

Using Story and an Interactive Movie to Immerse Students in a Regulated Workplace

ATE PI Conference 2017

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Lisa Seidman



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 TODAY'S SESSION

- Time constraints
- Overview by CEO- Welcome to Franklin Biologics
- Scene showing bad day
- 3 characters
 - Introduction to each character
 - Show a few dilemmas
- You get to vote on decision points
- How you can help
 - Give feedback to us and/or to project evaluator



Making the Call: Quality in Biomanufacturing

Introduction
About
Participant/Facilitator Guide
Overview
Opening Scene
Choose Your Character
Corinne - Upstream Technician
Aseem - Upstream Supervisor
Kevin - QC Analyst
Additional Resources






FRANKLIN

B I O L O G I C S

Making the Call: Quality in Biomanufacturing

Introduction	
About	
Participant/Facilitator Guide	
Overview	
Opening Scene	
Choose Your Character	
Corinne - Upstream Technician	Corinne: Scene 1
Aseem - Upstream Supervisor	Corinne: Scene 1A
Kevin - QC Analyst	Corinne: Scene 1B
Additional Resources	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
	Corinne: Scene 5
	Corinne: Scene 5A
	Corinne: Scene 5B
	Corinne: Scene 5C



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Welcome to Franklin Biologics

- <https://www.franklinbiologics.org/>
- Overview of Biomanufacturing at Franklin Biologics

THE BAD DAY



The BAD DAY

- <https://www.franklinbiologics.org/opening-scene>

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



<https://www.franklinbiologics.org/corinne>

CORINNE: Documentation Dilemma

- <https://www.franklinbiologics.org/corinne-scene-4>

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.



