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ACPL TIMES

A MONTHLY INTERNAL NEWSLETTER OF ACPL

CS Prasad **(MD)**

Good morning everyone,

I want to take a moment to say thank you—not just for the work you do, but for the effort, commitment, and teamwork you bring into this office every day.

In a small office like ours, each person truly matters. Every task completed, every idea shared, and every extra bit of effort makes a real difference. There's no "small role" here—what you do directly impacts our success, our environment, and how we move forward together.

We all face challenges. Some days are busy, some are stressful, and some require us to go the extra mile. But what makes this team special is how we support one another through those moments. When we work together, communicate openly, and respect each other's strengths, we turn challenges into progress.

Growth doesn't happen overnight. It happens through consistency, learning, and teamwork. Each of you brings unique skills and perspectives, and when those come together, we create something stronger than any one person could achieve alone.

I encourage everyone to take pride in your work, believe in your abilities, and continue supporting the people around you. Your contributions are noticed, they are valued, and they matter.

Let's keep moving forward with positivity, dedication, and teamwork. Together, even as a small team, we can achieve great things.

Thank you—and let's keep doing our best.

With regards
CS Prasad

IMPORTANCE OF QUALITY CONTROL (QC) AND QUALITY ASSURANCE (QA) IN MEDICAL DEVICE MANUFACTURING

Quality Control (QC) and Quality Assurance (QA) are critical pillars in medical device manufacturing because these products directly affect patient safety, clinical outcomes, and public health. Even small defects or process failures can lead to serious harm, regulatory action, or product recalls. Below is a clear explanation of why QC and QA are so important.

1. Patient Safety

Medical devices such as implants, diagnostic tools, and life-support equipment must function exactly as intended.

- **QC ensures each product meets specifications through inspections, testing, and measurements.**
- **QA ensures that the systems and processes used to make the device consistently produce safe and reliable products.**

Together, they reduce the risk of device failure, misuse, or harm to patients.

2. Regulatory Compliance

Medical device manufacturers must comply with strict regulations (e.g., ISO 13485, FDA Quality System Regulation).

- QA establishes documented procedures, audits, and training systems to meet regulatory requirements.
- QC provides evidence—such as test results and inspection records—that products meet those requirements.

Strong QC and QA help manufacturers pass inspections and avoid legal penalties or market withdrawal.

3. Product Reliability and Performance

Healthcare professionals rely on devices to work accurately and consistently.

- QC detects defects in materials, components, or finished products.
- QA focuses on improving manufacturing processes to prevent defects from occurring in the first place.

This ensures devices perform reliably throughout their intended lifespan.

4. Risk Management and Error Prevention

Medical device manufacturing involves complex processes and high-risk materials.

- QA emphasizes preventive actions, such as design controls, process validation, and risk analysis.
- QC identifies nonconforming products before they reach the market.

This proactive approach reduces recalls, adverse events, and costly failures.

5. Cost Efficiency and Waste Reduction

While QC and QA require investment, they save money long-term.

- Early detection of defects prevents large-scale recalls and rework.
- Well-designed QA systems reduce waste, downtime, and production errors.

This improves efficiency and protects the manufacturer's reputation.

6. Trust and Reputation

Hospitals, doctors, and patients must trust medical devices.

- Consistent quality builds confidence in the brand.
- Strong QC and QA demonstrate a commitment to safety, ethics, and professionalism.

Trust is essential for long-term success in the medical device industry.

7. Continuous Improvement

QA systems promote ongoing evaluation and improvement.

- Feedback from QC data, audits, and customer complaints is used to improve processes and designs.
- This leads to innovation, better products, and higher safety standards over time.

Conclusion

Quality Control and Quality Assurance are essential in medical device manufacturing because they protect patients, ensure regulatory compliance, improve product reliability, reduce risks, and maintain trust. Together, QC and QA ensure that medical devices are not only effective but also safe, consistent, and dependable throughout their lifecycle.

