Accredited Consultants Pvt. Ltd.

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ACPL TIMES

A MONTHLY INTERNAL NEWSLETTER OF ACPL

CS Prasad

Managing Director

Dear Team,

As you are aware, the current geo-political and global economic situation continues to create uncertainty across industries and markets. In view of these evolving challenges, it is important for us as an organization to remain prudent, agile, and financially disciplined.

While our business operations continue steadily, it is equally important to recognize that we are not a cash-surplus organization. Therefore, thoughtful and careful financial management and responsible spending are essential to maintaining operational stability and ensuring long-term sustainability.

Effective immediately, we request all departments and employees to exercise strict control over discretionary and non-essential expenses.

The following measures are to be observed across the organization:

- Avoid unnecessary travel and prioritize virtual meetings wherever possible.
- Optimize usage of utilities, office resources, and consumables.
- Postpone or reassess non-critical purchases and expenditures.
- Ensure all expenses are business-critical, justified, and appropriately approved.
- Encourage cost-conscious practices in day-to-day operations.

We also encourage all employees to adopt a similar approach of financial prudence and responsible expense management in their personal lives during these uncertain times. Thoughtful planning and disciplined spending at both professional and personal levels will help us collectively navigate the present situation more effectively.

These measures are preventive and proactive in nature, aimed at safeguarding the organization's resilience during uncertain times. Your cooperation, understanding, and commitment are essential in helping us navigate this situation responsibly.

I sincerely appreciate your continued dedication, professionalism, and support. Together, I am confident that we will overcome these challenges and emerge stronger.

Let us continue to work with unity, discipline, and a shared sense of responsibility.

With regards
CS Prasad

KNOWLEDGE CENTRE

eCTD Lifecycle Management

A Comprehensive Overview

1. Introduction

The Electronic Common Technical Document (eCTD) is a globally accepted standard for submitting regulatory information for pharmaceuticals and biologics to health authorities such as the US FDA, EMA, and others. It was developed by the International Council for Harmonisation (ICH) to replace paper-based submissions and streamline regulatory review processes.

Unlike traditional submissions, eCTD is not a one-time activity. It represents a dynamic, continuously evolving dossier, where updates are made throughout the entire lifecycle of a medicinal product. This ongoing process is known as eCTD lifecycle management.

2. Definition of eCTD Lifecycle Management

eCTD lifecycle management refers to the systematic process of creating, updating, maintaining, and submitting regulatory dossiers throughout a product's lifecycle, from initial application to post-approval changes and eventual withdrawal.

It ensures that:

- Regulatory information remains current and compliant
- Historical records are traceable and preserved
- Updates integrate seamlessly with previous submissions

In essence, it transforms regulatory submission from a static event into a continuous regulatory strategy.

3. Evolution from CTD to eCTD

The Common Technical Document (CTD) was introduced to harmonize regulatory submissions across regions. However, CTD lacked the ability to efficiently handle lifecycle updates.

The eCTD addressed this by introducing:

- XML backbone structure
- Metadata-driven document management
- Hyperlinked PDFs
- Lifecycle operators (New, Replace, Delete, Append)

This evolution enables regulators to view the current state of the dossier while retaining full history, improving efficiency and transparency.

