Facility Best Practices
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19 Feb 2015

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

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

Pathogen 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

- Common Practice
  - See how cheaply maintenance can be done
  - Give lip service to EHS
  - The budget is King

- Good Practice
  - 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

• Special recognition to my friends Bob Lam, Stan Cryz and Maureen Costello for many helpful discussions
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