

MAKING THE CALL: QUALITY IN BIOMANUFACTURING

by

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OPEN-1

INT. CORPORATE LOBBY, DAY

Schmaltzy music fades in over corporate logo:

Onscreen text: "Franklin Biologics: Putting patients first"

ALICIA SANDOVAL

Hello, I'm Alicia Sandoval--and I want to welcome you to your first day at Franklin Biologics.

As part of the Franklin team, you're joining a company with a long history of manufacturing products for major pharmaceutical firms. We specialize in treatments for rare and unusual diseases, and in some cases, we're the only source of those therapies in the country. As an employee, you'll be giving thousands of patients a new chance at life... And a better outlook for the future. Come on in.

INT. CELL BANK, DAY

SANDOVAL (CONT'D)

Our work starts here, in the cell bank. This is where we store cells that have been genetically engineered to make specific kinds of proteins--the key ingredients of new products.

Sandoval holds up a cell vial.

SANDOVAL (CONT'D)

From a tiny vial like this, we take just a few thousand cells, and nurture them as they divide and grow.

CUT TO shots of various sized stirrer flasks

SANDOVAL (CONT'D)

As the number of cells expands, we transfer the batch to larger and larger flasks...

INT. PRODUCTION SUITE, BIOREACTOR, DAY

SANDOVAL (CONT'D)

And eventually, to the bioreactor... Where the cells continue to grow and thrive until they've created enough protein for us to harvest.

INT. PRODUCTION SUITE, CENTRIFUGE, DAY

SANDOVAL (CONT'D)

When the batch is ready, it's sent to downstream processing, where our highly experienced technicians separate protein from the cells and purify it, removing any stray cell fragments or unwanted molecules... Then package it into sterile containers for delivery to our happy clients.¹

INT. QC LAB, WORKBENCH (GEN. PURPOSE), DAY

SANDOVAL (CONT'D)

At Franklin, we believe strongly that quality is king -- and with help from employees like you, we're proud to deliver a flawless product every time. We're thrilled that you're helping **US** help patients and families.

So on behalf of everyone here, welcome to the Franklin family.

Franklin logo appears onscreen; schmaltzy music fades up

¹ Burke, E. (2012). *The Biotech Primer*. CreateSpace Independent Publishing Platform.

OPEN-2

INT. SANDOVAL'S OFFICE - AFTERNOON

ALICIA SANDOVAL, CEO of Franklin Biologics, stares dejectedly out of the window of her office, drinking scotch. She turns to the camera before speaking:

SANDOVAL

It's been a rough couple of weeks. We lost a huge batch for a client. A *big* client. And it was *our* fault. The mistake cost us millions. And the lawsuit, well...

MONTAGE: shots of empty production suite.

NARRATOR

The company is facing a major crisis. When that batch was ruined, hundreds of patients with rare diseases were left without treatment.²

EXT. CORPORATE LOBBY, DAY

Employees walk out of the lobby holding boxes with office knick knacks inside. They wave off a reporter holding a microphone.

NARRATOR (CONT'D)

...And a bunch of technicians lost their jobs.

INT. SANDOVAL'S OFFICE, DAY

SANDOVAL

I never thought I'd be at the helm while a company went down like this... (Sighs deeply and looks out the window)

PAN OUT TO THE VIEW OUTSIDE THE WINDOW

² Thieman, William J, and Michael Angelo Palladino. *Introduction to Biotechnology*. 3rd ed. Pearson/Benjamin Cummings, 2013.

SANDOVAL (V.O.)
Except... I'm not. None of this
actually happened.

EXT. CORPORATE LOBBY

SANDOVAL
...But it *could*. In this
interactive, you can set back the
clock, and change the way this
whole thing plays out. Step into
the shoes of three different
characters working at Franklin, and
make real-world decisions about
quality. You can play the role of
an upstream production
supervisor... a production
technician... or a Quality Control
analyst. Each has a critical role
in bioprocessing--and each has to
follow strict guidelines for
quality. ...So: are YOU up to the
challenge? Could YOU stop this
disaster before it starts? Click
below to find out.

[NEXT] BUTTON TAKES USER TO MAIN MENU

MENU-1 (Main Menu)

WE SEE PHOTOS OF ALL THREE MAIN CHARACTERS IN OUR INTERACTIVE, ALONG WITH THE SERIES TITLE AND OTHER LINKS AS NEEDED (ACKNOWLEDGEMENTS, SUPPLEMENTARY MATERIAL, ETC).

NARRATOR

Main menu. To choose a character,
click on a photo below.

Each character's photo will have rollover text introducing their title, per the following:

Aseem Komani: Upstream Production Supervisor

Corinne Lawton: Associate Production Technician

Kevin Turner: QC Microbiology Analyst

C-INTR1

INT. PRODUCTION SUITE, DAY

CORINNE LAWTON and her teammates LORENZO and ASEEM are working together in the production suite.

C.U. CORINNE

NARRATOR

This is you. Corinne Lawton. You're an upstream technician at Franklin. You went back to community college to get special training. And now, you've got your dream job: making treatments that save hundreds of patients' lives every day. The benefits aren't bad either.³

C.U. LORENZO

NARRATOR (CONT'D)

Lorenzo here followed the same path. He's an old friend, but he's new to the industry. You helped land him a job at Franklin a few weeks ago.

C.U. ASEEM

NARRATOR (CONT'D)

Both of you work for Aseem. He's your supervisor, and you've learned a lot from him. With him as your mentor, you're hoping you can rise in the ranks.

NARRATOR (CONT'D)

Going back to school was one of the best decisions you ever made. Now, you've got a successful career in biotech, and you're making a difference in patients' lives.
(Beat) Click "next" to continue.

³ Ngan-Woodward, Vivian, Jeanette Mowery, and Lisa Seidman. Kickoff meeting / brainstorm session for "Making the Call: Quality in Biomanufacturing." Interview by David Levin, Anthony Manupelli, and Julie Benyo. Audio, Notes, March 24, 2014.

[NEXT] (BUTTON TAKES USER TO CORINNE SCENE C-DP1)

C-DP1

INT. GOWNING ROOM, DAY

Corinne and Lorenzo are gowning up for the production suite. We see them starting to gown; first gloves, hair cover, safety glasses, coverall, and finally, booties.

CORINNE LAWTON

Hey, man -- thanks for coming out last night.

LORENZO CARTAGENA

(Laughing)

You kidding? I'm always down for darts. So what's going on today?

CORINNE

I think we've got to prep the suite, like, NOW for that batch of Squabanin.

LORENZO

So... the usual.

CORINNE

Yeah. Aseem was pretty stressed out about this one, though. Not sure why.

LORENZO

(sarcastically)

Sounds like a fun week.

CORINNE

Could be. I'll let you unwind with a rematch tonight, though.

LORENZO

Perfect. But bring your wallet this time... I'm getting warmed up.

Lorenzo suddenly trips over the gowning bench while putting his booties on. He lands on his feet, but on the dirty side of the bench.

LORENZO (CONT'D)

Ah, man.

CORINNE
 (laughing)
 You okay?

LORENZO
 Yeah. You didn't see that.

Lorenzo looks up at the clock.

LORENZO (CONT'D)
 Ugh, -- now we're gonna be late.

Lorenzo keeps gowning, hurriedly, as if nothing happened.

NARRATOR:
 Technicians wear sterile gowns and booties to prevent microbes from getting into production suite. But Lorenzo just stepped on the dirty side of the bench, and might have contaminated his booties in the process. He's not changing them. What should you do?⁴

Text with options fills screen as Narrator recites each line.

(A) Let it go. He only touched the ground for a second.

[Go to C-DP1-a]⁵

(B) Talk to him and ask him to re-gown.

[Go to C-DP1-b]

⁴ Ibid.

⁵ Ibid.

C-DP1-a

INT. GOWNING ROOM, DAY

Corinne and Lorenzo are gowning up for the production suite. Lorenzo has tripped and fallen in the "dirty" area, and we see him get up and continue gowning. Corinne looks unsure of this situation, but keeps it to herself.

NARRATOR

You decide to let it go. He only touched the ground for a few seconds -- so you figure it's probably fine. Then, a few days later...

INT. CONFERENCE ROOM, DAY

Aseem is in the conference room with a group of employees including Corinne and Lorenzo.

ASEEM

Okay, so that's what we've got on tap. Any questions?

(No questions)

...Great. One more important thing... (Pauses) Environmental monitors tested the production suite, and they found more microbes than usual. We're still within spec, but I am NOT okay with this.⁶ Employees continue to ask questions and discuss the issue. [Use sound up where appropriate.]

NARRATOR

Guess you should have spoken up in the gowning room... Lorenzo might have contaminated the suite after all.⁷ A product's quality starts with YOU--so make sure you follow proper practices. Click "next" to continue.

⁶ Platco, Sheryl. Phone interview re: QC micro. Interview by David Levin. Audio, Notes, September 9, 2014.

⁷ *ibid.*

[NEXT] (BUTTON TAKES USER TO CORINNE SCENE C-DP2)

C-DP1-b

INT. GOWNING ROOM, DAY

Corinne and Lorenzo are gowning up for the production suite. Lorenzo has tripped in the "dirty" area, and lands on a sterile part of his suit. Lorenzo continues gowning after falling down.