KNOWLEDGE CENTRE

eCTD Lifecycle Management

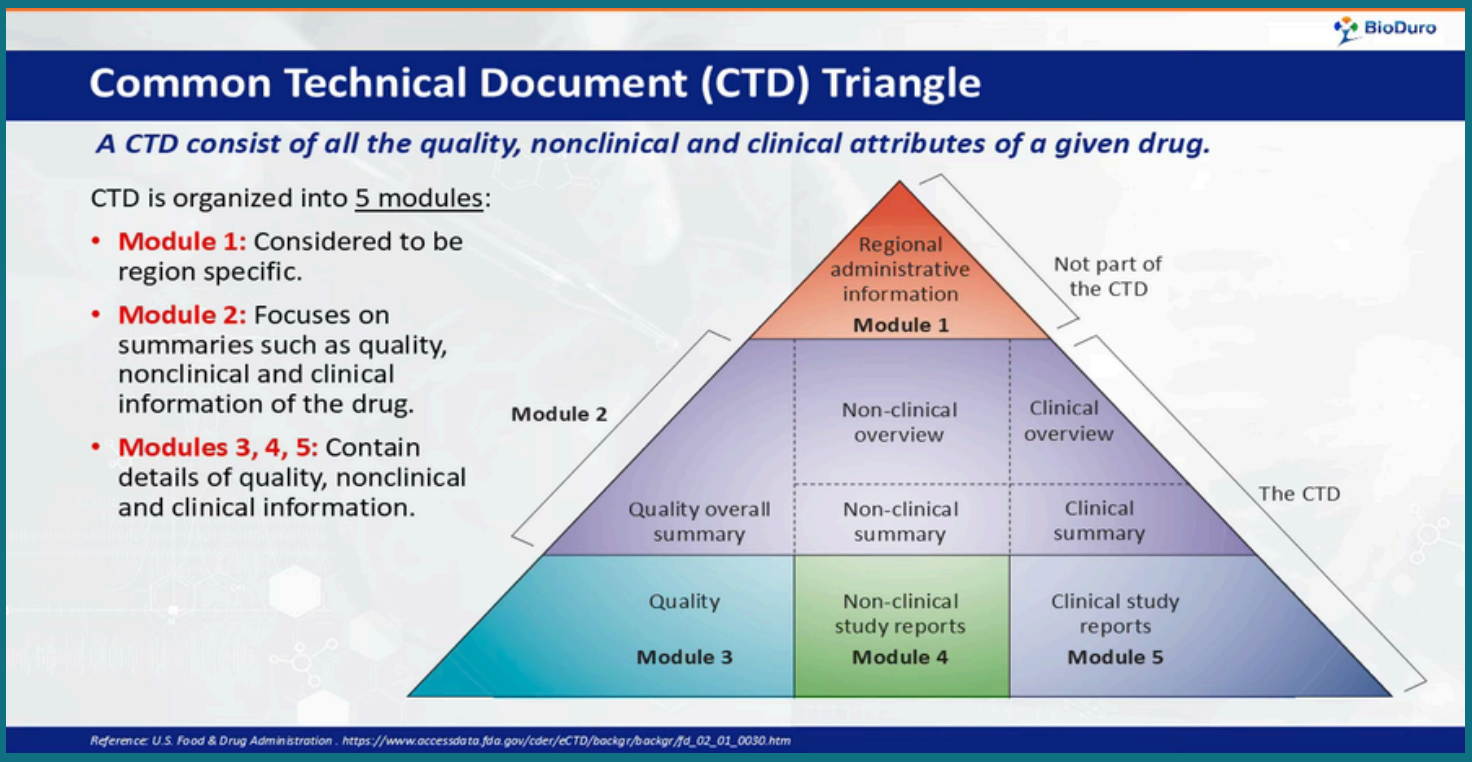
A Comprehensive Overview

4. Structure of eCTD

An eCTD submission consists of five modules:

1. Module 1 – Regional administrative information
2. Module 2 – Summaries and overviews
3. Module 3 – Quality (CMC) data
4. Module 4 – Non-clinical study reports
5. Module 5 – Clinical study reports

This modular structure allows updates to be made without resubmitting the entire dossier, which is essential for lifecycle management.



5. Key Components of Lifecycle Management

5.1 Sequence Management

- Each submission is assigned a sequence number (e.g., 0000, 0001, 0002)
- Sequences build cumulatively over time
- They form a regulatory history chain of the product

5.2 Lifecycle Operators

Documents are managed using standardized operations:

- New – Add new document
- Replace – Update existing document
- Delete – Remove outdated document
- Append – Add supplementary information

5.4 Metadata and Backbone

- XML backbone organizes content
- Metadata enables searchability and traceability

6. Lifecycle Phases

6.1 Pre-submission Phase

- Regulatory strategy planning
- Gap analysis
- Document preparation

6.2 Initial Submission

- Compilation of complete dossier
- Technical validation and publishing
- Submission to health authorities

6.3 Review Phase

- Handling queries and deficiency letters
- Submitting responses as new sequences

6.4 Post-Approval Lifecycle

- Variations (CMC changes, labeling updates)
- Periodic safety updates
- Renewals and maintenance

6.5 Product Retirement

- Withdrawal or discontinuation submissions

7. Importance of eCTD Lifecycle Management

Effective lifecycle management is critical because:

7.1 Regulatory Compliance

Authorities require continuous updates, not just initial approval.

