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# Making the Call: Quality in Biomanufacturing

Webinar: Friday, October 21

Lisa Seidman, Ph.D.  
Jeanette Mowery, Ph.D.



# Moderator



Sandra Porter, PhD  
Digital World Biology LLC, WA  
Sandy@bio-link.org, @bio\_link



# Bio-Link

- Works to increase the number and diversity of well-educated technicians in the bioscience workforce
- Our members are workforce-oriented college & high school programs, instructors, industry, students
- Bio-Link.org



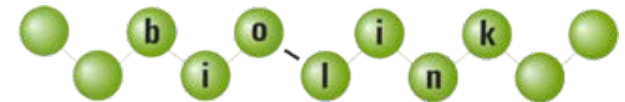
# Presenters



Jeanette Mowery, PhD  
Leadership Team, Bio-Link  
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Lisa Seidman, PhD  
Co-PI, Bio-Link  
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# MAKING THE CALL: QUALITY IN BIOMANUFACTURING

- [https://youtu.be/lc\\_cjEZFmo](https://youtu.be/lc_cjEZFmo)



# PURPOSE

- Use story to address the challenge of teaching Quality and Regulatory Affairs
  - What does it feel like to work in regulated environment?
  - Making right decisions
- Introduce students to the world of Biomanufacturing



# ABOUT THE COLLABORATION:

- Bio-Link
  - Instructors in Biotechnology workforce program for 20+ years
    - Lisa Seidman
    - Jeanette Mowery
    - Vivian Ngan-Winward
- Pellet Productions
  - Experienced video production company
    - Anthony Manupelli
    - Mary Ellen Gardiner
  - ATE TV



# ABOUT THE PRODUCTION:



- David Levin wrote the script in consultation with industry experts and with input from educators
- Filming took place at Worcester Polytechnic Biomanufacturing Education and Training Center
  - Greatly assisted by BTEC staffers
    - Dan Mardirosian
    - Chris Bellerive
    - Kristen Piccard
- Production Team
  - Executive Producer: Anthony Manupelli
  - Director: Bob Roche
  - Camera: Gilberto Nobrega and Jason York
  - Writer and science editor, David Levin





# INTERACTIVE ADDRESSES IMPORTANT THEMES:

- Cannot show every situation in the Interactive; but instructors can emphasize important themes
  - Importance of complying with established procedures to ensure quality
  - Importance of integrity
  - Importance of teamwork

# PLAN FOR WEBINAR

- Time constraints
- Overview by CEO- Welcome to Franklin Biologics
- Scene showing bad day
- 3 characters
  - Introduction to each character
  - Show a few dilemmas per character
- You get to vote on decision points
- Discuss how you can help
  - Ancillary materials are being developed
  - Feedback on whether this is helpful

**Welcome to Franklin Biologics**

# Welcome to Franklin Biologics

- <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview>

# THE BAD DAY



# The BAD DAY

- <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home>

# THE CHARACTERS

- Corinne Lawton, Associate Production Technician
- Kevin Turner, QC Microbiology Analyst
- Aseem Komani, Upstream Production Supervisor