CORINNE

Hey - you need to re-gown.

LORENZO

It's fine. Three second rule...

CORINNE

Seriously? How much time does it take to change? Here.

Corinne grabs a fresh pair of booties from the bin next to her, and hands it to LORENZO.

LORENZO

Okay, okay.

CORINNE

That's the spirit.

Lorenzo Takes off the old booties, and puts new gloves on.

LORENZO

Just tell Aseem I'm going to be late, okay? Because I'm doing things *right*?

CORINNE

(Sarcastically) I feel for you.

NARRATOR

Good call. When you're gowning, even a minor error could contaminate the production suite- and ruin a batch.⁸

If you see something that goes against good manufacturing

⁸ Hunsberger, Kay. Hunsberer Initial Phone interview. Interview by David Levin. Audio, Notes, July 11, 2014.

practices, you need to address it--
immediately.⁹

Click "next" to continue.

[NEXT] (BUTTON TAKES USER TO SCENE C-DP2)

⁹ Ibid.

C-DP2

INT. PRODUCTION SUITE, SHAKE FLASK LAB, DAY

CORINNE and LORENZO are getting ready to standardize pH and dissolved oxygen sensors for the seed bioreactor. Suddenly, a call comes in that Corinne's beloved dog has been hit by a car.

Lorenzo gathers equipment in the production suite and adds the items to a small wheeled cart. He talks to himself out loud as he checks them off his list.

LORENZO:

Ok, let's get rolling here. Got the pH meter... Deionized water... Kimwipes... Hey, Corinne-have you seen the 4.0 standard?

CORINNE

Yeah, right here. We should get moving. Aseem said the probes need to be done by lunch if we're gonna stay on schedule.

LORENZO

No prob.

The phone rings.

LORENZO

Production suite, Lorenzo... (Looks over at Corinne) No, she's tied up right now. Oh... Uh, sure, hang on a sec.

Lorenzo puts his hand over the mouthpiece and turns to Corinne.

LORENZO

It's your dog walker.

CORINNE

(without looking up)
Tell her the treats are on the fridge.

LORENZO

She said it's important.

Corinne takes the phone from Lorenzo.

CORINNE
Hello? Yeah, it's me. What?!?

Corinne's voice now sounds hurried, panicked.

CORINNE (CONT'D)
Is he okay? Uh, huh. Yeah, I'm at work... can I call you back? Yeah. Okay, Thanks.

LORENZO
What happened?

CORINNE
(upset)
Rufus got hit by a car. He was running after a squirrel or something and bolted into the street.

LORENZO
Oh, jeez. Is he okay?

CORINNE
I think so... my dog walker is being really cagey.

NARRATOR:
Your dog means everything to you. But you and Lorenzo are in the middle of standardizing sensors for the seed bioreactor. If you don't finish now, it could throw your team off-schedule. What do you do?¹⁰

Text with options fills screen as NARRATOR recites each line.

(a) Stick around and finish the standardization.

[Go to C-DP2-a]

(b) Let Lorenzo handle it. Sign off on the standardization now, and leave to take care of your dog.¹¹

[Go to C-DP2-b]

¹⁰ Menard, Jon. In-person followup. Audio, Notes, December 8, 2014.

¹¹ Ibid.

(c) Tell your supervisor about the situation, and arrange for someone to fill in for you.¹²
[Go to C-DP2-c]

¹² Meighan, Kelly. Tour of Merck, West Point PA - Kelly Meighan. Audio, Notes, September 9, 2014.

C-DP2-a

INT. PRODUCTION SUITE, WORKBENCH (IN-PROCESS), DAY

Corinne and Lorenzo are getting ready to standardize pH and dissolved oxygen sensors for a set of large shake flasks. A call comes in that CORINNE'S dog has been hit by a car.

CORINNE
(urgently, to LORENZO)
Ugh, I gotta go make some calls.
Can we finish this later?

LORENZO
(looks uncomfortable)
Yeah... I mean... I'm not trying to
be a jerk, but aren't we pressed
for time on that?

CORINNE
(unsure, then caves in.)
Ugh, fine. Can we hurry, though? I
really need to get over to the vet.

LORENZO
I'll step on it if you do.

NARRATOR:
Later that day...

INT. PRODUCTION SUITE, SHAKE FLASK LAB, DAY (DIFFERENT
ANGLE)

[Scene transitions to aftermath of standardization; a mess of wipes, beakers, and pH solution is sitting out on a cart as Lorenzo and Corinne finish their work. Aseem walks in.]

ASEEM
Whoa, guys... What's with the mess?

LORENZO
(glances at Corinne)
Oh. Yeah. Sorry. Something came up
and we had to rush a little...

ASEEM
(cuts him off)
So? There are still *procedures* for
cleanup. Come *on* guys! When I come

back, I need you to have it done
the *right* way.

¹³

(Walks away, shaking his head.
Corinne and Lorenzo look at each
other sheepishly)

NARRATOR

Even when you're stressed out, you
can't rush through procedures. If a
personal emergency comes up, talk
to your supervisor, and work with
them to find someone who can fill
in. Try that again.¹⁴

[NEXT] (BUTTON TAKES USER BACK TO C-DP2)

¹³ Tetzlaff, Ron. Phone interview. Audio, Notes, June 6, 2014.

¹⁴ Ibid.

C-DP2-b1

INT. PRODUCTION SUITE: WORKBENCH (IN-PROCESS), DAY

Corinne and Lorenzo are getting ready to standardize pH and dissolved oxygen sensors for a set of large shake flasks. A call comes in that CORINNE'S dog has been hit by a car.

CORRINE

Listen--you know how to do the pH stuff, right?

LORENZO

Uh, yeah -- *you* showed me.

CORINNE

(hurried, with a panicked look.)

Ok, great. I have to get over to the vet, like *now*...

LORENZO

(interrupting)

Whoa, wait--we have to do the work together, right? I mean, don't you need to sign off on it?

CORINNE

Yeah, but you've it down. I'll just sign now and verify it later to make sure it's good.

Lorenzo shoots her a look, unsure.

CORINNE (CONT'D)

I trust you.

LORENZO

I guess... But, I mean, I'm not sure that'll fly.

CORINNE

Come on. You've done it a million times. Help me out here!

Lorenzo is hesitant, but wants to help Corinne. She got him this job, after all.

LORENZO
(takes a deep breath and
rolls eyes, defeated)
Okay. But you **owe** me.

CORINNE
Awesome. You're the best! Remember,
I'll check it later...

With a sigh of relief, Corinne grabs the clipboard Lorenzo is holding and signs off on the documentation before running out the door.

NARRATOR
You figure signing off early can't
do any harm. After all - Lorenzo
knows how to do the procedure. But
when you're back in the suite later
that day...

INT. PRODUCTION SUITE, WORKBENCH (IN-PROCESS), DAY,
DIFFERENT ANGLE

Corinne is poring over some documents when the phone rings.
Lorenzo answers.

LORENZO
Production. ...oh, uh, sure. Hang
on. (To Corinne) Hey, Corinne?

CORINNE
It's Aseem. He says he wants to see
you in his office.

CORINNE
What, now?

LORENZO
Yeah. Sounds urgent.

CORINNE
Uh... Okay...

Corinne looks at Lorenzo quizzically, but he shrugs and shoots her a look. He knows this doesn't sound good, but isn't sure what's going on.

C-DP2-b2

INT. ASEEM'S OFFICE. DAY.

Corinne and Aseem walk into his small office. On the walls are photos of his family and artwork his kids have made. Softball trophies line the shelves. Vanessa Clark from QA is waiting inside. It's unusual to see her there. Corinne looks confused.

ASEEM

Have a seat.

Corinne sits. She looks worried.

CORINNE

So, uh... what's up?

ASEEM

Corinne, this is Vanessa Clark from the Quality Unit.

VANESSA

We just have a few questions.

CORINNE

Uh... Okay.

VANESSA (CONT'D)

So... You said that you and Lorenzo standardized the sensors on the seed bioreactor, right?

CORINNE

Yeah, this morning.

Corinne shifts in her seat uneasily.

ASEEM

(quietly)

Yeah. I've got your signature right here. Except that, uh... well...

Aseem looks uncomfortable, and glances over at VANESSA. She finishes his sentence.

VANESSA

...Except you weren't actually there when it happened.

Corinne looks panicked. She's been caught, but is trying to keep it under wraps.

CORINNE

Well... There was... I - I mean, I had an emergency, so...

VANESSA

(cutting her off)

I know. Your dog was hurt. But you signed off on Lorenzo's work without actually *seeing* it!

Corinne looks pleadingly at Aseem.

CORINNE

But, I...

ASEEM

(shaking his head)

When I came down to the production suite, Lorenzo was doing the work on his own. And your signature was already there.

CORINNE

(desperate)

But - he's done it a million times... You KNOW he's reliable. I just thought...

VANESSA

(Cuts her off)

Thought what? That it was okay to falsify documents? Corinne, you KNOW better. I'm just really disappointed.

