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ACPL TIMES

A MONTHLY INTERNAL NEWSLETTER OF ACPL



CS Prasad (MD)

Dear Colleagues,

We are living in an exciting era where technology is reshaping the way we design, manufacture, and deliver medical devices. Among these technologies, Artificial Intelligence (AI) stands out as a transformative force – not just globally, but right here in India, in our own company.

AI is no longer a distant concept or a futuristic idea. It is already enhancing how we innovate, how we maintain quality, and how we meet the growing needs of healthcare across the country. From smart design and faster prototyping to predictive maintenance in our production lines, AI is helping us work smarter, reduce errors, and deliver life-saving devices faster.

What makes this journey truly remarkable is our people. Each of you, in your roles, is a vital part of this transformation. AI does not replace human expertise – it augments it. It gives us the tools to make better decisions, be more creative, and focus on innovation that truly matters. Whether it's optimizing our production processes, ensuring impeccable quality, or reaching patients more efficiently, every contribution you make becomes more powerful with AI.

India's medical device industry is growing rapidly, and with AI, we have a chance to lead, not just participate. We are building systems that are not only efficient and precise but also intelligent, adaptable, and ready for the future. And this future is a collective effort – a collaboration of technology, talent, and vision.

As we embrace AI, I encourage each of you to explore, learn, and innovate. Think of how your daily work can leverage these tools to create better outcomes, improve processes, and enhance patient care. Together, we are setting new benchmarks in Indian healthcare – making devices that are safer, smarter, and more accessible.

Thank you for your dedication, curiosity, and commitment to excellence. With your creativity and passion, we will continue to shape the future of medical device manufacturing in India, powered by innovation, teamwork, and AI.

With regards
CS Prasad



KNOWLEDGE CENTRE

POST- MARKETING DSM (DRUG SAFETY MONITORING)

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Post Marketing DSM usually refers to Post-Marketing Drug Safety Monitoring, also known as Post-Marketing Surveillance (PMS) or Phase IV monitoring in pharmacovigilance.

It is the process of monitoring a drug's safety after it has been approved and released to the market by regulatory authorities such as the U.S. Food and Drug Administration or the European Medicines Agency.

What is Post-Marketing DSM?

After clinical trials (Phase I-III), a drug is approved for public use. However, clinical trials:

- Have limited participants
- Are conducted under controlled conditions
- May not detect rare or long-term side effects

Post-Marketing DSM monitors the drug in real-world conditions to ensure continued safety and effectiveness.

Functions of Post-Marketing DSM

1. Detection of Rare or Long-Term Adverse Effects

Identifies side effects not seen during clinical trials due to:

- Larger population exposure
- Longer duration of use
- Use in special populations (pregnant women, elderly, children)

1. Adverse Drug Reaction (ADR) Reporting

- Collects reports from doctors, pharmacists, and patients
- Uses systems like the FDA Adverse Event Reporting System

