17 CONGRESO URUMAN

TECNOLOGÍA Y CULTURA DIGITAL,
CONFIABILIDAD PARA EL MUNDO DEL MAÑANA

# Enfoque Estratégico de la Confiabilidad en la Industria Farmacéutica Según ISPE


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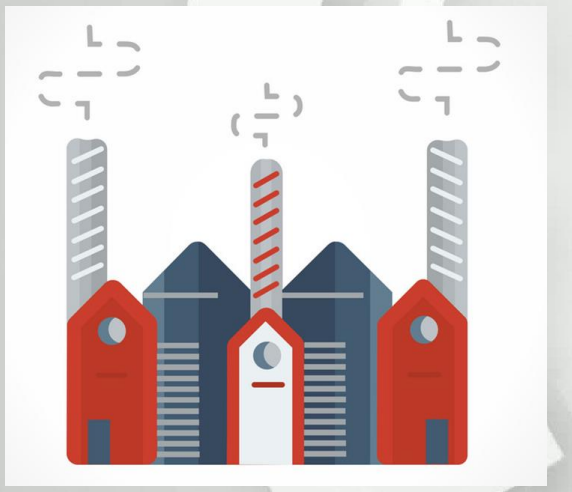
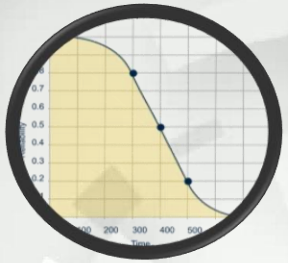
CEO Conscious Reliability


## 11 de Noviembre

## Hora: 14:00 hs (UTC -3)

# Webinar Topics





## What is Reliability?

## Reliability in the Pharma Industry

- Project and Operational Phases


## Holistic Approach

- Risk Management Principles
- Producing Effective Maint. Tasks

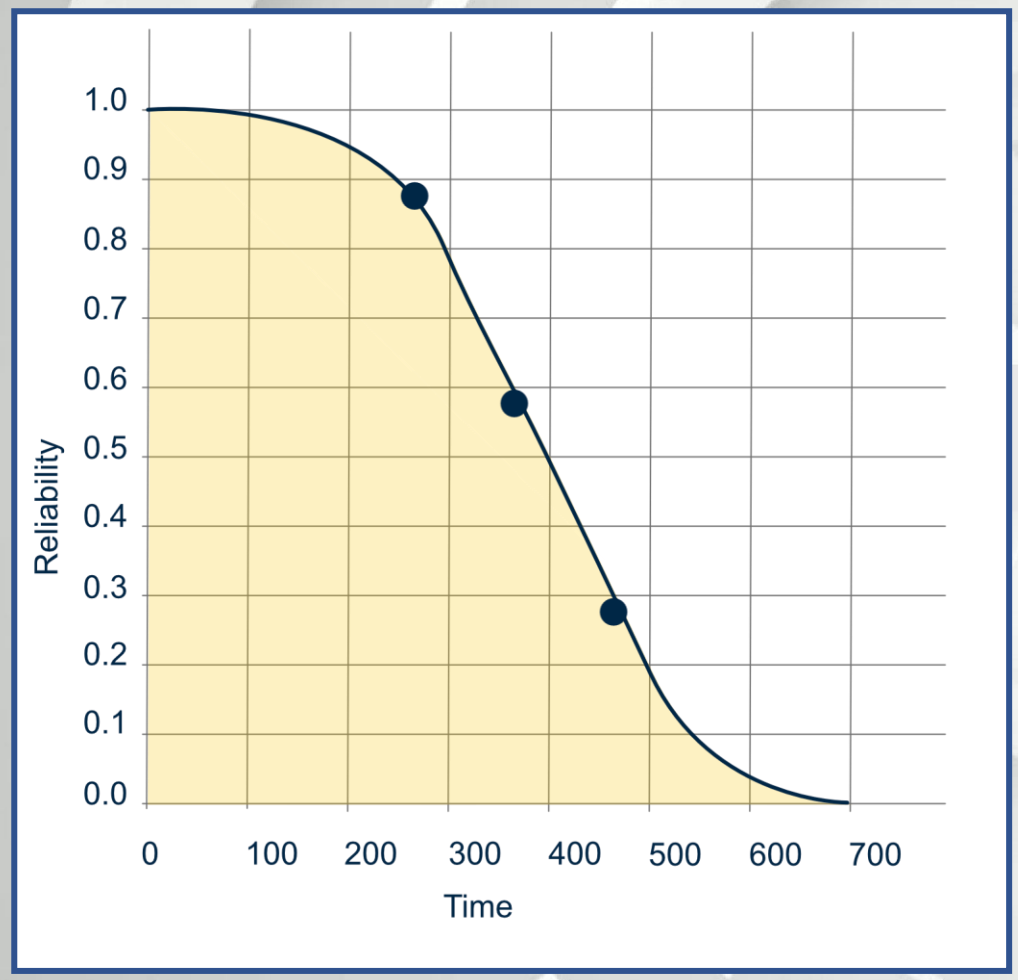
# What is Reliability?