NARRATOR

Falsifying documents in any way is illegal. Any work you do must be entered into the records *exactly*. If it's not, you might cause a problem that could lead to enforcement from the FDA, or even harm a patient.

¹⁵

The next day, you're fired.

Game over.

Video returns automatically to C-INTR1

¹⁵ Menard, Jon. In-person followup. Interview by David Levin. Audio, Notes, December 8, 2014.

C-DP2-c

INT. PRODUCTION SUITE, WORKBENCH (IN-PROCESS), DAY

Corinne and Lorenzo are getting ready to standardize pH and dissolved oxygen sensors for a set of shake flasks. A call comes in that Corinne's dog has been hit by a car.

NARRATOR

You decide you need to go deal with your dog.

CORINNE

(to LORENZO)

Listen, I need to get over to the vet.

LORENZO

But what about all this?

CORINNE

We'll figure it out. I'm giving Aseem a call.

She dials Aseem's number.

CORRINE (CONT'D)

Hey, it's Corinne. Listen, I have kind of an emergency...

WE SEE SHOTS OF ASEEM AND CORINNE TALKING ON EITHER END OF THE PHONE.

NARRATOR (V.O.)

Good choice. If a personal emergency comes up at work, make sure you talk to your supervisor *before* you leave. They can help find someone to cover for you so the batch isn't affected.¹⁶ Click "next" to continue.

[NEXT] (BUTTON TAKES USER TO SCENE C-INST)

¹⁶ Seidman, Lisa, Vivian Ngan-Woodward, and Jeanette Mowery. Script Review meeting. Interview by David Levin, February 19, 2015.

C-INST1

INT. CAFETERIA, DAY

Corinne and Lorenzo are sitting down for lunch.

LORENZO
So how's your dog?

CORINNE
He'll be okay... Turns out he just
needed a few stitches.

LORENZO
(preoccupied)
Glad everything turned out okay.
[Long beat while he chews
something.]

LORENZO (CONT'D)
Listen, can I ask you something?

CORINNE
About my dog?

LORENZO
No, no - about my career.

CORINNE
(surprised)
What about it?

LORENZO
I've just been trying to figure out
if this is what I want to do with
my life.

CORINNE
(laughing)
I can't help you there.

LORENZO
I know. But I mean, seriously. Why
do *you* do this?

CORINNE
Well, I originally I wanted to do
forensics...

LORENZO
Yeah, I know. But why didn't you?

CORINNE

Well... [Long beat] remember Craig Wilson?

LORENZO

From college? What about him?

CORINNE

Well, I don't think you knew this, but right after we graduated, he and his wife had baby. Super cute kid. But she had some kind of rare genetic disorder. Died a year later.

LORENZO

That's terrible!

CORINNE

Yeah. And I mean, I wasn't close with Craig or anything. But it got me thinking... Maybe I could use my lab skills to stop that from happening again.

LORENZO

So... That's why you went back to school?

CORINNE

Yeah. Biotech seemed like a good fit. I mean, we make stuff to treat sick kids.¹⁷

LORENZO

I guess so. But what about forensics?

CORINNE

Well, that's the thing - I get to play detective *here*.

Lorenzo shoots her a quizzical look.

CORINNE

Look - if anything goes wrong, we have to investigate, right? Maybe we made a mistake. Maybe it was bad materials. But we don't know the

¹⁷ Ngan-Woodward, Vivian, Jeanette Mowery, and Lisa Seidman. Kickoff meeting / brainstorm session for "Making the Call: Quality in Biomanufacturing." Interview by David Levin, Anthony Manupelli, and Julie Benyo. Audio, Notes, March 24, 2014.

cause until we start digging for clues.¹⁸

LORENZO
I never thought of it that way.

LONG PAUSE WHILE LORENZO DIGESTS THIS.

LORENZO
Well - thanks for the help.

CORINNE
That helped?

LORENZO
Yeah. I think so - I never really considered how important this stuff is. And for your advice, I offer you my cookie.

Lorenzo hands her a cookie, making a grand gesture of it.

CORINNE
(Laughing)
I'm honored.

[VIDEO CUTS DIRECTLY TO C-DP3]

¹⁸ Seidman, Lisa, Vivian Ngan-Woodward, Jeanette Mowery, and David Levin. Meeting at ATE Conference. Audio, Notes, October 21, 2014.

C-DP3

INT. PRODUCTION SUITE, WORKBENCH (IN-PROCESS), DAY

Corinne is doing some in-process tests, and jotting down results on her documentation.

NARRATOR

Later that day, you're back to work. You and Lorenzo are cruising through some in-process tests, filling out the documentation like you were trained. But then...

CORINNE:

tsk Ah, man...

LORENZO

Something wrong?

CORINNE

Nah... I just wrote down the wrong number.

Corinne puts down her pen and studies her mistake.

NARRATOR

Nobody's perfect. But your documentation still needs to be accurate. Should you...

Text with options fills screen as NARRATOR recites each line.

(A) Put a single line through the error, add the date, and your initials.¹⁹

[Go to C-DP3-c]

(B) Start over with fresh set of batch record forms.

[Go to C-DP3-b]

²⁰

¹⁹ NC Community Colleges BioNetwork. "GMP Lab Notes." Interactive. *GMP Requirements*. Accessed September 15, 2014. <http://www.ncbionetwork.org/iet/gmp/>.

²⁰ Stern, Hank, and Lisa Seidman. Initial Script table read. Interview by David Levin and Julie Benyo, n.d.

(C) Scribble over the mistake so it
can't be read.

[Go to C-DP3-a]

²¹

²¹ Kneller, Elizabeth. Phone interview: Elizabeth Kneller. Interview by David Levin. Audio, Notes, July 31, 2014.

C-DP3-a

INT. PRODUCTION SUITE, WORKBENCH (IN-PROCESS), DAY

Corinne realizes she made a mistake on her documentation.

NARRATOR

You don't want anyone to read the error, so you scribble it out and write the actual number above it. Later that day...

INT. PRODUCTION SUITE, WORKBENCH (IN-PROCESS), DIFFERENT ANGLE

Lorenzo is reviewing documentation for Corinne.

LORENZO

Hey, Corinne...

CORINNE

What's up?

LORENZO

I'm about to sign off on the batch record, but I'm not so sure about *this*. (Points to scribbled out error on paper)

C.U. LORENZO POINTING TO SCRIBBLED OUT ERROR

CORINNE

Oh, yeah - I wrote the wrong number, but I corrected it.

LORENZO

Yeah, but isn't QA going to send this back? I mean, we're supposed to keep errors legible, right?

CORINNE

Well, yeah... I was just trying to make the correction clear...

Corinne takes a closer look at the documentation.

CORINNE (CONT'D)

But... I guess you're right.

LORENZO

I just wanted to check - I mean,
you know better than I do.

CORINNE

No, no, you're right--I should have
just lined it out and added a note.

Corinne takes the document from Lorenzo and grabs a pen.

LORENZO

Don't forget the date.

Corinne glances up at him.

CORINNE

Grasshopper is becoming the master.

LORENZO

(grins, sheepishly)
So far, so good.

NARRATOR

If you write the wrong thing down,
make sure your error is readable.
Your documentation has to be a
faithful record of everything that
happened in the production process--
including mistakes and typos. Try
again.²²

**RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR SCENE C-DP3. ANY
CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.**

²² NC Community Colleges BioNetwork. "GMP Lab Notes." Interactive.
GMP Requirements. Accessed September 15, 2014. <http://www.ncbionetwork.org/iet/gmp/>.

C-DP3-b

INT. PRODUCTION SUITE, WORKBENCH (IN-PROCESS), DAY

Corinne realizes she made a mistake on her documentation. Lorenzo is quietly working next to her.

NARRATOR

You want to correct the error, but there's not much room on the page... So you copy your results onto a fresh document.

Corinne looks over her newly copied document, and seems pleased with herself.

NARRATOR (CONT'D)

That looks good.

Corinne tosses the old pages aside onto the lab bench.

NARRATOR

But later...

INT. PRODUCTION SUITE, WORKBENCH (IN-PROCESS), DAY
(DIFFERENT ANGLE)

Aseem comes in with a short stack of papers. It's the pages you set aside earlier.

ASEEM

Hey, Corinne--what's this?

CORINNE

Uh...

ASEEM

Is this part of your documentation?

CORINNE

Yeah... Sort of. I messed up, and there wasn't enough room to correct it on there, so I just re-wrote everything on fresh forms.

ASEEM

Huh. Listen, I appreciate that you're trying to be neat, but you

need to keep the original in the record.

CORINNE

But, it's the same info...

ASEEM

Yeah, but what if you made a mistake copying it? We'd never know. Besides, if the FDA found *this*...? (Holds up crumpled paper) It'd be a huge violation.

CORINNE

Okay... Sorry. I was just trying to be clear about it...

ASEEM

I know. But do it by the book next time, okay?

Corinne nods sheepishly, and Aseem walks off. She continues working.

NARRATOR

If you write the wrong thing down, you need to make sure your error can still be read after you correct it. Your documentation has to be a faithful record of everything that happened in the production process—including mistakes and typos. Try again.²³

RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR SCENE C-DP3. ANY CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.

²³ Ibid.