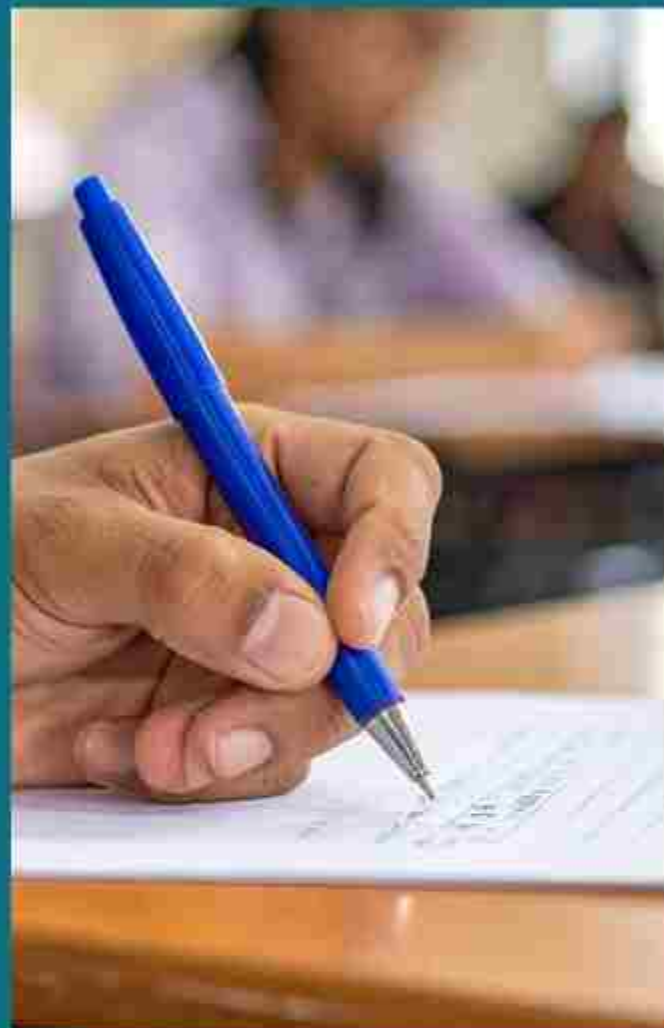
2. Risk Assessment and Risk Management

- Evaluates benefit-risk balance
- Develops Risk Evaluation and Mitigation Strategies (REMS)

3. Label Updates

- Updates warnings, precautions, or contraindications
- Adds new safety information

4. Drug Recall or Withdrawal



If serious safety concerns arise, authorities may:

- Restrict use
- Recall batches
- Withdraw the drug from the market

F. Monitoring Drug Interactions

Detects interactions with:

- Other medications
- Herbal products
- Alcohol

G. Monitoring Special Populations

Evaluates safety in:

- Pregnant women
- Pediatric patients
- Elderly individuals
- Patients with liver/kidney disease

Importance of Post-Marketing DSM

- Protects public health
- Ensures ongoing drug safety
- Maintains regulatory compliance
- Improves clinical practice

Post-Marketing DSM is continuous safety monitoring of medicines after they are sold, to make sure they remain safe and effective in real-world use.

Post-Marketing DSM (Drug Safety Monitoring)

Definition:

Post-Marketing DSM refers to the monitoring of a drug's safety after it has been approved and released to the market. It is also called Post-Marketing Surveillance (Phase IV study) and is carried out under regulatory authorities such as the U.S. Food and Drug Administration and the European Medicines Agency.

Functions of Post-Marketing DSM

1. Detection of rare and long-term adverse effects not identified during clinical trials.
2. Collection and evaluation of Adverse Drug Reaction (ADR) reports.
3. Assessment of benefit-risk ratio of the drug in real-world use.
4. Updating drug labels with new warnings, precautions, or contraindications.
5. Risk management and drug recall/withdrawal if serious safety issues arise.
6. Monitoring drug interactions and safety in special populations.

Post-Marketing DSM ensures continuous monitoring of drug safety and protects public health after a drug is marketed.



Post-Marketing DSM (Drug Safety Monitoring) is the monitoring of a drug's safety after it has been approved and released to the market (Phase IV study). It is conducted by regulatory authorities like the U.S. Food and Drug Administration and the European Medicines Agency.

Functions:

- Detects rare and long-term adverse effects.
- Collects and evaluates Adverse Drug Reaction (ADR) reports.
- Assesses benefit-risk ratio.
- Updates warning labels and safety information.
- Initiates drug recall or withdrawal if necessary.

It ensures continuous drug safety and protects public health.

SUCCESS IS NOT HOW HIGH YOU HAVE CLIMBED BUT
HOW YOU MAKE A POSITIVE DIFFERENCE TO THE WORLD

STERILIZATION OF MEDICAL DEVICES: PURPOSE, METHODS, AND IMPORTANCE

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1. Introduction

Sterilization of medical devices is one of the most critical processes in healthcare, medical device manufacturing, and infection control. Medical devices such as surgical instruments, catheters, implants, syringes, and diagnostic tools frequently come into direct contact with blood, tissues, or sterile body cavities. If these devices contain microorganisms, they can cause serious infections in patients.

Sterilization ensures that all forms of microbial life are completely eliminated from medical devices before they are used. This process is essential for maintaining patient safety, preventing healthcare-associated infections, and complying with international regulatory standards for medical device manufacturing and hospital practices. Healthcare systems and medical device companies follow strict sterilization procedures to ensure that devices are safe, effective, and ready for clinical use.

2. What is Sterilization?

Sterilization is defined as the complete destruction or elimination of all forms of microbial life from a material, surface, or medical device.

This includes the removal or destruction of:

- Bacteria
- Viruses
- Fungi
- Protozoa
- Bacterial spores (the most resistant form of microorganisms)

Sterilization is different from disinfection and cleaning.

