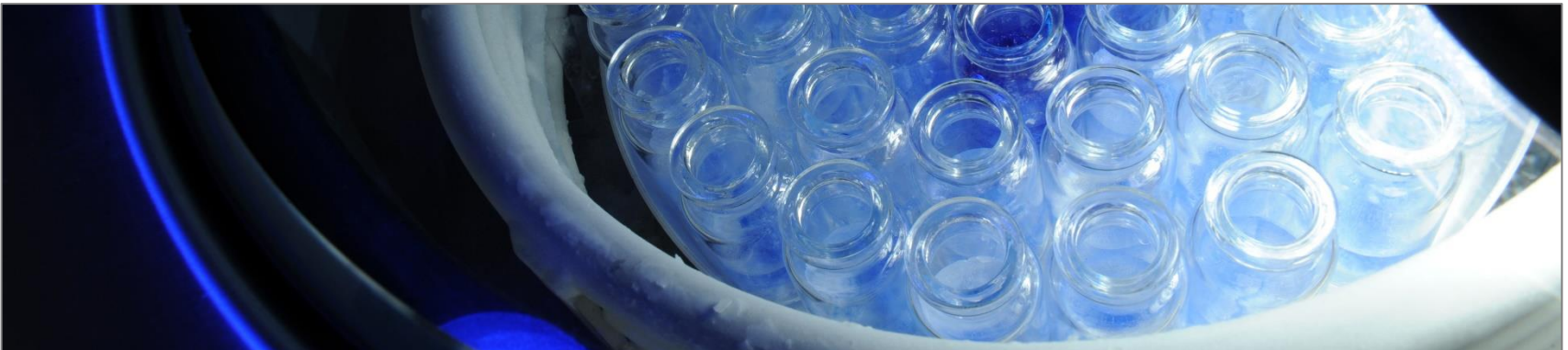

Theory 7, PDA-Seminar

Maintenance and fault correction

2024 PDA Europe
Freeze Drying in Practice



Outline

CHAPTER I: Introduction to a preventive maintenance concept

- What is & Why maintenance ?
- PM, CM, PdM
- Responsibility

CHAPTER II: Introduction to the most frequently occurring faults

- Diagnosis, causes, correction
- Failure report
- Presentation of examples of def. Components with explanation of causes

CHAPTER III: Documents

- Overview
- AMC, Maintenance Plan, Checklist, Protocol
- Spare parts

Introduction to a preventive maintenance concept



What is Maintenance?

- **Definition:** „Activities required or undertaken to conserve as nearly and as long as possible the original condition of an asset or resource while compensating for normal wear and tear.”
- **Important:** Maintenance is the combination of all technical measures and associated administrative actions intended to retain an item in, or restore it to, a state in which it can perform its required function. → Responsibility
 - Inspection
 - Preventive and scheduled maintenance
 - Corrective measures
 - Improvement
- **Types of Maintenance:**

European standard EN31051 explicitly names and defines basic measures and is structured in maintenance types.

Why Maintenance?

- Maintenance is required to ...
 - ...assure faultless operation
 - ...prevent large and costly repairs
 - ...avoid time consuming failure analysis in case the root cause is not obvious
 - ...prevent downtime and therefore production loss
 - ...avoid (hazardous) risk to operators
 - ...set a defined (validated) status of the equipment

Comparison of different maintenance tasks as a single or combined action

Maintenance tasks

Inspection



assessing
the actual
condition of
a unit

preventive
maintenance



activities to
reduce
wear stock

Corrective
maintenance



after wear,
malfunction or
breakdown

Predictive
maintenance



techniques
that help
forecasting
activities

Improvement



a process
making
something
better

PM: Inspection and Preventive maintenance

- The primary goal of PM is to avoid consequences of failure of equipment.
- This can be done by preventing the failure before they occur or turn into major defects by the following actions:
 1. Daily systematic check-ups & inspection
 2. Calibration, measurements & adjustments
 3. Planned shutdowns or
 4. Annual maintenance as per „maintenance protocol“ or „checklist“
Includes Replacement of wear and tear parts
 - replace gaskets, o-rings, membranes
 - replace or refill liquids
 - grease, paint, insulate,...



PM = relies on average and expected life statistics to predict when maintenance will be required.