7.2 Data Integrity and Traceability

Maintains a complete audit trail of all submissions

7.3 Efficiency

Avoids duplication and reduces workload through structured updates

7.4 Faster Approvals

Well-managed dossiers reduce technical rejection risks

7.5 Global Harmonization

Supports submissions across multiple regulatory regions

8. Challenges in eCTD Lifecycle Management

Despite its advantages, lifecycle management presents several challenges:

8.1 Technical Complexity

- XML backbone handling
- Hyperlinking and validation requirements

8.2 Regulatory Variability - Different requirements across regions

8.3 Version Control Issues - Managing multiple sequences over time

8.4 Resource Intensiveness - Requires specialized tools and expertise

8.5 Risk of Submission Errors - Even minor issues (e.g., broken links, incorrect metadata) can lead to rejection or delays.

9. Tools and Technologies

Modern lifecycle management relies on:

- eCTD publishing software
- Document management systems (DMS)
- Regulatory information management systems (RIMS)
- Validation tools

These technologies ensure:

- Compliance with regulatory standards
- Efficient document tracking
- Automated lifecycle operations

10. Best Practices

To ensure effective lifecycle management:

- Maintain consistent document naming conventions
- Ensure accurate metadata tagging
- Perform rigorous validation checks
- Implement centralized document repositories
- Train teams on evolving regulatory requirements
- Plan lifecycle strategy early

KNOWLEDGE CENTRE

eCTD Lifecycle Management

A Comprehensive Overview

11. Future Trends: eCTD v4.0

The next evolution, eCTD v4.0, introduces:

- HL7-based structured data exchange
- Improved data reuse
- Enhanced lifecycle tracking
- Greater automation

Regulatory agencies are gradually adopting this version, signaling a shift toward data-driven submissions.

12. Conclusion

eCTD lifecycle management is a critical component of modern regulatory affairs, transforming how pharmaceutical companies manage submissions. It ensures that regulatory dossiers remain accurate, compliant, and up-to-date throughout a product's lifecycle.

With increasing global harmonization and the transition to eCTD v4.0, lifecycle management is evolving into a strategic, technology-driven discipline, requiring both regulatory expertise and advanced digital tools.

LUCKY MEANS, WHO GET THE OPPORTUNITY, BRILLIANT MEANS, WHO CREATE THE OPPORTUNITY, WINNER MEANS, WHO USES THE OPPORTUNITY.

FUTURE OF HEALTHCARE INDUSTRY IN INDIA (2025-2035)

In Pharmaceutical Regulatory Affairs (India), especially for submissions to the Central Drugs Standard Control Organization (CDSCO) using CTD/eCTD format, deficiency letters are very common. Most are not due to poor science, but due to gaps in documentation quality, consistency, and regulatory compliance. Here's a structured overview of common deficiencies observed in dossiers in India, aligned with CTD modules and practical regulatory experience:

1. Administrative (Module 1) Deficiencies

These are among the most frequent causes of rejection before review starts.

Typical issues:

- Missing or incorrect application forms (e.g., Form 44)
- Incomplete fee payment or wrong challan details
- Mismatch in:
  - Product name, strength, dosage form across documents
  - Manufacturer/MAH address inconsistencies
- Expired legal documents (Power of Attorney, GMP certificates)
- Missing/not properly notarized or apostilled documents
- Labeling/artwork not aligned with dossier

Even small inconsistencies can lead to technical rejection without scientific review

2. Quality (CMC – Module 3) Deficiencies

This is the most critical and heavily scrutinized section.

A. Stability-related issues

- Lack of Zone IVb (30°C/75% RH) stability data (mandatory for India)
- Inadequate long-term data or ongoing studies
- Improper shelf-life justification (weak statistical analysis)
- Missing:
  - Photostability studies
  - In-use stability data

A very common CDSCO objection is incomplete climatic zone data

FUTURE OF HEALTHCARE INDUSTRY IN INDIA (2025-2035)

B. Specifications & Analytical Methods

- Incomplete or unjustified specifications
- Missing method validation summaries
- Lack of impurity profiling / degradation data
- No linkage between specifications and clinical relevance