C-DP3-c

INT. PRODUCTION SUITE, WORKBENCH (IN-PROCESS), DAY

Corinne realizes she made a mistake on her documentation.
Lorenzo is working quietly nearby.

NARRATOR

You think back to your training.
Everyone makes mistakes. But if you
write the wrong thing down, the
error--and the correction--all have
to be part of the batch record. So
you put a single line through the
mistake, add an explanation, then
initial and date the correction.²⁴

We see Corinne amending the document the right way, as
Lorenzo glances over in the background.

CLOSEUP OF CORINNE WRITING ON DOCUMENT

CORINNE

(talking to herself while
writing)

Okay. Wrote... grams... instead...
Of... milligrams...
March 14th... Yadda yadda yadda...
Signed... C. L.

NARRATOR

Nice job. Documentation is the
bedrock of quality... If you don't
record your work correctly, it's as
if it never happened. ²⁵

NARRATOR

Click "next" to continue.

[NEXT] (BUTTON TAKES USER TO SCENE C-DP4)

²⁴ Ibid.

²⁵ Ngan-Woodward, Vivian, Jeanette Mowery, and Lisa Seidman.
Kickoff meeting / brainstorm session for "Making the Call: Quality in Biomanufacturing."
Interview by David Levin, Anthony Manupelli, and Julie Benyo. Audio, Notes, March 24, 2014.

C-DP4

INT. PRODUCTION SUITE, SEED BIOREACTOR, DAY

Corinne needs to add a certain amount of media to a seed bioreactor, but no one qualified is available to witness it.

NARRATOR

Early the next morning, you're getting ready to fill the seed bioreactor with growth media. The cell culture has been growing in flasks, and it's ready to be transferred. Aseem wants to inoculate the reactor today, so you need to get moving.

We see Corinne setting up tubing and a peristaltic pump so she can add media to the seed bioreactor.

CORINNE

Okay, that's ready to roll, Aseem.
...Aseem? Hey, Lorenzo - where's Aseem?

LORENZO

Beats me. He was just here a second ago.

CORINNE

Ugh. He needs to witness this.
Wait, you've been trained in this, right?

LORENZO

Not yet. I mean, that's all new equipment. But I've *seen* it done...

CORINNE

Great.

Corinne sighs with frustration. She needs to get moving!

NARRATOR

The procedure says you can't weigh the media unless someone verifies your work... But Lorenzo isn't qualified to do that. Then again, you're racing against the clock. What do you do?

Text with options fills screen as Narrator recites each line.

NARRATOR

(A) Add the media and record the weight on your own.

[Go to C-DP4-a]²⁶

(B) Wait until Aseem is back.

[Go to C-DP4-c] ²⁷

(C) Ask Lorenzo to verify your work.²⁸

[Go to C-DP4-b]

²⁶ Menard, Jon. Phone followup. Interview by David Levin. Audio, Notes, September 17, 2014.

²⁷ Ibid.

²⁸ Ibid.

C-DP4-a

INT. PRODUCTION SUITE, SEED BIOREACTOR, DAY

Corinne needs to add a certain amount of media to a seed bioreactor, but no one qualified is available to witness it. She decides to act on her own.

NARRATOR

You decide to measure out the media on your own. This is time-sensitive, after all. You figure Aseem can check your work when he's back. But a few minutes later...²⁹

Aseem comes back into the suite, flustered.

ASEEM

Hey, sorry about that. I ran into the guys from QC in the hallway. Ready to do the media?

CORINNE

No need. I took care of it already.

ASEEM

Wait, what?

CORINNE

I measured out the media.

Corinne sees Aseem's expression and starts to backpedal.

...It was totally accurate!

ASEEM

(disbelief)

Corinne! The procedure says I needed to *watch* you do it.

CORINNE

But... It's time sensitive, so I figured we couldn't wait.

ASEEM

Well, yeah, technically, it *is*. But two minutes wouldn't kill us! We're going to have to file a

²⁹ Menard, Jon. In-person followup. Interview by David Levin. Audio, Notes, December 8, 2014.

deviation... I gotta talk to my manager about this.³⁰

NARRATOR

Uh, oh. Turns out Aseem has has to write you up for the incident.

For steps like this, there's no record of the measurement other than your own observation... if the procedure calls for a qualified witness, you *can't* go at it alone. Try again.³¹

RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR SCENE C-DP4. ANY CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.

³⁰ Ibid.

³¹ Ngan-Woodward, Vivian, Jeanette Mowery, and Lisa Seidman. Kickoff meeting / brainstorm session for "Making the Call: Quality in Biomanufacturing." Interview by David Levin, Anthony Manupelli, and Julie Benyo. Audio, Notes, March 24, 2014.

C-DP4-b

INT. PRODUCTION SUITE, SEED BIOREACTOR, DAY

Corinne needs to add a certain amount of media to a seed bioreactor, but no one qualified is available to witness it. She decides to ask Lorenzo, who is working nearby, to sign off.

NARRATOR

Where could Aseem be? This is time sensitive. You decide it can't wait any longer.

CORINNE

Hey, Lorenzo, can you sign off on this for me? I have no idea what happened to Aseem.

LORENZO

But I'm not allowed yet, remember?

CORINNE AND LORENZO CARTAGENA

It's just reading a scale. Look, it says 15 kilograms, right?

LORENZO

(leans in to look)

Uh, yeah?

CORINNE

Good. That's all we need. Sign here, please.

Lorenzo looks at documentation, then at CORINNE, quizzically... Then signs off.

LORENZO

(Slowly)

Okay...

CORINNE

(Keeps working)

Thank you, sir.

Cut to B-roll of Aseem coming in and looking unhappy (from C-DP4-a). The video plays out under the narrator's VO.

NARRATOR

A few minutes later, Aseem comes back into the suite and sees your signature. He's not happy! The procedure says you need someone *qualified* to witness your work... And Lorenzo hasn't been trained in this yet. So Aseem has to write you both up for the incident. Try again.³²

RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR SCENE C-DP4. ANY CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.

³² Ngan-Woodward, Vivian, Lisa Seidman, Jeanette Mowery, and David Levin. "Script Review: PelletBiotech_scripts_150113a_VNW LAS_rev_DL.docx," November 3, 2015.

C-DP4-c

INT. PRODUCTION SUITE, SEED BIOREACTOR, DAY

Corinne needs to add a certain amount of media to a seed bioreactor, but no one qualified is available to witness it. She and Lorenzo decide to wait for Aseem to come back.

NARRATOR

You decide to wait for Aseem. He's the only other person qualified to sign off on your work.

ASEEM

Hey, sorry about that. I ran into John from QC in the hallway...

CORINNE

Oh, yeah, *that* guy? Super chatty.

ASEEM

That's an understatement. Ready to handle this media?

CORINNE

I was ready 10 minutes ago.

ASEEM

Right - sorry. Let's do it.

Corinne measures out media while Aseem watches.

NARRATOR

Good choice. For steps like this, it's easy to make a mistake that could harm the batch. If the procedure calls for a witness, you *can't* go at it alone. Click "next" to continue.³³

[NEXT] (BUTTON TAKES USER TO SCENE C-DP6)

³³ Ngan-Woodward, Vivian, Jeanette Mowery, and Lisa Seidman. Kickoff meeting / brainstorm session for "Making the Call: Quality in Biomanufacturing." Interview by David Levin, Anthony Manupelli, and Julie Benyo. Audio, Notes, March 24, 2014.

C-DP5

[SCENE DELETED]

C-DP6

INT. PRODUCTION SUITE, SEED BIOREACTOR, DAY

Corinne is gathering equipment and getting ready to inoculate the 2,000 liter bioreactor.

NARRATOR

Production is moving along. So far, the batch looks healthy, and today, you're getting ready to transfer it from the seed reactor into the 2,000 liter bioreactor.

LORENZO

Okay, ready to roll?

CORINNE

Yeah, I think that's everything. Got the line cleaned and steamed, media's ready... gas lines are good, temp is solid... pH looks good...

Corinne pauses momentarily, with a glimmer of doubt on her face.

NARRATOR

At least, you *think* it looks good. Then you remember the procedure changed recently to improve yield.

³⁴

CORINNE

Wait--what's the new setting again?

LORENZO

(unsure)

Uh...

Corinne thinks for a moment.

CORINNE (CONT'D)

Ah. Right. Seven point one.

³⁴ Ngan-Woodward, Vivian, Jeanette Mowery, and Lisa Seidman. Biotech Script review phone call. Interview by David Levin. Audio, Notes, February 8, 2015.

NARRATOR

So you adjust the pH regulator and keep working. But the next day...

INT. PRODUCTION SUITE, WORKBENCH (GEN. PURPOSE), DAY

Corinne is going over some documents as Lorenzo works next to her. She seems concerned.

CORINNE

Hey, Lorenzo -

LORENZO

(without looking up from his work)

Yo.

CORINNE

Is this *today's* cell count?

Lorenzo glances over Corinne's shoulder.

LORENZO

Yeah. Just took it an hour ago.

CORINNE

Am I crazy, or does this look *low*?³⁵

LORENZO

(shrugs)

Eh. Maybe.