ONE IDEA

- <https://www.franklinbiologics.org/corinne-scene-4b>

OVER DONUTS



- <https://www.franklinbiologics.org/corinne-scene-3>

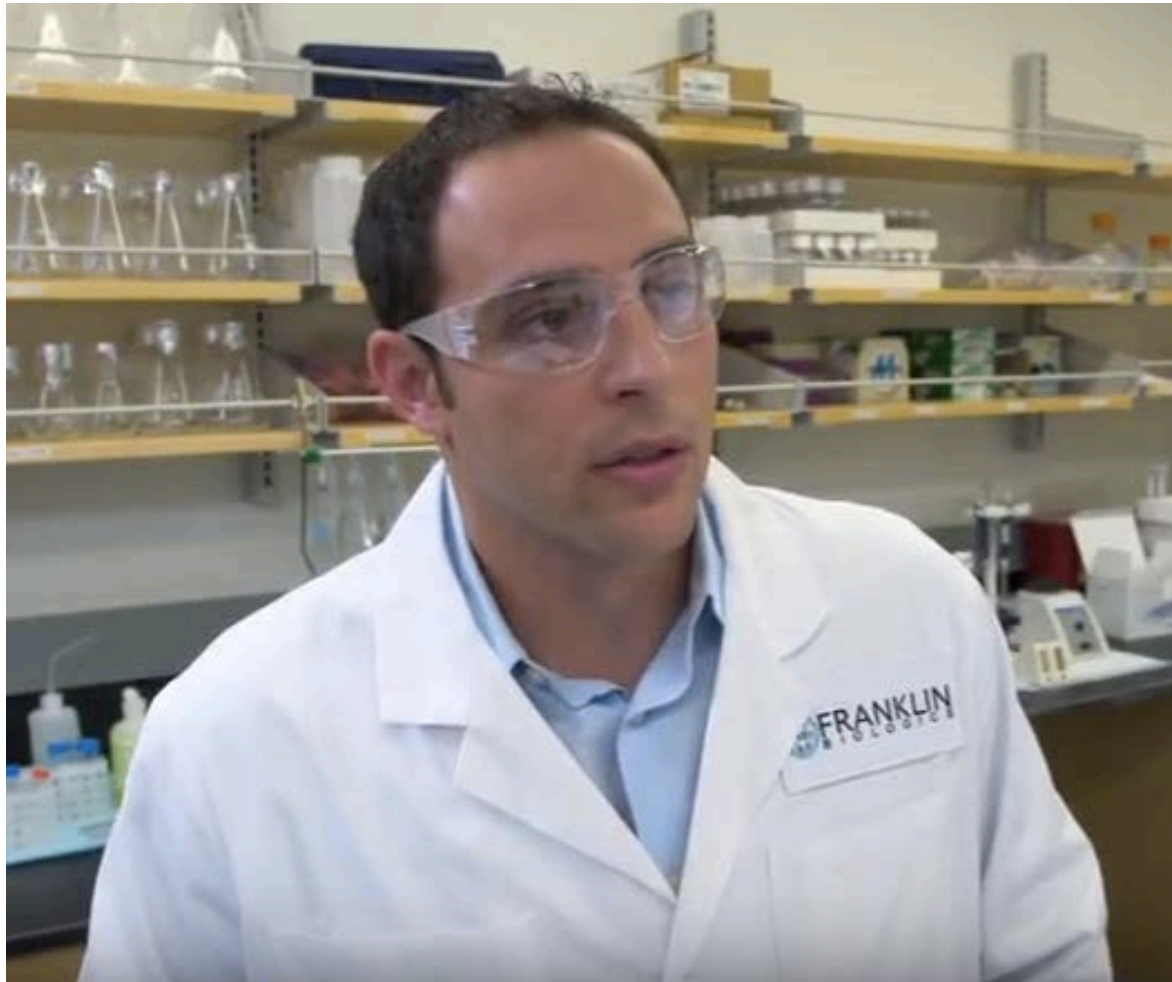
CORINNE AND RUFUS

- <https://www.franklinbiologics.org/corinne-scene-2>

NOT THE BEST IDEA

- <https://www.franklinbiologics.org/corinne-scene-2b>

MEET KEVIN



MEET KEVIN

- <https://www.franklinbiologics.org/kevin>

KEVIN:RETESTING

- <https://www.franklinbiologics.org/kevin-scene-7>

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.



