



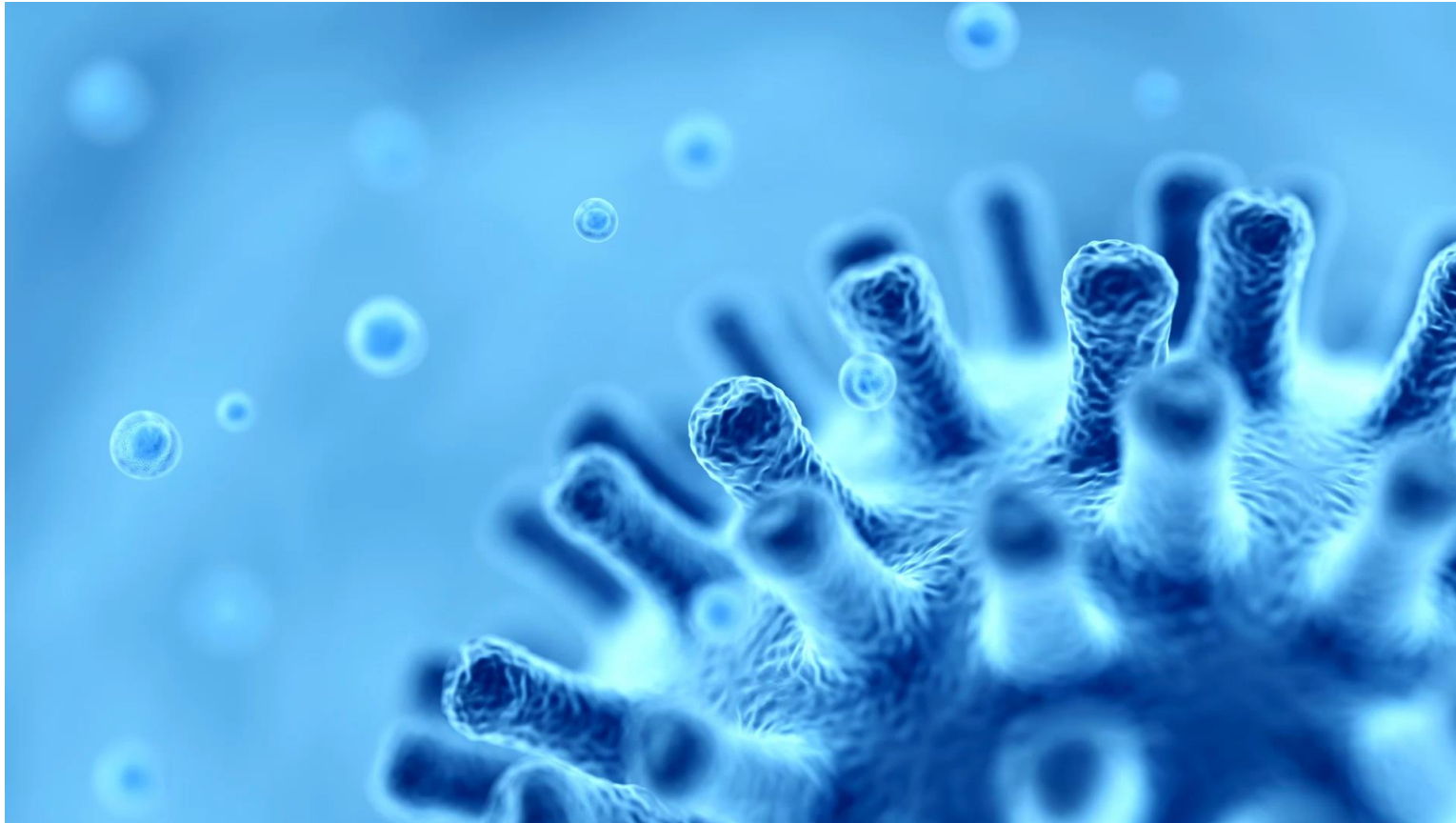
Experience what **Q** can do for you.