Lorenzo nonchalantly turns his attention back to his own work.

NARRATOR

You think back to the inoculation. Could you have done something wrong?

The batch record looks good, and you followed procedure... But then it hits you - you might have set the reactor to the old procedure's pH instead of the newest one.

³⁶Corinne sighs audibly. Lorenzo looks over.

³⁵ Meighan, Kelly. Tour of Merck, West Point PA - Kelly Meighan. Interview by David Levin. Audio, Notes, September 9, 2014.

³⁶ Ibid.

LORENZO
You all right? You look worried.

CORINNE
Yeah. Sorry, It's... nothing.

Lorenzo shrugs, then gets up and leaves to do other work.

NARRATOR
What do you do?

(A) Bring up the concern with your supervisor.

[Go to C-DP6-a]³⁷

(B) Forget about it and keep working. It's probably no big deal.

[Go to C-DP6-b2] ³⁸

³⁷ Ibid.

³⁸ Steinmetz, Sean. Initial Phone call - Sean Steinmetz, GSK Upper Merion, PA. Interview by David Levin. Audio, Notes, June 26, 2014.

C-DP6-a

INT. PRODUCTION SUITE, WORKBENCH (GEN. PURPOSE), DAY

A day after Corinne inoculated the 2,000 liter bioreactor, the pH looks low. She suspects she might have gone on automatic, and absentmindedly set the bioreactor to the old value instead of the new one. She decides to come clean about her mistake.

NARRATOR

You decide Aseem needs to know. If pH is out of spec, your team will have to fix it--fast--or it could have a big impact on the batch.

Corinne calls to Aseem, who is offscreen.

CORINNE

Hey, Aseem?

Aseem enters.

ASEEM

Hey. What's up?

CORINNE

So... I was looking at the in-process record, and the cell count seems, uh, *low*. I mean, it's in spec, but on the low side, and I, uh... I mean...

ASEEM

What are you trying to say?

CORINNE

I think I goofed yesterday.

ASEEM

(concerned)

Ok... What happened?

CORINNE

Well... the new procedure calls for pH 7.2 when we inoculate, right?

But I think I went on automatic and entered 7.1 instead.³⁹

ASEEM

But... how? It's spelled out right on the work instructions.

CORINNE

I know. I guess I was just used to our old procedure... I didn't realize I screwed up until this morning. I'm really sorry.

Aseem Takes a look at the documents Corinne is holding.

ASEEM (CONT'D)

Huh. The cell count *is* low, but not by much. We might be able to fix it.

Corinne nods expectantly.

ASEEM (CONT'D)

We'll need to file a deviation with QA...⁴⁰

CORINNE

Yeah, definitely.

ASEEM

Okay. Let's get started - we've gotta get on top of this.

NARRATOR

Looks like you caught the problem before it caused any major damage. Good thing you came clean about your mistake right away--if you had waited, it might have been too late to fix. Click "next" to continue.⁴¹

[NEXT] (BUTTON TAKES USER TO SCENE C-DP7)

³⁹ Steinmetz, Sean. Initial Phone call - Sean Steinmetz, GSK Upper Merion, PA. Interview by David Levin. Audio, Notes, June 26, 2014.

⁴⁰ Meighan, Kelly. Tour of Merck, West Point PA - Kelly Meighan. Interview by David Levin. Audio, Notes, September 9, 2014.

⁴¹ Ngan-Woodward, Vivian, Jeanette Mowery, and Lisa Seidman. Kickoff meeting / brainstorm session for "Making the Call: Quality in Biomanufacturing." Interview by David Levin, Anthony Manupelli, and Julie Benyo. Audio, Notes, March 24, 2014.

C-DP6-b1

[SCENE DELETED]

C-DP6-b2

INT. VANESSA CLARK'S OFFICE. DAY.

A few days later, Vanessa and Corinne sit on opposite sides of a desk, poring over open binders of production documents. The office is covered in aviation-themed knick-knacks; scale models of planes, an antique wooden propeller.

NARRATOR

You decide to stay quiet about your mistake. But later that week, the batch is doing even worse... so you're called in to talk to Vanessa Clark, the head of the Quality department⁴².

VANESSA

Okay, so walk me through this again. You started the batch normally.

CORINNE

Yep.

VANESSA

And *here*, it says you set the pH to seven point one.

CORINNE

Yeah.

Vanessa points to the work instructions. Corinne is silent. Vanessa grabs a different document and pulls it over to her.

VANESSA

Okay. But the new procedure calls for seven point *two*.

Vanessa puts down the paper and looks squarely at Corinne.

VANESSA

So what *happened*?

CORINNE

(exasperated)
I... I don't know.

⁴² Platco, Sheryl. Tour of Merck, West Point PA - Francis Torres (Upstream Supervisor). Interview by David Levin. Notes, September 9, 2014.

VANESSA
I think / do. You've done the old
procedure a million times, right?

CORINNE
Yeah?

VANESSA
So maybe you got a little TOO
comfortable with it. I'm guessing
you didn't double-check the
procedure.

Corinne is startled by this.

CORINNE
(defensively)
Wait, but I...

VANESSA
(cutting her off)
You had the work instructions. They
were crystal clear. Did you *follow*
them?

Corinne starts to wonder.

CORINNE
I mean... I could have *sworn* I did,
but...

VANESSA
(nods, gravely)
But you didn't double-check... And
even when you DID suspect
something, you didn't tell anyone.
And now the batch is screwed up.
It's just careless, Corinne.

NARRATOR
Looks like you should have told
someone. By keeping quiet, you let
the investigation go on until it
was too late to fix the problem.
Now there's a big delay in

production, and the company will
take a major hit.⁴³

Game over.

[VIDEO RETURNS TO C-INTR1]

⁴³ Ngan-Woodward, Vivian, Jeanette Mowery, and Lisa Seidman.
Kickoff meeting / brainstorm session for "Making the Call: Quality in Biomanufacturing."
Interview by David Levin, Anthony Manupelli, and Julie Benyo. Audio, Notes, March 24, 2014.

C-DP7

INT. PRODUCTION SUITE, C.I.P. SKID, DAY

Corinne and Lorenzo are setting up the Clean In Place (C.I.P.) skid to clean a harvest transfer line, and notice that the cleaning fluid has expired.

LORENZO

...So anyway, we're at the show,
and the drummer stands up and just
starts running around the stage
kicking over cymbals. It was
amazing.

CORINNE

(laughs)
Sounds awesome. Sorry I missed it.

A beat. Lorenzo looks down at the C.I.P. skid, and notices the label.

LORENZO (CONT'D)

Hey, wait a sec. Did you see this?

CORINNE

See what?

Lorenzo points to a label on the C.I.P. skid fluid tank.

LORENZO

The cleaning fluid expired
yesterday.⁴⁴

NARRATOR

Uh, oh. You need to replace the
fluid NOW. But if you call the
materials department, it could take
hours until they get around to it.
What do you do?

(A) Go ahead with the C.I.P.
procedure. It's probably fine.
[Go to C-DP7-a]

⁴⁴ Meighan, Kelly. Tour of Merck, West Point PA - Kelly Meighan.
Interview by David Levin. Audio, Notes, September 9, 2014.

(B) Contact the materials department about replacing the fluid before you clean.
[Go to C-DP7-b]

C-DP7-a

INT. PRODUCTION SUITE, C.I.P SKID, DAY

Corinne and Lorenzo are setting up the Clean In Place (C.I.P.) skid to clean a harvest transfer line, and notice that the cleaning fluid has expired.

NARRATOR

The fluid is only expired by *one day*. So you figure it's probably still good. Besides, you've got to clean the lines *now*.⁴⁵

CORINNE

Aggh. We don't have time to wait. The materials department takes forever to get anything to us.

LORENZO

Yeah, but if it's *expired*...

CORINNE

(cuts him off)

There's always wiggle room built in, right? I mean, it's not like it goes bad overnight.

LORENZO

(hesitant)

I don't know... I mean, I know I'm the new guy and everything, but don't we need to stick to procedure? Like, we can't just improvise.

Corinne considers this.

CORINNE

(reluctantly)

I guess... but-- [sighs; a beat] you're right. I'm just fed up with the materials guys.

NARRATOR

The expired fluid might be okay, but using it is a gamble. You need

⁴⁵ Meighan, Kelly. Tour of Merck, West Point PA - Kelly Meighan. Interview by David Levin. Audio, Notes, September 9, 2014.

to stick to procedure. Try that
again.⁴⁶

**RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR SCENE C-DP7. ANY
CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.**

⁴⁶ Ibid.

C-DP7-b

INT. PRODUCTION SUITE, C.I.P SKID, DAY

Corinne and Lorenzo are setting up the Clean In Place (CIP) skid to clean a harvest transfer line, and notice that the cleaning fluid has expired.

NARRATOR

You decide not to chance it.

CORINNE

Ugh. I guess we better call the materials department. We've got to replace this before we clean.

LORENZO

Those guys always take forever. Don't we need this done by tomorrow?

CORINNE

(reluctantly)

Looks like we'll have to put in some overtime. They should have something for us by the end of the day--we can do the cleaning then.

LORENZO

(irritated)

Great. There goes my date tonight.

