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ACPL TIMES

A MONTHLY INTERNAL NEWSLETTER OF ACPL

CS Prasad

Managing Director

Dear Colleagues,

As a regulatory consulting organization, our commitment to quality, compliance, safety, and customer trust remains non-negotiable. Regulatory requirements are continuously evolving, and it is imperative that we remain informed, proactive, and fully aligned with the latest developments issued by various regulatory and standards-setting authorities.

I would like to emphasize the importance of staying up to date with all notifications, circulars, guidelines, amendments, advisories, and regulatory updates issued by agencies such as the Central Drugs Standard Control Organization (CDSCO), Bureau of Indian Standards (BIS), Ministry of Health & Family Welfare, Food Safety and Standards Authority of India (FSSAI), and other relevant statutory and regulatory bodies applicable to our business operations.

I therefore expect all team members to:

1. **Regularly review and monitor notifications, circulars, and updates issued by relevant regulatory authorities.**
2. **Assess the applicability of new requirements to their respective functions and operations.**
3. **Maintain accurate documentation and records demonstrating adherence to applicable regulatory requirements.**

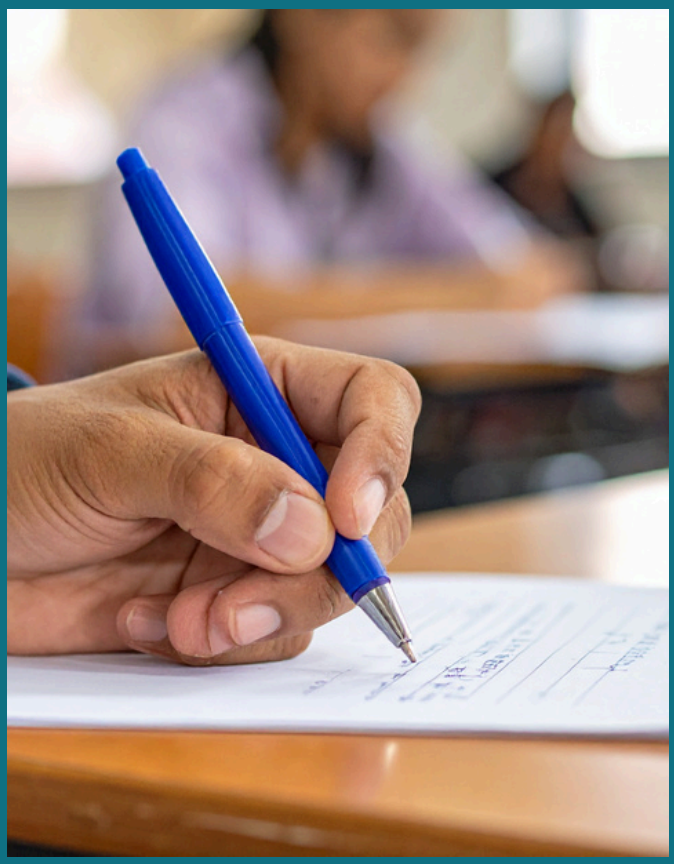
I encourage each one of you to make regulatory awareness an integral part of your daily professional responsibilities. Together, we can continue to uphold the highest standards of excellence and ensure that our organization remains compliant, competitive, and future-ready.

Thank you for your continued dedication, professionalism, and commitment.

With regards
CS Prasad

KNOWLEDGE CENTRE

ICH GUIDELINES: THE GLOBAL LANGUAGE OF PHARMACEUTICAL REGULATION



In today's interconnected pharmaceutical landscape, a medicine developed in one country is often intended for patients across multiple regions. As companies pursue global registrations, one question consistently arises: How can regulatory expectations be aligned across different health authorities?

The answer lies in the work of the International Council for Harmonisation (ICH).

Over the past three decades, ICH guidelines have transformed pharmaceutical development and regulation by creating a common scientific and technical framework accepted by major regulatory agencies worldwide. For regulatory professionals, understanding and effectively implementing ICH requirements is no longer a competitive advantage–it is a fundamental necessity.

