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Accredited Consultants Private Limited

ACPL NEWSLETTER

A monthly Internal News Letter of ACPL



Happy Diwali!



Dear Team,

As we celebrate the joyous festival of Diwali, I extend my warmest wishes to all our employees and their families.

Diwali symbolizes the victory of light over darkness, knowledge over ignorance, and hope over challenges. May this auspicious occasion bring happiness, good health, prosperity, and success to everyone.

At **ACPL Group of Companies**, our greatest strength lies in the dedication, teamwork, and commitment of our people. Let us continue to work together with renewed enthusiasm, embrace new opportunities, and achieve greater milestones in the coming year.

May the light of Diwali illuminate our paths with fresh ideas, positive energy, and continued growth, both personally and professionally.

Wishing you and your family a very Happy, Safe, and Prosperous Diwali!

Warm regards,

C. S. Prasad
Managing Director
ACPL Group of Companies

KNOWLEDGE CENTRE

Understanding Clinical Trials

Importance & Process

A **clinical trial** is a structured scientific study conducted in human participants to evaluate the **safety, efficacy, dosage, side effects, and overall benefits and risks** of a new medicine, vaccine, medical intervention, or treatment. Clinical trials are an essential part of the development and regulatory approval of healthcare products.

1. Why Are Clinical Trials Important?

Clinical trials generate evidence that helps determine whether a healthcare intervention is:

- **Safe** for use in humans
- **Effective** in treating or preventing a disease
- Appropriate in terms of **dose and duration**
- Associated with any significant **side effects or risks**
- Suitable for specific patient populations
- Beneficial compared with existing treatments or a placebo

The data generated during clinical development forms an important part of the evidence submitted to regulatory authorities for marketing authorization.

2. Clinical Trial Development Process

The clinical development process generally progresses through several stages:

Preclinical Research → Regulatory/Ethics Approval → Phase I → Phase II → Phase III → Regulatory Review → Post-Marketing/Phase IV

Preclinical Research

Before testing in humans, the investigational product undergoes laboratory and, where applicable, animal studies. These studies provide preliminary information regarding:

- Pharmacology
- Toxicity
- Pharmacokinetics
- Potential efficacy
- Safety profile

If the available evidence supports human testing, the sponsor can proceed toward clinical development.

3. Phase I – Initial Safety

Phase I is generally the first stage of testing in humans.

Main objectives:

- Assess safety and tolerability
- Study pharmacokinetics and pharmacodynamics
- Identify appropriate dosage ranges
- Observe common adverse effects

Phase I studies are often conducted in a relatively small number of participants, although the design can vary depending on the product and disease.

4. Phase II – Preliminary Efficacy

Phase II studies provide more information about whether the intervention works for the intended condition.

They generally focus on:

- Preliminary efficacy
- Dose selection
- Safety
- Short-term adverse effects
- Appropriate treatment regimen

The number of participants is usually larger than in Phase I.

5. Phase III – Confirmatory Studies

Phase III trials are generally large-scale studies designed to generate **confirmatory evidence of efficacy and safety**.

They may compare the investigational product with:

- Placebo
- Standard treatment
- Another approved therapy

The results from Phase III studies can form a major component of the clinical evidence package submitted for regulatory review.

6. Regulatory Review and Marketing Authorization

After sufficient clinical evidence has been generated, the sponsor compiles the required technical, quality, non-clinical and clinical information into a regulatory submission.

The regulatory authority evaluates the available evidence to determine whether the product can

be approved, and under what conditions.

7. Phase IV – Post-Marketing Studies

Clinical evaluation does not necessarily end after marketing authorization.

Phase IV/post-marketing studies may provide additional information about:

- Long-term safety
- Rare adverse events
- Effectiveness in broader populations
- Special patient populations
- Real-world use
- Additional indications

This stage contributes to the continuing safety monitoring of approved products.