# What is Reliability About?

- The level of certainty that an asset will fulfill its mission as established by its user

- Related words
  - Trust
  - Hope
  - Certainty
  - Assurance

# Reliability is also…




- The probability of performing as intended within a specific operating context
- Design-related
- Measurable
  - Decreases with time
- Recovered by maintenance
- Improved by a better design

# How is Reliability Measured?

It is very common and practical to utilize the statistical Weibull distribution to measure the reliability of simple components at any given age

$$R(t) = e^{-\left(\frac{t}{\eta}\right)^{\beta}} \qquad (1)$$

Where:

- $R$ is the surviving probability
- $e$ = 2.718
- $t$ = component age
- $\beta$ = shape parameter
- η = characteristic life

# How is Reliability Measured?

The exponential distribution is the main tool to model the Reliability of multi-component systems. MTBF instead of η is used as failure events are assumed to occur randomly for which a value $\beta$ equal to 1 corresponds.

$$R(t) = e^{-\left(\frac{t}{MTBF}\right)} \qquad (2)$$

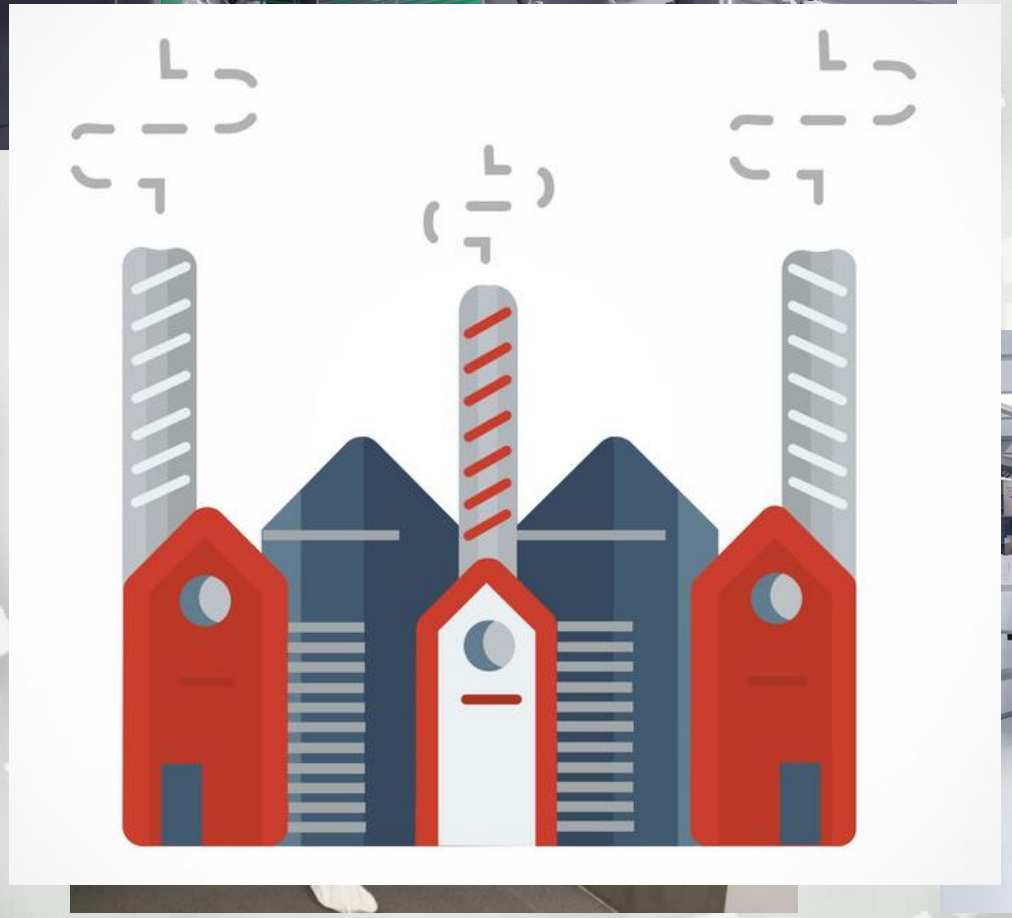
Where:

- $R$ is the surviving probability
- $e$ = 2.718
- $t$ = component age
- $MTBF$= Mean Time Between Failures

# How do pharma assets look like?


Chemical Reactors
Indoor Operation - No HVAC Required

Solvent Recovery
Outdoors Operation



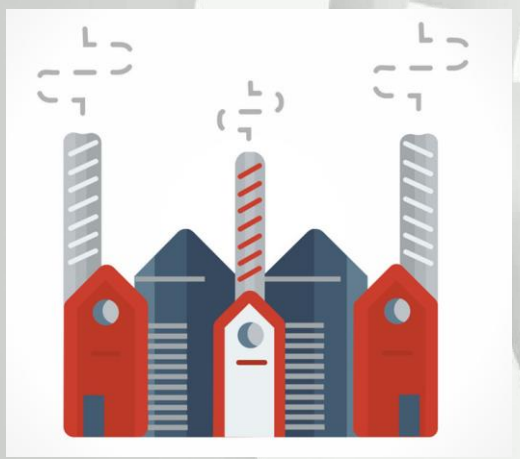
Lyophilization Process
ISO 5 Clean Room Class


Medical Devices
ISO 8 Clean Room Class

# Unique Aspects of the Pharma Industry


- Products are administered to humans and animals
  - Via ear, cheek, conjunctiva, trachea, intestines, abdomen, bursa, heart, mouth, etc.
- GMP System – Safeguards Product Quality
  - Cross contamination, adulteration and mislabeling
- QA System – Aims to:
  - Ensuring products are designed and developed meeting the requirements for Good Manufacturing Practice.
- Q and V – Provides supporting documentation
  - Premises, Utilities, Assets and Processes
    - Design Qualification, Installation (IQ),
    - Operational Qualification(OQ), Performance Qualification (PQ)
- Management of Change - Change control is:
  - a formal system to review changes affecting the validated facilities, systems, equipment or processes.

# Summarized Live Cycle of Pharma Assets



## Project Phase

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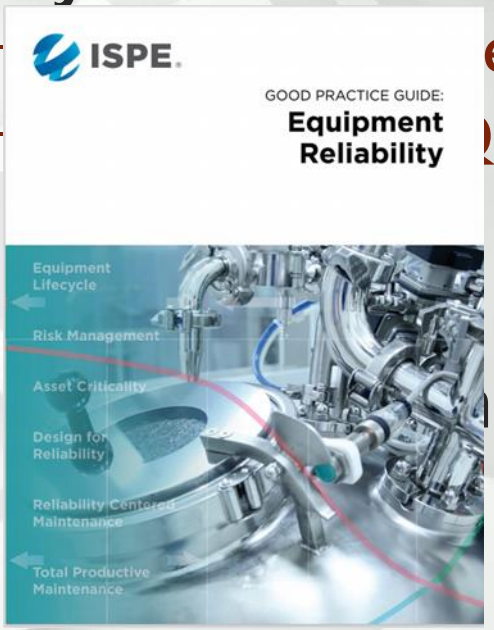
- ual, Val.