Corinne Lawton  
Upstream Technician



Aseem Komani  
Upstream Supervisor



Kevin Turner  
QC Analyst

# MEET CORRINE





# MEET CORRINE



- <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/C-INTR1>

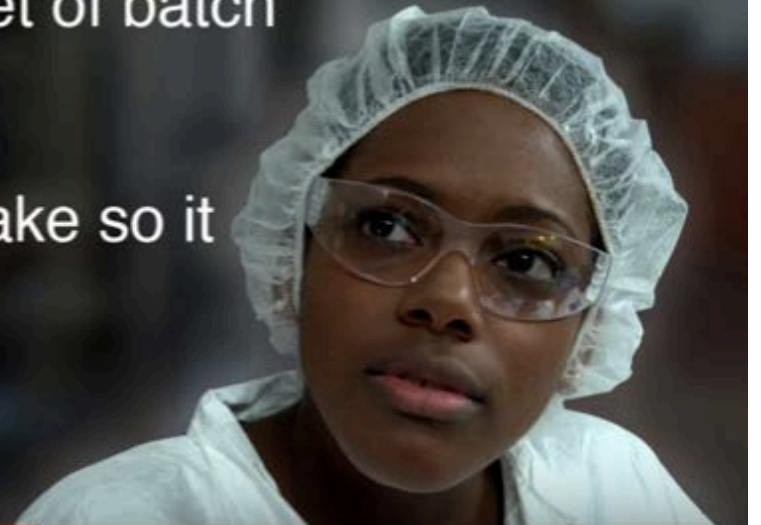
# CORINNE: Documentation Dilemma

# CORINNE: Documentation

- <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/C-INTR1/C-DP3>

# VOTE

- [A] Put a single line through the error, then add the date and your initials.
- [B] Start over with fresh set of batch record forms.
- [C] Scribble over the mistake so it can't be read.



# Choices

- <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/C-INTR1/C-DP3/C-DP3-a>
- B: <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/C-INTR1/C-DP3/C-DP3-b>
- C: <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/C-INTR1/C-DP3/C-DP3-c>

# CORINNE AND RUFUS

# CORINNE AND RUFUS

- <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/C-INTR1/C-DP2>

# VOTE

[A] Stick around and finish the standardization.

[B] Let Lorenzo handle it.

[C] Arrange for someone to fill in for you.





# CHOICES

- A:  
<https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/C-INTR1/C-DP2/C-DP2-a>
- B:  
<https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/C-INTR1/C-DP2/C-DP2-b>
- C:  
<https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/C-INTR1/C-DP2/C-DP2-c>

QUESTIONS SO FAR?

# MEET ASEEM



# MEET ASEEM



- <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/A-INTR1/A-DP1>

# ASEEM: BACKGROUND

- <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/C-INTR1/C-DP2>

# ASEEM AND ALARM

# ASEEM AND ALARM

- <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/A-INTR1/A-DP7>

# VOTE

[A] Improvise and add more anti-foaming agent.

[B] Ignore the alarm. It's probably a malfunction.

[C] Stop and troubleshoot the alarm now.





# CHOICES

- A:

<https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/A-INTR1/A-DP7/A-DP7-a>

- B:

- <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/A-INTR1/A-DP7/A-DP7-b>

- C:

<https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/A-INTR1/A-DP7/A-DP7-c>

# ASEEM AND DOCUMENTATION

# ASEEM AND DOCUMENTATION

- <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/A-INTR1/A-DP4>

# VOTE

[A] Pull Lorenzo aside and talk to him about the sloppy work.

[B] Talk to your colleague in QA about it. She'll know what to do.

[C] Correct the documents yourself.



# CHOICES

- A:

<https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/A-INTR1/A-DP4/A-DP4-a>

- B:

<https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/A-INTR1/A-DP4/A-DP4-b>

- C:

<https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/A-INTR1/A-DP4/A-DP4-c>

# MEET KEVIN



# MEET KEVIN



- <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/K-INTR1>

# KEVIN:RETESTING



# KEVIN:RETESTING

- <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/K-INTR1/K-DP8>

# VOTE

- [A] Find the procedure for a positive test result. That'll tell you what to do.
- [B] Redo the test. You must have made a mistake somewhere.
- [C] Alert the production staff to the issue.



# CHOICES

- A:

<https://sites.google.com/a/pelletproductions.com/bio-tech-interactive-video-test-site/overview/home/menu-1/K-INTR1/K-DP8/K-DP8-a>

- B:

<https://sites.google.com/a/pelletproductions.com/bio-tech-interactive-video-test-site/overview/home/menu-1/K-INTR1/K-DP8/K-DP8-b>

- C:

<https://sites.google.com/a/pelletproductions.com/bio-tech-interactive-video-test-site/overview/home/menu-1/K-INTR1/K-DP8/K-DP7-c>

# KEVIN AND TEAMWORK

# KEVIN AND TEAMWORK

- <https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/K-INTR1/K-DP7>

# VOTE

[A] Ignore it. Not your samples, not your problem.

[B] Go over and check it out yourself.