- Cleaning removes visible dirt and organic material.
- Disinfection reduces the number of microorganisms but may not eliminate spores.
- Sterilization destroys all microorganisms completely.

For medical devices that enter sterile body areas, sterilization is mandatory.



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3. Why Sterilization of Medical Devices is done

Sterilization is performed for several important reasons in healthcare and medical device manufacturing.

3.1 Prevention of Infection

Medical devices may carry harmful microorganisms if they are not properly sterilized. When contaminated devices are used on patients, they can introduce pathogens directly into the body, causing infections. Sterilization eliminates these microorganisms and prevents infection transmission.

3.2 Patient Safety

Patient safety is the primary objective of sterilization. Devices such as implants, catheters, and surgical tools must be sterile to prevent complications during medical procedures.

Without proper sterilization, patients may develop:

- Surgical site infections
- Bloodstream infections
- Organ infections

3.3 Compliance with Medical Regulations

International regulatory bodies require medical devices to be sterilized before clinical use. Manufacturers must follow validated sterilization processes to comply with quality standards. These standards ensure that medical devices are consistently safe and reliable.

3.4 Prevention of Cross-Contamination

In hospitals, medical devices may be used on multiple patients. Proper sterilization prevents the transfer of microorganisms between patients and healthcare workers.

3.5 Protection of Healthcare Workers

Sterile equipment reduces the risk of healthcare professionals being exposed to infectious agents during procedures.

4. Types of Sterilization Methods

Sterilization methods for medical devices are broadly categorized into three major groups:

1. Physical Sterilization Methods
2. Chemical Sterilization Methods
3. Radiation Sterilization Methods



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Typical Sterilization Conditions

Temperature

Pressure

Time

121°C

15 psi

15-30 minutes

134°C

30 psi

3-5 minutes

Applications

- Surgical instruments
- Laboratory glassware
- Metal equipment
- Medical trays

Advantages

- Highly reliable and effective
- Non-toxic process
- Economical and widely available

Limitations

- Not suitable for heat-sensitive materials such as plastics or electronic components.

5.2 Dry Heat Sterilization

Dry heat sterilization uses hot air ovens to destroy microorganisms.

Principle

Microorganisms are destroyed through oxidation of cellular components.

Typical Conditions

Temperature

Time

160°C

2 hours

170°C

1 hour



Applications

- Glassware
- Metal surgical tools
- Powders
- Oils and petroleum products

Advantages

- Suitable for moisture-sensitive materials
- No corrosion of metal instruments

Limitations

- Requires higher temperature and longer exposure time.

5.3 Filtration Sterilization

Filtration sterilization removes microorganisms from liquids or gases using microporous filters.

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Principle

Microorganisms are physically removed by passing fluids through filters with very small pore sizes. Typical filter pore size: 0.22 microns

Applications

- Vaccines
- Antibiotic solutions
- Intravenous fluids
- Heat-sensitive biological products

Advantages

- Suitable for heat-sensitive liquids

Limitations

- Does not destroy microorganisms; it only removes them.

6. Chemical Sterilization Methods

Chemical sterilization uses gases or liquid chemicals to eliminate microorganisms, especially for heat-sensitive medical devices.

6.1 Ethylene Oxide (EtO) Sterilization

Ethylene oxide sterilization is widely used in the medical device industry.

Principle

Ethylene oxide gas disrupts microbial DNA and proteins, preventing microorganisms from surviving or reproducing.

Applications

- Catheters
- Plastic syringes
- Dialysis tubing
- Implantable devices
- Disposable medical products

Advantages

- Effective at low temperatures
- Can sterilize complex and packaged devices
- Excellent material compatibility

Limitations

- Toxic gas requiring careful handling
- Requires aeration time to remove residual gas.



6.2 Hydrogen Peroxide Plasma Sterilization

This method uses vaporized hydrogen peroxide that is converted into plasma to destroy microorganisms.

Applications

- Endoscopes
- Surgical equipment
- Heat-sensitive medical devices

Advantages

- Low temperature sterilization
- Fast cycle time
- No toxic residues

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Limitations

- Limited penetration for complex devices.

6.3 Liquid Chemical Sterilization

Some chemical solutions can sterilize devices when they are immersed for a specific time.

