Facility Optimization

A Facility Team Perspective

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19Feb15

Connecting a World of Pharmaceutical Knowledge

Facility Optimization

What is it? - What is an Optimal Facility?

Depending on who you ask, you may get different perspectives.

- Plant Manger - Capacity?
- Manufacturing - Process?
- Quality – Audit & Compliance?
- Facilities – Maintenance, Calibration, Operating Costs?

Facility Optimization

New Facilities, Capacity Increases, Process Improvements and Capital Expansion programs are often less than perfect.

Series of compromises.

Pressures from:

- Budget
- Schedule
- Information

All can lead to sub-optimal decisions.

Facility Optimization

You get what you get and you don't get upset.

So - How do I make the best of what I have?

Thoughts on:

- Robustness.
- Maintenance and Calibration.
- Making the most of existing budgets and resources.
- Managing Capital.
- Facilities Team.
- Culture.

Facility Optimization

Perspective from Facility Team focused on considerations for optimizing what you have.

Facilities Team – What's the point?

Provide the vision, leadership and technical expertise necessary to **protect and preserve** the **capacity** of company assets and increase the **efficiency** and **value** of engineering, **operations** and **maintenance** practices while working cooperatively with all departments to meet operating objectives.

Facility Optimization

"protect and preserve the **capacity"**

Ability to do the thing it is intended to do

- Uptime
- Quality
- Compliance
- Efficiency
- Maintenance
- Capable [in units of output (GPM, CFM, PSI)]

"efficiency and **value"**

Balance between cost, quality and progress.

- "Common Sense"

Robustness

"protect and preserve the **capacity"**

Product, process, or system designed for continuous operation with very low downtime, failure rate, variability, and very high insensitivity to a continually changing external environment.

Up Time – Common Sense

Robustness

"protect and preserve the **capacity"**

What gets all the attention

Maintenance and Calibration

"operations and **maintenance"**

Masters of Investigation - root cause / failure mode analysis

Deviations
OOT / OOP
Equipment Failures

CAPA
Increase Frequency
Tighten Tolerance
Tighten / Increase Range
Decrease Interval
Training
Added Steps / Procedures

Maintenance and Calibration

" Deviation and Error Investigations – Problem solving tools and **models that have been effectively used in many other industries** (such as the auto manufacturing industry) to determine root/actual cause should be encouraged in a risk-based approach to cGMP."[1]

"A quality system for investigations should be designed and implemented which involves management notification, timeliness, and trending of corrective and preventive actions. The goal of such a system is to **prevent recurrence of manufacturing errors**."[1]

"Risk-based cGMPs encourage technological advances that can improve the manufacturing process because it frees the manufacturer from prescriptive regulations that **do not improve quality**."[1]

[1]Taken from FDA Website, "Risk Based Approach to cGMP" Committee notes 10/16/02

Maintenance and Calibration

Leveraging Existing Budgets and Resources

- Impact Assessments
- Direct / Indirect
- Critical / Functional / Reference Only
- Data Collection
- Risk based approach to performance
- Extend Intervals
- Consolidate or remove PM steps
- Expertise & Historical Performance

Maintenance and Calibration

- Masters of Data: collecting data, storing data, analyzing data to trend, trigger alarms, investigation failure.
- We brag about how much data we collect.
- What about all the things that are always going right?
- What about the devices that are always in spec., never OOT, OOP?
- Air Handler filter changes come up clean every interval.
- Maintain to the point of failure – Literally.

Maintenance and Calibration

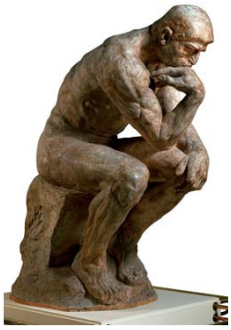
- How much as an industry do we use this data to provide an objective rationale for lessening our workload?
- Utilize failure rates as rationale for CAPA
- Utilize performance rates as a rationale for extended or lessening PM's.

Maintenance and Calibration

Is it Optimal?