8. Key Stakeholders in a Clinical Trial

A clinical trial involves several important stakeholders:

Stakeholder	Major Responsibility
Sponsor	Overall responsibility for initiating and managing the study
Principal Investigator	Conducts the study at the clinical site
Clinical Research Organization (CRO)	May provide outsourced clinical development and trial-management services
Regulatory Authority	Reviews regulatory requirements and oversees compliance
Ethics Committee/IEC	Protects the rights, safety and well-being of participants
Clinical Trial Site	Conducts trial-related activities
Study Participants	Voluntarily participate according to the approved protocol
Clinical Research Team	Performs study procedures, documentation and data collection

9. Important Clinical Trial Documents

Some important documents include:

- Clinical Trial Protocol
- Investigator's Brochure
- Informed Consent Form
- Case Report Forms (CRFs/eCRFs)
- Clinical Study Report
- Essential Documents
- Safety Reports
- Investigational Product documentation

- Statistical Analysis Plan

Proper documentation is essential for demonstrating **data integrity, participant protection and regulatory compliance**.

10. Clinical Trial in the Indian Regulatory Context

In India, clinical trials are regulated under the applicable provisions of the **New Drugs and Clinical Trials Rules, 2019 (NDCTR)** and other applicable regulatory requirements. Depending on the study and product, requirements can involve the **Central Drugs Standard Control Organisation (CDSCO)**, Ethics Committee oversight, registration and other prescribed procedures.

For a regulatory consultancy such as **ACPL**, clinical-trial support can therefore be developed as a service area covering **regulatory strategy, documentation, submission support, regulatory intelligence, compliance support and coordination with sponsors/CROs/clinical sites**.

Conclusion

Clinical trials are the bridge between **scientific discovery and evidence-based patient care**. A properly designed and conducted clinical trial protects participants while generating reliable evidence on the safety and effectiveness of a healthcare intervention. The different phases of clinical development progressively build this evidence, ultimately supporting regulatory decision-making and, where appropriate, wider patient access.



Cosmetics Licensing and Registration in India through CDSCO

Cosmetics regulatory requirements should be divided into Indian manufacturing, import of cosmetics, and new cosmetics. The licensing authority and application forms differ for each pathway.

The primary legislation is the Drugs and Cosmetics Act, 1940, read with the Cosmetics Rules, 2020. CDSCO regulates the import registration of cosmetics, whereas cosmetics manufacturing licences are issued by the respective State Licensing Authorities.

1. Identify the applicable regulatory pathway

A. Manufacture cosmetics in India

State Licensing Authority

Apply to the State Drug Control Department/FDA where the manufacturing premises are located. CDSCO does not ordinarily issue the domestic cosmetics manufacturing licence.

Main forms: COS-5 / COS-6 → COS-8, as applicable.

B. Import cosmetics into India

Apply to the Central Licensing Authority through the CDSCO SUGAM portal for registration of imported cosmetic products and their manufacturing sites.

Main forms: COS-1 → COS-2.

C. New cosmetics

A product that falls within the regulatory definition of a new cosmetic may require prior permission from the Central Licensing Authority before manufacture or import.

Main form: COS-3. Confirm the definition and applicability under the Cosmetics Rules, 2020.

An important distinction: COS-2 is an Import Registration Certificate, not a domestic manufacturing licence. Also, a foreign brand's product registration should not be confused with a general company or importer registration.

2. Indian cosmetics manufacturing licence

A. Applicable forms

Form	Purpose
COS-5	Application for a licence to manufacture cosmetics for sale or distribution
COS-6	Application for a loan licence to manufacture cosmetics for sale or distribution
COS-7	Self-certificate of compliance with Good Manufacturing Practices (GMP)
COS-8	Licence to manufacture cosmetics for sale or distribution
COS-3	Permission relating to new cosmetics, where applicable

The application is submitted to the competent State Licensing Authority, not to CDSCO as the ordinary manufacturing-licence authority.