QUALITY ASSURANCE (QA)

Core Responsibilities

- Develop, implement, and maintain the Quality Management System (QMS)
- Ensure compliance with regulatory standards (e.g., ISO 13485, FDA QSR)
- Create and approve Standard Operating Procedures (SOPs)
- Conduct internal audits and support external/regulatory audits
- Manage document control and record retention
- Oversee training programs and employee competency records
- Review and approve design controls and validation activities
- Lead Corrective and Preventive Actions (CAPA)
- Perform risk management and process improvement activities
- Review nonconformances and quality metrics
- Handle supplier quality management and supplier audits
- Oversee change control and quality impact assessments

Key Skills

- Regulatory knowledge
- Documentation and auditing skills
- Risk analysis and problem-solving
- Strong attention to detail and communication

THE GREATEST ADVANTAGE OF SPEAKING THE TRUTH IS THAT YOU DON'T HAVE TO REMEMBER WHAT YOU SAID.

QUALITY CONTROL (QC)

Focus: Product-oriented and detective (checking quality after or during production)

Core Responsibilities

- **Inspect raw materials, in-process, and finished products**
- **Perform testing and measurements using approved methods**
- **Ensure products meet specifications and acceptance criteria**
- **Record inspection and test results accurately**
- **Identify, segregate, and report nonconforming products**
- **Support investigations into defects and quality issues**
- **Calibrate and maintain inspection and testing equipment**
- **Follow SOPs and work instructions precisely**
- **Assist with process validation and verification testing**
- **Prepare inspection reports and certificates of compliance**

Key Skills

- **Technical and analytical skills**
- **Knowledge of inspection tools and testing methods**
- **Ability to follow procedures precisely**
- **Attention to detail and accuracy**

DRUG APPROVAL & CLASSIFICATION TERMINOLOGY

These terms are commonly used in drug regulation and drug approval, especially in pharmaceutical sciences and regulatory affairs (e.g., CDSCO / Drugs & Cosmetics Rules in India). Explaining each category below:

1. Fixed Dose Combination (FDC)

A Fixed Dose Combination is a single pharmaceutical product containing two or more active pharmaceutical ingredients (APIs) in a fixed ratio, intended to be used together.

Key points:

- **APIs are combined in one dosage form (tablet, capsule, syrup, etc.)**
- **May improve patient compliance, therapeutic efficacy, or reduce resistance**
- **Requires justification of safety, efficacy, and rationale of combination**

Examples:

- **Paracetamol + Ibuprofen**
- **Amoxicillin + Clavulanic acid**
- **Rifampicin + Isoniazid + Pyrazinamide + Ethambutol**

2. Investigational New Drug (IND)

An Investigational New Drug is a new chemical or biological substance that is not yet approved for marketing and is under clinical investigation in humans.

Key points:

- Used only for clinical trials
- Requires regulatory permission before human studies
- Includes new drugs, new indications, new dosage forms, or new routes

Purpose:

- To assess safety, efficacy, pharmacokinetics, and pharmacodynamics

Phases involved:

- Phase I – Safety
- Phase II – Efficacy
- Phase III – Confirmation

DRUG APPROVAL & CLASSIFICATION TERMINOLOGY

3. New Drug

A New Drug is a drug that:

- Has not been approved previously in a country OR
- Has been approved but is proposed with:
  - New indication
  - New dosage form
  - New route of administration
  - New strength
  - New combination (FDC)

In India (as per Drugs & Cosmetics Rules):

A drug is considered “new” for 4 years from the date of first approval.

4. Subsequent New Drug

A Subsequent New Drug is a drug that contains the same active ingredient as an already approved new drug but differs in:

- Salt form
- Ester
- Isomer
- Dosage form
- Strength
- Route of administration

Key points:

- Approval is based on comparative data with the already approved new drug
- May require bioequivalence or bridging studies

QUICK COMPARISON TABLE

Term	Main Feature	Approval Status
FDC	Combination of ≥2 APIs	May be new or approved
IND	Drug under clinical trial	Not approved
New Drug	Newly approved or modified drug	Restricted period
Subsequent New Drug	Variant of approved new drug	Needs comparative data

REGULATORY HORIZONS 2026: TRENDS SHAPING GLOBAL PHARMA APPROVALS

Introduction

The global pharmaceutical landscape is evolving faster than ever. Regulatory agencies worldwide are introducing new frameworks, leveraging technology, and emphasizing patient-centric development. For regulatory professionals, staying ahead of these trends isn't just advantageous–it's essential. This article explores the key developments shaping the industry in 2026 and offers practical insights for consultancy teams guiding clients through complex regulatory pathways.

