The Role of the Pharmaceutical Microbiologist

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What is a Pharmaceutical Microbiologist?

A subject matter expert with broad understanding of the sources and impact of microorganisms on the quality of pharmaceuticals.
Are you lonely?
Tired of working on your own?
Do you hate making decisions?
HOLD A MEETING!

You can—
• See people
• Show charts
• Feel important
• Point with a stick
• Eat donuts
• Impress your colleagues

All on company time!

MEETINGS
THE PRACTICAL ALTERNATIVE TO WORK

Image source: http://www.funnycoolstuff.com/images/hold-a-meeting.jpg
Benefits to the Individual

- Break from your silo!
- Avoid managing people!
- Broaden your exposure
- Solve problems
- Become a consultant in your own job
- Demonstrate leadership
- Learn new skills
- Imagine a life outside the lab
- Raise your profile
- Meet new people
Benefits to the company

- The Pharmaceutical Microbiologist sees the whole picture
- Regulatory agencies spend time with microbiologists during inspections
Ideal Competencies of a Pharmaceutical Microbiologist

- Theoretical knowledge
- Practical knowledge
- Curiosity
- Creativity
- Teamwork

Developing Yourself

* I can’t do this:
  * This role doesn’t exist where I work?
  * But I’m happy here with my mycelia!
  * I don’t want to talk to the FDA!
  * I have a mountain of work to do already!

* Career Development is life long
  * There is a lot to learn
  * Much is cross functional
  * Support from your manager is important
Development Plan for a Pharmaceutical Microbiologist

* Homework
  * Read your BLA & MAA
  * Validation Master Plan
  * Facility Drawings
    personnel flows, material and waste flows
  * Orange guide
  * FDA guides
  * PDA guides

* Assignments
  * Get gown qualified to enter a cleanroom
  * Take a class or have someone to teach you to read Piping & Instrumentation Diagrams
  * Walk down a system e.g. water, steam product, etc
Get Certified as a Microbiologist

- National Registry of Certified Microbiologists (NRCM) offers two levels of certification:
  - Registered Microbiologist ([RM]NRCM)—baccalaureate level - Specializing in Food Safety and Quality or Pharmaceutical and Medical Device
  - Specialist Microbiologist ([SM]NRCM)—baccalaureate, master’s, or doctoral level - Specializing in Biological Safety or Pharmaceutical and Medical Device
Becoming a Certified Microbiologist

- Meet certain education and experience requirements
- Apply to test
- The application deadline for the April 2015 exam is February 1, 2015
- For more information visit asm.org
Exam Content

- Lab instruments
- Lab preparations
- Lab procedures
- Lab operation
- Sample collection & handling
- Sterilization & depyrogenation
Interactive Session

In the interactive session we will discuss building a learning plan around developing a Pharmaceutical Microbiologist.
Interactive Session Debrief

- What is the biggest gap in your current knowledge?
- What can you do this week to remedy it?
- Where else would you like to strengthen?
- What do you need to do to make this happen?
Pharmaceutical Microbiologist

Summary

- Broad scope
- Vast knowledge
- Cross-functional
- Important role

Image source: http://rlv.zcache.com/microbiologist_assume_i_am_never_wrong_shirt-rd28eb30b27274a15b098f30bae779793_8nhmi_512.jpg
What next?

- Leadership
- Quality Assurance
- Manufacturing
- Auditing
- Consulting
- Research
- FDA / Government Agency
Thank You!

“An investment in knowledge pays the best interest”
Benjamin Franklin