C. Manufacturing & Process

- Inadequate process validation data
- Incomplete batch analysis (fewer batches submitted)
- Missing details of:
  - Critical process parameters (CPPs)
  - Critical quality attributes (CQAs)

D. Packaging & Container Closure

- Missing extractables/leachables (E&L) data
- No container closure integrity (CCI) justification
- Lack of compatibility studies

3. Bioequivalence (BE) / Clinical Deficiencies (Module 5)

Common gaps:

- Improper selection of reference product (not Indian innovator)
- Missing comparator justification or procurement details
- Statistical issues:
  - No clarity on TOST method
  - Improper handling of outliers
- Incomplete bioanalytical method validation
- Missing ethical approvals / GCP compliance evidence

Regulators often question traceability and statistical transparency

4. Non-Clinical (Module 4) Deficiencies

(Not always required for generics, but applicable in some cases)

- Missing toxicity studies (acute/repeat dose)
- Lack of justification for waivers
- Poor literature summaries without critical evaluation

FUTURE OF HEALTHCARE INDUSTRY IN INDIA (2025-2035)

5. eCTD / Publishing Deficiencies

Increasingly important in India.

Common issues:

- Non-searchable PDFs (scanned documents)
- Missing bookmarks or incorrect hierarchy
- Broken hyperlinks between modules
- Incorrect file naming / XML backbone errors

These can lead to technical validation failure before review

6. Data Integrity & Documentation Issues

Often linked to both dossiers and inspections:

- Inconsistent data across modules
- Missing raw data or audit trails
- Manipulated or backdated data (serious compliance risk)
- Poor documentation practices

Data integrity is a major focus area for CDSCO inspections

7. Labeling & SmPC/PI Deficiencies

- Label claims not supported by data
- Storage conditions not aligned with stability results
- Missing warnings/precautions
- Mismatch between carton, leaflet, and dossier

8. General Cross-cutting Deficiencies

Across all modules:

- Lack of consistency across dossier sections
- Poor justification/rationale for decisions
- Missing hyperlinks and traceability
- Incomplete responses to previous queries
- Poor dossier organization (hard to review)

Many deficiencies arise from “discoverability issues” rather than science gaps

DREAMS BECOME REALITY WHEN THOUGHTS BECOME ACTION.

THE ART OF LETTING GO

A man once said to the Buddha, “I want happiness.” The Buddha replied, “First remove ‘I,’ that is ego. Then remove ‘want,’ that is desire. See, now you are left with only happiness.”

I have always liked this quote, even though there is no credible evidence that the Buddha ever said it. It floats around the internet, unattributed and unverified, yet something about it feels true, not in a historical sense but in spirit. It captures the essence of Buddhist thought: how attachment creates suffering, how ego clouds perception, and how desire keeps us endlessly reaching for what we already have within us. Whether or not these were the Buddha’s words, they point to a universal truth that happiness is not something we chase or manufacture, but something revealed when we begin to let go. And that idea, more than any verified scripture, feels worth sitting with.

We spend our lives chasing happiness. We climb ladders, buy things we do not need, and scroll through curated lives on glowing screens. Yet the more we reach, the further it seems to drift. We think of happiness as a thing to be achieved, like a promotion or a purchase, rather than something that quietly remains once we stop grasping.

This quote, whether legend or lesson, endures because it distills something timeless: our suffering is not caused by what we lack, but by the mind that insists we are incomplete without it. The Stoics, though separated from Buddhism by centuries and continents, reached the same conclusion. “ “We suffer more in imagination than in reality.” That single line bridges centuries of thought, connecting Stoic clarity with the insight attributed to Buddha. Both point to the same root: the mind’s tendency to cling, to project, to demand.

We are rarely disturbed by events themselves, but by the stories we build around them. A delayed message becomes rejection. A small failure becomes a lifelong verdict. A desire, once formed, grows teeth–it tells us we cannot be at peace until it is fulfilled. And so we wait. And chase. And postpone our contentment.

The Stoics argued that peace comes not from controlling the world, but from understanding what lies within our control. Our thoughts, our responses, our judgments–these are ours. Everything else is borrowed, temporary, and uncertain. When we confuse the two, suffering follows.

Letting go, then, is an act of clarity. It is recognizing that not every thought deserves belief, not every desire deserves pursuit, and not every emotion demands reaction. It is the discipline of stepping back and asking: Is this within my control? Is this essential?