CM: Corrective maintenance

- CM is a maintenance task performed to identify, isolate, and rectify a fault so that the failed equipment, machine, or system can be restored to an operational condition within the tolerances or limits
- A corrective action to bring back to system into an operational state by
 - replacing defective components
 - repair damage or defective components or modules
- Negative impact:
 - is the time delay (down time of machine)!
 - Lead time for planning, spare parts and manpower
 - Especially within a GMP environment not acceptable approach.



CM = Restore systems functionality after occurring failures.

PdM: Predictive maintenance

- PdM techniques are designed to help determine the condition of in-service equipment in order to predict (forecast) when maintenance should be performed.
- For PM it is necessary to permanent collect data from the actual condition of the equipment.
 - Compare batch records for abnormalities (i.e aging effects)
 - Frequency of actuations or switching frequency (i.e. valves)
 - Running times of equipment and stress analysis
 - Leak-Test or Filtertests results that worsen over time
 - Brake pads
- Positive: right action in the right time. Cost efficient.



PdM = differs from PM because it relies on actual condition of equipment. PM relies on average and expected life statistics.

IMP: Improvement maintenance (Refit/Retrofit)

- Techniques undertaken to make an asset better or more capable to its duties
- Improvements can include
 - replacing components with more sustainable, rugged or accurate of its kind
 - Updates for software, firmware, operating system,..
 - Replacement of gases, liquids (i.e. refrigerants phase-down)
 - Retrofit, overhaul
 - Customize functions
- Positive: keep the system up to date with latest technology

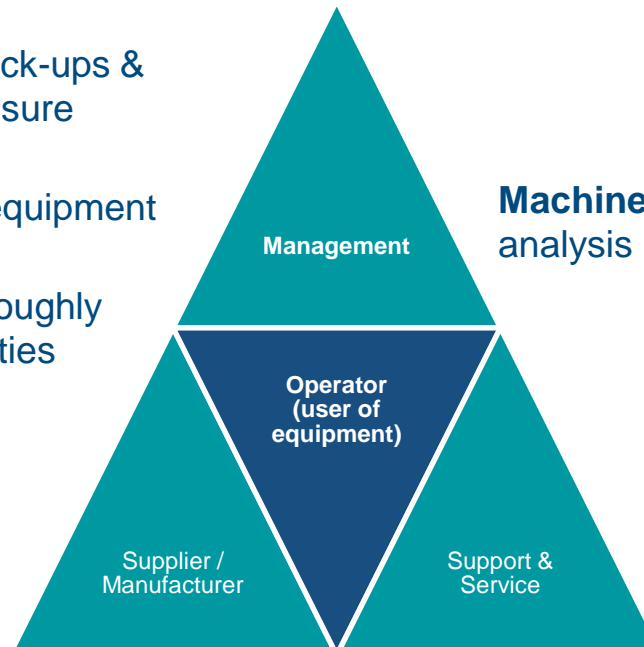


Responsibility - Maintenance is not a one man show!

Maintenance is an administrative responsibility! It is a **management** responsibility to provide resources, money and time to plan maintenance

Operator follow Daily systematic check-ups & inspections recommendations and assure availability of peripheral media: PM

- Operators are responsible for equipment (DGUVV3) (EN378)
- Operators are responsible thoroughly documentation towards authorities



Machine & Operator collect data for analysis purpose: PdM

Suppliers provide documents (Maintenance-Plan) acc. to OEM documentation and detailed lifetime considerations (Failure reports).

