HUMAN SIDE OF GMP

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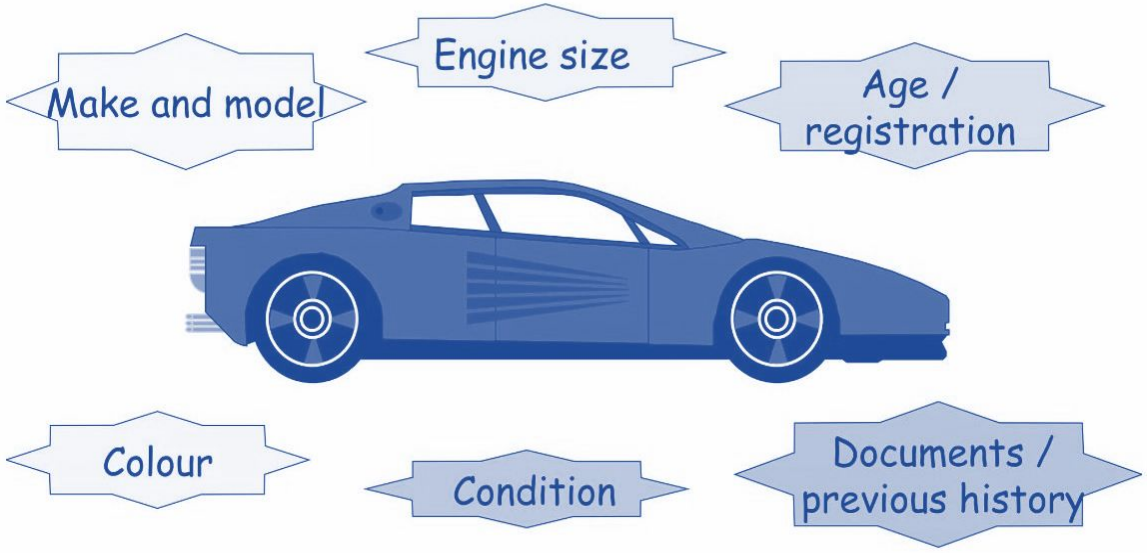
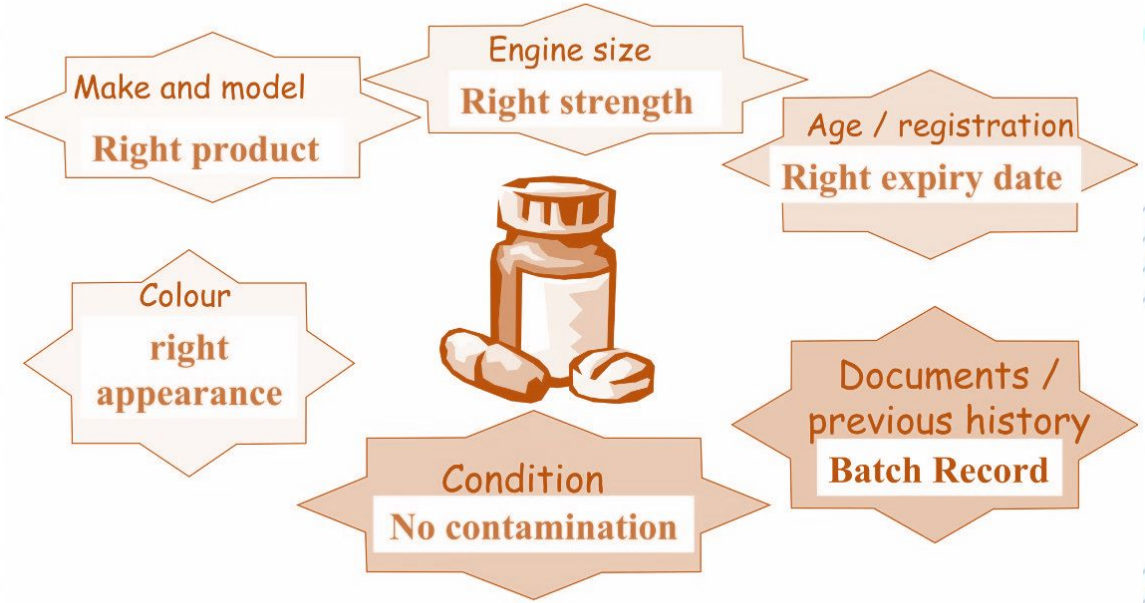
Pharma vs Other Products !