KEVIN:RETESTING, CHOICE B

- <https://www.franklinbiologics.org/kevin-scene-7b>

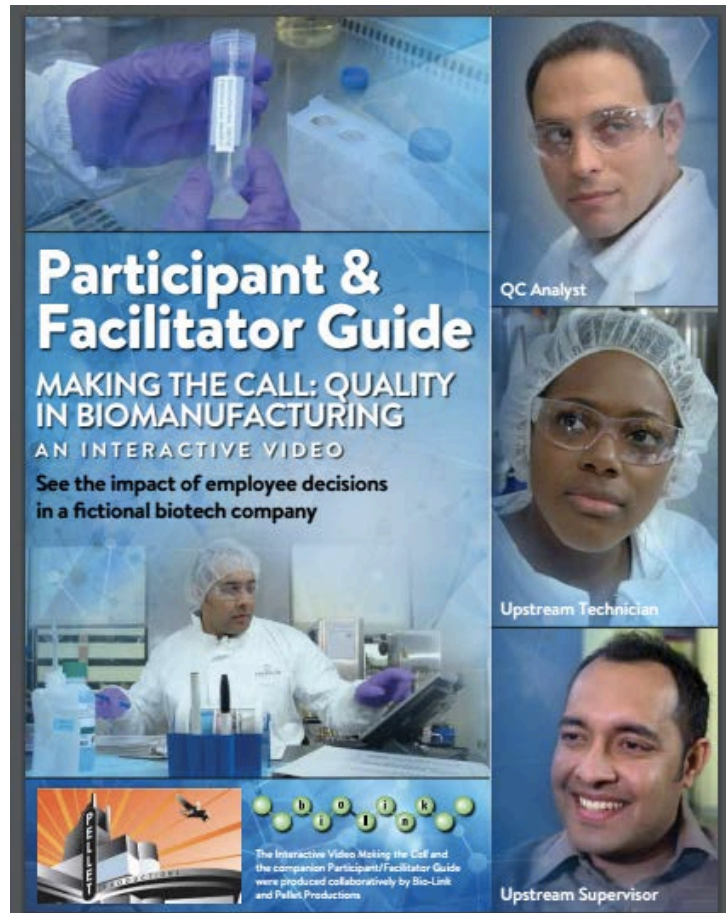
MEET ASEEM



MEET ASEEM

- <https://www.franklinbiologics.org/aseem>

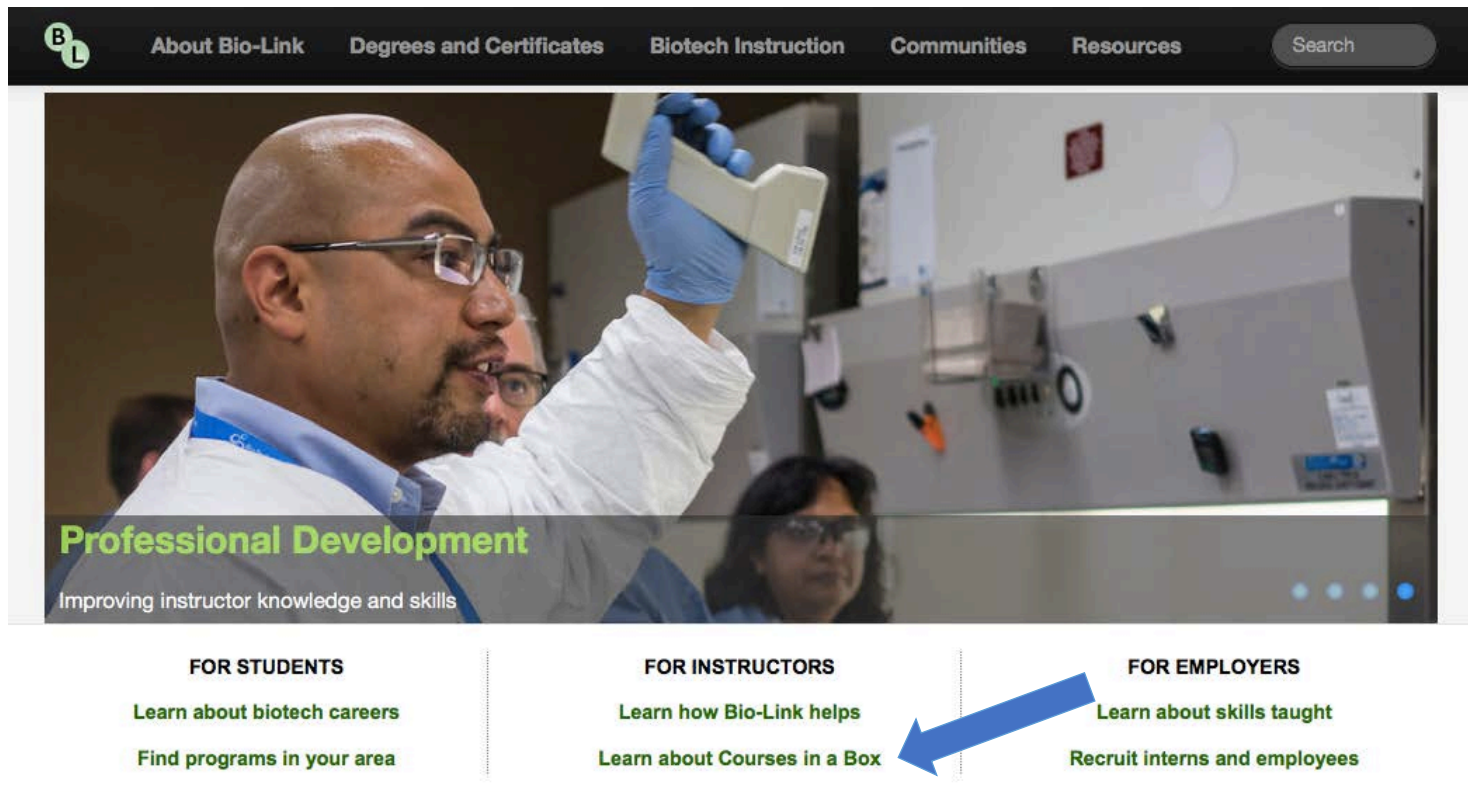
Participant and Facilitator Guide



OTHER RESOURCES

- Bio-Link.org
- NBC2: Biomanufacturing.org
- NCBionetwork: NCBionetwork.org
- Others

Bio-Link: COURSES IN A BOX



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

Bio-Link About Bio-Link Degrees and Certificates Biotech Instruction Communities Resources Search

Professional Development
Improving instructor knowledge and skills

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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10/28/2016

National Institutes of Health Community College Day

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PROFESSIONAL DEVELOPMENT

Protein is Cash 2017

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[Metrology](#)
[Validation](#)
[Environmental Health & Safety](#)
[Operational Excellence](#)
[Quality Assurance](#)
[Microbiological Control](#)
[Quality Control Biochemistry](#)
[Upstream Processing](#)
[Downstream Processing](#)
[Process Development](#)
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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

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Aktaprime HPLC

Aseptic Technique

Autoclave Operation

BioFlow 110

Centrifugation

Chromatography

Clinical Research Study Management

Comparing Title 45 and Title 21

Counting Cells Using a Hemocytometer

Deliberate Documentation

Determining Glassware Accuracy

Drug Development Overview

Environmental Monitoring

Fermentation

Filtration

Filtration Simulator

Gas Chromatography (GC)

Good Laboratory Practices (GLP)

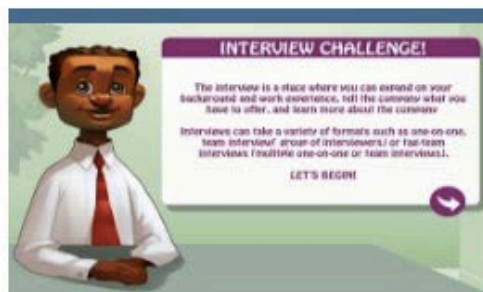
Good Manufacturing Practice (GMP)...

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

QUESTIONS or COMMENTS?



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