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## Decommission Phase


# The Project Phase

# Reliability is Built into Assets by Design

Project Phase

- About 85% of assets' LCC is committed during the design phase
- Concept and Design
  - Asset Requirements
  - Asset is Built
  - DfR Analysis is Performed
    - Operational Strategy
    - Maintenance Strategy
    - LCCA
    - Risk Assessment (ACA, RCM)
- DfR performs reliability, maintainability, operability, accessibility, cleanability, repairability and serviceability analyses

# DfR Evaluates Performance Requirements

Project Phase

- Safety Requirements
- Operational Context
- PdM Techs, CBM and Instrumentation
- Maintenance Service and Support
- Others

# The Role of ACA at the Project Phase

Project Phase

- Identifies Significant Risks
- Ranks Systems for Maintenance Strategy Development
  - Asset Criticality Classification

| | |
|---|---|
| ▪ Class 5 – High Criticality<br>▪ Class 4 – Significant Criticality | Apply RCM |
| ▪ Class 3 – Moderate Criticality<br>▪ Class 2 – Low Criticality | Apply QM |
| ▪ Class 1 – Very Low Criticality | RTF |

- Always Apply Regulatory Requirements

# Typical Hurdles Affecting Reliability at the Project Phase

Project Phase

- **Skipping Relevant Reliability Analyses**
  - Preliminary ACA and RCM
  - Reliability and Maintainability
  - Operability, Accessibility, Cleanability
- **Disconnect of Design Teams with O & M People**
  - May Prompt Continue Using Bad Design Actors
  - Reliability and Maintainability Feedback
  - Operability Feedback
- **No Maint./Eng. Involvement During Validation**
  - Avoid Operating Close to Critical Speeds
  - Enable Operating at Max Efficiency Parameters

# Project Phase Hurdles – Cases

Project Phase

### Cargo Elevator Design Flaw

- A couple of million USD avoided in construction
- Prompted a $1000.00/day expense
- Caused the acquisition of a crane
- 15-20 is the ratio of Operational Cost / Design Costs over the course of the asset life cycle
- Life Cycle Cost study ruled out

### WWTP Pumps Design Flaws

- Wrong Sealing Technology Used
- Caused Start Up Delays
- Maintenance / Operations not Consulted

### Tumble Dryer Installation Flaws

- Contractor not Competent at Precision Maintenance

# The Operational Phase

# Keep Reliability at Optimal Levels - Training

Oper. Phase

- Who is the Asset Owner?
  - Process, Facility, Utility, Laboratory
- Operator Training is Vital for a Reliable Operation
  - Operating Manuals / Emergency Procedures
  - TPM Principles / 5S / RCA
  - Process FMEA
- Maintainers Training and Qualification
  - GMP & EHS Regulatory Requirements
  - PdM, Precision Maintenance, Lubrication
  - Troubleshooting and Corrective Procedures
- Maintenance and Reliability Staff Training & Qualification
  - RCM, RCA, ACA, RAM, Failure Data Analysis, Process FMEA
  - PdM , Precision Maintenance, Lubrication
  - Maint. Management, Work and Material Management

# Keep Reliability at Optimal Levels

## Assessing Risks with ACA

Oper. Phase

### Who Determines Asset Critically?

- A Competent Multidisciplinary Team / Facilitator
  - Maintenance, Operations, EHS, Quality, Engineering
  - Middle Management Level

### How is ACA Performed at the Operational Phase?

- Review the Project Phase ACA Exercise
- Review Business Goals
- Bear in Mind that Asset Criticality Evolves with Time
- Select Business and Asset Drivers
- Agree on a Criticality Matrix / Apply to Assets