THE ART OF LETTING GO

When we remove ego, we stop taking everything personally. Criticism becomes information, not an attack. When we remove compulsive desire, we stop treating every want as a need. We begin to see that much of what we chase adds little to our actual well-being.

What remains is not emptiness, but space. Space to think clearly. Space to respond instead of react. Space to experience life without the constant pressure to improve or possess it.

This does not mean life becomes perfect. Challenges remain. Loss still hurts. Uncertainty does not disappear. But the relationship to these experiences changes. There is less resistance, and therefore less suffering layered on top of what is already there.

In a way, happiness stops being a goal and becomes a byproduct—something that arises naturally when we are no longer at war with reality.

That is the quiet wisdom hidden in the quote you began with. Whether or not it was ever spoken by the Buddha does not diminish its value. Because its truth is not in its authorship, but in its application.

The art of letting go is not about losing something important. It is about releasing what was never truly serving us—ego that isolates, desire that agitates, and thoughts that distort.

And when those fall away, even briefly, what remains is simple, steady, and enough.

DREAMS BECOME REALITY WHEN THOUGHTS BECOME ACTION.

QUIZ ON CDSCO OPERATIONS

(Answers in the subsequent pages)

1. What is the apex advisory body to CDSCO on technical matters?
2. Which committee advises on amendments to drug rules and regulations?
3. Who chairs the Drugs Technical Advisory Board (DTAB)?
4. Which CDSCO committee evaluates new drugs before approval?
5. What was the earlier name of Subject Expert Committee (SEC)?
6. Which committee reviews serious adverse events (SAEs) in clinical trials?
7. Which body gives final approval for new drugs in India?
8. Which committee ensures coordination between central and state drug authorities?
9. Which committee deals with classification of drugs and regulatory policy issues?
10. Which CDSCO committee is involved in reviewing clinical trial protocols?

SPOTLIGHT ON MEDTECH DEVICES PRODUCTS

Hemodialysis Catheters & Related Devices

1. Long-Term (Chronic) Dialysis Catheter - Provides long-term vascular access for repeated hemodialysis.

Usage:

- Inserted into central veins (e.g., internal jugular vein)
- Used in patients with chronic kidney failure
- Often tunneled under the skin to reduce infection risk

2. Single Lumen Hemodialysis Catheter - Has one channel for either blood removal or return.

Usage:

- Rarely used alone for dialysis (since dialysis needs two flows)
- More common for temporary or special situations

3. Double Lumen Hemodialysis Catheter - Two lumens: One removes blood , One returns filtered blood

Usage:

- Standard catheter for hemodialysis
- Used in acute or chronic renal failure

4. Triple Lumen Hemodialysis Catheter: Three channels:Two for dialysis , One for medications or fluids

Usage: ICU patients needing dialysis + drug administration simultaneously

5. Single Lumen Femoral Catheter (Premium)- Provides vascular access via femoral vein.

Usage:

- Emergency or short-term dialysis
- Used when upper body access is not feasible

6. Hemodialysis Catheter Kits (Double/Triple Lumen)- Complete set for catheter insertion. Includes Catheter, Guidewire, Needle & Dilator.

Usage: Used during sterile catheter insertion procedures

SPOTLIGHT ON MEDTECH DEVICES PRODUCTS

Guidewires & Insertion Tools

7. Dialysis Guidewire - Guides catheter placement into blood vessels.

Usage:

- Inserted first into vein
- Catheter is passed over it (Seldinger technique)

8. Nitinol Guidewire (Care Wire) - Flexible, kink-resistant wire made of nitinol alloy.

Usage: Used when navigating complex vascular paths

9. SS (Stainless Steel) Guidewire - Provides strong support for catheter insertion.

Usage: Used when more rigidity is needed

10. Introducer Needle (Standard/Premium)- Initial needle used to access the vein.

Usage: First step in catheter insertion

11. Y-Shape Introducer Needle - Allows dual access or guidewire manipulation.

Usage: Used in advanced or multi-wire techniques

Dialysis Needles & Accessories

12. AV Fistula Needle - Used to access arteriovenous fistula.

Usage:

- One needle draws blood
- One returns blood during dialysis

13. Hand Control Pencil / With Cleaner - Controls flow or assists in procedural handling (varies by system).

Usage: Used by clinicians during dialysis setup or intervention

14. Dressing Kit (ON/OFF Kit)- Used for catheter site care.

Usage:

- Cleaning and dressing insertion site
- Preventing infection

15. Transducer Protector - Prevents contamination of dialysis machine pressure sensors.

Usage: Placed between patient line and machine

WHEN FEAR LEAVES, GROWTH BEGINS.