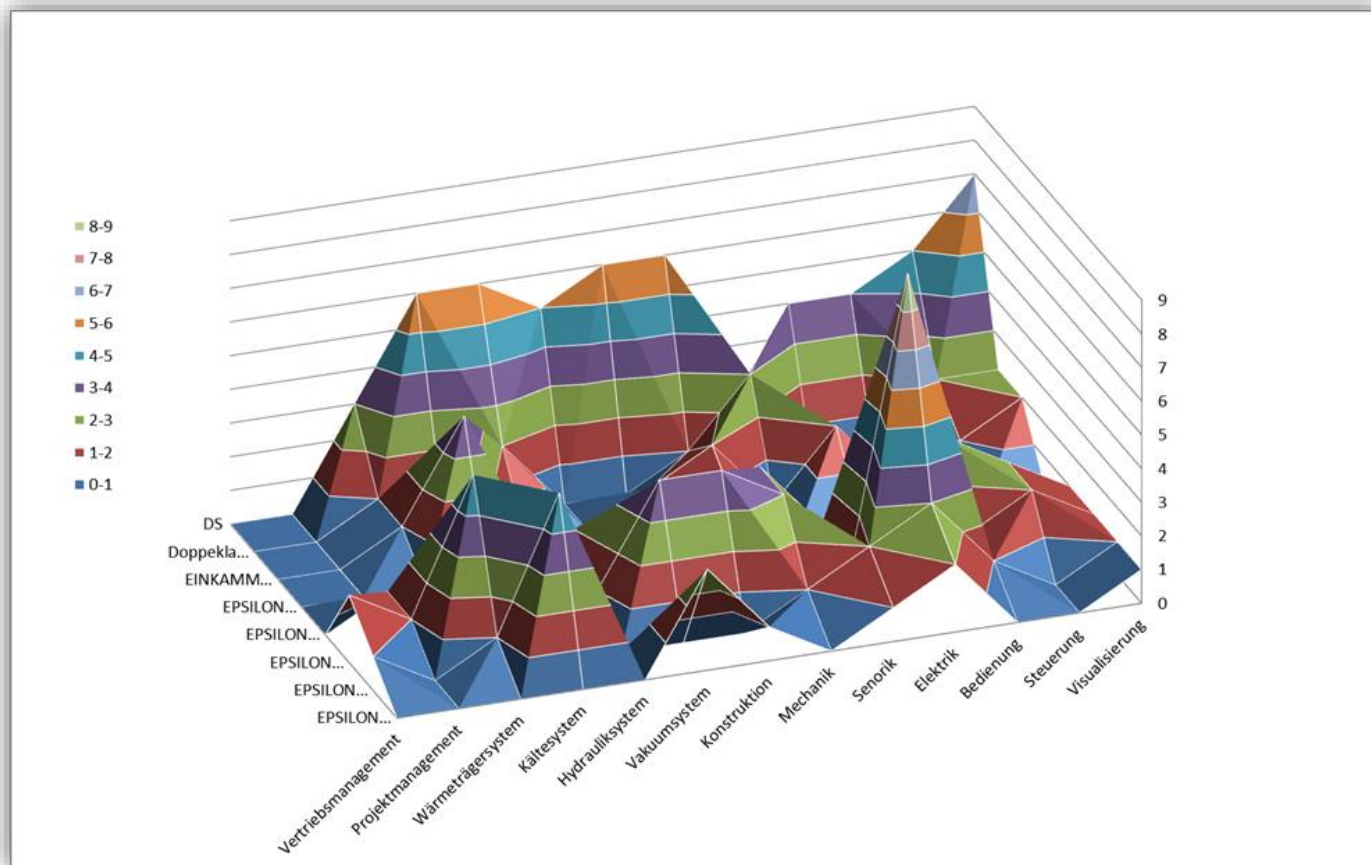
Support provides service according to Maintenance-Checklist/Protocol: PM
Suggest improvements, weak point, updates,...