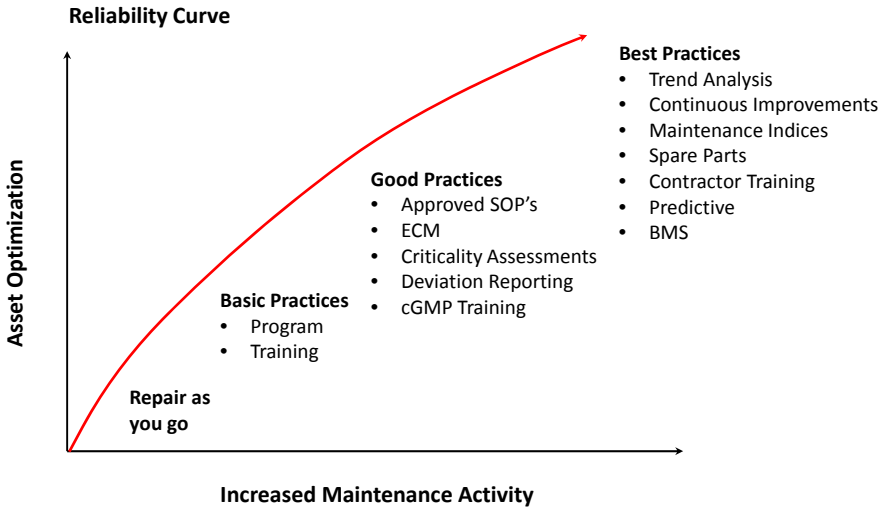
- Safer not to do it, leave it alone.
- Zero risk of failure (personnel or otherwise)
- Quick to add resources / staff augmentation / expense to address CAPA, but what about to drive out waste?

Maintenance and Calibration



What is our typical focus? – Where does that drive our resources?

Maintenance and Calibration

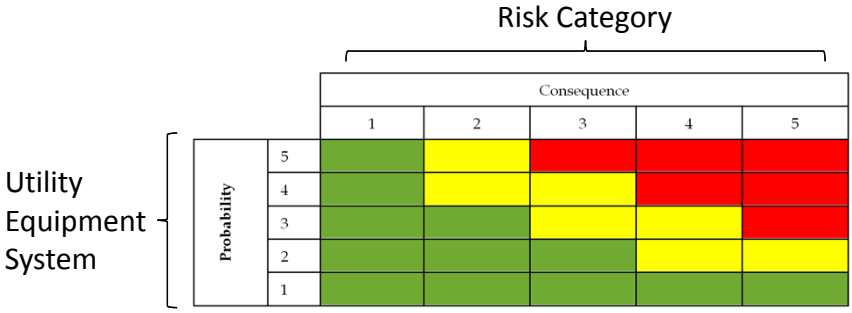


ISPE Good Practice Guide - Maintenance

Managing Capital

"efficiency and **value"**

Optimal Capital budgets – Risk Based Approach



Managing Capital

"efficiency and **value"**

Quarterly Reviews

- Stakeholder Buy-In / Ownership
- Specific or Vague, Anecdotal or Objective
- Risk allocated by RPN number and fed into a serialized capital budget
- Can all agree to reallocate, but helps to optimize capital spending and allocation

Managing Capital

"efficiency and **value"**

Building A		Status	Comments
Chilled Water			
	Chiller A1001		
	Chiller A1002		
	Chiller A1003		
	Pump A1001		
	Pump A1002		
	Pump A1003		
WFI			
	Still A1001		
	Tank A1001		
	Pump A1001		
	Pump A1002		
	Distribution		
Steam			
	Boiler A1001		
	Boiler A1002		
	CR A1001		

Team review weekly at turn over. 20 min to go thru the whole plant w/ the whole team.

Drove Specific vs. Anecdotal

Record of what drive funding requests.

Team in touch w/ equipment = Ownership.

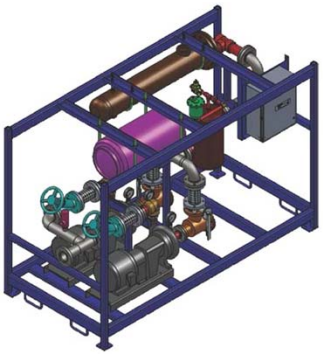
Facilities Team / Culture

Typical

- Equipment Knowledge
- Experience
- Training

Non - Typical

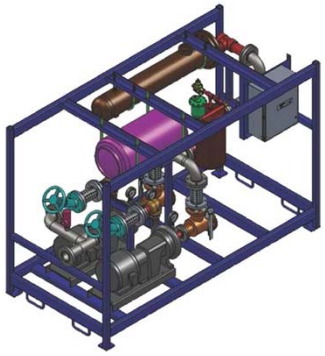
- Ownership
- Creativity
- Common Sense
- Ego / Pride – Willingness to put it aside
- Shoe Leather
- Walk-About
- Willingness to make it better



Facilities Team / Culture

Development

- Force the experience
- Find a mentor
- Ask – put your pride in your pocket
- Listen
- Walk-About
- What are you going to do to make better.



Closing

Optimization:

- Optimal – Depends who you ask.
- Desired State – Drive Continuous Improvement.
- Make the most of what we have.

Robustness :

- Common Sense.

Maintenance and Calibration / Making the most of existing budgets and resources:

- Use rationale / data to your advantage.
- Work to lessen the load – pays dividends.

Closing

Managing Capital:

- Follow the Risk

Facilities Team / Culture:

- Force the experience
- Find a mentor
- Ask – put your pride in your pocket
- Listen
- Understand your role
- Shoe Leather

Closing

Thank You!