ISO 17025
ACCREDITED LABORATORY

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 issues^{1,2}:

1. Poor Personnel Practices

○ *Training, Process Validation, Investigations*

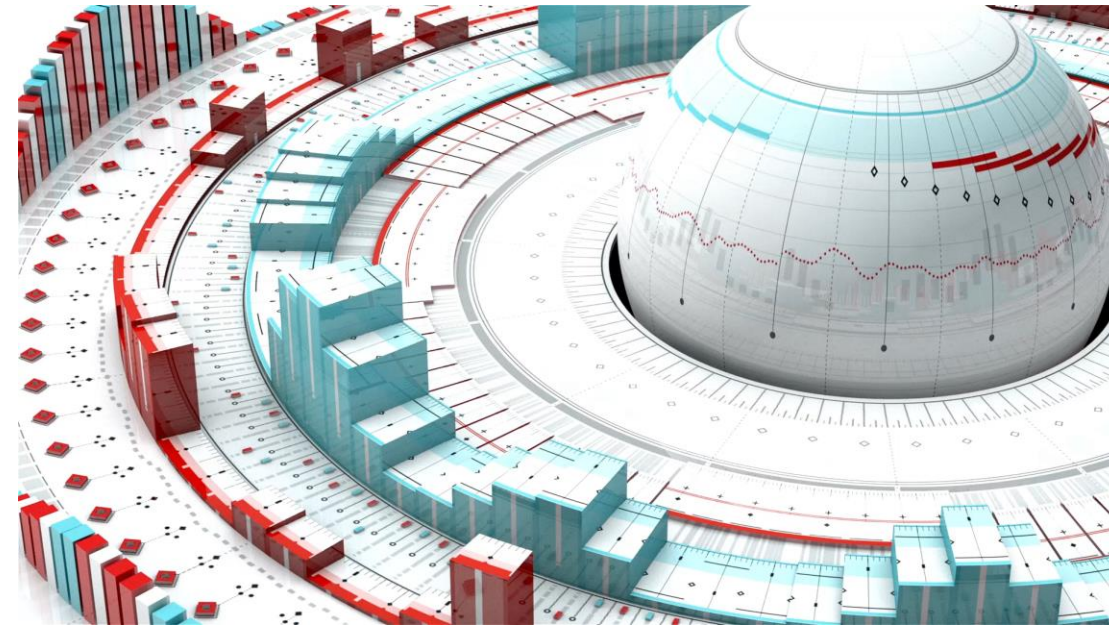
2. Loss of Environmental Control/Lack of EM

○ *Training, Process Validation, Investigations, Maintenance*

3. Flawed Operational Design

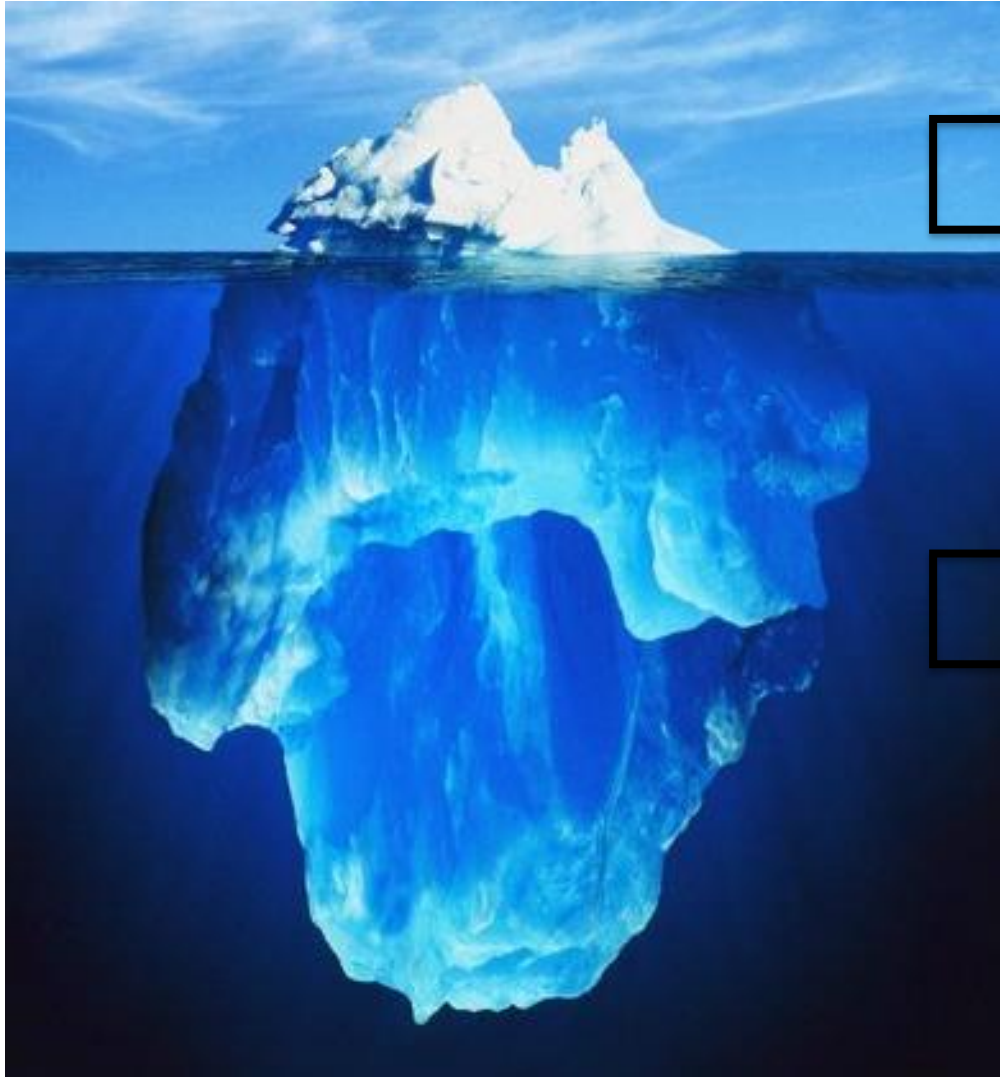
○ *Equipment Design, Process Validation*

