The Next Generation of Microbiologists in Drug Manufacturing

Michael Loewenstein, VP of Scientific Consulting, Q Labs LLC
WHAT IS A MICROBIOLOGIST?

WHAT IS A MICROBIOLOGIST’S ROLE IN MANUFACTURING?
Effective microbiologists take years to develop.

WHY ARE THEY SO CRUCIAL?
Lack of sterility assurance #1 reason for sterile drug recalls 2012-2019¹

#1 reason cited was “unknown cGMP issue”¹

Common issues¹,²:

1. Poor Personnel Practices
   - Training, Process Validation, Investigations

2. Loss of Environmental Control/Lack of EM
   - Training, Process Validation, Investigations, Maintenance

3. Flawed Operational Design
   - Equipment Design, Process Validation

QC results can give a false sense of security.


 QC Testing

- Finished Product
- In-process/Raw Material/Water
- Environmental Monitoring

Foundation

- HVAC
- Water System
- Equipment Design
- C&S
- Technique/Training/
- Segregation/Flow
WHAT IS A MICROBIOLOGIST?

WHAT IS A MICROBIOLOGIST’S ROLE IN MANUFACTURING?
Manufacturing Microbiologists “Conduct the Symphony”

Commercial functions
- Equipment Design
- Facilities Design
- Process Development
- R&D Microbiology

Formulating Chemist

Capital Spending

Engineering

Quality Assurance

Plant Management

Senior Management

Accounting

Operating Teams

Maintenance

Plant Microbiology

Environmental Management

Microbiologists wear many hats in manufacturing.

WHERE DO THEY COME FROM?
University Degree

Related Degree

Chem/Biochem/MolGen

Related Function

QC Lab/QA/Engineering

University Research

Academia

Microbiologist by Degree
Microbiologists come from diverse backgrounds.

HOW ARE THEY TRAINED?
➢ Microbiology as the Foundation
  o Academic background enriched by continued education.

➢ End → Beginning Approach
  o QC Lab – not just the what/how, but why?

➢ Opportunities for Process Exposure
  o OOS, NC, etc. → Get out on the “shop floor”!

➢ Recognize the Scale
  o Dedicated training (e.g., Clean Design principles, risk assessment, etc).

➢ Identify Candidates Early for Further Development
  o Active discussion on career direction

➢ Don’t Neglect Soft Skills
  o Effective influencing, cross-functional engagement, etc.
Microbiologists of the future will have different concerns

- parametric release
- continued reduction of preservatives
- antimicrobial resistance

Microbiologists of the future will have different tools

- Alternate methods (i.e., rapid)
  - Different metrics → molecular
  - How to investigate (e.g., VBNC)
- Strain typing/tracking
Effective microbiologists are critical to drug manufacturing.

WHAT CAN WE DO?
• Define the role

• Be deliberate

• Specific Recruiting

• Not a stepping-stone; a journey

• Defined Career Path

• Internal/external training

• Continuous Education

• Use trade organizations/business relationships to collaborate

• Industry Engagement

• Educate universities on the needs – help develop educational material

• Academic Engagement
Hygienic Manufacturing of Cosmetic Products Graduate Certificate

Next Term Application Deadline: August 01, 2023
Total Credits: 13
Next Term Starts: August 21, 2023

Program of Interest:
- Hygienic Manufacturing of Cosmetic

Desired Start Date:
- Summer 2023

The Hygienic Manufacturing of Cosmetic Products Graduate Certificate Program Created with the Personal Care Products Council (PCPC)
Specific Recruiting
- Define the role – be deliberate

Defined Career Path
- Not a stepping-stone; a journey

Continuous Education
- Internal/external training

Industry Engagement
- Use trade organizations/business relationships to collaborate

Academic Engagement
- Educate universities on the needs – help develop educational material
QUESTIONS?

Thank you!