One day, the wife casually said,
“Listen, I’m going out for a while with my friend.”
Her husband, who was looking at his phone, simply glanced up and said,
“Okay. Have fun.”
She was a bit surprised. Usually, he would say things like, Is it necessary? Do you really have to go? Don’t be late. But that day—nothing. No sigh, no questions—just a calm, “Okay.”
A few hours later, their teenage son came into the kitchen. He held a paper in his hand, his face pale.
“Dad,” he said softly, “my mock exam results are out… and they’re very bad.”
He stood frozen, expecting to be scolded as usual. His father always worried about his studies, so he braced himself for lectures about wasting time and not living up to his potential.
But instead, his father calmly said,
“Okay.”
The son, wide-eyed, asked, “Just… okay?”
“Yes,” he said gently.
“If you study more, you’ll do better next time. If you don’t, you may have to repeat the semester. Your choice. I’ll support you in either situation.”
The boy was stunned. Since when had his father become this calm?
The next afternoon, their daughter walked in nervously. She hesitated in the hall and said,
“Dad… I… I hit the car. It’s not very big, but there’s a dent.”
The father didn’t shout, didn’t get angry. He simply said,
“Okay. Take the car to the workshop tomorrow.”
The daughter froze. “You’re… not angry?”
He smiled softly.
“No. Getting angry won’t fix the car. Just be careful next time.”
Now everyone in the house was worried. This man—the same husband, the same father—was no longer the way he used to be. He had always been short-tempered, easily stressed, quick to react. Now he seemed calm, steady, almost peaceful.

WHEN FEAR LEAVES, GROWTH BEGINS.

They began whispering among themselves–Is something wrong? Is he unwell? Did something happen?
Finally, that evening, they all sat him down at the kitchen table.
“Listen,” the wife said,
“You’ve changed a lot lately. No matter what happens, you don’t get angry or react. Is everything okay?”
He looked at their faces and smiled.
“Nothing is wrong,” he said. “Everything is perfectly fine. I’ve just understood one thing.”
They all fell silent.
“After many years,” he said, “I realized that every person is responsible for their own life.”
The wife raised her eyebrows.
“What do you mean?”
He folded his hands and said,
“Earlier, I used to worry about everything–if you were late, I worried; if the kids scored low, I felt guilty; if something broke, I got angry; if someone was upset, I tried to fix it. I treated everyone’s problems as my own. But one day I realized–my worrying doesn’t solve their problems. It only destroys my peace.”

The daughter listened quietly.
He continued,
“My stress doesn’t help you. My struggle doesn’t make your life easier–it only makes mine harder. I can give you advice, love, and support. But I cannot live your life for you. The consequences of your decisions–good or bad–are yours to face.”
He paused for a moment and smiled again.
“So I decided–I will stop trying to control what is not in my control.”
The son leaned forward and asked,
“So… you don’t care about us anymore?”
He replied,
“Of course I care. But there’s a difference between caring and controlling. I can love you, provide for you–but not at the cost of losing my peace.”
Silence filled the room.

WHEN FEAR LEAVES, GROWTH BEGINS.

Looking at all three of them with affection, he said,
“My role is to love you, guide you, provide what you need, and stand by you when required. But your role is to handle your own lives. To make decisions. To face their consequences. That’s how everyone grows.”
He added calmly,
“So now, when something goes wrong, I remind myself—this is not mine to fix. I will stay calm and trust that you will learn from it. Because that’s how life is—it teaches lessons.”
For a while, the house was completely silent. But something had changed in the atmosphere.
The wife held his hand and said,
“Today, you’ve taught all of us something.”
He smiled.
“Maybe. But I had to learn it myself first.”
That night, everyone reflected on his words.