➤ QC results can give a false sense of security.



¹Jimines L., Analysis of FDA Enforcement Reports (2012-2019) to Determine the Microbial Diversity in Contaminated Non-Sterile and Sterile Drugs. 2019. <https://www.americanpharmaceuticalreview.com/Featured-Articles/518912-Analysis-of-FDA-Enforcement-Reports-2012-2019-to-Determine-the-Microbial-Diversity-in-Contaminated-Non-Sterile-and-Sterile-Drugs/>

²Friedman, R.L. Aseptic processing contamination case studies and the pharmaceutical quality system. PDA Journal of Pharmaceutical Science and Technology 59, 118-126, (2005).

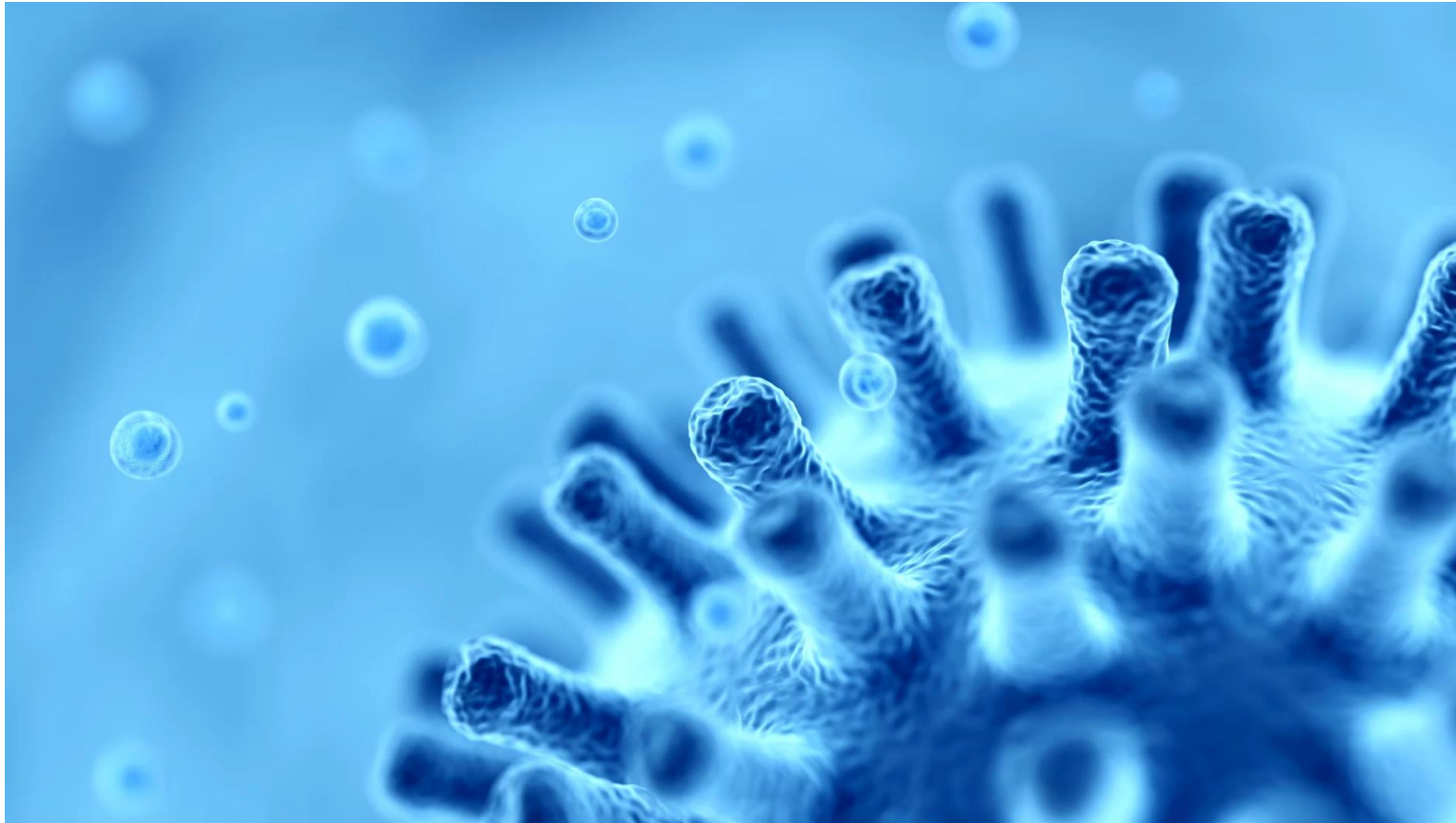


QC Testing

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

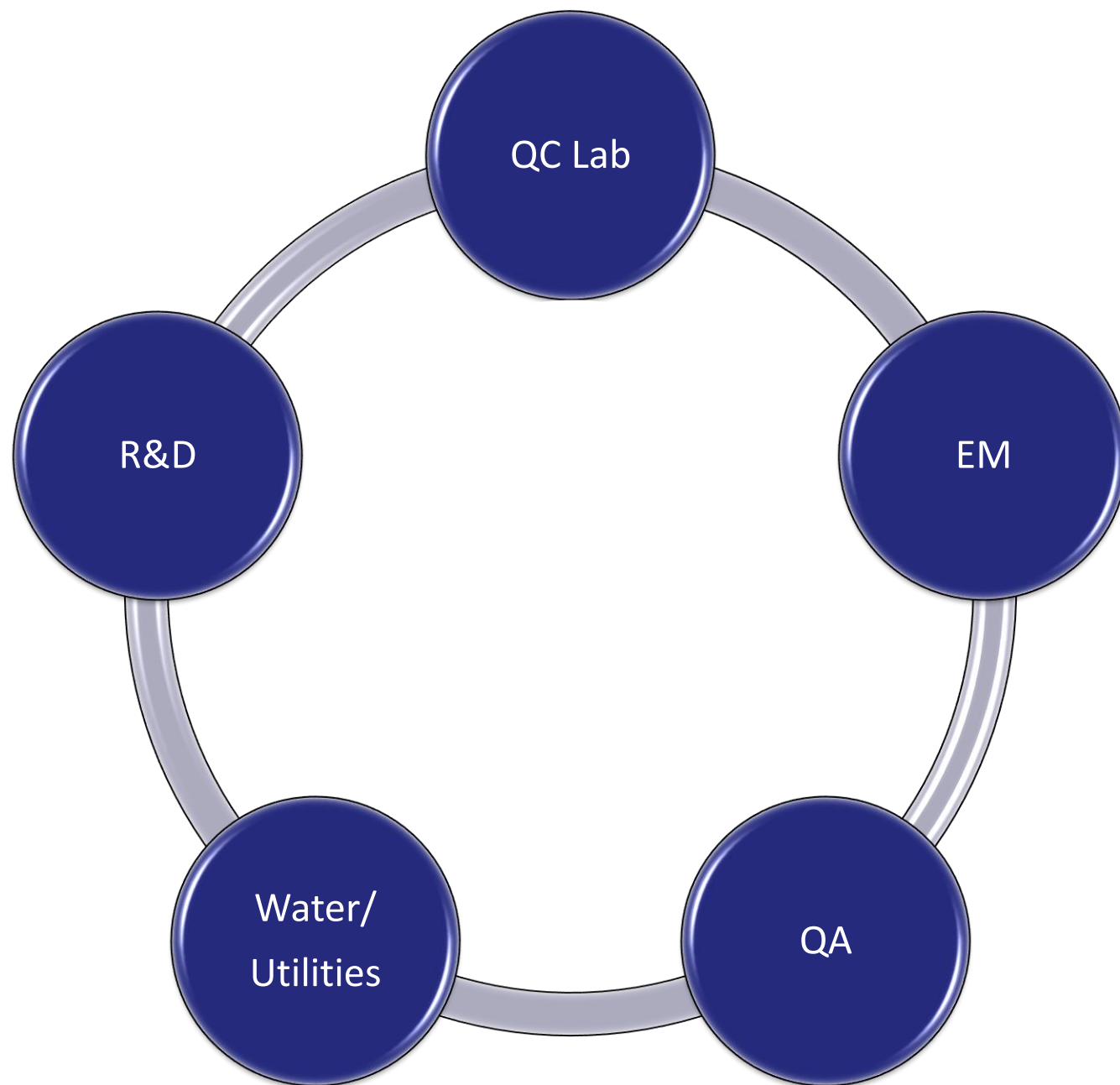
Foundation

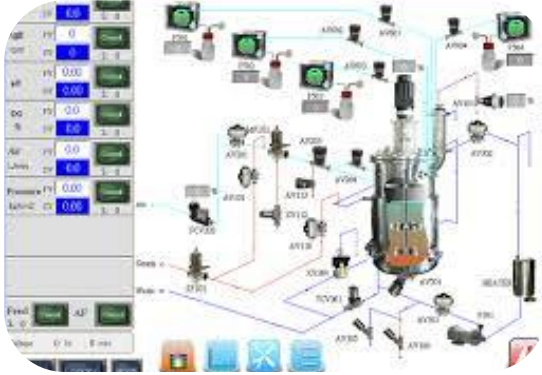
- HVAC
- Water System
- Equipment Design
- C&S
- Technique/Training/
- Segregation/Flow



WHAT IS A MICROBIOLOGIST?

WHAT IS A MICROBIOLOGIST'S ROLE IN MANUFACTURING?