Common sterilizing agents include:

- Glutaraldehyde
- Peracetic acid
- Hydrogen peroxide solutions

These are commonly used for delicate medical equipment.

7. Radiation Sterilization Methods

Radiation sterilization is mainly used in industrial sterilization of disposable medical devices.

7.1 Gamma Radiation Sterilization

Gamma radiation uses high-energy rays generated from radioactive sources to kill microorganisms.

Principle

Gamma rays damage the DNA of microorganisms, preventing them from surviving or reproducing.

Applications

- Syringes
- Surgical gloves
- Catheters
- Disposable medical products
- Implantable devices

Advantages

- Highly effective
- Suitable for large-scale sterilization
- Can sterilize products in final packaging.

7.2 Electron Beam Sterilization

Electron beam sterilization uses high-energy electrons to destroy microorganisms.

Advantages

- Fast processing
- No radioactive materials required



Limitations

- Lower penetration compared to gamma radiation.

8. Sterilization Monitoring and Validation

To ensure that sterilization is successful, monitoring and validation methods are used.

Physical Monitoring

Measures sterilization parameters such as:

- Temperature
- Pressure
- Exposure time

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Chemical Indicators

Special tapes or strips change color when exposed to sterilization conditions.

Biological Indicators

These use highly resistant bacterial spores to confirm the effectiveness of sterilization.

Common biological indicators include spores of resistant bacteria used to verify sterilization performance.

9. Factors Affecting Sterilization Effectiveness

Several factors influence the success of sterilization:

- Type and number of microorganisms present
- Nature of the medical device material
- Device design and complexity
- Temperature and exposure time
- Packaging materials
- Presence of organic contaminants

Proper cleaning before sterilization is essential to ensure effective microbial elimination.

10. Conclusion

- Sterilization of medical devices is a fundamental requirement in healthcare and medical device manufacturing. It ensures the complete elimination of microorganisms, thereby preventing infections and protecting patient safety.
- Different sterilization methods such as steam sterilization, dry heat sterilization, chemical sterilization, and radiation sterilization are used depending on the nature of the medical device and its material compatibility.
- A properly validated sterilization process, along with continuous monitoring and adherence to regulatory standards, ensures that medical devices remain safe, effective, and reliable for clinical use.



RAM KUMAR SHARMA - MEDTECH DEVICES

CHALLENGES ARE WHAT MAKE LIFE INTERESTING AND
OVERCOMING THEM IS WHAT MAKES LIFE MEANINGFUL.

SEO stands for Search Engine Optimization, and it's the practice of improving a website's visibility in search engines like Google, Bing, or Yahoo. The goal is to make your website appear higher in search results when users search for keywords related to your business, product, or service.

How SEO Works

SEO works by optimizing various aspects of your website and online presence so that search engines understand it as valuable and relevant. It involves three main areas:

a) On-Page SEO

These are optimizations done directly on your website, such as:

- Using relevant keywords in titles, headings, and content.
- Optimizing meta tags (title and description) for search engines.
- Ensuring good website structure and fast loading speed.
- Making content high-quality, informative, and user-friendly.

b) Off-Page SEO

This refers to actions outside your website that influence its authority:

- Backlinks from other reputable websites.
- Social media mentions and shares.
- Online reviews and business listings.



c) Technical SEO

This focuses on the backend of your website:

- Ensuring mobile-friendliness.
- Fixing broken links and errors.
- Using sitemaps and structured data for better indexing.
- Optimizing website speed and security (HTTPS).

Search engines use algorithms to rank pages based on relevance, authority, and user experience. SEO aligns your website with these ranking factors.

Benefits of SEO for Clients

SEO provides measurable and long-term benefits:

- **Increased Visibility & Traffic** : Appearing higher in search results means more potential customers visit your website.
- **Cost-Effective Marketing** : Compared to paid ads, organic traffic from SEO is free and sustainable over time.
- **Better User Experience** : SEO often improves website design, speed, and usability, making visitors happier.
- **Builds Credibility & Trust** : Sites that rank high are seen as more trustworthy and authoritative.
- **Higher ROI** : Targeted traffic from SEO usually converts better because users are actively searching for your services.
- **Competitive Advantage** : Businesses investing in SEO can outrank competitors in search results.



WHEN YOUR INTENTIONS ARE PURE, YOU DON'T LOSE
ANYONE. THEY LOSE YOU.