B. Step-by-step manufacturing process

1. Determine the product category. Identify each product, intended use, formulation, ingredients, claims, and applicable quality standards. Check whether the product is a cosmetic or falls under another regulatory category.
2. Choose the manufacturing model. Decide whether the company will manufacture at its own facility or use an existing third-party manufacturer's premises under the applicable loan-licence arrangement.
3. Establish compliant premises. Prepare the manufacturing, storage, quality-control and ancillary facilities appropriate to the product types and scale of operations.
4. Appoint qualified personnel. Arrange the prescribed technical and supervisory staff and ensure their qualifications and experience meet the applicable requirements.
5. Compile the technical dossier. Prepare product formulations, manufacturing methods, specifications, testing arrangements, proposed labels, GMP documents and supporting records.
6. Submit the application. File COS-5 or COS-6, as appropriate, with the State Licensing Authority using its prescribed application procedure and fee schedule.
7. Inspection and assessment. The authority may inspect the premises and review the facilities, equipment, personnel, records and GMP compliance.
8. Address deficiencies. Respond to observations and provide revised documents, evidence or corrective actions requested by the authority.
9. Obtain the licence. Manufacture for sale or distribution only after the required licence has been granted and the approved scope is understood.
10. Maintain compliance. Keep batch manufacturing and testing records, complaint and recall procedures, product specifications, change-control records and other applicable quality documentation.

    The exact online portal, inspection requirements, fees and document checklist should be confirmed with the relevant State Licensing Authority.

C. Documents required for an Indian manufacturing licence

Prepare the following master checklist before filing. The State authority may require additional documents depending on the product category and the proposed manufacturing arrangement.

No.	Document / information	Purpose

1	Application in Form COS-5 or COS-6	Formal licence application
2	Constitution documents of the firm	Incorporation certificate, partnership deed or other applicable legal documents
3	Premises ownership or lease documents	Proof of possession and address
4	Site plan and layout	Manufacturing, storage, testing and ancillary areas
5	List of manufacturing equipment	Equipment inventory and suitability
6	List of technical staff	Qualifications, experience and appointment details
7	Product list	Names, categories, variants and intended pack sizes
8	Master formula for each product	Ingredients, quantities and composition
9	Manufacturing process	Stepwise process, controls and in-process checks
10	Finished-product specifications	Physical, chemical and microbiological parameters, as applicable
11	Testing methods and laboratory details	Quality-control arrangements and test capability
12	GMP compliance documents	Applicable self-certification in Form COS-7 and supporting records
13	Standard operating procedures (SOPs)	Manufacturing, cleaning, testing, storage and documentation
14	Water-quality and environmental controls	Evidence appropriate to the manufacturing operations
15	Packaging and proposed labels	Compliance with applicable labelling requirements
16	Product-specific supporting documents	Stability data, safety information or other evidence as applicable
17	Prescribed fee receipt	Evidence of payment under the State's applicable fee schedule

Important: This is a working preparation checklist, not a substitute for the official State-specific checklist. Verify the prescribed application annexures and requirements against the Cosmetics Rules, 2020 and the relevant State Licensing Authority's current instructions.

D. Loan licence versus own manufacturing licence

Point	Own manufacturing licence	Loan licence
Manufacturing premises	Applicant's own or appropriately controlled facility	Existing licensed manufacturer's facility
Main application	COS-5	COS-6
Infrastructure	Applicant must establish compliant facilities	Existing facilities must satisfy applicable requirements
Regulatory responsibility	Licence holder must comply with licence conditions	Loan licence holder and host manufacturer must fulfil their respective legal obligations
Key assessment	Premises, staff, equipment and quality systems	Host facility, manufacturing arrangements, permissions and quality controls

Do not assume that a contract-manufacturing agreement alone authorises production. The applicable licence and approved scope must cover the intended arrangement and products.

3. Import cosmetics registration through CDSCO

For imported cosmetics, the main regulatory reference is the CDSCO Guidance Document on Application Submission for obtaining Import Registration Certificate for import of cosmetics into India, read with the current Cosmetics Rules and applicable CDSCO amendments.