From Regional Requirements to Global Harmonization

- Before the establishment of ICH in 1990, pharmaceutical companies frequently had to conduct duplicate studies and prepare different dossiers to satisfy varying regulatory requirements across regions. This often resulted in increased development costs, delayed product approvals, and unnecessary use of resources.
- ICH was created to address these challenges by bringing together regulatory authorities and industry representatives to develop harmonized standards for pharmaceutical quality, safety, efficacy, and submission formats.
- Today, ICH guidelines influence regulatory expectations far beyond its founding regions and are widely adopted by health authorities across the globe, making them the cornerstone of modern pharmaceutical regulation.

Understanding the Four Pillars of ICH

- The ICH guideline framework is organized into four major categories:
- Quality (Q) - Quality guidelines establish expectations for pharmaceutical development, manufacturing, analytical validation, stability studies, risk management, and lifecycle management.

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ICH GUIDELINES: THE GLOBAL LANGUAGE OF PHARMACEUTICAL REGULATION

Guidelines such as Q8 (Pharmaceutical Development), Q9 (Quality Risk Management), and Q10 (Pharmaceutical Quality System) have significantly influenced the industry's transition from traditional compliance-based approaches toward science- and risk-based decision-making.
Safety (S) - Safety guidelines define non-clinical testing requirements necessary to characterize potential risks before human exposure.
These guidelines help ensure that toxicological assessments are conducted consistently and efficiently while maintaining patient safety as the highest priority.

Efficacy (E) - Efficacy guidelines focus on clinical development, trial design, statistical considerations, and Good Clinical Practice (GCP).
Recent revisions emphasize quality-focused clinical trial design, data integrity, and patient-centered approaches that reflect the evolving clinical research environment.
Multidisciplinary (M) - This category addresses cross-functional topics such as electronic submissions, data standards, and the Common Technical Document (CTD).
Among these, the CTD has arguably had the greatest impact by creating a globally recognized dossier structure that enables more efficient regulatory submissions and reviews.

- The Shift Toward Risk-Based Regulation
- One of the most significant contributions of ICH has been the promotion of risk-based thinking throughout the product lifecycle.
- The principles introduced through Quality Risk Management and Quality by Design have encouraged organizations to move beyond simple regulatory compliance and focus on understanding processes, identifying critical risks, and implementing proactive controls.
- For regulatory consultants, this evolution has changed the nature of client support. Regulatory strategy today requires not only knowledge of requirements but also an ability to interpret scientific data, assess risks, and align development programs with regulatory expectations from the earliest stages.
- Recent Trends Shaping the ICH Landscape
- The ICH framework continues to evolve in response to scientific innovation and emerging healthcare needs.

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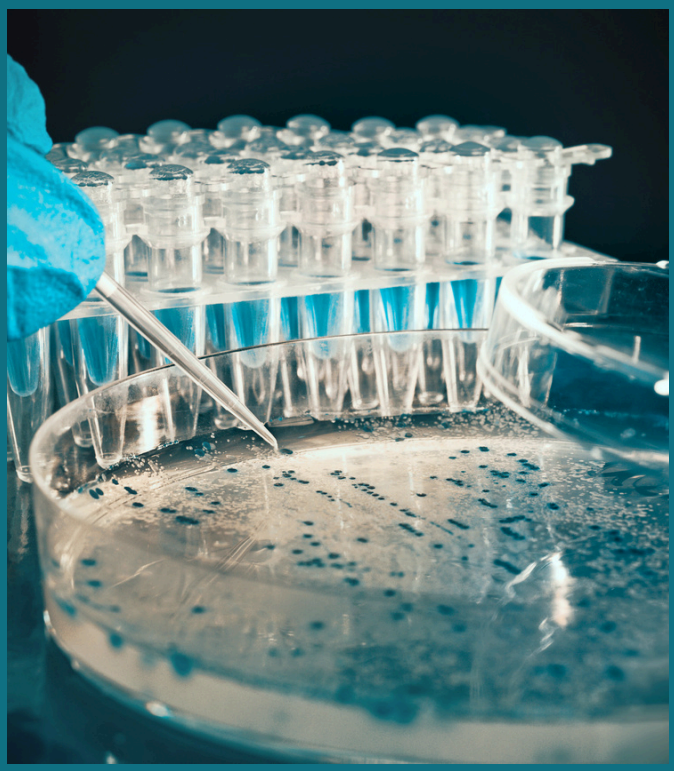