Introduction to the most frequently occurring faults



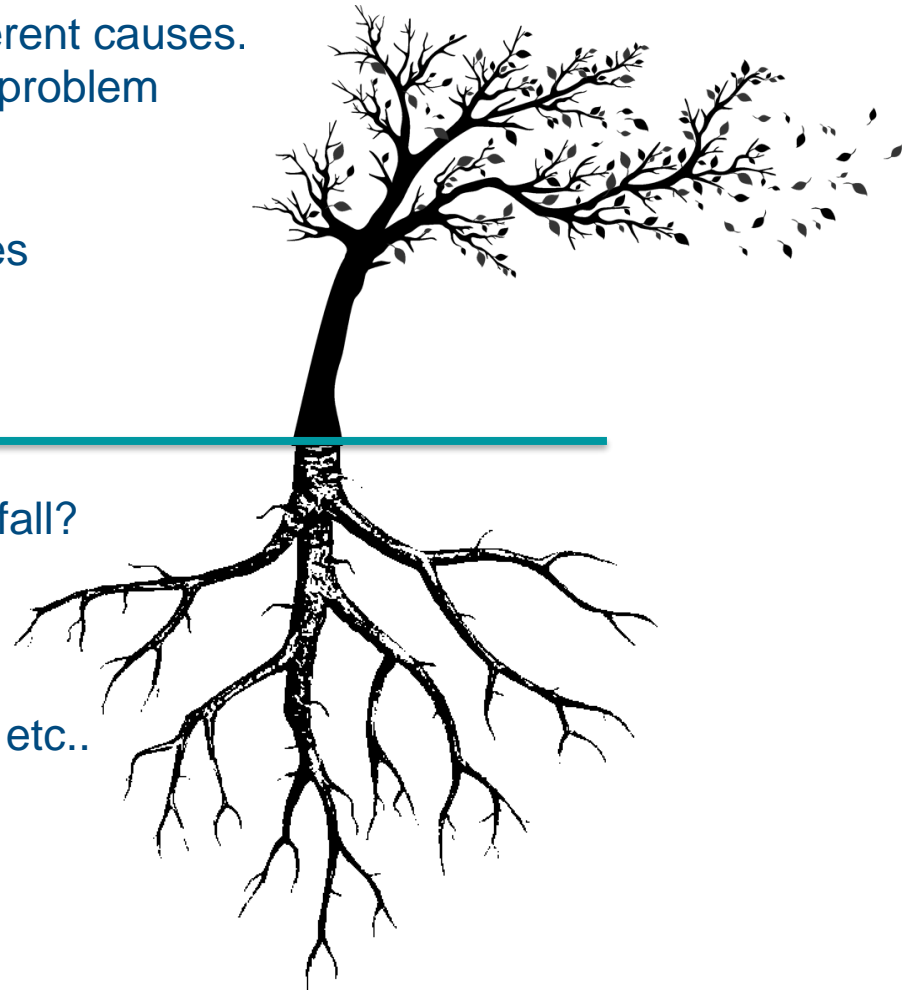
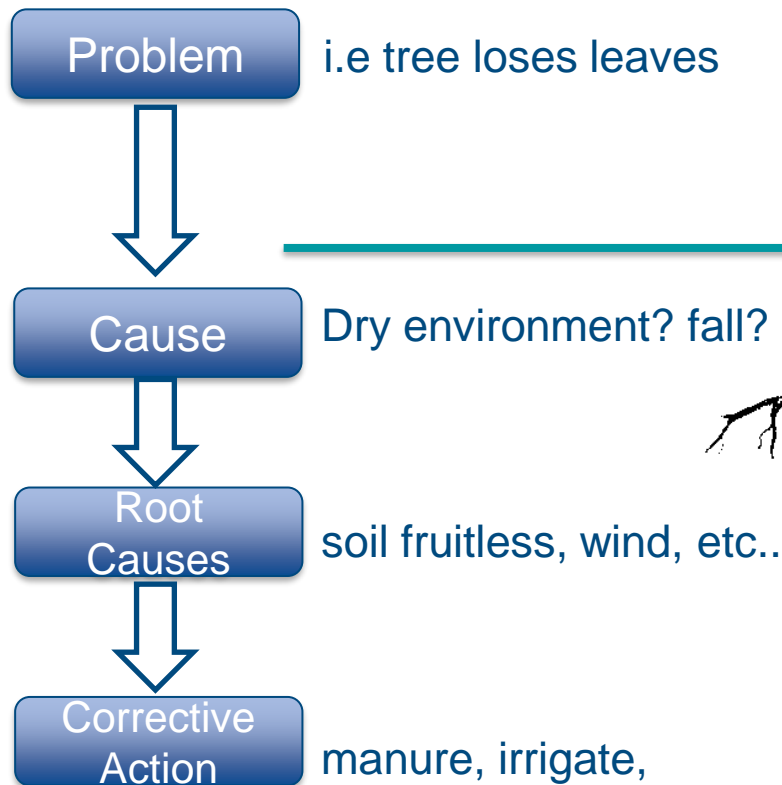
Failure and fault report

- Definition of fault: „a defect, imperfection or wrongful act“ -> abnormality
- A database of failures can help to trace weak points and help to generate remedial actions (graphic shows peaks and valleys)



Diagnosis, causes, correction

Each failure (effect) has a source of different causes.
We are trying to find the *root cause* of a problem