CORINNE

Aw, cheer up. You can just tell her you're busy saving sick kids. Which you kind of are...

LORENZO

(skeptical)

I guess so.

CORINNE

No, seriously! We're the only people making Squabanin. People's lives depend on it. That's worth a little overtime...

Corinne gestures to the production suite around her.

LORENZO

Fair point.

CORINNE

Thank you. Feel free to use that on your date, by the way.

NARRATOR

Good work. The solution might be okay, but if the expiration date has passed, the procedures say it's officially unusable.⁴⁷ Even if it takes extra time, you need to make sure you're not using expired materials. Click "next" to continue.⁴⁸

[NEXT] (BUTTON TAKES USER TO SCENE C-DP8)

⁴⁷ Tetzlaff, Ron. Phone interview. Interview by David Levin. Audio, Notes, June 6, 2014.

⁴⁸ Meighan, Kelly. Tour of Merck, West Point PA - Kelly Meighan. Interview by David Levin. Audio, Notes, September 9, 2014.

C-DP8

INT. PRODUCTION SUITE, DELTA V PANEL, DAY

After steaming the transfer line, CORINNE accidentally opens a valve leading into the line while it's cooling. She realizes what she's done immediately.

[TEXT ON SCREEN: "ONE WEEK LATER"]

NARRATOR

A week later, you're almost ready to harvest the batch. But first, your team needs to sterilize the line used to transfer the cells out of the bioreactor.

CORINNE

(to LORENZO)

So you finally got signed off on the new equipment, huh?

LORENZO

Yeah, Aseem trained me. We did the main transfer line yesterday.

CORINNE

So it's holding pressure and everything?

LORENZO

Yep, looking good.

CORINNE

Great.

Corinne checks documentation to see what's left to do.

CORINNE (CONT'D)

Looks like we just need a few filters... Can you grab those? I'll hook the lines up.

LORENZO

Sure, be right back.

INT. PRODUCTION SUITE, FLUID TRANSFER PANEL, DAY

CORINNE

Let's see here... Transfer line
three goes to the point 5 filter,
so...

Corinne starts to remove the elbow, first opening the tri-clamp holding it in place. As soon as she does, she's startled by a loud hissing sound,

CORRINE (CONT'D)

aggh...!

Corinne checks the documentation next to her, and realizes she screwed up.

NARRATOR

Looks like you opened the wrong port. This one leads to the harvest line. It's supposed to be held under pressure so no contamination can get in... and you just broke the seal.⁴⁹ But, then again, it was just for a second. What do you want to do?⁵⁰

NARRATOR

(A) Talk to Aseem before re-steaming the line.

[Go to C-DP8-c]

(B) Mention it to Lorenzo.

[Go to C-DP8-b]

⁵¹

(C) Nothing. The valve wasn't open long enough to do any harm.⁵²

[Go to C-DP8-a1]

⁴⁹ Mardirosian, Dan, and Chris Bellerive. WPI Phone Interview. Audio, June 11, 2014.

⁵⁰ Reiken, Fernando. Site visit: Boehringer-Ingelheim, Fremont, CA. Audio, Notes, September 23, 2014.

⁵¹ Meighan, Kelly. Tour of Merck, West Point PA - Kelly Meighan. Interview by David Levin. Audio, Notes, September 9, 2014.

⁵² Armstrong, Patrick. Phone interview - Patrick Armstrong, BMS. Interview by David Levin. Audio, Notes, June 27, 2014.

C-DP8-a1

INT. PRODUCTION SUITE, FLUID TRANSFER PANEL, DAY

After steaming the transfer line, Corinne accidentally opens a valve leading into the line while it's cooling. She realizes what she's done immediately.

NARRATOR

You decide to keep quiet. You only opened the line for a second, so you figure it's still fine.

Lorenzo walks up to CORINNE.

LORENZO

So what **was** that, anyway? I thought I heard a hissing sound.

CORINNE

(thinking fast)

Oh, it was... Uh... It was nothing. I think there was a little pressure in the filter line.

LORENZO

That's weird. We're steaming that one, right?

CORRINE

Yeah, that's the one. I'll just get this hooked up and we're good to go.

LORENZO

Okay - let me know when you've got it in place and I'll open the valves.

Corinne looks relieved.

NARRATOR

Your team harvests the batch as planned, and passes it on to the downstream folks for purification. But a few days later...

INT. ASEEM'S OFFICE. DAY

The phone rings.

ASEEM
Production, Aseem here.

KEVIN
Hey, Aseem. It's Kevin.

ASEEM
Hey, Kev, what's up?

KEVIN
Listen - I think we've got a problem. The last in-process sample we tested for microbes came up positive.

ASEEM
(alarmed)
It *what??*

KEVIN
You heard me. Kendra asked me to call.

ASEEM
Are you sure? I mean, all the other micro samples were clean. Maybe it happened in handling?

KEVIN
We thought of that. But we're getting endotoxins in the downstream samples, so we know *something* got in.⁵³

ASEEM
(worried)
So... what are we looking at?

KEVIN
Some sort of bacteria. We haven't ID'd them yet.

ASEEM
I don't understand. We got normal in-process readings all the way through!

Aseem picks up the documentation on his desk and throws it down again.

⁵³ Ibid.

KEVIN

Beats me... But we'll need to investigate, now. I just wanted to let you know so you weren't blindsided.

ASEEM

(takes a deep breath)
Well... Thanks. I guess.

Aseem hangs up the phone and starts massaging his temples.

NARRATOR

The investigation that follows eventually leads back to your error. Turns out the harvest line was contaminated. When you released the pressure, you let air in--along with bacteria, causing low-level contamination. Now, the batch is ruined. If you had just re-steamed--or told your supervisor--this all could have been avoided. Game over.

Video returns automatically to C-INTR1

RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR SCENE C-DP8. ANY CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.

C-DP8-b

INT. PRODUCTION SUITE, FLUID TRANSFER PANEL, DAY

After steaming the transfer line, Corinne accidentally opens a valve leading into the line while it's cooling. She realizes what she's done immediately.

NARRATOR

You decide to let Lorenzo know.

CORINNE

So... I think I opened the wrong line.

Lorenzo walks in quickly from offscreen.

LORENZO

(concerned)

What do you mean?

CORINNE

That hissing sound came from this... (Points to the port she opened) but the filter line is *here*.

LORENZO

Isn't that the main transfer line?

CORINNE

Yeah, I think so.

LORENZO

Ugh. How long was it open?

CORINNE

Only for a split second. There's still positive pressure in there.

LORENZO

You sure?

CORINNE

(thinks about it)

Yeah... Yeah.

LORENZO

(shrugs)

Well, as long as there's pressure in there, it should be fine, right? I won't tell Aseem if you don't.

NARRATOR

You and Lorenzo figure everything is okay. The next day, your team harvests the batch as planned. But later that week...

INT. ASEEM'S OFFICE. DAY

The phone rings.

ASEEM

Production, Aseem here.

KEVIN

Hey, Aseem. It's Kevin.

ASEEM

Hey, Kev, what's up?

KEVIN

Listen - I think we've got a problem. The last in-process sample we tested for microbes came up positive.

ASEEM

(alarmed)

It *what??*

KEVIN

You heard me. Kendra asked me to call.

ASEEM

Are you sure? I mean, all the other micro samples were clean. Maybe it happened in handling?

KEVIN

We thought of that. But we're getting endotoxins in the downstream samples, so we know *something* got in.⁵⁴

ASEEM

(worried)

⁵⁴ Ibid.

So... what are we looking at?

KEVIN

Some sort of bacteria. We haven't ID'd them yet.

ASEEM

I don't understand. We got normal in-process readings all the way through!

Aseem picks up the documentation on his desk and throws it down again.

KEVIN

Beats me... But we'll need to investigate, now. I just wanted to let you know so you weren't blindsided.

ASEEM

(takes a deep breath)

Well... Thanks. I guess.

Aseem hangs up the phone and starts massaging his temples.

NARRATOR

The investigation that follows eventually leads back to your error. Turns out the harvest line was contaminated. When you released the pressure, you let air in--along with bacteria, causing low-level contamination. Now, the batch is ruined. If you had just re-steamed--or told your supervisor--this all could have been avoided. Game over.

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C-DP8-c

INT. PRODUCTION SUITE, FLUID TRANSFER PANEL, DAY

After steaming the transfer line, Corinne accidentally opens a valve leading into the line while it's cooling. She realizes what she's done immediately.

NARRATOR

You start to doubt that the harvest transfer line is still sterile. If the pressure was released, some bacteria *could* have gotten in⁵⁶. So you decide to re-steam it.

CORINNE

Ugh. I think I opened the wrong line.

Lorenzo walks in quickly from offscreen.

LORENZO

(concerned)
Wait, seriously?

CORINNE

Well, maybe. That hissing sound came from *this*. (Points to the port she opened) I thought it was the filter line, but that's over *here*. (Points to the next port over)

LORENZO

Doesn't this one go to the harvest transfer line?

CORINNE

Yeah.

LORENZO

But... That's supposed to be held under pressure.