A. Applicable forms

Form	Purpose
COS-1	Application for an Import Registration Certificate
COS-2	Import Registration Certificate issued by the Central Licensing Authority
COS-3	Permission for new cosmetics, where applicable
COS-4	Application for an Import Registration Number for cosmetics already registered
COS-4A	Import Registration Number issued for eligible already-registered cosmetics

COS-4/COS-4A may be relevant to an eligible applicant seeking to import a cosmetic already registered under the rules. Confirm eligibility and the current CDSCO checklist before choosing this route.

B. Step-by-step import registration process

1. Regulatory classification: Confirm that the product is a cosmetic under Indian law and determine the relevant category under the Cosmetics Rules, 2020. Review ingredients, claims, intended use and any applicable BIS standards.
2. Identify the applicant: The application may be submitted by the foreign manufacturer, its authorised agent, an eligible importer in India, or a manufacturer-authorised Indian subsidiary, as permitted by the rules.
3. Obtain manufacturer authorisation: Arrange the prescribed authorisation under the First Schedule, including the required authentication or apostille formalities. Ensure the product list and manufacturing-site details are consistent throughout the dossier.
4. Collect the product dossier: Obtain complete ingredient composition, manufacturing and product details, specifications, test methods, labels, Free Sale Certificate and other required supporting documents.
5. Prepare the application: Complete Form COS-1 and the applicable Second Schedule information and undertakings. Prepare a product-wise correlation chart connecting the application, authorisation and Free Sale Certificate.
6. Create a SUGAM account: Register or log in to the CDSCO online portal at CDSCO SUGAM portal and select the relevant cosmetics application type.
7. Upload the dossier and pay fees: Upload documents against the electronic checklist, complete the applicable payment process and submit the application as directed by the portal.
8. Regulatory scrutiny: CDSCO reviews the application. The authority may request clarification, additional documents, revised labels or correction of inconsistencies.
9. Respond to deficiencies: Submit complete, consistent responses within the stipulated period and track the application on the portal.
10. Obtain COS-2: Once approved, download the Import Registration Certificate and verify the registered products, manufacturing premises, variants and pack sizes.
11. Complete import-readiness checks: Ensure the product labels, importer details, import documentation, quality requirements and other applicable legal requirements are satisfied before commercial import.

The CDSCO guidance describes this online workflow and the documentary requirements for Form COS-1.

C. Documents required for CDSCO import registration

The following is the principal dossier checklist for a fresh Form COS-1 application.

No.	Document	Key checks
1	Covering letter	Clearly state fresh application, product category, manufacturer, sites and product list
2	Manufacturer's authorisation / Power of Attorney	Use the First Schedule format; meet the required authentication or apostille formalities
3	Authorisation undertaking	Indian agent's acceptance and applicable undertakings
4	Form COS-1	Complete applicant, manufacturer, product, site, variant and pack-size details
5	Second Schedule, Part I information and undertakings	Complete the prescribed information about the manufacturer, applicant and products
6	Product-wise ingredient composition	Standard ingredient nomenclature and percentages; signed/stamped by an authorised manufacturer representative
7	Product specifications	Finished-product quality and safety specifications
8	Testing methods	Applicable test procedures and acceptance criteria
9	Proposed product labels	Labels for each relevant product, variant and pack presentation
10	Free Sale Certificate (FSC)	Issued by an acceptable authority or organisation, with required authentication and product correlation
11	Manufacturing licence or marketing authorisation	Authenticated evidence from the country of origin, where applicable; prescribed undertaking if no such licence is required there
12	Non-animal-testing declaration	Manufacturer's undertaking addressing applicable Indian requirements
13	Heavy-metal and microbiological compliance	Relevant test reports or acceptable manufacturer undertaking, as applicable
14	Package insert	If applicable
15	Product/site/pack-size correlation chart	Match product names and identifiers across all supporting documents
16	Payment acknowledgement	Evidence of the applicable registration fee
17	Other supporting documents	Any additional documents required by the current checklist or CDSCO

The CDSCO checklist and guidance specifically cover the manufacturer authorisation, composition, labels, specifications, testing, Free Sale Certificate, manufacturing authorisation, animal-testing declaration and heavy-metal compliance.