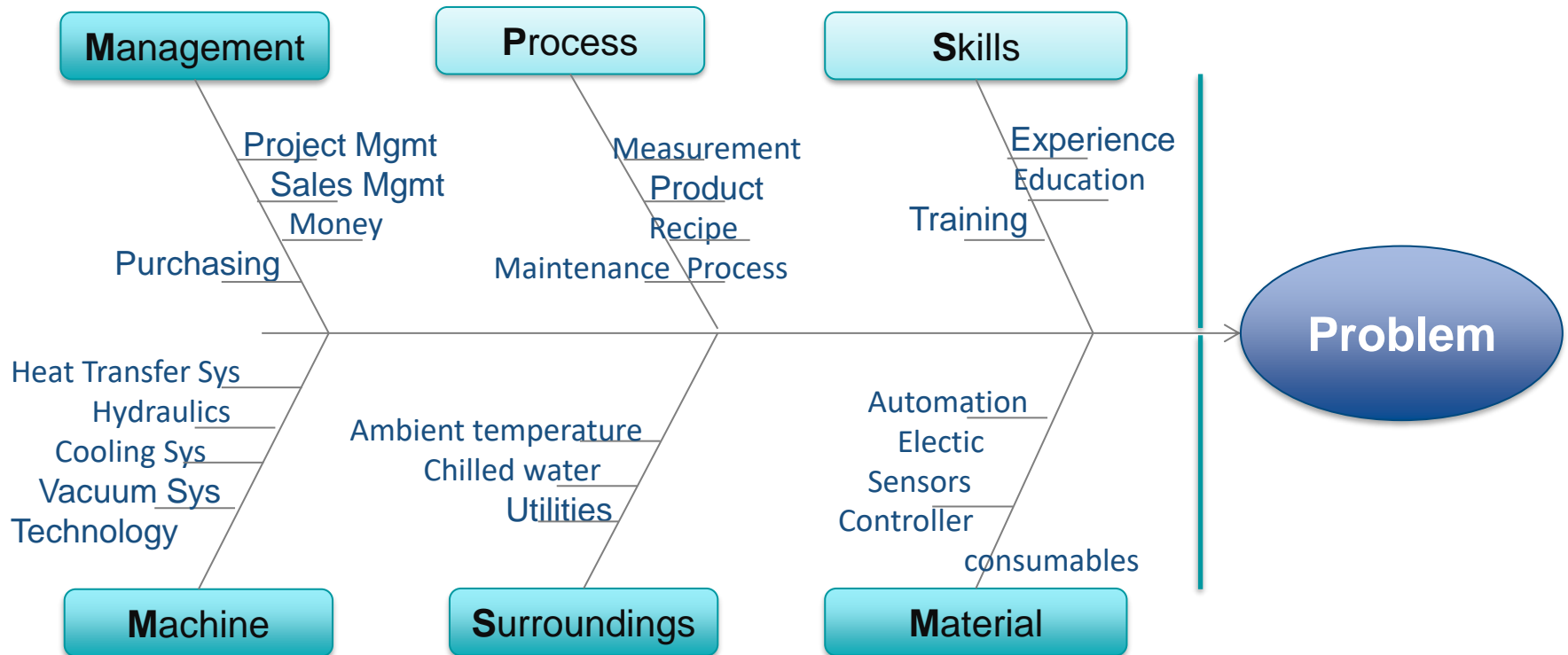


Diagnosis, causes, correction

Root cause analysis is going back to the 60th, were *Kaoru Ishikawa* invented a diagram

Root cause analysis is intended to reveal relationships

Each potential cause is tracked back to reveal the root cause (The 3Ss , 5Ms)



Database collecting and sort data

The more complex a functional unit, the more components involved

Collect and transfer all data (facts) into Database and investigate

Draw major categories; i.e. Management, Process, Skills, Material, Environment

Categorize and brainstorm causes

Start questioning (Why) to determine deeper causes and identify root causes



Introduction to the most frequently occurring faults

General terms:

- Failure database: gathering failures and incidents to determine critical points (week point analysis) to prevent „frequently occurring faults“
 - Using methods such as 5D or 8D reports (D = disciplines, automotive)
 - Asking the following to reveal the trigger
 1. Effect: What happened ?
 2. Action: Immediate response required by/with ?
 3. Measure: How to solve it ? → Corrective Action
 4. RCA: Why did it happen ?
 5. Virtue: How to avoid in future ? → Preventive Action

- Just identifying and replacing i.e a defective component is not the solution – RCA (root cause analysis) starts at this point with questioning.

- Similar approach is CAPA, 6σ - DMAIC (Define - Measure - Analyse - Improve – Control)

Pictures taken from incidents

Effect: vacuum leak observed during Sublimation-phase.