Quality Choices



You can tell by looking

Quality Choices



You can't tell just by looking

cGMP – Current Good Manufacturing Practices

What is cGMP?	Where?	Why?
Current Good Manufacturing Practices (cGMPs) are a set of regulations that aim to ensure the quality and safety of products manufactured for human and animal use.		To establish a robust framework that governs every aspect of the manufacturing process: from raw materials to final product distribution, to deliver safe and effective products to consumers.

It’s about PEOPLE

Behind every compliant batch and validated system is a team that chooses integrity, quality, and patient safety every day.

Content

1. The Robot Mentality
2. The 4 Pillars
3. Making it Real

PART I: The Robot Mentality

Why do we treat our most valuable asset like a liability?

Where Do People Fit?

- We manage “Processes, Procedures, Premises, and Products” with rigorous metrics
- But the most critical, variable, and complex **'P'** is **People**
- GMP is a framework built on rules, but success is built on **trust and motivation**

The "Robot" Mentality

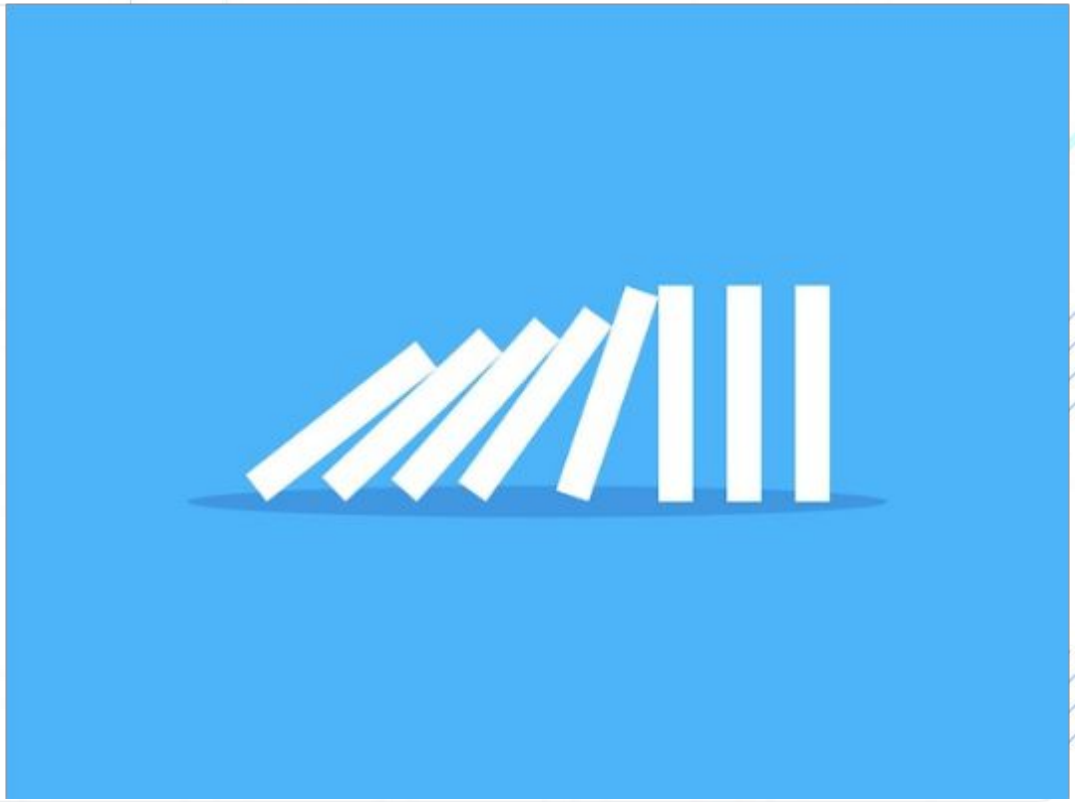
We expect perfect, role execution, ignoring the cognitive load and complexity of the task.

The Fear of the Red Pen

We operate under the implicit threat that any mistake—no matter how small—will lead to blame, punishment, or investigation.

