Enfoque Estratégico de la Confiabilidad en la Industria Farmacéutica Según ISPE

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.

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

Where:
- \( R \) is the surviving probability
- \( e = 2.718 \)
- \( t \) = component age
- \( \beta \) = shape parameter
- \( \eta \) = characteristic life
How is Reliability Measured?

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

\[
R(t) = e^{-\left(\frac{t}{MTBF}\right)} \tag{2}
\]

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
  - Concept and Design
  - Inst., Comm., Qual, Val.

• Operational Phase

• Decommission Phase
The Project Phase
Reliability is Built into Assets by Design

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

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

Project Phase
The Role of ACA at the Project Phase

- Identifies Significant Risks
- Ranks Systems for Maintenance Strategy Development
  - Asset Criticality Classification
    - Class 5 – High Criticality
    - Class 4 – Significant Criticality
    - Class 3 – Moderate Criticality
    - Class 2 – Low Criticality
    - Class 1 – Very Low Criticality

- Always Apply Regulatory Requirements

Project Phase

Always Apply Regulatory Requirements
Typical Hurdles Affecting Reliability at the 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

- **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

**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

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

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

- 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

- Relying on OEM for Maintenance of Critical Assets
  - Ruling out the actual operating context
  - 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.
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
# Use a Risk Management Approach for Evaluating Failure Effects

## Risk Identification

- **Risk Sources**: Assets and processes
- **Events**: Failure modes
- **Their Causes**: Potential root causes
- **Their Consequences**: Failure effects (qualitative analysis)

## Risk Analysis

- **Risk Nature and Level**: Failure effects (quantitative analysis)

## Risk Evaluation

- **Risk Criteria**: Failure effects risk matrix

## Table: Risk Analysis and Evaluation

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6-Use a Reliability Engineering Approach for Selecting Tasks

Utilize Reliability Math for Freq. Calculation

RCM Decision Diagrams

Every Tasks Must be Justified

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
SUMMARY & QUESTIONS
Summary

Unique Aspects of the Pharma Industry

- Products are administered to humans and animals
  - Oral, injectable, transdermal, inhalation, suppository, transmucosal, vaginal, rectal, etc.
- 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

- Shipping Relevant Reliability Analyses
  - Preliminary ACA and RCM
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  - Avoid Operating Close to Critical Systems
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Typical Hurdles Affecting Reliability at the Operation Phase

- Relying on OEM for Maintenance of Critical Assets
  - Relying on the actual operating context
  - Unforeseen failures
- Skippng Risk Management Approach
  - No multidisciplinary team
  - Copy and paste of old plans
  - Disengagement from company goals
- Lack of Training on MRO and Poor Management Practice
  - Reluctance to move forward with MRO
  - Poor life cycle maintenance data
  - Operational rather than data-driven, biased decision
- Poor Precise Maintenance Practices
  - Lubrication, rotor dynamics, shaft alignment, etc.

Holistic View for Producing Effective Maintenance Tasks for Critical Pharmaceutical Assets

6-Use a Reliability Engineering Approach for Selecting Tasks

Utilize Reliability Math for Freq. Calculation

RCM Decision Diagrams

Every Task Must be Justified

Coordinate FM Patterns
Time for Questions!

Thanks for your attention!

[Image of a book cover titled "Reliability Centered Maintenance - Reengineered: Practical Optimization of the RCM Process with RCM-R"]

Procura que tus metas sean tan gigantescas, que si solo alcanzas la mitad, aún sigan siendo grandes.

Jesús Sifonte, PE

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