4. Cosmetics labelling requirements

Label compliance should be reviewed before submitting the registration dossier, rather than after registration.The CDSCO guidance identifies the following key requirements under the Cosmetics Rules, 2020.

Label element	Regulatory check
Product identity	Name of the cosmetic and applicable product identification
Manufacturer	Name and address of the actual manufacturer and relevant manufacturing premises
Country of origin	Required country-of-origin declaration for imported products, as applicable
Batch identification	Distinctive batch or lot number
Expiry	Applicable use-before, expiry or other permitted date declaration
Net contents	Quantity in the prescribed units, subject to applicable exemptions
Ingredients	Ingredient declaration in the prescribed order, subject to applicable exemptions
Warnings	Required directions for safe use, cautions and warnings
Manufacturing licence number	Applicable requirements, including permitted exceptions for certain imports
Registration certificate number	For imported products, the applicable registration number and required importer/registration-holder particulars
Indian standards	Any additional labelling requirements applicable under relevant Indian standards

Importantly: Indian-specific labelling may, in permitted cases, be applied by stickers at a bonded warehouse before clearance. This is not a blanket exemption from compliant labelling. Verify the exact requirements for the product and import route.

5. New cosmetics: additional regulatory assessment

A product classified as a new cosmetic under the Cosmetics Rules, 2020 may require permission in Form COS-3 from the Central Licensing Authority before it can be manufactured or imported.

The assessment should establish:

- Whether the product meets the applicable definition of a new cosmetic.
- Whether its composition, ingredients, intended use and claims trigger the new-cosmetic pathway.
- What safety and supporting technical data are required.
- Whether permission must be obtained before proceeding with the manufacturing or import application.
- Whether the proposed claims could change the product's classification from a cosmetic to another regulated category.

Do not assume that every new brand, new variant or newly imported cosmetic is automatically a new cosmetic in the regulatory sense. Confirm the statutory definition and current

requirements before determining the application pathway.

7. Post-registration and post-licensing compliance

Obtaining a licence or registration certificate is not the end of the regulatory process.

Product and site changes

Assess changes to composition, manufacturing premises, pack sizes, variants, sourcing arrangements, labels and specifications before implementation. Determine whether prior approval, endorsement or notification is required.

Quality and batch documentation

Maintain applicable specifications, test reports, batch records, complaint records, recall procedures and other quality documentation.

Market surveillance

Document complaints, safety issues, adverse reactions where applicable, and corrective or recall actions.

Regulatory renewals and changes

Track certificate retention or renewal requirements, licence conditions, applicable reporting obligations and amendments to the rules.

For imported cosmetics, the CDSCO guidance includes undertakings regarding compliance with the registered product's standards and notification of certain changes and regulatory actions. Review the exact obligations applicable to the registration.

7. Common deficiencies to check before filing

These are practical pre-submission checks based on the official documentary requirements; they are not a claim that every item is a formally published CDSCO deficiency statistic.

Common issue	Recommended preventive action
Product names differ across documents	Use one master product list and a correlation chart
Manufacturer authorisation is incomplete	Verify signatures, authentication, validity period and product/site coverage
FSC does not adequately cover the proposed products	Confirm the issuing authority, authentication and product list
Ingredient composition is incomplete	Provide standard ingredient names and

	percentages
Manufacturing site details do not match	Reconcile the application, authorisation, FSC and manufacturing documents
Labels are not India-compliant	Conduct a product-wise label review before submission
Specifications or testing methods are inadequate	Prepare signed, product-specific quality documentation
Required declarations are missing	Check the current electronic checklist line by line
Product category or new-cosmetic status is unclear	Complete the classification assessment before filing
Fee payment or upload is incomplete	Reconcile payment evidence and verify successful portal submission

8. Let us identify the exact licensing route

The most important first step is to identify whether the proposed client needs an Indian manufacturing licence or a CDSCO import registration.