Equipment
Design



Disinfectant
Efficacy



Process
Validation



Investigations



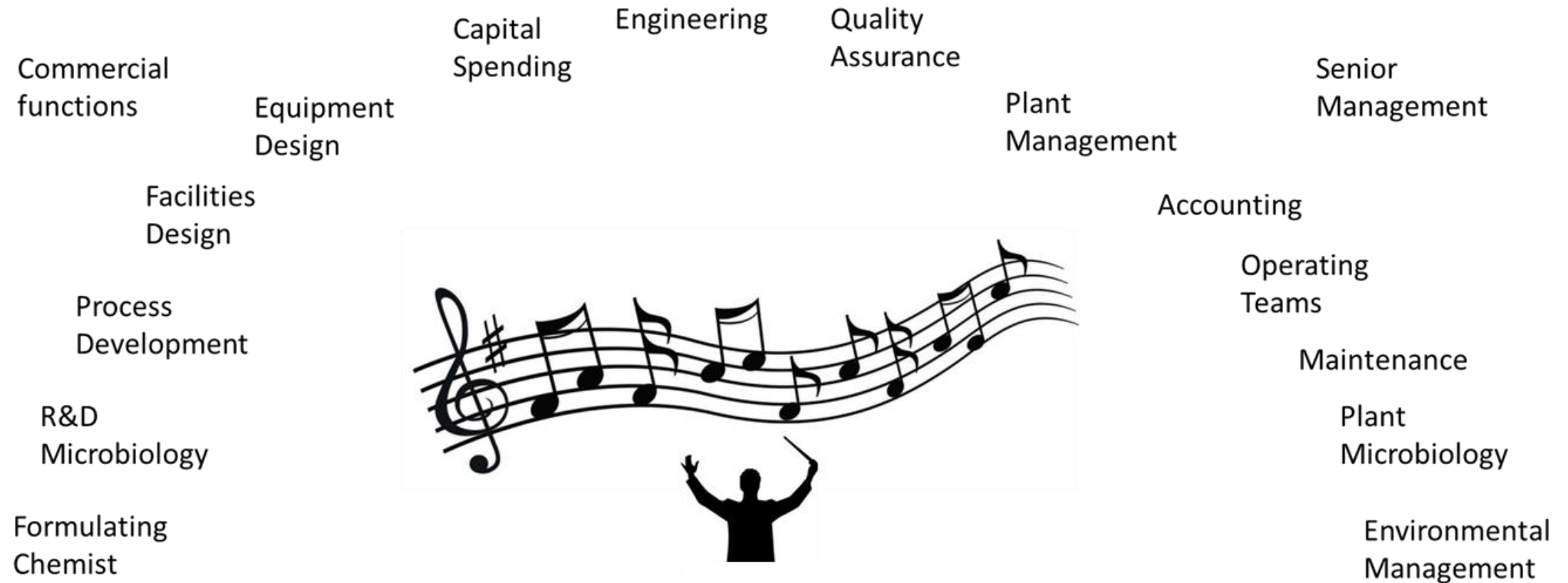