### Benefits of ACA at the Operational Stage

- Determine Process for Maintenance Optimization
- Prioritize Maintenance Works per Criticality
- Identify Critical Spares, Capital Expenditures
- Better Back Log Management

# Reliability to be Kept at Optimal Levels

## Maintenance Tasks

Oper. Phase

- Who is Responsible for Ensuring Assets Have Effective Maintenance Tasks?
  - The Asset Owner
  - Maintenance
  - Reliability Engineers
  - QC and EHS

- Maintenance Tasks for Critical Pharma Assets Must be:
  - Created by a Multidisciplinary Team
  - Able to reduce risks to tolerable levels
    - Quality, Economical, Environmental and Safety
  - Targeted to specific potential failure causes
  - Accepted by the Asset Owner

# Reliability to be Kept at Optimal Levels

## Info for Maintenance Tasks

Oper. Phase

- Business, Process and Asset Related Goals
- Asset Criticality, Desired Performance Levels
- Failure, Quality and EHS Events Data; Spare Parts Usage
- Technical Information (P&ID, Manuals, Drawings, etc.)
- KPI's (RAM, Downtime Cost, PM, Calibration, etc.)
- Analysis Expectations of Stakeholders

# Typical Hurdles Affecting Reliability at the Operation Phase

CONSCIOUS RELIABILITY

Oper. Phase

- **Relying on OEM for Maintenance of Critical Assets**
  - Ruling out the actual operating context
  - T Tasks are Ineffective for random failures
- **Skipping the Risk Management Approach**
  - No multidisciplinary team
  - Copy and paste of old plans
  - Disengagement from company goals
- **Lack of Training on MRE and Poor Management Practices**
  - Reluctance to move forward with PdM
  - Poor failure and maintenance data
  - Opinion rather than data analysis-based decision
- **Poor Precision Maintenance Practices**
  - Lubrication, rotor dynamics, shaft alignment, etc.

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# Holistic View for Producing Effective Maintenance Tasks for Critical Pharmaceutical Assets

# 1-Asset Data Integrity


- Producing maintenance tasks is a Decision-Making Process
- Make sure to use reliable data
- Convert data into useful information
- Use proven data analysis tools
- Obtain the most value from data

# 2-Understand Asset Criticality First




Applying ACA

## Typical Pharma Business Drivers

- Product Quality
- Regulatory Requirements
- Level of Service Reduction
- Good Corporate Citizenship
- EHS Stewardship

## Typical Pharma Assets Drivers

- Remaining Useful Life
- Equipment Utilization
- MTBF
- Output
- Availability

## Bear in mind that AC evolves with time

# 3-Understand the Asset Mission

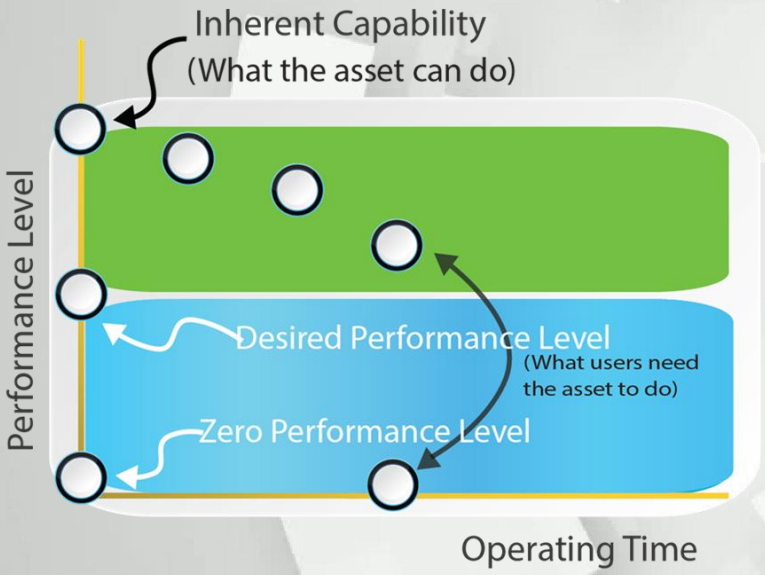

- Operating Context
  - Regulatory Aspects
    - Quality, EHS, PSM
  - Technologies Involved
  - Reliability Requirements
  - Product Demand
  - Location, etc.