The "Human Error" Fallacy

When an incident occurs, our standard response is often: "Operator X made an error." This label is a shortcut. It ends the investigation prematurely and fails to improve the system.



The Regulatory View

Regulatory bodies, including the FDA and EMA, now mandate a deeper look:

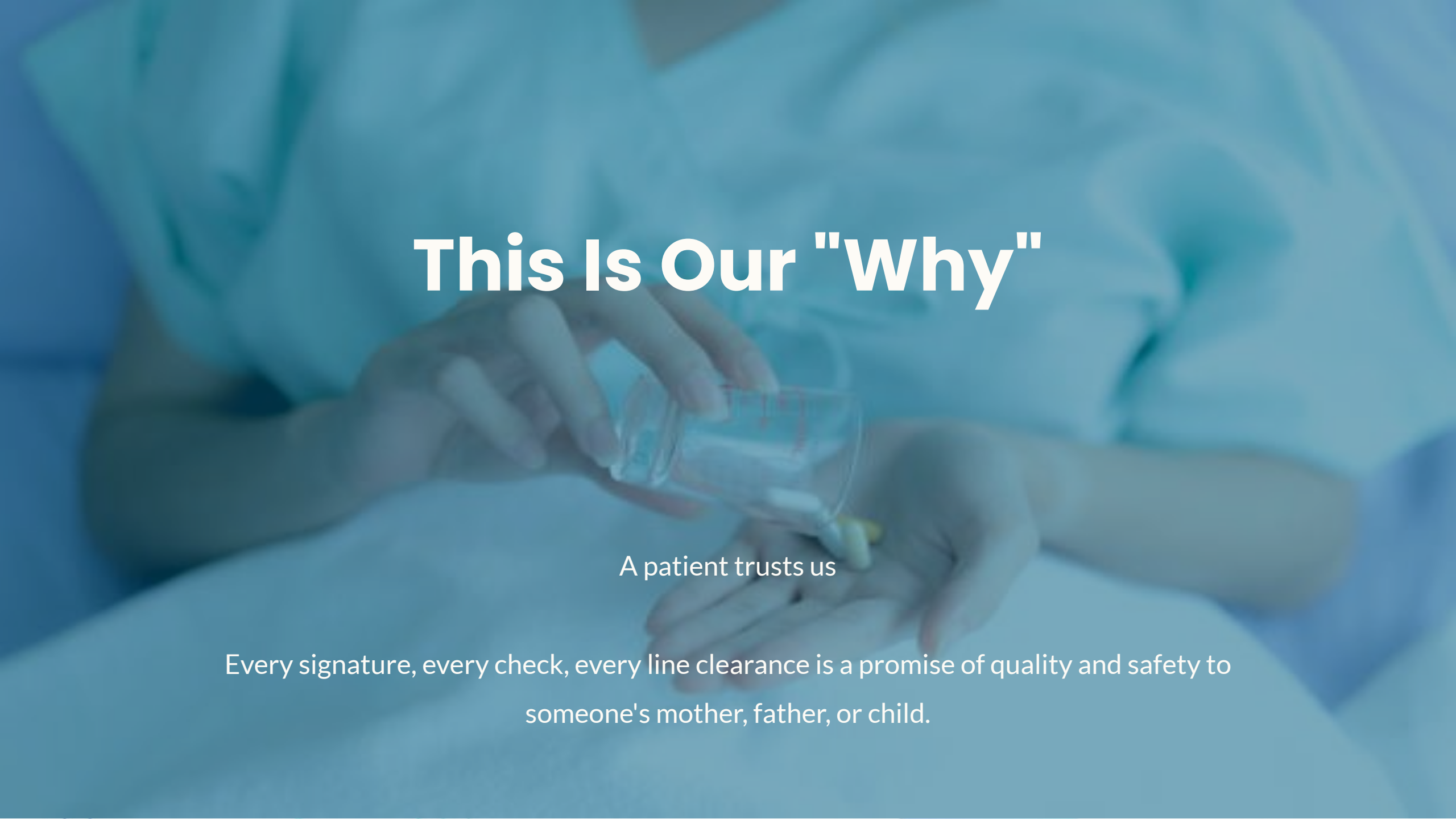
Human Error is a Symptom.