⁵⁶ Armstrong, Patrick. Phone interview - Patrick Armstrong, BMS. Interview by David Levin. Audio, Notes, June 27, 2014.

CORINNE

Yeah. and I think I just let it all out. We're going to have to re-steam it.⁵⁷

LORENZO

Can we *do* that?

CORINNE

According to the procedures, yeah. Here, I'll add it to the batch record so we can re-do it.⁵⁸

LORENZO

Wait, you want to re-steam *now*?

CORINNE

When else? We're not harvesting until tomorrow. We've still got time.

LORENZO

But... What about lunch?

CORINNE

You mean you'd rather get burritos than do this right?

LORENZO

Oh, fine. I'll stay. But you owe me dessert.

NARRATOR

Good move. If the procedure allows it, re-steaming the line won't hurt anything. Besides, it's better to play it safe than risk contaminating the batch. You tell Aseem about it, and make a note in the documentation. And then...⁵⁹

INT. PRODUCTION SUITE, WORKBENCH (GEN. PURPOSE), DAY

Aseem enters.

⁵⁷ Meighan, Kelly. Tour of Merck, West Point PA - Kelly Meighan. Interview by David Levin. Audio, Notes, September 9, 2014.

⁵⁸ Tetzlaff, Ron. Phone interview. Interview by David Levin. Audio, Notes, June 6, 2014.

⁵⁹ Ibid.

ASEEM
Hey, Corrine?

CORINNE
Yeah?

ASEEM
Listen, I just wanted to say nice
job yesterday. You called that just
right.

CORINNE
Oh... thanks!

ASEEM
Of course! If you hadn't caught the
mistake, we could have contaminated
the whole batch. So... Uh, way to
be.

NARRATOR
Looks like you handled that pretty
well. Mistakes happen, but if
follow procedures, you can avoid a
bigger problem that could harm the
quality of the batch.⁶⁰

Click "next" to continue.

[NEXT] (BUTTON TAKES USER TO CORINNE SCENE C-OUT1)

⁶⁰ Ibid.

C-OUT1

INT. PRODUCTION SUITE, DAY

Aseem, Corinne, and Lorenzo are wrapping up work, straightening up the lab, and high living each other.

NARRATOR

You finally made it. Your team harvested the batch, and now it's being purified downstream. Soon, that shipment of Squabanin will be out the door, and Franklin will have another happy customer.

INT. BAR AND GRILL, EVENING

NARRATOR (CONT'D)

Congratulations. You and your team saw the batch through successfully, and stuck to good manufacturing practices. You'll do well in this field.

You can go back and explore other outcomes for this character, or choose another character to play. Click next to continue.

[NEXT] (BUTTON TAKES USER TO MENU-1)

A-INTR1

INT. PRODUCTION SUITE, WORKBENCH (GEN. PURPOSE), MORNING

CORINNE LAWTON and LORENZO CARTAGENA are working in the production suite, when Aseem Komani walks in.

NARRATOR

This is you. Aseem Komani. You're a production supervisor at Franklin... And an all around nice guy. You've spent six years at the company, first as a technician, and now a production supervisor. It feels good to have a team of your own.

NARRATOR (CONT'D)

Corinne Lawton is your protégé. When she joined the company two years ago, you took her under your wing. Today, she's a solid technician. Or so they say.

NARRATOR (CONT'D)

Lorenzo Cartagena. The new guy. He's an old friend of Corinne's. He doesn't have a lot of work experience, but was a star student in undergrad. You think he's got potential.

NARRATOR (CONT'D)

As a successful mentor, you get to help other technicians come up in the ranks. It's a pretty good gig. Click "next" to continue.

[NEXT] (BUTTON TAKES USER TO SCENE A-DP1)

A-DP1

INT. CONFERENCE ROOM, DAY.

NARRATOR

Later that morning...

Aseem and other employees crowd around a conference table, as the CEO sits on the end.

SANDOVAL

(clears throat)

Good morning, everybody. Thanks for taking time out of your schedules to come here. So as you may have heard, we're facing a major challenge as a company in the coming months. Stilton Pharmaceuticals is reorganizing... And our contract might be the first casualty.⁶¹

The crowd murmurs audibly at this. SANDOVAL pauses, and tries to quiet the room with her hands.

SANDOVAL (CONT'D)

Look, it's not a done deal...

Crowd noise continues.

SANDOVAL (CONT'D)

Folks, please, [pauses as crowd murmur dies down] I know you're concerned. They're our biggest client. But that's why I called you here. You've got the training. You've got the procedures. If we stick to those, we'll be fine. Remember--at Franklin, what do we do? We do it...

SANDOVAL gestures at the room, expecting their participation.

WHOLE ROOM (TOGETHER)

...right the first time.

⁶¹ Crawford, Jim. Phone call: Jim Crawford. Interview by David Levin. Audio, Notes, July 30, 2014.

SANDOVAL

Yes! *Good*. Now... We're scheduled to deliver Squabanin in four months. If any questions come up, any problems, you *talk to management*, okay? Keep the dialogue open. And if you see something...

SANDOVAL gestures to the room, expectantly.

WHOLE ROOM (TOGETHER):

SAY something.

SANDOVAL

Excellent! Okay. Now, let's go over a few new policies.

C.U. Aseem. He looks worried.

NARRATOR

That doesn't sound good. If something goes wrong with the next batch, Stilton could pull their contract. And *that* would mean huge layoffs at Franklin.⁶² Better stay on your toes.

NARRATOR (CONT'D)

Click "next" to continue.

[NEXT] (BUTTON TAKES USER TO SCENE A-DP2)

⁶² Armstrong, Patrick. Phone interview - Patrick Armstrong, BMS. Interview by David Levin. Audio, Notes, June 27, 2014.

A-DP2

INT. PRODUCTION SUITE, WORKBENCH (GEN. PURPOSE), DAY

The production team is about to prepare the suite for the next big batch of SQUABANIN, the product they're manufacturing for STILTON PHARMACEUTICALS. Corinne and Lorenzo meet with Aseem for a quick morning check-in.

NARRATOR

That afternoon...

ASEEM

...Okay, so Corinne, you're set to clean and steam the seed bioreactor...

CORINNE raises her hand tentatively.

ASEEM (CON'T)

Uh, yeah?

CORINNE

So... We're happy to get rolling on that, but you know we're up for cGMP refresher training, right?

ASEEM

(perplexed)

What, already? They told me that was coming *after* this batch.

CORINNE

They just moved it up. We got an email this morning. Shouldn't take more than a couple hours, though.

Aseem looks irritated at this news.

NARRATOR

Great. This means your team has to complete training ASAP... But *you* need them to finish prepping the production suite to stay on schedule. What do you want to do?⁶³

⁶³ Ducoat, Raymond. Tour of Merck, West Point PA - Ray Ducoat. Interview by David Levin. Audio, Notes, September 9, 2014.

(A) Ask them to hold off on the training until you can re-work your schedule.⁶⁴

[Go to A-DP2-a]

(B) Have them do the training now.⁶⁵

[Go to A-DP2-b]

⁶⁴ De La Rosa, George. Phone call - George De la Rosa. Interview by David Levin. Audio, Notes, July 2, 2014.

⁶⁵ Ibid.

A-DP2-a

INT. PRODUCTION SUITE, WORKBENCH (GEN. PURPOSE), DAY

Aseem asks Lorenzo and Corinne to hold off on the training.

NARRATOR

You ask your team to hold off on the training for now.⁶⁶

ASEEM

Listen guys - I know this just came out, but I need you to focus on getting the suite ready right now.

CORINNE

You sure?

ASEEM

Yeah. You know that meeting with Sandoval this morning?

CORINNE

What about it?

ASEEM

So... The CEO said Stilton is thinking of pulling the contract.⁶⁷

CORINNE

(dumbfounded)
Seriously??

ASEEM

Yeah. I know. It just means that prepping the suite is the priority right now. You can do the training later this week, right?

CORINNE

I guess so - We've got to do the training by next week, though.

⁶⁸ASEEM

Understood. We'll figure it out.

⁶⁶ Ducoat, Raymond. Tour of Merck, West Point PA - Ray Ducoat. Interview by David Levin. Audio, Notes, September 9, 2014.

⁶⁷ Crawford, Jim. Phone call: Jim Crawford. Interview by David Levin. Audio, Notes, July 30, 2014.

⁶⁸ Ibid.

NARRATOR

Later that week, things get even busier. You ask your team to push the training back again. But soon, you're up against the deadline. So you send them off... And you're shorthanded for most of the day.⁶⁹ Guess you shouldn't have let this wait. Remember: training is an essential part of current good manufacturing practices.⁷⁰

[NEXT] (BUTTON TAKES USER TO SCENE A-DP3)

⁶⁹ De La Rosa, George. Phone call - George De la Rosa. Interview by David Levin. Audio, Notes, July 2, 2014.

⁷⁰ Ducoat; September 9, 2014.

A-DP2-b

INT. PRODUCTION SUITE, WORKBENCH (GEN. PURPOSE), DAY

Aseem reluctantly sends Lorenzo and Corinne to training ASAP.

NARRATOR

You decide you need to schedule training for your team *now*.

ASEEM

Okay. We've got some time in the schedule Wednesday... you guys should get rolling on the training then.