Why We Must Avoid War Globally and Its Side Effects on the Human Beings.

War is one of the greatest threats to humanity. Throughout history, wars have caused immense destruction, suffering, and loss of life. Even in today's modern world, where science and technology have advanced greatly, war continues to harm not only the countries involved but the entire globe. For these reasons, it is essential that nations work together to avoid war and promote peace.

One of the most serious consequences of war is the loss of human life. Soldiers and civilians, including women and children, are often killed or injured. Families are torn apart, and generations are left traumatized. The emotional and psychological scars of war can last for decades, affecting mental health and social stability long after the fighting ends.

War also causes economic destruction. Cities, industries, schools, hospitals, and infrastructure are damaged or completely destroyed. Countries involved in war often face poverty, unemployment, and debt. Globally, war disrupts trade, increases the price of food and fuel, and slows down economic growth, affecting even nations far from the conflict. Another major side effect of war is environmental damage. Bombings, chemical weapons, deforestation, and oil spills destroy ecosystems. Land becomes unusable due to mines and pollution, and clean water sources are contaminated. These environmental impacts do not stop at borders; they contribute to global problems such as climate change and biodiversity loss.



War also leads to mass displacement and refugee crises. Millions of people are forced to flee their homes to escape violence. This creates humanitarian emergencies and places pressure on neighbouring countries. Refugees often face hunger, lack of education, and limited healthcare, which affects global human development.

Furthermore, war increases global insecurity. Conflicts can spread to other regions, encourage terrorism, and increase the risk of larger international wars. In a world with nuclear weapons, the consequences of large-scale war could be catastrophic for all humanity.

Avoiding war allows nations to focus on development, cooperation, and human progress. Resources spent on weapons and military conflict could instead be used for education, healthcare, scientific research, and environmental protection. Peace encourages dialogue, mutual respect, and understanding between cultures and countries.

In conclusion, war brings suffering, destruction, and long-lasting global consequences. Avoiding war is not just the responsibility of individual nations but a shared duty of the entire world. By choosing peace, diplomacy, and cooperation, humanity can build a safer, healthier, and more prosperous future for all.

WORLD WAR I (1914–1918)

Following are the causes for World War 1.

1. **Militarism** – European powers built up huge Armies and Navies, leading to an arms race, especially between Germany and Britain.
2. **Alliances** – Europe was divided into two major alliances:
 - **Triple Entente:** France, Russia, Britain
 - **Triple Alliance:** Germany, Austria-Hungary, Italy (Italy later switched sides)



THE WARS THAT SHAPED THE 20TH CENTURY – FROM TRENCHES TO ATOMIC BOMBS : THE STORY OF WORLD WARS.

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3. Imperialism – Competition for colonies in Africa and Asia created tension.
4. Nationalism – National pride and ethnic groups seeking Independence (especially in the Balkans) caused conflicts.
5. Assassination of Archduke Franz Ferdinand (June 28, 1914) – The heir to Austria-Hungary was killed by a Serbian nationalist; this triggered a chain reaction of declarations of war.