Several recent developments deserve particular attention:

Modernization of Good Clinical Practice

The updated Good Clinical Practice framework reflects advances in technology, decentralized trials, electronic systems, and risk-proportionate quality management. These changes aim to maintain participant protection while improving trial efficiency and flexibility.

Greater Focus on Lifecycle Management

Guidelines such as Q12 have introduced structured approaches for managing post-approval changes, enabling companies to implement improvements more efficiently while maintaining regulatory compliance.

Data Integrity and Digitalization

As regulatory submissions become increasingly electronic, data governance, traceability, and integrity continue to receive heightened scrutiny from health authorities worldwide.

Global Convergence

Many emerging markets are progressively aligning their regulatory frameworks with ICH principles. This trend is simplifying global development strategies while raising expectations for regulatory maturity across organizations.

What This Means for Industry

For pharmaceutical companies, ICH compliance is no longer limited to preparing registration dossiers. It influences every stage of a product's lifecycle–from development and clinical evaluation to manufacturing, post-approval management, and pharmacovigilance.

Organizations that successfully integrate ICH principles into their operating models often benefit from:

- More efficient development programs
- Reduced regulatory risks
- Enhanced product quality
- Faster global market access
- Improved inspection readiness
- Stronger regulatory credibility

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ICH GUIDELINES: THE GLOBAL LANGUAGE OF PHARMACEUTICAL REGULATION

Conversely, failure to align with evolving ICH expectations can lead to delays, deficiencies, increased costs, and challenges during regulatory review.

The Consultant's Role in an Evolving Regulatory Environment

As the regulatory landscape becomes increasingly complex, consulting firms play a critical role in helping organizations interpret and implement ICH requirements effectively.

The value of regulatory consulting has expanded from dossier preparation to strategic partnership –supporting companies in gap assessments, quality systems, development planning, lifecycle management, and global regulatory strategy.

Success today requires a combination of scientific expertise, regulatory intelligence, and practical implementation experience.

Looking Ahead

The future of pharmaceutical regulation will likely be shaped by advanced manufacturing technologies, artificial intelligence, real-world evidence, digital health solutions, and increasingly globalized development programs.

As these innovations emerge, ICH will continue to serve as the platform through which regulators and industry establish common expectations and harmonized standards.

For regulatory professionals, staying current with ICH developments is not merely about compliance. It is about enabling innovation, supporting global market access, and ultimately contributing to the delivery of safe, effective, and high-quality medicines to patients worldwide.

Conclusion

ICH guidelines have become the universal language of pharmaceutical regulation. They provide the framework through which regulators and industry collaborate to ensure quality, safety, and efficacy while fostering innovation and efficiency.For regulatory consulting professionals, a deep understanding of ICH is more than technical knowledge–it is a strategic capability that helps clients navigate complexity, anticipate change, and succeed in an increasingly global regulatory environment.

BE SLOW TO CRITICIZE AND FAST TO APPRECIATE.

WHAT IS CE CERTIFICATION / CE MARKING FOR MEDICAL DEVICES?

CE Marking is a regulatory conformity mark that indicates a medical device complies with the applicable requirements of the European Commission and relevant European regulations, allowing the device to be legally marketed in the European Economic Area (EU member states plus certain associated countries).

For medical devices, CE marking is primarily governed by:

- EU Medical Device Regulation (MDR) 2017/745
- EU In Vitro Diagnostic Regulation (IVDR) 2017/746 (for IVD devices)

A CE mark on a medical device does not mean the product is "approved" by the EU government in the same way that some countries issue product approvals. Rather, it demonstrates that the manufacturer has established and documented compliance with applicable regulatory requirements and undergone the required conformity assessment process.