# CHOICES

- A:

<https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/K-INTR1/K-DP7/K-DP7-a>

- B:

<https://sites.google.com/a/pelletproductions.com/biotech-interactive-video-test-site/overview/home/menu-1/K-INTR1/K-DP7/K-DP7-b>

# www.franklinbiologics.org

## Making the Call: Quality in Biomanufacturing

### Navigation Menu

#### Overview

- ▼ Opening Scene
- ▼ Main Menu
  - ▼ Aseem: Introduction
    - Aseem: Scene 1
    - ▼ Aseem: Scene 2
      - Aseem: Scene 2a
      - Aseem: Scene 2b
    - ▶ Aseem: Scene 3
    - ▶ Aseem: Scene 4
    - ▶ Aseem: Scene 5
    - ▼ Aseem: Scene 6
      - Aseem: Scene 6a
      - Aseem: Scene 6b
      - Aseem: Scene 6c
    - ▶ Aseem: Scene 7
    - Aseem: Scene 8
  - ▼ Corinne: Introduction
    - ▼ Corinne: Scene 1
      - Corinne: Scene 1a
      - Corinne: Scene 1b
    - ▼ Corinne: Scene 2
      - Corinne: Scene 2a
      - Corinne: Scene 2b
      - Corinne: Scene 2c
    - Corinne: Scene 3
    - ▼ Corinne: Scene 4
      - Corinne: Scene 4a
      - Corinne: Scene 4b
      - Corinne: Scene 4c