Major Participants of World War 1

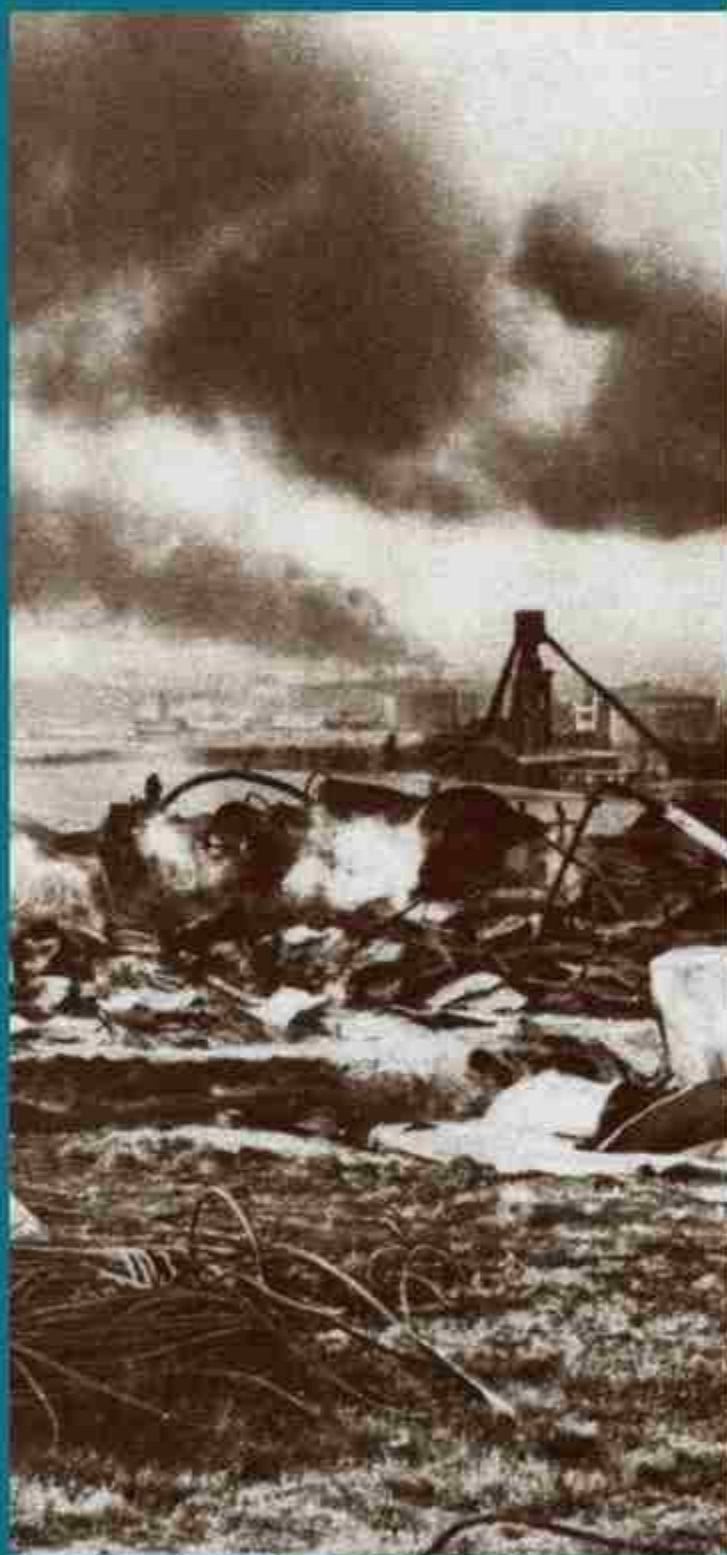
- Allied Powers: Britain, France, Russia (later joined by Italy, USA, Japan)
- Central Powers: Germany, Austria-Hungary, Ottoman Empire, Bulgaria

Major Events during World War 1

- Trench warfare on the Western Front (France & Belgium)
- Eastern Front battles between Germany/Austria-Hungary and Russia
- Use of new weapons: machine guns, poison gas, tanks, submarines
- Entry of the USA in 1917 tipped the balance in favour of the Allies

Result / Outcome of World War 1

- Armistice signed on November 11, 1918
- Treaty of Versailles (1919):
 - Germany forced to accept full responsibility
 - Heavy reparations imposed
 - Military restrictions and loss of colonies
- Collapse of empires: Austro-Hungarian, Ottoman, Russian, and German
- Redrawing of European borders and creation of new countries (e.g., Poland, Czechoslovakia)
- League of Nations formed to prevent future wars (but weak)



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Casualties: ~16 million deaths (160 Lakhs) , - 21 million wounded (210 Lakhs)

WORLD WAR II (1939-1945)

Following are the causes for World War II

- Treaty of Versailles – Harsh conditions on Germany caused resentment.
- Rise of totalitarian regimes – Adolf Hitler (Germany), Benito Mussolini (Italy), militarists in Japan.
- Expansionism – Germany invaded neighbouring countries; Italy invaded Ethiopia; Japan expanded in Asia.
- Failure of League of Nations – Unable to prevent aggression.
- Appeasement policy – European powers initially allowed Hitler to annex Austria and Sudetenland.
- Major Participants
- Allied Powers: Britain, France, USA, Soviet Union, China, and others
- Axis Powers: Germany, Italy, Japan

Major Events

- 1939: Germany invaded Poland → Britain & France declare war
- Blitzkrieg: Germany quickly conquered much of Europe
- 1941: Germany invades Soviet Union; Japan attacks Pearl Harbour → USA enters war
- 1942-1943: Turning points – Stalingrad (USSR victory), Midway (USA victory)
- 1944: D-Day Invasion of Normandy by Allies
- 1945: Germany surrenders in May; Japan surrenders in August after atomic bombs on Hiroshima and Nagasaki