Training



Maintenance



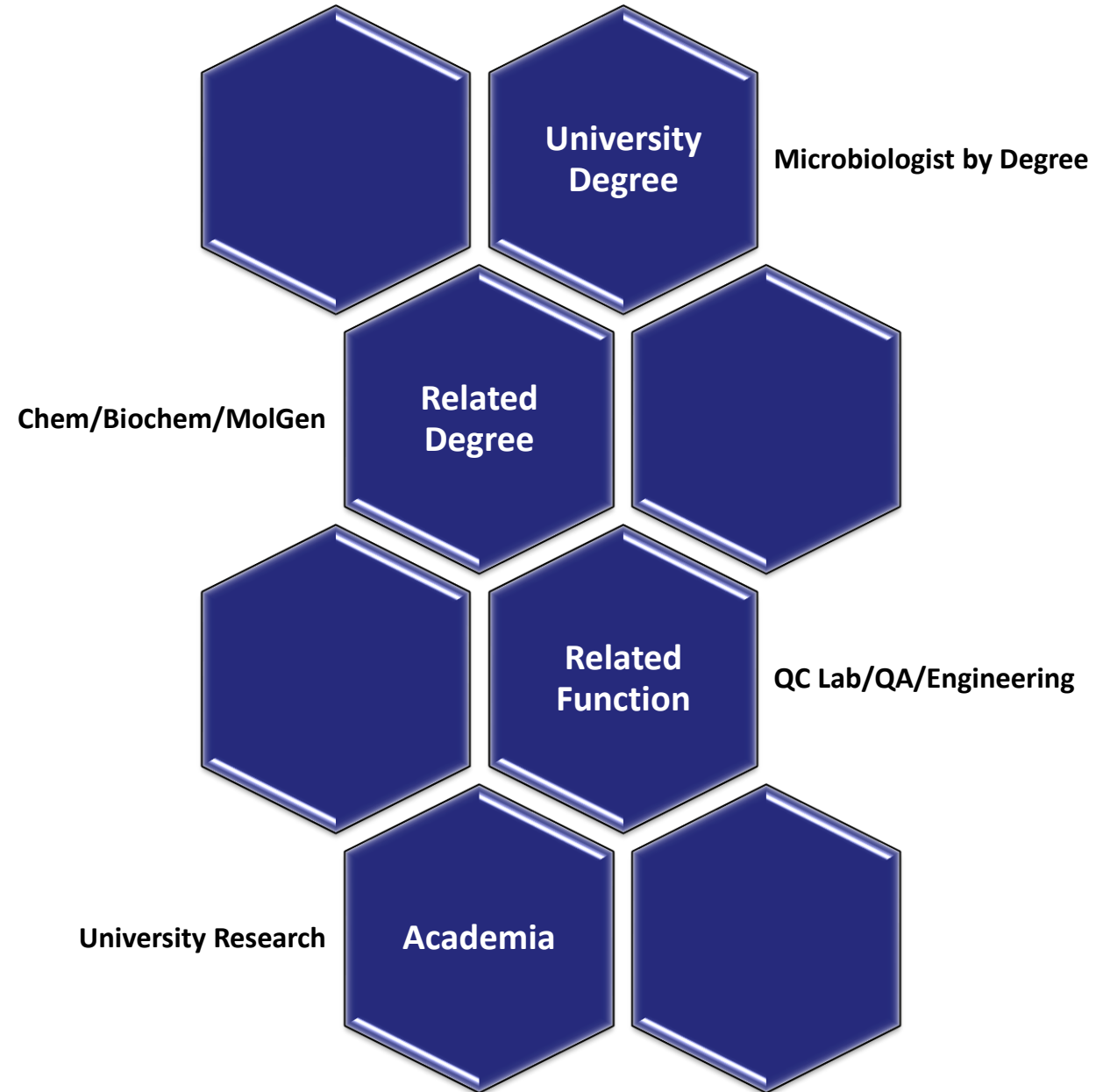
Manufacturing Microbiologists “Conduct the Symphony”