It is NOT a Root Cause.

It signals a flaw in the process, the training, or the environment.

But Who Does the Error Affect?

Before we build a better system, we must reconnect with our purpose.



This Is Our "Why"

A patient trusts us

Every signature, every check, every line clearance is a promise of quality and safety to someone's mother, father, or child.

IPA
INNOVATION. QUALITY. GLOBAL REACH.

10th Edition
Advanced GMP
Advanced Good Manufacturing Practices

The Quality of our Product is the Quality of our Promise.

PART II: The Four Pillars

Why do we treat our most valuable asset like a liability?

Advanced GMP

Shifting from

Compliance

to

Culture.

The Mindset Shift

The Old Way (Compliance)

"I have to do this." Focus on paperwork, passing the audit, and meeting the minimum requirement.

The New Way (Culture)

"I want to do this." Focus on preventing harm, continuous improvement, and ownership.

Pillar 1: A Just/ CI Culture

Creating psychological safety to report, learn, and grow.

The Foundation

When we blame people, we fix nothing! When we analyze systems, we fix everything.

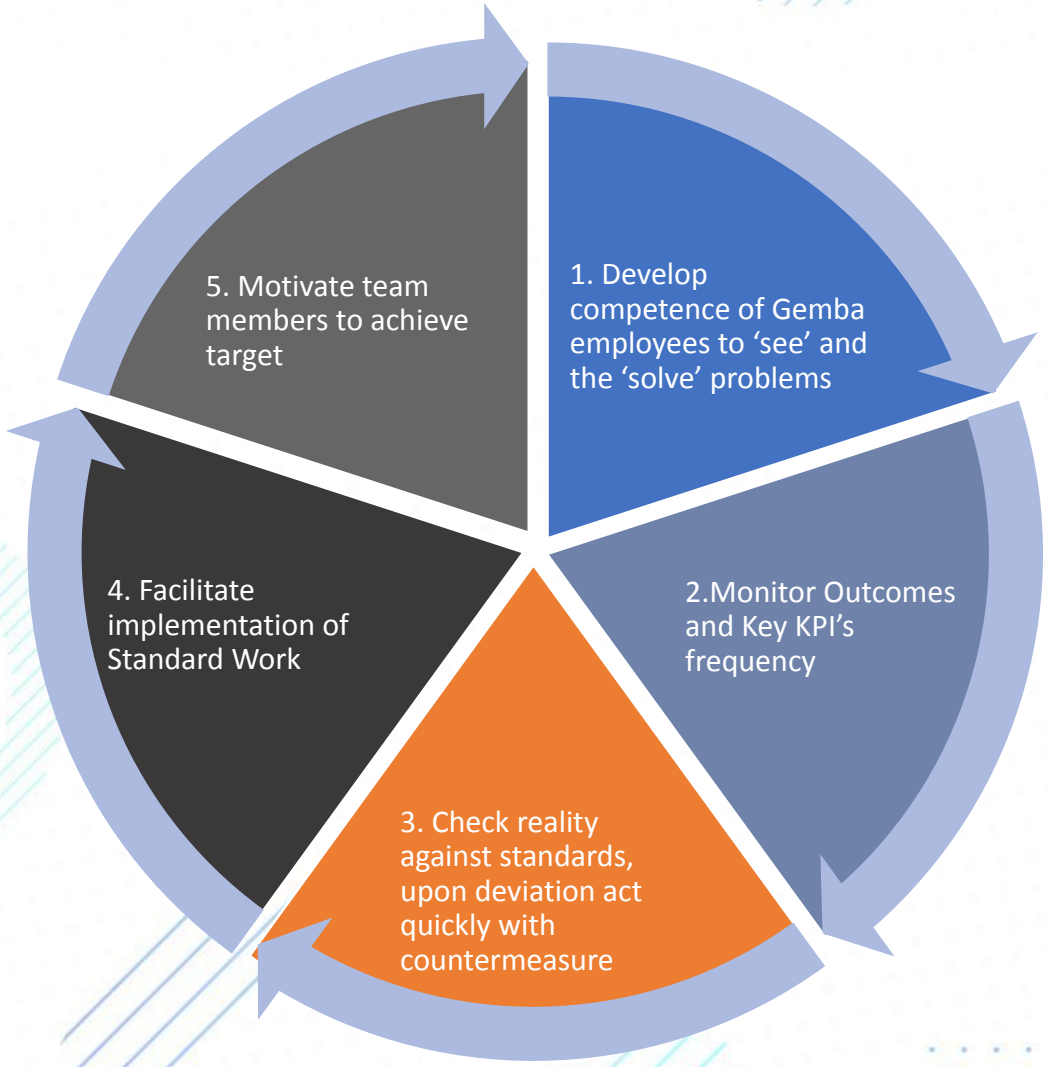
DAILY WORK MANAGEMENT

MEET
DISCUSS
SOLVE
IMPROVE

DAIL

To Create a culture to see, highlight, solve problem

Daily Work Management



Use Escalation through proper tiered mechanism

The Just Culture Test

If the person who made the error was your Best operator, would you treat the incident differently?

If the answer is yes, you are blaming the person, not the system.

Pillar 2: Human Factors

Designing the workplace “for” the human mind, not against it.

Fixing the System, Not the Person

Human Factors Engineering (HFE) studies how people interact with the tasks, tools, and environment.

We ask: **What pressures, distractions, or bad designs forced the person to fail?**

- Are labels too small or faded?
- Is lighting poor during the critical step?
- Does the process require 17 steps without a break?

Case Study: The 3-Hour Transfer

The Incident:

Operator missed one valve status check, leading to contamination during a long, non-stop material transfer.

The Root Cause:

The SOP mandated a non-stop, three-hour procedure. The System provided no scheduled break, rest zone, or peer-review checkpoint. Fatigue was engineered into the task.