Result / Outcome of World War II

United Nations formed to maintain world peace

Germany divided into East and West

Japan occupied by USA

Europe and Asia heavily destroyed; massive rebuilding needed

Start of Cold War between USA and USSR

Holocaust revealed: ~6 million Jews murdered (60 Lakhs)

Global shift: USA & USSR became superpowers

Casualties: 70-85 million people (including civilians) (700 - 850 Lakhs)



HAPPINESS IS A CHOICE, NOT A RESULT. NOTHING WILL MAKE YOU HAPPY UNTIL YOU CHOOSE TO BE HAPPY.

A large manufacturing company had a problem. Every evening, one section of the warehouse remained poorly lit. Workers complained about it for months. Reports were filed, emails were sent, and the issue was discussed in meetings again and again. Everyone agreed the lighting was bad. But nothing changed.

One evening, a junior technician stayed a little late to finish his shift. As he walked through the dim section, he noticed the switchboard mounted on a nearby pillar. Curious, he opened it. Inside was a single switch labeled "Auxiliary Lights." He flipped it.

Instantly, the entire section of the warehouse lit up. Rows of bright lights turned on, illuminating an area that had been dim for years.

The next morning, people were surprised. "When did they install new lights?" someone asked. "They were always there," the technician said. "They just weren't turned on."

Later that week, the operations director mentioned it during a meeting. "For months we discussed the problem," she said. "We wrote reports, escalated requests, and waited for approval."

She paused.

"But the solution was a switch—five steps away from where we were standing."

The room fell silent.

"Sometimes," she continued, "the biggest delays in progress aren't caused by complex problems. They happen because everyone assumes someone else is responsible for flipping the switch."



From that day on, the story of the warehouse lights spread across the company.

Whenever teams faced a problem that everyone talked about but no one acted on, someone would simply ask:

"Who's going to flip the switch?"

Message

Not every solution requires a new system, budget, or approval.

Sometimes progress begins the moment someone decides to turn the lights on.

CONTENTMENT IS NATURAL WEALTH. LUXURY IS ARTIFICIAL POVERTY.

A well-known professor once went to visit a Zen master to learn about peace and wisdom.

The professor was very proud of his knowledge. As soon as he sat down, he started talking about all the books he had read, the degrees he had earned, and the subjects he had mastered. The Zen master quietly began pouring tea into the professor's cup.

The cup became full, but the master kept pouring.

Soon the tea started overflowing onto the table and the floor.

The professor shouted,

"Stop! The cup is already full. No more can go in!"

The master calmly replied,

"Just like this cup, your mind is already full of your own opinions, knowledge, and pride. How can I teach you anything unless you first empty your cup?"

The professor suddenly fell silent.

He realized that all his knowledge had made him arrogant rather than wise.

True learning begins when we accept that we do not know everything.

Many people think education means collecting degrees, titles, and achievements.

But real wisdom comes from humility, curiosity, and the willingness to listen.

A person whose mind is always full cannot receive new ideas.

Life itself is the greatest teacher, but only those who keep their minds open can learn from it.

When the cup is empty, fresh tea can be poured.

When the mind is humble, wisdom can enter.

So in life, try to empty your cup from time to time.

Let go of ego, assumptions, and the belief that you already know everything.

Because the moment we stop learning is the moment we stop growing.

Stay curious. Stay humble. Stay open.



TRUE FULFILMENT COMES FROM WALKING YOUR OWN WAY,
NOT TRACING SOMEONE ELSE'S FOOTSTEPS.

1. According to MDR 2017, the classification of medical devices in India is based on:
2. Which class includes high-risk life-supporting devices?
- 3 The risk classification system used in India is largely aligned with which international forum?
4. Under MDR 2017, Notified Bodies are involved in regulatory assessment for which device classes?
5. Application for manufacturing license for Class A and B devices is submitted in:
6. Manufacturing license for Class A and B devices is granted in..
7. The import license issued for medical devices is:
8. Which quality management system standard is generally required for medical device manufacturers in India?
9. Clinical investigation of medical devices in India is governed by:
10. Post-market surveillance of medical devices in India is monitored through which program?