Microbiologists wear many hats in manufacturing.

WHERE DO THEY COME FROM?





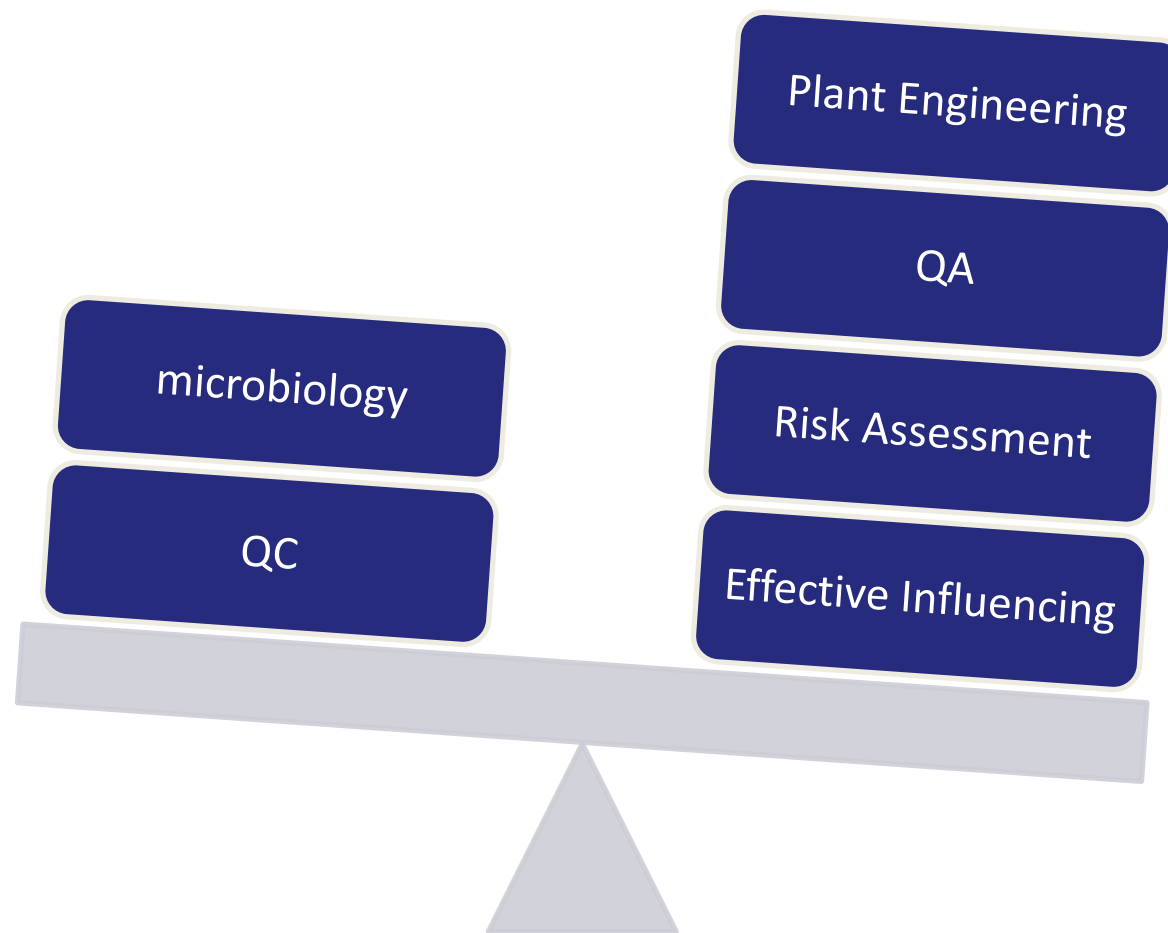
Microbiologists come from diverse backgrounds.