1. Accelerated Approvals and Adaptive Pathways

Regulators such as the FDA and EMA are increasingly using accelerated pathways to bring critical therapies to patients faster. Programs like the FDA's Breakthrough Therapy Designation and EMA's PRIME scheme focus on diseases with high unmet needs.
Practical Insight: Consultants must align client development strategies with these pathways early in the drug lifecycle. Mapping trial design, data collection, and submission timelines to regulatory expectations can significantly shorten time-to-market.

2. Harmonization Across Global Markets

While ICH guidelines remain the cornerstone of international regulatory alignment, regional nuances continue to grow, especially in Asia-Pacific, Latin America, and Africa. Understanding both global standards and local requirements is crucial for seamless product registration.
Practical Insight: Maintain a global-local checklist for dossier submissions, ensuring that client filings meet both ICH guidelines and region-specific regulations simultaneously.

3. Technology and Regulatory Intelligence

Digital tools are transforming regulatory operations. From AI-assisted document review to eCTD submission platforms and real-time regulatory intelligence dashboards, technology increases efficiency and reduces errors.
Practical Insight: Incorporate AI tools to automate repetitive compliance checks and track changes in global regulations, freeing teams to focus on strategic advisory.

4. Emphasis on Data Quality and Real-World Evidence (RWE)
Regulatory agencies are increasingly relying on robust data from clinical trials and real-world evidence to make informed decisions. This trend is particularly strong in oncology, rare diseases, and personalized medicine.
Practical Insight: Guide clients to build comprehensive data strategies that integrate clinical, post-market, and RWE data for stronger submissions.

5. Sustainability and Ethical Considerations

Sustainability and ethical sourcing are now part of regulatory evaluations in many regions. Agencies are asking more questions about environmental impact, patient safety, and ethical clinical practices.
Practical Insight: Advising clients on compliance with these evolving expectations can enhance their reputation and minimize regulatory hurdles.

Conclusion

The next few years will be defined by agility, technological adoption, and strategic alignment across global regulatory landscapes. For consultancy teams, the opportunity lies in anticipating changes, integrating technology, and guiding clients proactively. Staying informed and adaptable ensures that our clients not only comply but thrive in a dynamic pharmaceutical environment.

THE EMPTY CHAIR

On the first day after a major restructuring, employees walked into the office and noticed something unusual: an empty chair placed in the middle of the conference room. No name tag. No explanation.

Whispers spread quickly.

"Is someone leaving?"

"Is this a warning?"

"Is it symbolic?"

At the weekly town hall, the MD began without addressing the chair. He spoke about market changes, tight deadlines, and rising expectations. Then he paused and finally pointed to the empty chair.

"That chair," he said, "belongs to the future version of our company."

He explained:

"This chair represents the role we haven't grown into yet, the idea we haven't tried, the solution we haven't built, and the customer we haven't fully understood. It's empty not because something is missing—but because it's waiting to be filled."

He continued,

"No strategy, technology, or policy can sit in that chair. Only people can. Every time you take ownership instead of waiting for instructions, you move closer to that chair. Every time you collaborate instead of competing, learn instead of resisting, and act instead of delaying—you earn your place in it."

Over the next few months, something changed.

- Teams stopped saying, "That's not my job."
- Employees began asking, "What else can we improve?"
- Mistakes were treated as lessons, not failures.

The empty chair remained—but it no longer felt empty. It became a reminder that growth is not assigned; it is claimed.

At the end of the year, during the final town hall, the MD announced,

"We're removing the chair."

Someone asked, "Why?"

He smiled and said,

"Because it's no longer empty. You filled it—together."

THE EMPTY CHAIR

Message for Employees thru above story.

Growth doesn't come from titles, promotions, or perfect conditions.
It comes from initiative, adaptability, and belief in collective effort.

