCO Regulatory Updates

- CDSCO issued a Gazatte notification on 6th August 2026 for amendment under Rule 89 of Drugs Rules 1945, for obtaining licence under Form 29 for different categories falling under Form 25A, 25F, 28A, 28B, 28D, 28DA, 28E, 28F.
- CDSCO issued a public notice on 6th August 2026 on Stakeholder Consultation on Operational Guidelines for Single Ethics Committee Review of Multi-Centre Research in India.
- CDSCO issued a Public notice on 10th August 2026 Inviting comments on standard IVD evaluation protocols drafted by ICMR and CDSCO.
- CDSCO issued a circular dated 10th August 2026 on Clarification on the submission of applications for grant of Permission to Import and Market New Drugs not approved anywhere in the world, wherein phase III Global Clinical Trials (GCT) are ongoing or completed with participation of Indian subjects under the New Drugs and Clinical Trials Rules, 2019.
- CDSCO issued a public notice on 11th August 2026 on Manufacturing and marketing of un-approved drug products containing Enclomiphene and its combinations.

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.

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