PERFECTION MEANS DOING THE BEST BUT CONFIDENCE MEANS
KNOWING HOW TO HANDLE THE WORST.

Why wisdom watches patterns, not promises.
An old lion couldn't hunt anymore. So he changed his strategy.
He stopped chasing prey and started hosting visitors.

From inside a dark cave he sent out a message:
"I'm weak... come see me."

One by one, the animals entered.
None returned.

Then the fox arrived.

He didn't rush in.

He didn't get emotional.

He didn't get flattered by the invitation.

He studied the ground.

Tracks everywhere

leading into the cave.

Not one leading out.

So he called from a distance:

"Your Majesty, I care about you deeply...
but the data says this is a one-way meeting."

And he walked away alive.

Here's the real lesson:

Most people make decisions with their ears.
Smart people make decisions with their eyes.

Marketing says "everyone is winning"

→ Show me the receipts.

A business says "people are joining fast"

→ Who has actually succeeded and exited?

An opportunity says "trust me"

→ Where are the results, not the testimonials?



Hype is words. Truth leaves tracks.

Before you enter any room, funnel, partnership, investment, or mastermind...
look for the exit footprints.

If nobody can show you how they got out
with profit, growth, or transformation,
you're not looking at an opportunity.

You're looking at a cave. And caves don't
need more visitors. They need better
observers.

Stay sharp. Evidence over emotion.

YOU CAN ONLY WIN WHEN YOUR MIND IS STRONGER THAN
YOUR EMOTIONS.

1. Risk associated with device
2. Class D (high risk)
3. Global Harmonization Task Force (GHTF) model
4. Class B and Class C
5. MD-3
6. MD-5 (License)
7. MD - 15
8. ISO 13485.
9. Chapter VII of MDR 2017
10. MvPI (Materialiovigilance Programme of India)

- CDSCO circular dated 6.3.26 on Implementation of Prior intimation System for Forms CT-10, CT-12 and CT-13 in pursuance of G.S.R. 46(E) dated 20.01.2026.
- CDSCO Circular dated 9.3.2026 on Online Applications for Post Approval Changes (PAC) w.r.t Marketing Authorization (MA) for r-DNA products.
- CDSCO Circular dated 10.3.2026 on Online Applications for grant of license in Form 28-D/28-DA for r-DNA products
- CDSCO Gazette notification on 2026.03.02 G.S.R. 165(E)_Inclusion of Qualifications of Inspector Medical Devices and Government Analyst.
- CDSCO Gazette notification on 2026.03.09 G.S.R. 164(E)_Draft Notification regarding Blood product testing under Drugs Rules,1945
- CDSCO Gazette notification on 2026.03.09 G.S.R. 173(E)_Draft Notification reg PAC for amendment in Drugs Rules, 1945.
- CDSCO Public notice on 10.3.2026 on Testing Laboratories approved by Statas&UT in Form 37 of Drugs Rule 1945 and Cos 23 of Cosmetics Rule 2020.
- CDSCO Public notice on 11.3.2026 on Advisory to all manufacturers, importers and marketing authorization holders.
- CDSCO Public notice on 13.3.2026 on Transfer of certain functions and delegation of powers to the zonal offices of CDSCO under Rule 22 of the Drugs and Cosmetics Rules, 1945.
- CDSCO Public notice on 13.3.2026 on Addendum to FAQ on Medical Devices Rules, 2017.
- CDSCO Public notice on 17.3.2026 on Guidance document on dossier based licensing of Drugs for uniform product licensing in the country.
- CDSCO Public notice on 18.3.2026 on Manufacturing and marketing of unapproved drug product Sodium Hyaluronate Eye Drops 0.3% w/v.



In the blink of an eye, a day slips away.
In the blink of an eye, a week becomes yesterday.
In the blink of an eye, a month fades into memory.
In the blink of an eye, a year becomes history.

And in the blink of an eye, I'll be gone someday.
And so will you, in life's quiet, certain way.
So perhaps instead of drifting half-awake,
We should cherish each breath and every step we take.

Let's open our eyes to the beauty around,
To the lessons in silence, to every small sound.
Let's grow into who we're meant to be,
The truest, strongest version we can see.

Before time whispers, and moments depart,
Before regrets ever visit the heart.
Whether this life is one or many, few or fast,
The only wisdom is to live while it lasts.

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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