The future of an organization is not built someday.
It's built every day–by people who choose to step into it.

In a day, when you don't come across any problems – you can be sure that you are traveling in a wrong path - Swami Vivekananda.

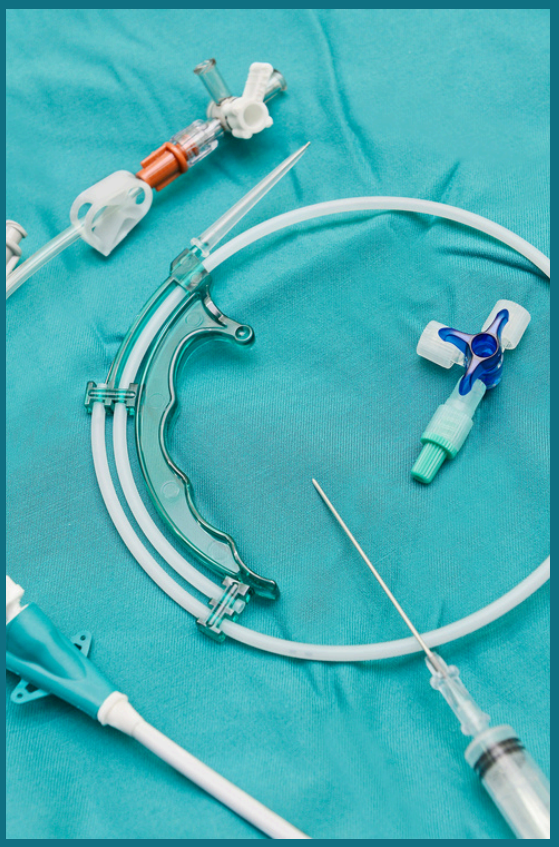
QUIZ – MEDICAL DEVICES (ANSWERS IN THE COMING PAGES)

1. Which catheter is commonly used for long-term urinary drainage?
2. A suprapubic catheter is inserted through the ...
3. Which device is used to break kidney stones non-surgically?
4. A cystoscope is used to examine the:
5. Which catheter has a balloon to keep it in place?
6. Which device acts as an artificial kidney in hemodialysis?
7. Which access is preferred for long-term hemodialysis?
8. Which device records the electrical activity of the heart?
9. A pacemaker is used to:
10. Which device delivers an electric shock to restore normal heart rhythm?

THE MOST EXPENSIVE THING IN THE WORLD IS TRUST. IT CAN TAKE YEARS TO EARN BUT JUST A MATTER OF SECONDS TO LOSE.

ANSWERS TO QUIZ :

i. Foley catheter
ii. Abdominal wall
iii. Lithotripter
iv. Bladder
v. Foley catheter
vi. Dialyzer
vii. Arteriovenous fistula
viii. ECG machine
ix. Regulate heart rhythm
x. Defibrillator



THE BEST WAY TO GET STARTED IS TO QUIT TALKING AND BEGIN DOING." - WALT DISNEY.

- CDSCO issued a public notice on 2nd January 2026 on Risk classification list of medical devices pertaining to Oncology.
- CDSCO issued a public notice on 1st January 2026 on SoP - Compounding of Offences Rules, 2025.
- CDSCO issued a public notice on 1st January 2026 on FAQs on Drugs and Cosmetics (Compounding of Offences) Rules, 2025.
- CDSCO issued a public notice on 1st January 2026 on Compounding of Offences under the Drugs and Cosmetics Act, 1940 in accordance with the Drugs and Cosmetics (Compounding of Offences) Rules, 2025.
- CDSCO issued a public notice on 1st January 2026 on Guidelines on Compounding of Offences under the Drugs and Cosmetics Act, 1940 as per Drugs and Cosmetics (Compounding of Offences) Rules, 2025.
- CDSCO issued a public notice on 16th January 2026 regarding disposal/rejection of long pending applications on SUGAM portal.
- CDSCO issued a public notice on 19th January 2026 with updated list of laboratories for conducting performance test of IVDs.