Significance and Importance of CE Marking

1. Access to the European Market

CE marking is mandatory for selling most medical devices in EU/EEA countries. Without CE marking, a device generally cannot be legally placed on these markets.

2. Demonstrates Regulatory Compliance

It shows that the manufacturer has addressed requirements relating to:

- Safety - Performance
- Risk management - Clinical evaluation
- Post-market surveillance - Quality management

3. Enhances Global Credibility

Many countries outside Europe recognize CE-marked devices as evidence of a mature regulatory system, making international registrations easier.

4. Improves Patient Safety

The MDR framework requires:

- Clinical evidence - Risk-benefit assessment
- Vigilance reporting - Continuous monitoring after Commercialization.

5. Competitive Advantage

Hospitals, distributors, procurement agencies, and healthcare providers often prefer CE-marked products because they indicate compliance with internationally accepted standards.

6. Supports Export Growth

For Indian manufacturers, CE marking is often one of the first major regulatory milestones when entering international markets.

Key Parties Involved

Manufacturer

Responsible for:

- Device design
- Technical documentation
- Quality management system
- Regulatory compliance

WHAT IS CE CERTIFICATION / CE MARKING FOR MEDICAL DEVICES?

Authorized Representative (EU)

If the manufacturer is located outside Europe (e.g., India), an EU-based Authorized Representative must be appointed.

Notified Body

A designated independent organization that assesses compliance for medium- and high-risk devices.

Examples include:

- TÜV SÜD
- BSI Group
- DEKRA

Step-by-Step Process for CE Marking of Medical Devices (Indian Manufacturers)

Step 1: Determine Device Qualification : Confirm that the product meets the definition of a medical device under MDR.

Questions include:

- Is it intended for diagnosis?
- Prevention of disease?
- Monitoring or treatment?

Step 2: Classify the Device : Determine the correct MDR risk class:

- Class I , Class IIa ,Class IIb ,Class III

Classification drives the conformity assessment route.

Step 3: Appoint an EU Authorized Representative : Since the manufacturer is based in India, appoint an EU-based Authorized Representative.

The representative:

- Interfaces with EU authorities
- Maintains required documentation access
- Supports vigilance activities

Step 4: Establish a Quality Management System : Implement a quality management system compliant with ISO 13485:2016

Key elements include: Design control , Supplier management ,CAPA , Complaint handling ,Traceability ,Risk management

Step 5: Conduct Risk Management : Implement risk management according to ISO 14971

Activities include: Hazard identification , Risk estimation , Risk Control ,Residual risk evaluation

Step 6: Perform Clinical Evaluation : Prepare a Clinical Evaluation Report (CER).

This may involve: Literature review , Clinical investigations ,Equivalent device data ,Post-market clinical data

Clinical evidence must demonstrate safety and performance.

Step 7: Prepare Technical Documentation : Compile a Technical File or Design Dossier including:

Device Description : Intended use,Variants, Specifications

Design Information : Drawings ,Manufacturing information

Risk Management File : Hazard analysis ,Risk controls

Verification & Validation : Performance testing ,Biocompatibility ,Electrical safety ,Software validation

Clinical Evaluation Report : Clinical evidence package

Labeling and IFU : Labels , Instructions for Use

WHAT IS CE CERTIFICATION / CE MARKING FOR MEDICAL DEVICES?

Step 8: Implement Post-Market Surveillance (PMS)
Create procedures for: Complaint management ,Vigilance reporting ,Trend analysis ,Periodic safety review
MDR places strong emphasis on lifecycle monitoring.
Step 9: Select a Notified Body (if required)
For: Class Is , Class Im , Class IIa, Class IIb ,Class III
A Notified Body review is mandatory.
Class I devices may be self-certified in many cases.
Step 10: Undergo Notified Body Assessment
Assessment may include: QMS Audit
Review of ISO 13485 system.
Technical Documentation Review
Evaluation of: Clinical evidence, Risk Management , Device testing
On-Site Audit : Manufacturing facility inspection in India.
Step 11: Obtain MDR Certification
Upon successful assessment, the Notified Body issues:

- MDR Certificate (where applicable)
- Quality Management System Certificate

Step 12: Register Economic Operators and Device
Under MDR requirements, the manufacturer and authorized representative obtain registration within the European regulatory framework and associated databases as applicable.
Step 13: Affix the CE Mark
After compliance is demonstrated:

- CE mark may be placed on device
- Packaging
- Instructions for Use

For devices requiring Notified Body involvement, the CE mark is accompanied by the Notified Body identification number.
Example: CE 0123 - is the notified Body number
Typical Documentation Required
Common documents include:

1. ISO 13485 Certificate
2. Quality Manual
3. Technical File
4. Risk Management File
5. Clinical Evaluation Report
6. Post-Market Surveillance Plan
7. IFU and Labels
8. Declaration of Conformity
9. Supplier Controls.
10. Verification & Validation Reports

ONE HONEST ‘NO’ IS BETTER THAN TEN POLITE EXCUSES.

LESSONS FROM YAYATI AND THE MILESTONES OF LIFE

In the southern part of India, there is a tradition of celebrating the ages of 60, 70, 80, 90, and 100 in a grand manner.

Once, someone asked me the reason behind this: “Why do we celebrate ages like 60, 70, 80, 90, and 100 so magnificently?

Are these numbers spiritual, or merely cultural traditions?”

The answer lies in a powerful story from the Mahabharata–the story of King Yayati.

King Yayati lived life to the fullest–power, pleasure, success, everything. But when old age suddenly came, it shook him deeply. After deep reflection, he realized a profound truth:

“Pleasures have limits, but desires do not.”

This realization transformed his life. He accepted old age and explained that life has five inner turning points–based not on age, but on understanding.

Interestingly, these five turning points align with the traditional milestones of 60, 70, 80, 90, and 100 years in Indian culture. Let us understand them in simple terms:

60 – Shashti (Shashtipoorthi) - The mind turns from accumulation to understanding.

Around 60, something changes–not in the body, but in priorities.

The question “How much more can I gain?” slowly fades, and is replaced by “What truly matters now?”

Self-reflection begins. The need for noise, praise, and external validation diminishes.

Clarity becomes the focus. This is not decline–it is maturity surpassing ambition.

70 – Bhimaratha Shanti - Peace feels more powerful than proving oneself.

In our 40s and 50s, we try to prove ourselves to the world.

At 70, a quiet shift occurs. You no longer react instantly. The attraction to arguments fades. Preserving relationships feels more important than winning debates.

You realize: Being calm is more valuable than being right. That is why the 70th year is celebrated.

80 – Shatabhishekam - Your presence itself becomes healing.

At 80, people don’t come to you for advice alone. They come seeking something deeper–assurance that life can be lived, understood, and fulfilled.

Your presence itself becomes a blessing. Words are no longer necessary. Your very being conveys: “Everything was alright. Life finds its way.” That is why 80 is considered sacred.

90 – Navati - The ego quietly retires. At 90, something rare happens.

You no longer feel the need to correct others. You don’t cling to your opinions. You don’t take things personally. You are not easily hurt. Not because of weakness – but because life has already shown you so much. Small things no longer deserve your energy.

LESSONS FROM YAYATI AND THE MILESTONES OF LIFE

A gentle stillness settles within. This humility is true spirituality.
100 – Shatamanam - Life moves beyond personal stories. Reaching 100 is not just counting years. It is a state where the bigger picture becomes clear.
You realize many of your worries were unnecessary. The love you gave was what truly mattered. And life was always guided by a mysterious, compassionate force.
At 100, a person is less an “individual” and more a “presence.”
Summary
Our sages did not celebrate age– they celebrated the inner transformation that comes with it.
60 – Priorities change
70 – Peace becomes strength
80 – Presence becomes healing
90 – Ego dissolves quietly
100 – Life reaches completeness
Age is not weakness. Age is a process of refinement– through which wisdom, gentleness, and grace remain.
Thought for today
Growing older means becoming purer, wiser, and gentler in life.
The above post is highly commendable. It serves as a guide for how our retired life should be. It provides direction for the gradual evolution of human life.
How long will we keep entangling ourselves by making life outward-focused? At some point, we must pause. Becoming inward-looking does not mean becoming inactive, nor does it mean renouncing everything. Rather, it means living selflessly–rising above attachment and desires (such as the longing for recognition, wealth, and progeny)–and living with contentment.