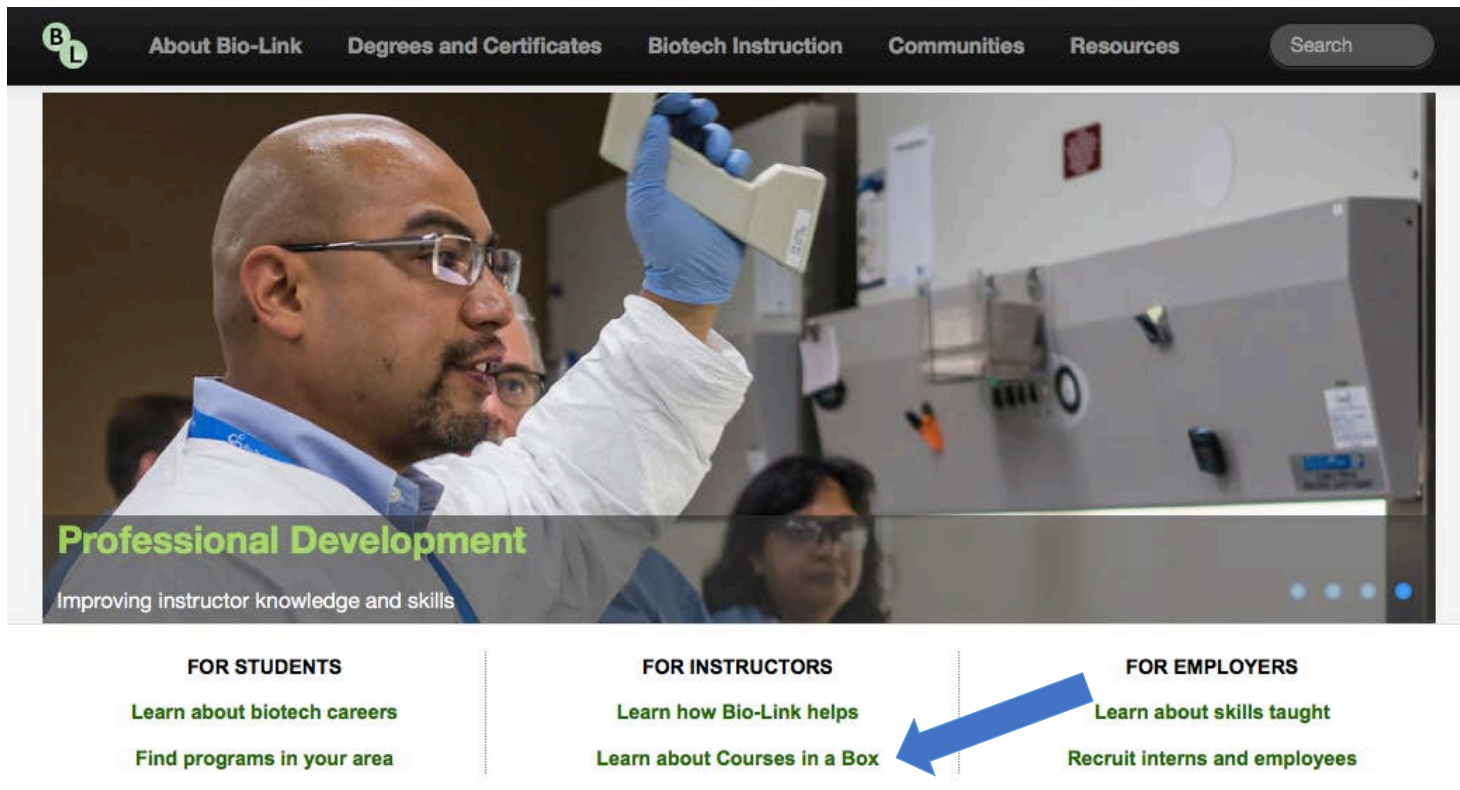




# RESOURCES

- Available Now
  - Bio-Link.org
  - NBC2: Biomanufacturing.org
  - NCBionetwork: NCBionetwork.org
  - Others
- More to come from this project

# Bio-Link: COURSES IN A BOX



The screenshot shows the Bio-Link website interface. At the top, there is a navigation bar with the Bio-Link logo (a 'B' and 'L' in circles) and several menu items: "About Bio-Link", "Degrees and Certificates", "Biotech Instruction", "Communities", and "Resources". A search bar is located on the right side of the navigation bar. Below the navigation bar is a large image of a man in a white lab coat and blue gloves holding a pipette tip. Overlaid on the bottom left of this image is the text "Professional Development" in green, with the subtitle "Improving instructor knowledge and skills" below it. Below the image, there are three columns of text separated by vertical dotted lines. The first column is titled "FOR STUDENTS" and contains two items: "Learn about biotech careers" and "Find programs in your area". The second column is titled "FOR INSTRUCTORS" and contains two items: "Learn how Bio-Link helps" and "Learn about Courses in a Box". The third column is titled "FOR EMPLOYERS" and contains two items: "Learn about skills taught" and "Recruit interns and employees". A blue arrow points from the "FOR EMPLOYERS" column towards the "FOR INSTRUCTORS" column, specifically pointing to the "Learn about Courses in a Box" item.

**FOR STUDENTS**  
Learn about biotech careers  
Find programs in your area

**FOR INSTRUCTORS**  
Learn how Bio-Link helps  
Learn about Courses in a Box

**FOR EMPLOYERS**  
Learn about skills taught  
Recruit interns and employees

# Course-in-a-Box

## The Courses

### Basic Laboratory Methods in a Regulated Environment

Submitted by Lisa Seidman on Sun, 2011-03-06 19:04

Biotechnology transforms knowledge that emerges from life science research into technology, the creation of products of value to people. Beginning biotechnology students therefore need to develop a strong foundation in laboratory science that is integrated with an ... [Read more](#)

### Cases in Industry Practice in Biotechnology

Submitted by Jeanette Mowery on Wed, 2012-01-04 14:26

Cases in Industry Practice in Biotechnology (CIPB)

Authors : V. Celeste Carter and Kristen Hershbell Charles

These instructional materials were developed in collaboration with industry partners and utilize a case-method approach with hands- ... [Read more](#)

### Embryonic Stem Cell Course (Stanford)

Submitted by Jeanette Mowery on Wed, 2011-07-20 11:46

These instructional materials were developed with support from the National Science Foundation and have been used in embryonic stem cell courses at Stanford and at San Francisco State University. Materials include Laboratory Protocols for both mouse and human embryonic stem cells, Lectures, ... [Read more](#)

### Hazardous Materials

Submitted by Mary Ellen Kraus on Fri, 2015-07-10 07:29

Welcome to the Hazardous Materials course-in-a-box. This course is not designed as a safety training course. The educational philosophy of this course, like that of most of the courses in the Biotechnology Laboratory Technician Program, is that properly educated technical students will have the ... [Read more](#)

### Laboratory Math for Biotechnology

Submitted by Mary Ellen Kraus on Fri, 2012-09-28 07:50

Bench work in the biotechnology laboratory requires that technicians possess certain fundamental math skills and the ability to apply these skills. Beginning biotechnology students often need a "refresher" of basic algebra, scientific notation, logarithms and graphing. They also need practice ... [Read more](#)