The son sat down to study again—not because his father scolded him, but because he realized the responsibility was his.
The daughter took charge of getting the car repaired and understood the insurance process.
The wife began managing things at home more mindfully—not because she was forced to, but because she wanted to.
And slowly, the home began to feel lighter.
No one acted out of fear anymore, but out of understanding. No one felt suppressed by the fear of being scolded.
Because when even one person in a home chooses peace, it begins to spread to everyone.
When one person lets go of control, others learn to control themselves.
And in this way—peace spreads, just like love.
Don’t try to control others through anger, pressure, or authority.
Instead, act responsibly yourself and help others realize their own responsibility.
See if this resonates with you. 🙏

WATER BREAKS ROCK NOT BECAUSE OF ITS STRENGTH, BUT BECAUSE OF ITS CONSISTENCY. BE LIKE WATER, DON’T GIVE UP.

THE STRAIT OF HORMUZ

The Strait of Hormuz occupies a uniquely critical position in global geopolitics, particularly during periods of heightened tension in West Asia. Linking the oil-rich Persian Gulf to international markets, this narrow maritime corridor serves as a lifeline for global energy supplies, with a significant share of the world's petroleum shipments passing through it each day.

Bordered by Iran and Oman, the strait lies at the center of regional rivalries and strategic calculations. In times of conflict or diplomatic strain, its vulnerability to disruption transforms it into a powerful geopolitical tool, capable of influencing global oil prices and economic stability. As a result, the Strait of Hormuz is not merely a geographic passage, but a focal point where regional tensions intersect with global interests, making its security and stability a matter of international concern.

Why the Strait of Hormuz Matters ?

1. Global Energy Lifeline

- Roughly 20–25% of the world's oil supply passes through this narrow passage.
- Major oil producers like Saudi Arabia, Iran, Iraq, Kuwait, and United Arab Emirates depend on it to export crude oil.

2. Narrow but Vital Passage

- At its narrowest, it is about 33 km wide, with shipping lanes only a few kilometers across.
- This makes it highly vulnerable to blockades, attacks, or military disruptions.

Relevance During West Asia Tensions

1. Iran's Strategic Leverage

- Iran controls the northern coast of the strait and has repeatedly threatened to close or disrupt it during conflicts or sanctions (e.g., tensions with the US).
- Even the threat of closure can spike global oil prices.

2. Impact on Global Economy

- Any disruption leads to:
  - Surge in oil prices
  - Inflation worldwide
  - Supply chain instability
- Countries heavily dependent on oil imports, like India, are especially vulnerable.

THE STRAIT OF HORMUZ

3. Military Significance

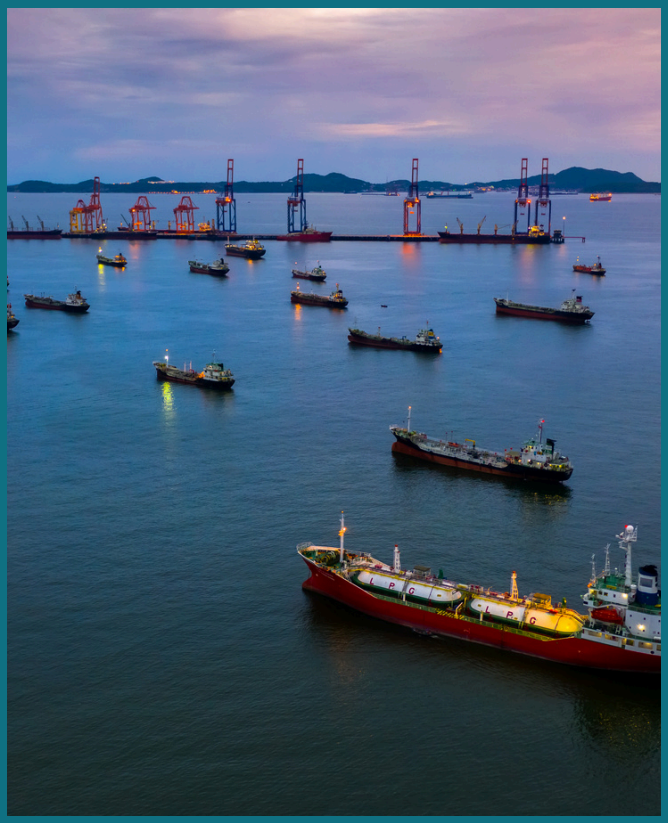
- Presence of major naval forces, especially the United States Navy, to ensure freedom of navigation.
- Frequent patrols, surveillance, and occasional confrontations increase the risk of escalation.