DON’T DEPEND TOO MUCH ON ANYONE IN THIS WORLD, BECAUSE EVEN YOUR OWN SHADOW LEAVES YOU WHEN YOU ARE IN THE DARK

PLAY THE BATTLE DRUMS - GAUTAM BUDDHA

A king had many elephants, but one elephant was very powerful, very obedient, sensible and skillful in everything especially his fighting skills. In many wars, he was sent on the battlefield and he used to return only after getting victory for the king. Therefore, he was the most loved elephant of the king.

Time went by and there came a time when the elephant started getting old. Now he was not able to perform as before. Therefore, now the king did not even send him to the battlefield but he still remained as a part of the king's team.

One day the elephant went to a lake to drink water, but unfortunately his feet got stuck in the mud there and he went on sinking. He tried a lot, but he could not remove himself from the mud. People came to know from the sound of his screams that the elephant was in trouble. The news of the elephant trapped also reached the king. All the people, including the king, gathered around the elephant and made various efforts to get him out. But alas, even after trying for a long time, there was no way out.

At that time, Gautama Buddha was passing by. Gautam Buddha stopped and inspected the site of the incident and then suggested to the king that the battle drums should be played around the lake. The listeners felt shocked at the bizarre suggestion as to how the trapped elephant would come out by playing the battle drums. But they could not say anything to Gautam Buddha and started playing the drums.

As soon as the drums of war started ringing, there was a change in the gestures, behaviour and determination of the troubled elephant.

At first, the elephant slowly stood up and then gradually used his force and intelligence and before long, came out of the mud on his own, shocking everyone. Gautama Buddha smiled and said:

There was no lack of physical ability in the elephant, but only the need to infuse enthusiasm, Motivation and Will within it was missing.

To maintain enthusiasm in life, it is necessary that humans maintain purposeful thinking and do not let despair dominate their thoughts...!!!

In today's tough times we all need to enthuse ourselves & people around us with Hope & enthusiasm by playing, if need be the BATTLE DRUMS, that we will again Celebrate Abundance of Joy, Health & Happiness today

REMEMBER: THIS TOO SHALL PASS!!

BE LOYAL TO YOUR FUTURE NOT YOUR PAST

QUIZ ON CLINICAL TRIALS (ANSWERS IN THE SUBSEQUENT PAGES)

1. What is the primary purpose of a clinical trial?
2. Which phase of a clinical trial primarily assesses safety in humans?
3. Informed consent means :
4. Which phase typically involves the largest number of participants?
5. What is a placebo?
6. Randomization in clinical trials is used to:
7. A "double-blind" study means:
8. Which document outlines the protocol and procedures of a clinical trial?
9. Good Clinical Practice (GCP) guidelines are intended to:
10. What is an adverse event (AE)?

DO NOT LET THE BEHAVIOR OF OTHERS DESTROY YOUR INNER PEACE.

We are delighted to share that Mrs. Simran Rao and Mrs. Divya Sharma have successfully cleared the Trainer Assessment conducted by the Life Sciences Sector Skill Development Council (LSSSDC) and have earned the prestigious certification as Certified Trainers in Drug Regulatory Affairs.Their accomplishment strengthens our organization's capability to develop skilled talent and promote high standards of learning and compliance within the industry.

We extend our heartfelt congratulations to Mrs. Simran Rao and Mrs. Divya Sharma on this significant milestone and wish them continued success as they inspire, mentor, and contribute to the growth of future professionals in Drug Regulatory Affairs.

THE BAMBOO STRATEGY

A young manager named Neha was given responsibility for a newly formed business unit. The team was talented, but results were disappointing. Quarter after quarter, targets were missed. Competitors seemed to move faster, and pressure from leadership continued to grow.