### Mammalian Cell Culture

Submitted by Jeanette Mowery on Sun, 2012-09-09 13:36

This course, from City College San Francisco, teaches the techniques necessary to maintain mammalian cells in culture. The course includes a laboratory exercise using mouse embryonic stem cells (takes 3 weeks to complete). Laboratory exercises provide instruction in basic techniques of routine ... [Read more](#)

### Quality Regulations and Standards

Submitted by Jeanette Mowery on Mon, 2012-11-19 09:02

Survey of Quality, Regulations, and Standards for Biotechnology

This Course-in-a-Box is about teaching quality and regulatory affairs. "Quality" products in this context means products that are suitable for their intended use and are free of defects and variability. Many vital ... [Read more](#)

# NBC2: Biomanufacturing.org



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[Careers](#)



PROFESSIONAL DEVELOPMENT

## mini-BIOMAN 2016

[VIEW EVENT](#)

10/28/2016

## National Institutes of Health Community College Day

[VIEW ARTICLE](#)

PROFESSIONAL DEVELOPMENT

## Protein is Cash 2017

[VIEW ARTICLE](#)

## Visit NBC2 at STEMtech 2016

[VIEW ARTICLE](#)



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## Program Units

[Introduction to Biomanufacturing](#)

[Facilities](#)

[Metrology](#)

[Validation](#)

[Environmental Health & Safety](#)

[Operational Excellence](#)

[Quality Assurance](#)

[Microbiological Control](#)

[Quality Control Biochemistry](#)

[Upstream Processing](#)

[Downstream Processing](#)

[Process Development](#)

[Manufacture of a Drug Product](#)

[Biofuels](#)

[Other Content](#)

## Textbooks & Manuals

[Introduction to Biomanufacturing](#)

[Biomanufacturing Laboratory Manual](#)

[Escherichia coli - GFP Core Production Manual](#)

[CHO Cell - tPA Core Production Manual](#)

[Pichia pastoris - HSA Core Production Manual](#)

## Resources

[Audio/Video](#)

[Presentations](#)

[Standard Operating Procedures](#)

[Skill Standards](#)

# NCBionetwork.org



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[Filtration Simulator](#)

[Gas Chromatography \(GC\)](#)

[Good Laboratory Practices \(GLP\)](#)

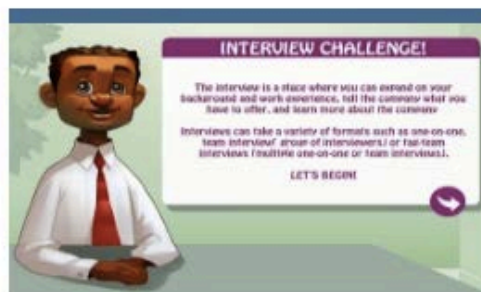
[Good Manufacturing Practice \(GMP\)...](#)

you for working in a... [read more](#)



### Sterile Gowning Procedures

Sterile Gowning Procedures is a serious game that teaches the steps for proper sterile gowning and gloving.



### Job Interviewing

Getting ready for a job interview can be a stressful task. Being prepared

# COMING SOON: Ancillary Materials

- Companion Guide to the Movie
  - Background information
  - More details
- What else would you like to see?
  - Tell us now or....
  - Email Jeanette or Lisa
    - [Jmowery@madisoncollege.edu](mailto:Jmowery@madisoncollege.edu)
    - [lseidman@madisoncollege.edu](mailto:lseidman@madisoncollege.edu)



**QUESTIONS?**

# Bio-Link Resources

- [Biotech-Careers.org](http://Biotech-Careers.org)
- [Bio-Link.org](http://Bio-Link.org)
- Links to archived webinars
- Summer Fellows Forum – June 7-10th
- Sign up for our newsletter



THANK YOU!



Lisa Seidman: [lseidman@madisoncollege.edu](mailto:lseidman@madisoncollege.edu)

Jeanette Mowery: [jmowery@madisoncollege.edu](mailto:jmowery@madisoncollege.edu)

**TIME FOR THE SURVEY**