- Understand the Asset's Desired Performance Levels

- Be aware of the asset's additional requirements (regulatory and others)

- Do not overlook its protective devices

# 4-Understand What Could Cause Assets to Fail




**Consider all possible events**
- Design Flaws
- Natural Deterioration
- Human Errors

**Classify FM's by their failure mechanisms**
- How failure may occur
- MEC, ELE, INS, MAT, EXT, etc.

**Identify and classify all potential root causes**
- Why failures may occur
- DSG, FAB, O&M, MGT, AGE, etc.

***Evaluate failure events happening and the ones being prevented**

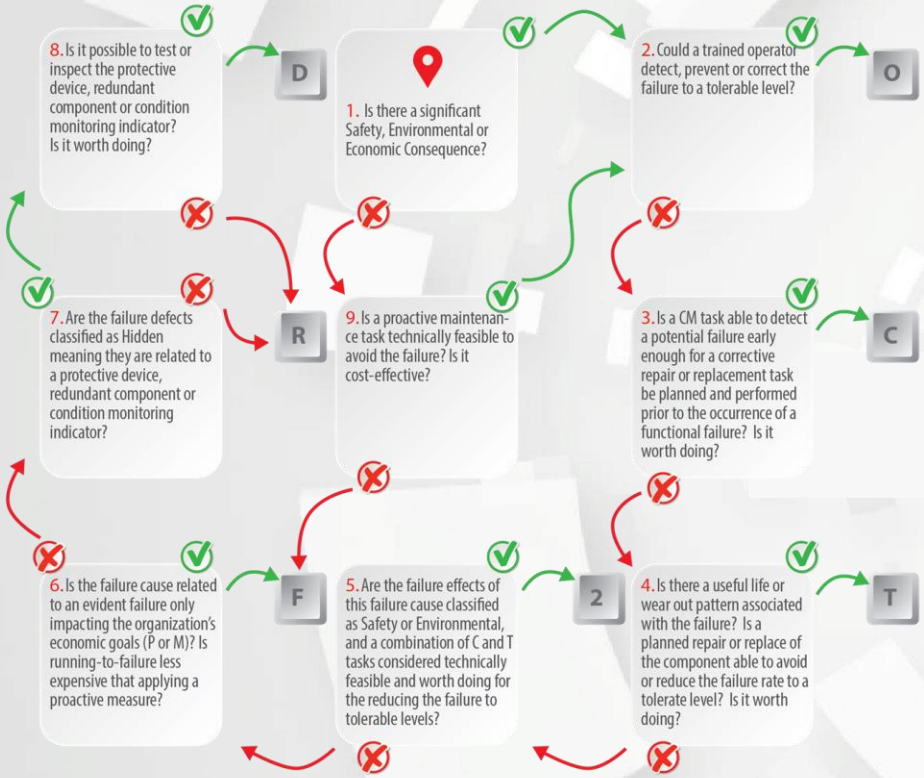
* All possible events under the current operating context

