

Facility Best Practices

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Connecting a World of
Pharmaceutical Knowledge

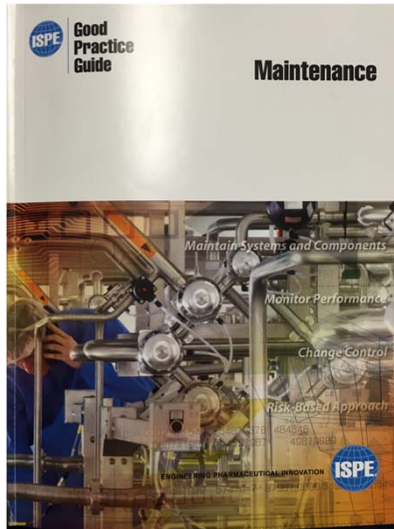
Biotech Facility Maintenance Practices

(from ISPE Good Practice Guide – Maintenance)

- There are levels of Maintenance
 1. Repair as you go
 2. Basic Maintenance Practice
 3. Good Practice
 4. Best Practice
- Not everyone can be “Best Practice”

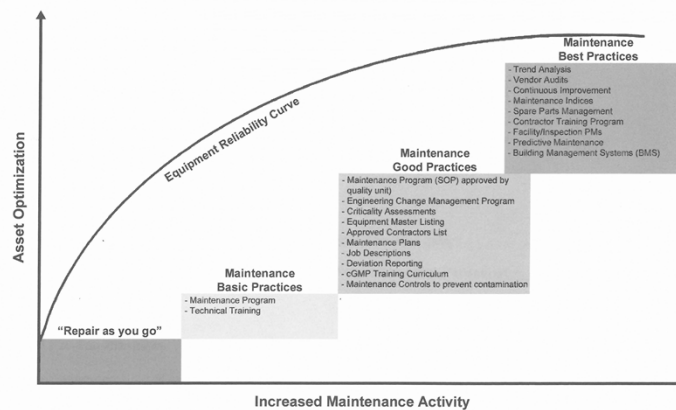


Recommended Book: ISPE Good Practice Guide - Maintenance



Biotech Facility Maintenance Practices

Figure 3.1: Reliability Curve



From ISPE Good Practice Guide - Maintenance

Biotech Facility Myths

- Designing and Building
- Startup
- Operations



Designing and Building

- Setting a Project Budget
- Common Design Mistakes
- Contractor Issues



Capital Project Budgets

Common Practice

- At the beginning, no one knows the budget except “The Boss”
- Negotiating Internally with Finance/using bid phase for estimates
- Set the Budget Maximum
- Overruns and Surprises
- Avoid the risk



Best Practice

- Focus on the Business Case, not the budget, and involve everyone
- Paying for a Third Party estimate
- Focus on the desired NPV
- Bad news is not like wine
- Share the risk

Common Design Mistakes

Common Practice

- Equipment on the roof
- Epoxy Resin Floors
- Slab on Grade
- Reuse an old Building
- Make an Exact Copy



Best Practice

- Equipment in an “attic”
- Resilient floors
- Basement
- Build new or rehab
- Don’t

Contractor Issues

Common Practice

- Get a +/- 10% Estimate ASAP – “needed for Capital Budgets”
- Waste Pipe is Plumbing
- Hire a “Big” or “Small” contractor for more capability or better service

Best Practice

- Use CII Principles – tailor the estimate to the Project Phase and sell that internally
- Waste Pipe is Process Pipe
- “Right Size” the contractor for the job



Startup

Common Practice

- Failure to hire employees in time to participate in or lead startup
- Failure to buy spare parts – not part of Capital Budget, can't be capitalized

Best Practice

- Plan to hire as early as possible
- Do what the project needs to do, not what Accounting says. Buy the spares with the equipment



Operations

- Water on the Floor
- Overdue PMs
- Outsourcing Maintenance
- Cleaning
- Shutdowns



Water on the Floor

- Lots of excuses:
 - They just cleaned the floor
 - It's just condensation from a heat exchanger
 - That pump always leaks a little bit – it's a water seal
 - The floor isn't level
- Bottom line: *water on the floor means the facility is not being maintained properly*



Overdue PMs

- Could be a sign of:
 - Lack of attention by Maintenance Dept
 - Production unwilling to allow time for maintenance
 - Broken scheduling process
- Whatever the reason, it is all-too-common



Outsourcing Maintenance

- Maintenance is outsourced for two reasons:
 - Expertise does not reside in house
 - Ex. – HEPA filter integrity testing
 - Finance says it is a good way to save money
 - Outsourcing firm pays lower salaries and benefits



Outsourcing Maintenance

- Results of Outsourced Maintenance:
 1. Abandon Continuous Improvement
 2. Reduced responsiveness
 3. Leading Indicator of Impending Quality Problems
- *The Vision of Finance to Reduce Costs has taken the place of any possible Maintenance Vision*



Cleaning

- Myth #1 – Rotating Disinfectants is a good idea to prevent microorganisms from developing resistance
 - There is actually no evidence to support this
 - “Rotation of a common disinfectant and a sporicidal helps ensure that bacterial spores do not take hold in manufacturing and aseptic areas. But the rotation of common disinfectants such as those based on phenol-derivatives (except TLN), aldehydes, and oxidizing agents, has no scientific basis. If antibiotic-like disinfectants are used, however, rotation is a necessity.” Martinez, Pharmaceutical Technology 2 Feb 2009



Cleaning

- Myth #2 – Using SporKlenz in the air lock to wipe down equipment entering the clean room is good practice
 1. Per the manufacturer SporKlenz is only to be used occasionally, and on a previously cleaned surface
 2. SporKlenz itself is a lousy detergent
 3. Many airlocks have not been designed with adequate ventilation to use SporKlenz safely
 4. If there IS a detectable presence of spore-formers, and one has already used SporKlenz, there is no way to escalate as a CAPA



Cleaning

- Try This Instead
 - Consider use of uv light
 - Using very strong uv light to treat equipment in the airlock can be quite effective at killing all surface microorganisms
 - Plus no use of chemicals, no residues
 - Clean the surface first!
 - Reportedly already in use at a pharma manufacturer



Pathogon uv Light System



Shutdowns

- FDA looks for evidence of periodic shutdowns
- There are some production strategies that do not require a shutdown but these are rare in Biotech
- Lack of shutdowns usually a leading indicator of impending quality problems
- Plan shutdowns a year in advance to get the maximum possible results



Focus on the Right Things

- | | |
|---|---|
| <ul style="list-style-type: none">• Common Practice<ul style="list-style-type: none">– See how cheaply maintenance can be done– Give lip service to EHS– The budget is King | <ul style="list-style-type: none">• Good Practice<ul style="list-style-type: none">– See how reliable the plant can become– Concentrate on Safety and your employees will respect you for it– Set budgets carefully so you can live by them |
|---|---|



Recap

- Don't let Finance run Maintenance – HAVE A VISION!
- Use CII Principles when performing major projects
- Use manufacturer's expertise when designing processes that use their products
- Maintenance deserves an equal place at the Scheduling table with Production



Thanks

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