SUCCESS SEEMS TO BE CONNECTED WITH ACTION. SUCCESSFUL PEOPLE KEEP MOVING. THEY MAKE MISTAKES, BUT THEY DON'T QUIT." – CONRAD HILTON

THE BROKEN CUP

An employee once visited a senior mentor in the organisation to discuss a mistake she had made.

On the mentor's desk sat a plain ceramic cup filled with tea. As they talked, the mentor accidentally knocked the cup off the table. It fell to the floor and shattered.

The employee gasped.

"I'm so sorry!" she said quickly. "That was careless."

The mentor smiled and replied,

"It was already broken."

The employee looked confused.

The mentor continued,

"From the moment this cup was made, it was destined to break—today, tomorrow, or years from now. Because I understood that, I could enjoy using it fully. And when it broke, I didn't lose my peace."

Seeing her puzzled expression, the mentor added,

"In work and in life, projects fail, plans change, and mistakes happen. When we cling to the idea that things must stay perfect, we suffer twice—once from the event, and once from our resistance to it."

The employee thought for a moment and then smiled.

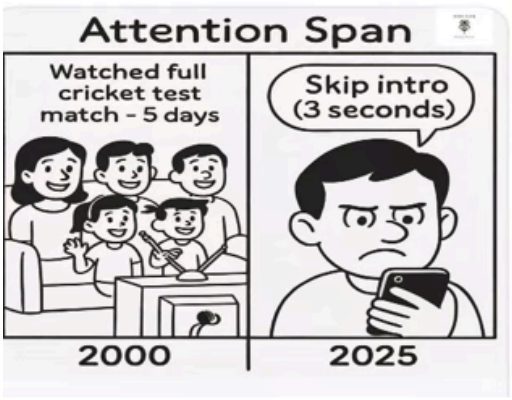
"So the lesson is not to be careless—but not to be afraid of outcomes?"

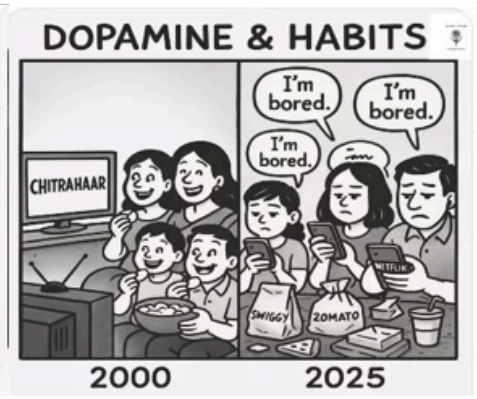
The mentor nodded.

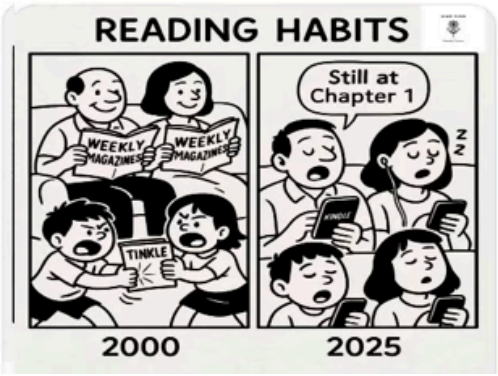
"Exactly. We take responsibility, learn, and move forward—without carrying unnecessary weight."

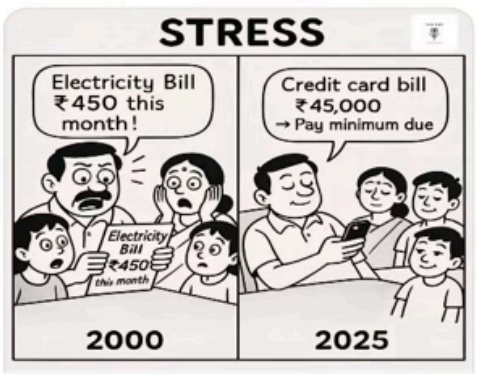
Reflection

- Mistakes are part of progress, not the end of it.
- Holding on to blame or regret costs more energy than learning and improving.
- When we accept change calmly, we respond better and lead more clearly.









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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