The Solution (HFE):

Process redesigned to incorporate a **mandatory 15-minute scheduled break/shift change** at the 90-minute mark, requiring a peer to verify critical valve positions before continuing.

Result: Error Rate reduced by 95%.

HF Tool: Error-Proofing (Poka-Yoke)

Poka-Yoke means "**mistake-proofing**". We remove the possibility of error through design. There are 3 levels of Poka-yoke (Awareness, Detection & Prevention)

Examples in GMP:

- Color-coding raw material bins to match the SOP.
- Software requiring two separate credentials (A & B) for critical data entry.
- "Go/No-Go" gauges for equipment setup.

Pillar 3: Leadership

Culture is driven from the top and sustained at the bottom.

Leadership: The Tone at the Top

- **Model the Behavior:** Leaders must follow the rules, too. If management cuts corners, the team will follow. "Walk the Talk"
- **Prioritize Quality over Speed:** Never celebrate a batch completed "early" if corners were cut. Celebrate Zero deviations
- **Listen First:** The operator on the floor is the expert. Do their suggestions make it easy or difficult to maintain compliance?

The Gemba Walk: Going to the Source

Gemba is a Japanese term meaning “the actual place”

Leaders must regularly leave their offices and spend time on the manufacturing floor.

The goal is not to audit, but to **observe and ask:**

- "How could this process make your job easier?"
- "What is the most frustrating part of your shift?"

This builds trust and highlights systemic issues that are invisible from a desk.

Pillar 4: Training for "Why" & "CI"

Turning SOP readers into critical thinkers.

Need of Rapid Upskilling

According to International Research Journal, the pharmaceutical industry in India is grappling with high level of attrition of

30 to 35%.

Globally the rate of attrition in pharmaceutical industry is only 10 to 12%

Beyond the Checkbox

Compliance training often teaches the "what" and the "how". Quality training must teach the "why"—the risk profile behind the rule.

If an operator understands “why” a room clean-down is critical, they will police their own process, even when no one is watching.

We must move past "Death by PowerPoint" and create true competency.