Cause: destroyed/burned diaphragm of the steam inlet valve

- Why is the membrane destroyed?
- Why not replaced/uncovered?
- Why was the membrane beyond its useful service life?
- Why not capable to resist steam temperature?

- No manufacturers batch issue
- No missing maintenance as it was replaced a week before
- Not installed in a wrong manner

Root cause:

- Steam generator runs at wrong offset
- Steam temperature too high (pressure) and exceeding the spec limit.
- Operators trained according to utility specification



Pictures taken from incidents

Effect: Vacuum performance out of spec.

Cause: Vacuum pump oil mixed with condensate (water).

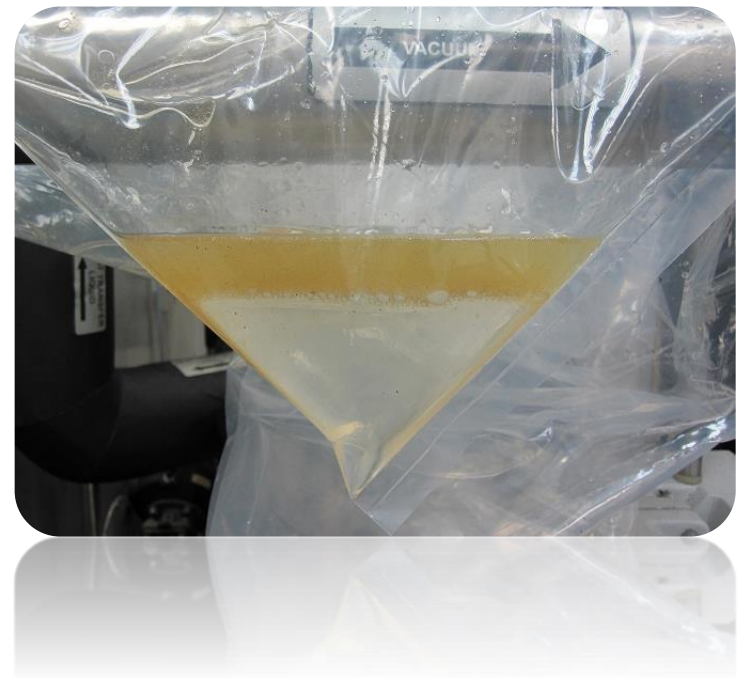
- Why is the oil contaminated?
 - Why was vapor not collected by ice condenser?
 - Why was the oil not replaced?
 - Why not adapted the recipe?
-
- No recipe change possible as validated cycle
 - Oil not replaced as not realized

Root cause:

- Recipe created lots of vapor
- Ice-condenser capacity reached
- Operators do not change oil frequently

Corrective action:

- Replaced oil sealed pump with dry pump
- Adapted batch size and recipe



Pictures taken from incidents

Effect: overload of Vacuum Pump motor.

Cause: Blocked Vacuum Pump exhaust filter



Root cause:

- No maintenance happened
- Operators not aware (trained)

Pictures taken from incidents

Effect: Refrigeration System fails due to excess pressure

Cause: Algae causes insulation layer in water-condenser



Root cause:

- No maintenance happened
- No agent added to chiller (i.e. glycol)

Pictures taken from incidents

Effect: Vacuum leakages

Cause: Porous o-rings



Root cause:

- „No maintenance“ philosophy by management

Pictures taken from incidents

Effect: Leaking silicon oil through ss-hose

Cause: pinhole at stainless steel hose



Root cause:

- No 10 year maintenance happened
- Friction between hoses, routing to be optimized