1. What is the proposed activity?

Import cosmetics into India
Manufacture cosmetics in India
Third-party / loan-licence manufacturing in India
Develop or introduce a new cosmetic

2. What type of products?

Skin care, creams, lotions and face wash
Hair care, shampoo and hair colour
Make-up, lipstick and nail products
Perfumes and deodorants
Other or multiple categories

3. Country of manufacture

Outside India
India

4. Current stage

Starting a fresh application
Already have a licence or registration

> “Failure is not the opposite of progress; sometimes, it is the path that leads us forward.”

Laugh it out

The Power of SOPs

Auditor: “What do you do when you don't know how to perform a task?”
Employee: “I refer to the SOP.”
Auditor: “And what if the SOP doesn't explain it?”
Employee: “Then I raise a change request to improve the SOP!”

The CDSCO Surprise

Executive: “Sir, good news! Our application has moved forward.”
Manager: “Excellent! Has it been approved?”
Executive: “Not yet, Sir. It has moved from ‘Under Review’ to ‘Additional Information Required’!”

The Perfect Application

Boss: “Have you checked the dossier thoroughly?”
Executive: “Yes, Sir. I checked it twice.”
Boss: “Then why did we receive a deficiency letter?”
Executive: “Sir, I checked the dossier. I didn't know the authority was going to check it too!”





Moments of Insight

The Power of a Positive Attitude

Success is not determined only by our skills or knowledge, but also by the attitude we bring to every situation. A positive attitude helps us face challenges with confidence, learn from mistakes, and find opportunities where others see obstacles.

In the workplace, a willingness to cooperate, respect different opinions, and approach problems constructively can make a significant difference. We may not always control what happens around us, but we can choose how we respond.

"A positive attitude may not change every situation, but it can change how we face it."

The right attitude turns challenges into lessons, teamwork into strength, and everyday efforts into meaningful achievements.



Moments of Devotion



A blessed occasion filled with devotion, positivity and festive spirit, bringing the ACPL family together to celebrate tradition, strengthen bonds and seek blessings for a prosperous future.Glimpses of ACPL Group of Companies Navratri Pooja held at Medtech Devices premises at Okhla on 19th October 2026.



Quiz on Clinical Trials -Answers in the subsequent pages

1. What is the primary purpose of a Phase I clinical trial?
2. What is the main purpose of informed consent?
3. Which clinical trial phase generally provides confirmatory evidence of efficacy and safety before marketing approval?
4. What is the primary role of an independent Ethics Committee?
5. What is the primary purpose of a clinical trial protocol?
6. What is the main responsibility of a clinical trial sponsor?
7. Which document provides investigators with relevant nonclinical and clinical information about an investigational product?
8. What is the main function of a Case Report Form (CRF)?
9. What is the main purpose of a clinical trial audit?
10. What does an adverse event (AE) mean in a clinical trial?

The Small Bridge

Small efforts can connect big differences

Together We Move Forward

In a busy town, there was a small office where many people worked together. Everyone had different responsibilities. Some handled clients, some prepared documents, some managed accounts, and others worked behind the scenes.

One day, an important client project was nearing its deadline. The team was under pressure.

The regulatory team needed some information from the documentation team. The documentation team was waiting for data from another department. Meanwhile, the client was asking for an update.

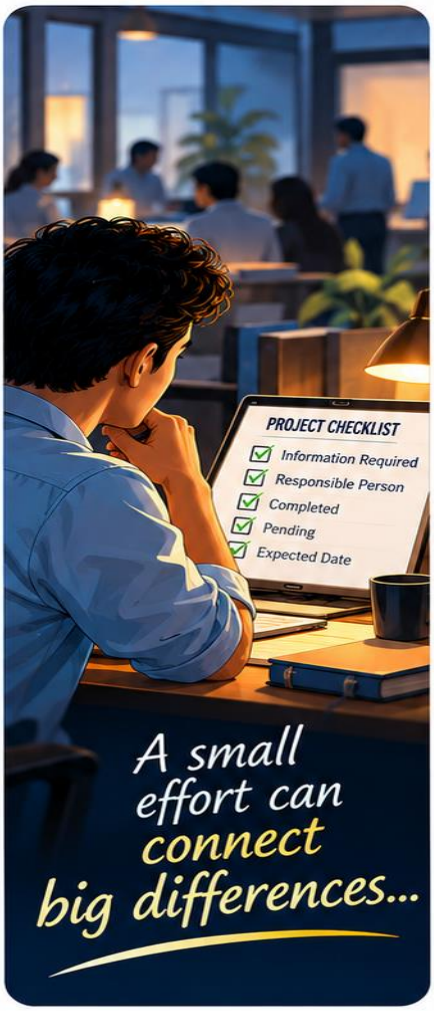
Everyone was busy with their own work.