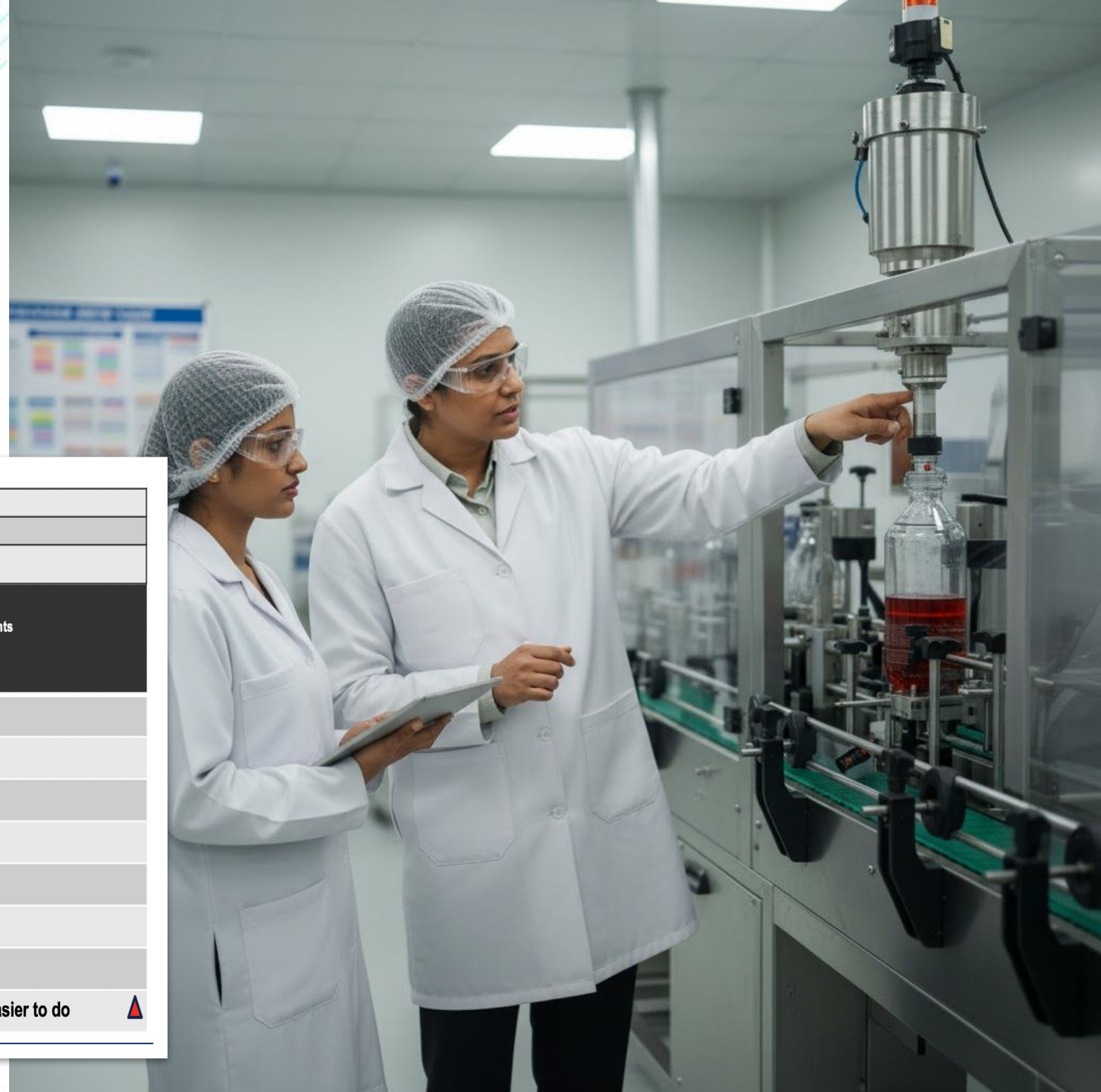
TWI - JI

Magic of Training Within Industry Job Instruction

Description:	
Parts:	
Tools and Materials:	

Important Step (What) A logical statement of the operation when something happens to advance the work	**Key Points (How)** Anything in a step that might: 1. Make or break the job 2. Injure the worker 3. Make the work easier	**Reasons (Why)** Reasons for the key points

Make or break | Injure the worker | Makes the work easier to do



PART III: **Making It Real**

Making it Real: Start with Measurement

Training Time

Skill Index

Improvements per person

Errors per team

Near misses

CI Projects coached

Gemba Walk adherence

First Time Right

Your Call to Action

Stop asking "Why did you make that mistake?"

Start asking "What in the system made that mistake easy to make?"

Questions?

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