One afternoon, during a leadership workshop, Neha heard a story about bamboo.

The speaker explained that after bamboo seeds are planted, very little appears above the ground for several years. To an observer, it may seem as though nothing is happening. Yet beneath the surface, the plant is developing an extensive root system. Then, when the foundation is strong enough, the bamboo can grow astonishingly fast.

The story stayed with her.

Back at work, Neha realized her team was focused almost entirely on short-term outcomes. They chased immediate results but had neglected the foundations that create long-term success—skills, processes, collaboration, and trust.

She decided to change the approach.

The team invested time in learning new technologies, documenting best practices, mentoring younger employees, and improving communication across departments. Progress seemed slow at first. Some questioned whether the effort was worthwhile because the visible results were modest.

But Neha remained committed.

Months later, the impact became clear. Projects were completed faster. Employee engagement increased. Customer satisfaction improved. New opportunities that once seemed out of reach began arriving regularly.

Within two years, the business unit became one of the company's strongest performers.

At a company town hall, Neha shared the lesson that had transformed her leadership:

"Everyone celebrates growth when it becomes visible. Few people appreciate the discipline required to build the roots that make growth possible."

The audience understood exactly what she meant. Success had not appeared overnight. It had been quietly built through preparation, learning, and persistence.

The Lesson

In business, not every effort delivers immediate recognition. Some of the most important work happens behind the scenes–developing people, strengthening systems, and building relationships.

Just like bamboo, organizations that invest in strong foundations may not see instant results. But when the time comes, their growth can be extraordinary.

Message

Sustainable success is not created by quick wins alone. It is built through patience, preparation, and consistent investment in the foundations that support future growth. Focus on strengthening the roots today, and the results will follow tomorrow.

SOMETIMES, BEAUTY IS NOT WHAT THE EYES CAN SEE –
IT'S WHAT THE SOUL TRULY FEELS.

MIN OF HEALTH & FAMILY WELFARE/CDSCO REGULATORY UPDATES

- CDSCO issued a circular on 3rd June 2026 on the Transfers of Officers.
- CDSCO issued a circular on 3rd June 2026 Implimentation of Pharmacovigilance (PV) system as per the requirement of Schedule M of Drugs & Cosmetics Act 1940 and the Rule made there after.
- CDSCO issued a Gazatte Notification on 1st June 2026 ,G.S.R. 444(E)_Notification for amendment in Schedule V w.r.t. unit of measurement of Folic Acid under the Drugs Rules, 1945
- CDSCO issued a Public notice on 4th June 2026 on Prohibits to Import, manufacture, sale, distribution and use in any food producing animal rearing system of drug formulations containing "Chloramphenicol or Nitrofurans drugs with immediate effect
- CDSCO issued a circular on 10th June 2026 on Submission of Compliance for Imported/manufactured hair color cosmetics products and applicable BIS standards.
- CDSCO issued a circular on 24th June 2026 on Registration of formulation intermediates such as Directly compressible granules, taste masked granules, modified release granules/pellets.
- CDSCO issued a circular on 24th June 2026 on submission of Post Approval Changes Applications of Registration Certificate and Import Licence of Human Vaccines and Anti-Sera though Sugam Portal
- CDSCO issued a circular on 24th June 2026 on sale of In-Vitro Fertilization Media, reagents and related consumables used in Assisted Reproductive Technology procedures.

Bhoomi Poojan of Medtech Devices at Plot 61, Medtech Park, YEIDA. UP on 27th May 2026.

Birthday Celebration of Prasad Sir & Mrs Premalatha Madam at Office .

ANSWERS OF THE PHARMA QUIZ

1. To evaluate the safety and effectiveness of a medical intervention
2. Phase I
3. Participants voluntarily agree after understanding risks and benefits
4. Phase III
5. An inactive substance designed to resemble the treatment.
6. Reduce bias and ensure comparable groups
7. Both participants and researchers do not know treatment assignments
8. Study protocol
9. Ensure ethical and scientific quality of trials
10. Any unfavorable medical occurrence during a study

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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