A young employee named Arjun noticed that the departments were not communicating properly.

He did not have the authority to solve the whole problem. He thought,

"What can I do now?"

Instead of waiting for someone else, Arjun created a simple one-page checklist.



It showed:

- What information was required
- Who was responsible
- What had already been completed
- What was still pending
- The expected completion date

He shared the checklist with everyone involved.

At first, some people thought it was unnecessary.

But gradually, the confusion started disappearing.

The documentation team knew exactly what was required.

The regulatory team could see what was pending.

The manager could quickly identify the delay.

And the client received the required information on time.

At the end of the project, the manager thanked the entire team.

Then he looked at Arjun and said,

"Your checklist may look like a small thing, but it helped us cross a big gap."

Arjun smiled.

He realized that he had not solved the entire problem.

He had simply built a small bridge between people.



The Lesson

We often think that making a difference requires a big position, a big decision or a big achievement.

But sometimes, a small idea can connect people, remove confusion and move an entire team forward.

> "Success is not built in a single day; it is built through small, consistent efforts every day."

Moments of Insight

The Value of Continuous Learning

Learning does not end with education or experience. Every day offers us an opportunity to gain new knowledge, develop better skills, and discover improved ways of doing things. Those who remain curious and open to learning are better prepared to face change and embrace new opportunities.

In the workplace, even a small lesson learned from a colleague, a mistake, or a challenging assignment can lead to meaningful improvement. Growth begins when we are willing to listen, adapt, and keep moving forward.

"The moment we stop learning is the moment we stop growing."

Every new lesson adds to our knowledge, every experience strengthens our understanding, and every effort to improve brings us closer to becoming the best version of ourselves.

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Our Trainees, Our Pride!

We are delighted to announce that two of our trained candidates from **Pharma Regulatory Institute (PRI)** have secured jobs with reputed multinational companies.

Mr Gaurav Pal – IQVIA, PV Associate.
Mr Yash Sharma – APCER Life Science, PV Associate.

This achievement reflects our commitment to industry-oriented training and career development. We congratulate our candidates on their success and wish them a bright and rewarding professional future.

Pharma Regulatory Institute (PRI)
Empowering Aspirations. Building Careers





Min of Health & Family Welfare/CDSCO Regulatory Updates

CDSCO issued a public notice on 9th October 2026 on Draft Guidance document for Manufacturers of In-vitro diagnostic Medical device for stakeholders comment.

CDSCO issued a public notice on 14th October 2026 on Clarification regarding requirement of Export NOC for already approved r-DNA products.

CDSCO issued a public notice on 27th October 2026 on Strict compliance with the Drugs Rules, 1945, for testing of raw materials and finished formulations

CDSCO issued a public notice on 27th October 2026 on Digital Monitoring System on the ONDLS portal for monitoring the supply chain of high-risk solvents.

Answers for the Quiz on Clinical Trials.

1. **To assess initial safety and tolerability**
2. **To support a voluntary, informed decision to participate.**
3. **Phase III.**
4. **To protect participants' rights, safety and well-being.**
5. **To describe the study objectives, design and methods.**
6. **To initiate, manage and/or finance the clinical trial**
7. **Investigator's Brochure**
8. **To record protocol-required data for each participant.**
9. **To independently examine trial activities and records for compliance and reliability.**
10. **An Adverse Event (AE) is any unwanted medical occurrence in a clinical trial participant after receiving a study drug or medical device, whether or not it is related to the treatment. Examples include headache, nausea, or skin rash.**



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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