# 5-Use a Risk Management Approach for Evaluating Failure Effects

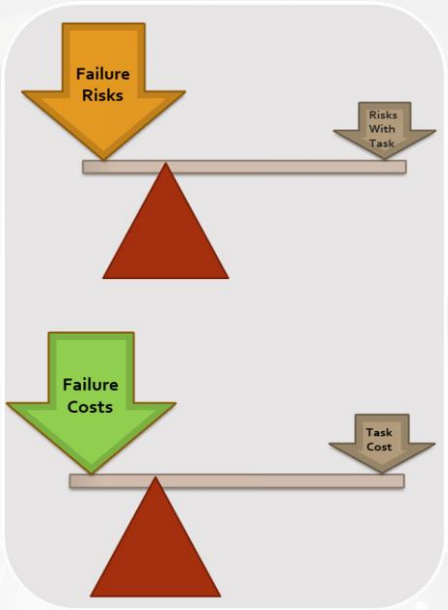
| F # | F # cd | Function | FF # | FF # Cd | Functional Failure | FM # | FM Code | Failure Mode | RC # | RC Code | Root Cause | P-Inf | F-Inf | F. Loc | De cisi on | Severity | Prob. | Detect. | Failure Effects & RPN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | PRI | To circulate a minimum of 30 GPM of caustic water through the SC-1 system | A | | Unable to circulate caustic water through the SC-1 system at all | 1 | MEC | Pump bearing seizure | a | DSG | Inadequate bearing capacity | ✔ | ✔ | ✔ | | 7.00 | 7.6 | 7 | 372.4 |
| | | | | | | | | | b | AGE | Normal wear and tear | ✔ | ✔ | ✔ | | 5.00 | 4.8 | 6 | 144 |
| | | | | | | 2 | ELE | Pump shaft fracture | a | FAB | Contractor installation error | | | | | 7.00 | 6.4 | 6 | 268.8 |
| | | | | | | | | | b | O&M | Over-torque due to operating errors | | | ✔ | | 7.00 | 7.2 | 6 | 302.4 |
| | | | | | | 3 | INS | No signal in control valve | a | DSG | Inadequate software | | | ✔ | | 3.00 | 3.2 | 5 | 48 |
| | | | | | | | | | b | FAB | Programming mistake | | | ✔ | | 3.00 | 2.8 | 5 | 42 |
| | | | | | | 4 | ELE | Motor Windings earth fault | a | AGE | Normal use | | | ✔ | | 9.00 | 9.6 | 9 | 777.6 |
| | | | | | | | | | b | DSG | Moisture ingress due to incompatible seals | | | ✔ | | 9.00 | 9.2 | 5 | 414 |
| | | | | | | 5 | EXT | Blocked inlet pipe | a | O&M | Operation error | | | ✔ | | 3.00 | 2.4 | 2 | 14.4 |
| | | | | | | | | | b | MGT | Lack of cleaning procedure | | | | | 2.00 | 0 | 1 | 0 |

# 6-Use a Reliability Engineering Approach for Selecting Tasks

## Utilize Reliability Math for Freq. Calculation



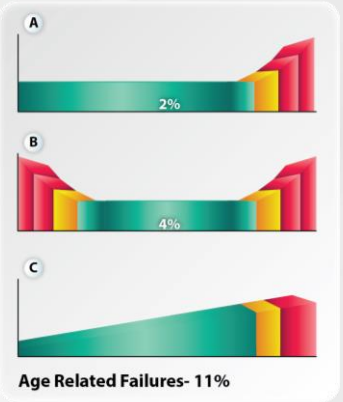

RCM Decision Diagrams

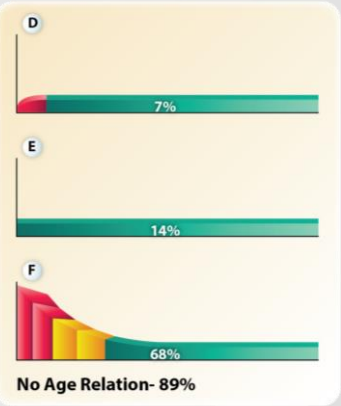


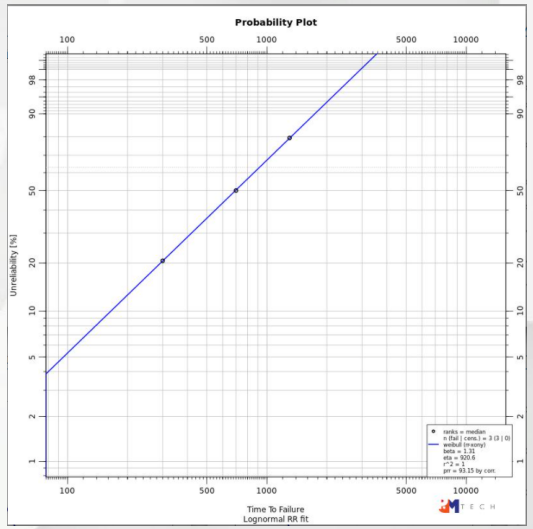

Every Tasks Must be Justified

$$n = \frac{ln\left(\frac{-\frac{MTBF}{PF}Ci}{(Cnpm-Cpf)ln(1-S)}\right)}{ln(1-S)}$$

Use Reliability Math.