Documents



Document order and content

Maintenance
(Master)Plan

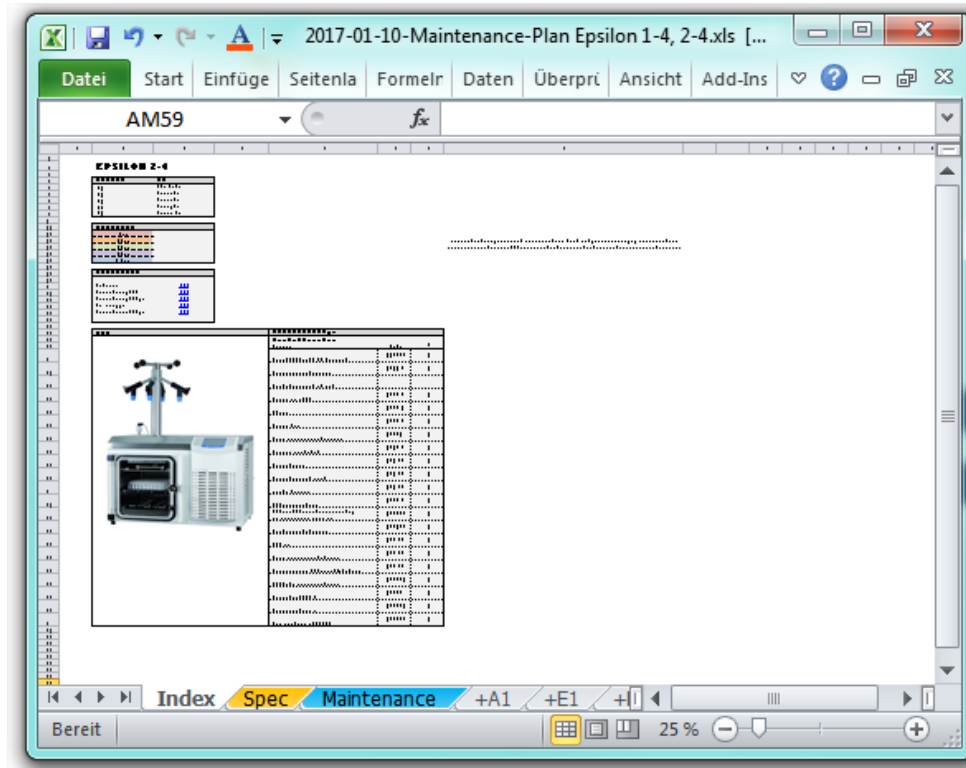
Includes all necessary information: What, how, specs, spares, maintenance, OEM manuals, P&ID and electrical drawings ... Maintenance Plan also considers information from „Failure Report database“

Maintenance
Protocol

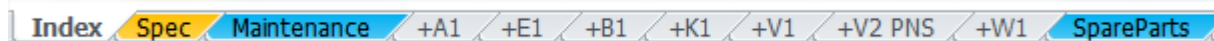
Maintenance protocol describes all relevant points in a protocol manner.

Maintenance Plan

Maintenance
(Master)Plan




- Structure according to electrical drawings E-Plan



Maintenance Protocol

Maintenance Checklist

- Maintenance plan to prove actions taken




Anlagenart Type of freeze-dryer	Seriennummer Serial number	Baujahr Built	Ident-Nummer Kunde Ident number customer	Auftragsnummer, von Order number, from
EPSILON 1-4, 2-4				

Martin Christ Geräte- und Anlagen GmbH **Telefon:** 05522 / 5007-0
 Eggelsch, 1713 - 37507 Osterode am Harz **Telefax:** 05522 / 5007-12
 Am der Unteren Sösse 50 **Internet:** www.martinchrist.de
 37520 Osterode am Harz **E-Mail:** supportepsilon@martinchrist.de
 Germany

Maintenance Protocol for EPSILON 1-4, 2-4
Wartungsbericht für EPSILON 1-4, 2-4
 Comprehensive Version for GMP environment.

Customer: **XXXX**
 Street: **XXXX**
 ZIP CITY: **XXXX**
 Contact Person: **XXXX**
 Tel: **XXXX**



Freeze-dryer

Executive Summary: - maintenance results after completion:

<input type="checkbox"/> Successful / erfolgreich	<input type="checkbox"/> Successful, Rework required. Erfolgreich, aber mit nacharbeiten.	<input type="checkbox"/> Not successful, Nicht erfolgreich
--	---	---

Signature, Date **Unterschrift, Datum** Technician CHRIST: Customer:

2017-06-27 1

Maintenance conclusion

- An appropriated maintenance concept is a **combination of different administrative and technical measures**
- A **maintenance plan** (individually adapted) provides required information and based on that a maintenance protocol is generated
- The **maintenance protocol** provides requirements and recommendations for the user and operator to assure and increase availability of the equipment and helps to discover wear and tear in defined intervals.
- Supplier or distributors provide **maintenance contracts (AMC)**. This should include a mixture of inspection and replacement of wear parts. Advantage: The customer is always on the safe side as suppliers latest findings (weak point analysis, improvements) can be considered during PM.
- Critical items/parts are stored near the machine to reduce lead time for order and shipping.

Questions?



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