4. Insurance & Shipping Risks

- During crises, shipping insurance costs skyrocket.
- Some vessels reroute or halt, reducing supply flow even without an official blockade.

Real-World Context

- During US-Iran tensions (especially after the US withdrawal from the Iran nuclear deal), attacks on oil tankers and seizures of ships occurred near the strait.
- Events like the Tanker attacks in the Gulf of Oman highlighted how fragile the situation can be.



Why It Still Matters Today

- Rising tensions involving Iran, Israel, and Gulf countries keep the region volatile.
- The Strait remains:
  - A pressure point in global diplomacy
  - A trigger for energy crises
  - A focus of military strategy

The Strait of Hormuz is not just a geographic feature–it's a global economic artery and geopolitical flashpoint. During West Asian tensions, control or disruption of this narrow waterway can have immediate worldwide consequences, especially for energy security and international trade.

LIGHT DOES NOT ARGUE WITH DARKNESS. IT SIMPLY SHINES.

LAUGH IT OUT

ON A LIGHTER NOTE !

1. Guitar, for sale. Cheap... No strings attached !
2. **Ad In Hospital Waiting Room**: Smoking Helps You Lose Weight. One Lung At A Time !
3. **On a bulletin board**: Success Is Relative. The more The Success, The more The Relatives !
4. When I Read About The Evils Of Drinking. I Gave Up Reading !
5. My Grandfather Is Eighty And Still Doesn't Need Glasses. He Drinks Straight Out Of The Bottle !
6. **You Know Your kids Have Grown Up When**: Your Daughter Begins To Put On Lipstick. Or when your Son starts To wipe It Off !
7. **Sign In A Bar:** 'Those Of You Who Are Drinking To Forget. Please Pay In Advance' !
8. **Sign In Driving School**: If Your Wife Wants To Learn To Drive, Don't Stand In Her Way !
9. **Sign At A Barber's Saloon in Houston** : We Need Your Heads To Run Our Business
10. **Sign In A Restaurant:** All drinking water in this establishment has been personally passed by the management 🤣🤣

LUXURY AND LIES HAVE HUGE MAINTENANCE COSTS, BUT TRUTH AND SIMPLICITY ARE SELF MAINTAINED WITHOUT ANY COST.

AUDIT VISIT OF THE YEMEN TEAM

SNAPSHOT FROM THE AUDIT VISIT OF THE YEMEN TEAM TO OUR MEDTECH DEVICES MANUFACTURING FACILITY IN OKHLA ON 19TH MAY 2026."

- CDSCO Circular on 12th May 2026 on Appointment of CPIO for the purpose of RTI(Technical) Matters.
- CDSCO Circular on 4th May 2026 on Disposal/Rejection of Long Pending Applications on SUGAM Portal Awaiting Query Response
- CDSCO issued a Gazatte Notification on 13th May 2026 on amendment in Schedule H1 for inclusion of Pregabalin and its drugs formulations.
- CDSCO issued a public notice on 18th May 2026 on strengthening enforcement against unauthorized promotion and distribution of GLP-1 based Drugs.
- CDSCO issued a public notice on 19th May 2026 on Cosmetics
- CDSCO issued a public notice on 22nd May 2026 on BE-NOC Prior Intimation and procedure for CT-16 application on NSWS Portal.

DON'T STRUGGLE TO MAKE YOUR PRESENCE NOTICED. JUST MAKE YOUR ABSENCE FELT.

ANSWERS OF THE PHARMA QUIZ

1. Drugs Technical Advisory Board (DTAB)
2. Drugs Consultative Committee (DCC)
3. Director General of Health Services (DGHS)
4. Subject Expert Committee (SEC), earlier called NDAC
5. New Drug Advisory Committee (NDAC)
6. Expert Committee for SAE analysis (under CDSCO)
7. Drug Controller General of India (DCGI)
8. Drugs Consultative Committee (DCC)
9. Drugs Technical Advisory Board (DTAB)
10. Subject Expert Committee (SEC)

BE SURE YOU PUT YOUR FEET IN THE RIGHT PLACE, THEN STAND FIRM." ABRAHAM LINCOLN

THANK YOU FOR READING

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