Corroborate FM Patterns

# 7-Monitor Continuous Improvement


- Review your analysis and results whenever:
  - The operating context changes
  - Unexpected failures occur
  - New maintenance technologies are available
  - Asset becomes aged
- Root cause analysis
  - RCA is a reactive approach to continual improvement
  - It will catch failure modes and causes that may have been missed in RCM-R®
  - This happens after the fact
  - RCA is not suitable for use in developing an entirely new PM program
- Implementation Plan and KPI's
  - Make sure the implementation plan is followed
  - Agree on a useful set of KPI's
  - Monitor RAM and other relevant indicators
  - Monitor the results of the analyses implementation

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# SUMMARY & QUESTIONS

# Summary

## Unique Aspects of the Pharma Industry

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- GMP System
- QA and QC
- Qualification and Validation
- Management of Change
- Others

## Summarized Live Cycle of Pharma Assets

- Project Phase
  - Concept and Design
  - Inst., Comm., Qual, Val.
- Operational Phase
- Decommission Phase

## Typical Hurdles Affecting Reliability at the Project Phase

Project Phase

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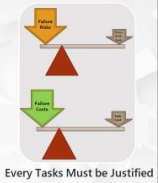

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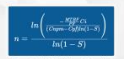

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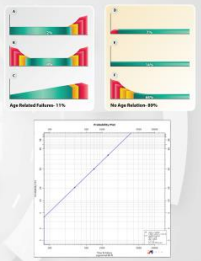
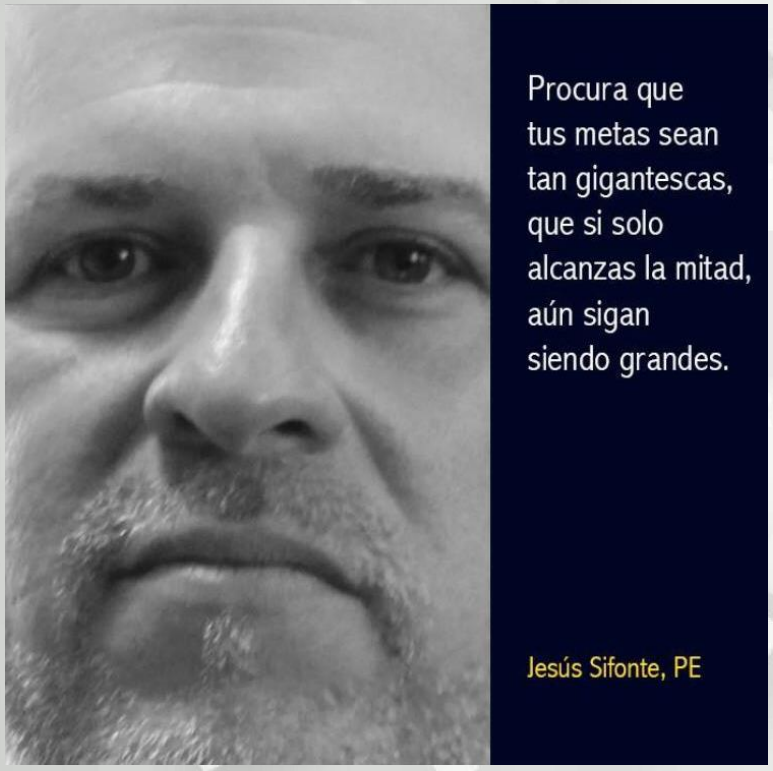


Corroborate FM Patterns

# Time for Questions!

## Thanks for your attention!





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