HOW ARE THEY TRAINED?



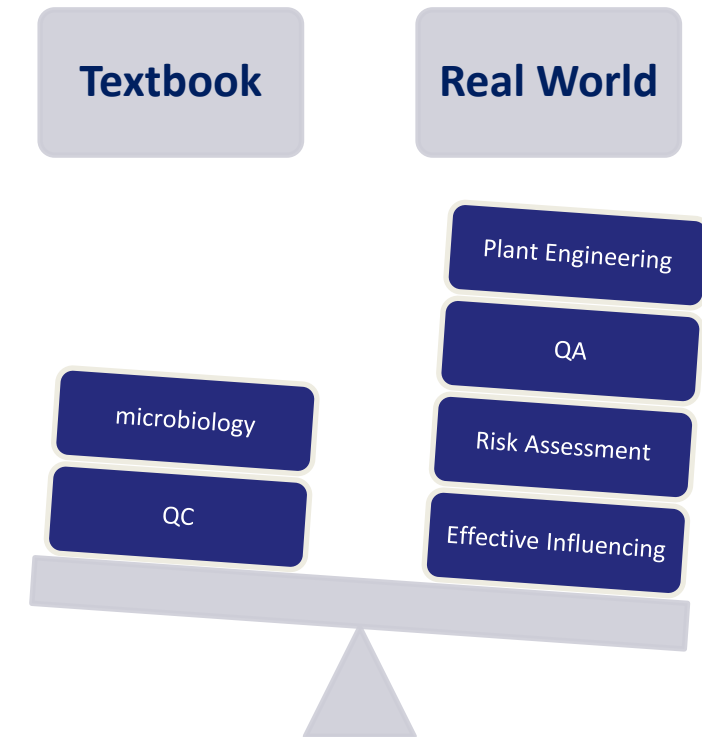
Textbook

Real World





- **Microbiology as the Foundation**
 - Academic background enriched by continued education.
- **End → Beginning Approach**
 - QC Lab – not just the what/how, but why?
- **Opportunities for Process Exposure**
 - OOS, NC, etc. → *Get out on the “shop floor”!*
- **Recognize the Scale**
 - Dedicated training (e.g., Clean Design principles, risk assessment, etc).
- **Identify Candidates Early for Further Development**
 - Active discussion on career direction
- **Don't Neglect Soft Skills**
 - 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?





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Business Partnerships Student Resources Search...

Degrees & Programs ▶ Pharmacy ▶ Hygienic Manufacturing of Cosmetic Products Graduate Certificate

Hygienic Manufacturing of Cosmetic Products Graduate Certificate

Request More Information from an Enrollment Advisor

Step 1 of 2

Program of Interest*

Hygienic Manufacturing of Cosmetic ▼

Desired Start Date*

Summer 2023 ▼

Continue to Step 2

Next Term Application Deadline August 01, 2023	Total Credits 13	Next Term Starts August 21, 2023
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Program Overview Academic Calendar Admission Requirements Careers Curriculum Faculty Tuition

COSMETIC SCIENCE VIRTUAL INFORMATION SESSION
Listen in while program director Dr. KP Ananth discusses the program, curriculum, work-life balance, and online school.

➔

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!