LORENZO

You sure?

ASEEM

Yeah. We need to make sure we do this batch right... a GMP refresher could be handy.

NARRATOR

Good call. Even if the timing is tight, it's important that you and your team are signed off on the most current training requirements.

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We see CORINNE and LORENZO doing training exercises on their computers.

NARRATOR (CONT'D)

At first, it seems like a formality, but this round of training gives examples of where things went wrong at other companies, so your team gets some food for thought. Looks like time well spent after all. Click "next" to continue.

[NEXT] (BUTTON TAKES USER TO SCENE A-DP3)

A-DP3

INT. PRODUCTION SUITE, DELTA-V PANEL, DAY

In addition to his team's online cGMP training, Aseem often has to provide them with on-the-job training himself. Today, he needs to get LORENZO, the new guy, qualified on a couple of procedures. We see the two studying a steam in place control unit.

We see Aseem and LORENZO going over some documents in the production suite together. They're standing in front of a control panel.

NARRATOR

A day later. In addition to online training, you need to give your team on-the-job training as well. Today, you're getting Lorenzo up to speed on a new procedure.

ASEEM

Okay, so steam in place... The basics are the same as what you've always done...

LORENZO

Huh. this is nothing like what I learned on.

ASEEM

Well, just follow as best as you can, ok? We're a little short on time.

Aseem taps a touchscreen and pulls up a block diagram of Franklin's entire facility. The screen should look similar to Delta-V, a common automation system.

ASEEM

So... this is your control panel. It handles partial automation, which...

LORENZO

Wait, so we still have to do stuff manually?

ASEEM

Well... Sort of.

LORENZO

Like what?

ASEEM

Uh--I'll get to that. So this can steam to almost any line in the plant.⁷² Which means...

LORENZO

Wait, we can control rooms from here? That's cool.

ASEEM

Right. But...

LORENZO

Is all that done from this screen, or is there like a master menu?

NARRATOR

He's asking a *lot* of questions. You're on a tight schedule... But at this rate, training Lorenzo is going to take all day. What do you want to do? You could...⁷³

(A) Postpone the training until another time so you can finish the procedure.⁷⁴

[Go to A-DP3-a]

(B) Tell him to pay attention, but save his questions for another time.⁷⁵

[Go to A-DP3-c]

(C) Answer each of his questions as best as you can.⁷⁶

[Go to A-DP3-b]

⁷² Reiken, Fernando. Site visit: Boehringer-Ingelheim, Fremont, CA. Interview by David Levin. Audio, Notes, September 23, 2014.

⁷³ Kneller, Elizabeth. Phone interview: Elizabeth Kneller. Interview by David Levin. Audio, Notes, July 31, 2014.

⁷⁴ Ibid.

⁷⁵ Ibid.

⁷⁶ Ibid.

A-DP3-a

INT. PRODUCTION SUITE, DELTA-V PANEL, DAY

Aseem is training Lorenzo on a steam in place procedure, but Lorenzo keeps asking tons of questions. Aseem decides to just postpone the training so he can finish.

NARRATOR

You decide this training is just going to take too long. You've got time sensitive work to do. So...

ASEEM

(frustrated)

Tell you what - why don't we finish the training another time? I really need to get this steamed before lunch.

LORENZO

(a little disappointed)

Oh. Uh, sure.

ASEEM

Sorry, man - we're just in a time crunch. You should still watch the procedure, though.

LORENZO

Yeah, that'd be great.

Shots of Aseem tapping away on the Delta-V panel, and jotting things down in the batch record.

NARRATOR

You take over doing the steam in place procedure yourself, and document the work accordingly. You manage to get things done in time, but you weren't able to finish training Lorenzo. And a few days later...

INT. PRODUCTION SUITE, WORKBENCH (GEN. PURPOSE), DAY

CORINNE picks up the phone and dials Aseem's extension. We see him pick up in his office.

ASEEM

This is Aseem.

CORINNE

Hey, man. So... Lorenzo never got signed off on the Steam in place system?

ASEEM (V.O.)

No... We're going to try again this week.

CORINNE

Okay... Then I still need *you* to sign off on my work.

ASEEM (V.O.)

Yeah, I know.

CORINNE

(chiding)

Good. 'Cause I'm done, and I need your autograph.

ASEEM

(lightly irritated)

Be right down.

NARRATOR

Cutting Lorenzo's training short may have saved you some time last week, but you're paying for it now. He can't sign off on the procedure, so *you've* got to drop everything you're doing to verify Corinne's work. Try again.

⁷⁷**RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR SCENE A-DP3. ANY CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.**

A-DP3-b

INT. PRODUCTION SUITE, DELTA-V PANEL, DAY

Aseem is training LORENZO on a steam in place procedure, but LORENZO keeps asking tons of questions. Aseem decides to try and answer the questions as they come up.

We see Aseem showing LORENZO a Delta-V control panel.

NARRATOR

You decide you should try to answer all of Lorenzo's questions. But before you know it, an hour has gone by, and you're not much closer to finishing. If you push it into the afternoon, your team is going to be behind schedule. It's important to make sure your team members know the ropes, but even training can't get in the way of time-sensitive procedures.⁷⁸ Try again.

RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR SCENE A-DP3. ANY CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.

⁷⁸ Ibid.

A-DP3-c

INT. PRODUCTION SUITE, DELTA-V PANEL, DAY

Aseem is training Lorenzo on a steam in place procedure, but Lorenzo keeps asking tons of questions. Aseem asks him to pay attention, and hold his questions until another time.

We see Aseem showing Lorenzo a control panel like Delta-V.

NARRATOR

Lorenzo has been asking questions for a solid 15 minutes. You still need to show him how the procedure is done, though. So...

LORENZO

Wait, so where's the temp preset again?

ASEEM

It's here. But tell you what - why don't you just jot down your questions as they come up? I'm behind schedule now, and really need to get this done before lunch.

LORENZO

Oh - sure.

ASEEM

Thanks. I can answer any other questions once we're done, okay?

LORENZO

No problem. I think I got most of it - I'll just watch you one more time.

Lorenzo studiously takes notes while Aseem taps away on the Delta-V panel, and jots things down in the batch record.

NARRATOR

On-the-job training is important, but it can't get in the way of time-sensitive procedures.

⁷⁹Luckily, it seems like Lorenzo is getting the hang of things. Looks

⁷⁹ Ibid.

like you handled that just right.
Click "next" to continue.

[NEXT] (BUTTON TAKES USER TO SCENE A-DP4)

A-DP4

INT. ASEEM'S OFFICE, AFTERNOON

Aseem is reviewing batch documents and notices that one of his team members' batch records are consistently sloppy. He flips from page to page, shaking his head.

NARRATOR

A week later. You're going over your team's batch documents, and notice Lorenzo has been pretty sloppy lately. He's leaving out some units on his measurements... And when he makes a mistake, he keeps scribbling it out. You need to send today's documents on to the Quality unit, but there's no way they'll accept it like this. What should you do?⁸⁰

(A) Pull Lorenzo aside and talk to him about the sloppy work.

[Go to A-DP4-a]

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

[Go to A-DP4-b]⁸¹

(C) Correct the documents yourself.

[Go to A-DP4-c]⁸²

⁸⁰ Menard, Jon. Initial phone call. Interview by David Levin. Audio, Notes, September 10, 2014.

⁸¹ Ibid.

⁸² Ibid.

A-DP4-a

INT. PRODUCTION SUITE, WORKBENCH (GEN. PURPOSE), DAY

After reviewing batch documents, Aseem notices some errors in LORENZO's work. It's become a pattern--so he decides to confront him.

NARRATOR

You decide to talk to Lorenzo directly.

Aseem walks into the production suite holding the documentation.

ASEEM

Hey. Got a sec?

LORENZO

What's up?

ASEEM

(holds up papers)

So you've been making the same errors pretty consistently.

LORENZO

Like what?

ASEEM

Well, for starters... (Spreads documents on the bench in front of him) There were at least three or four times in the last week when you didn't add units.

LORENZO

Oh - yeah, sorry about that... But I mean, when we're dealing with the bioreactor, we always work in liters, right? So shouldn't it be clear by context?

ASEEM

You and I know that, but...

LORENZO

But...

Aseem cuts him off.

ASEEM (CONT'D)

Look, bottom line is: we have to document by the book. All units need to be on there... Got it?

LORENZO

(slowly)

Okay. I'll... keep a closer eye on that. Sorry.

NARRATOR

Good call. As a supervisor, it's up to you to make sure your staff documenting their work the right way. That way if anything goes wrong, you'll know exactly what you did along the way.⁸³

INT. PRODUCTION SUITE, WORKBENCH (IN-PROCESS), DAY

We see Aseem working with LORENZO on some documentation.

NARRATOR (CONT'D)

Over the next few weeks, you work closely with Lorenzo, and help him improve his documentation. Before long, it looks like he's shaping up. Good thing you talked to him. Click "next" to continue.

[NEXT] (BUTTON TAKES USER TO SCENE A-DP6)

⁸³ Platco, Sheryl. Tour of Merck, West Point PA - Ray Ducoat (Upstream Supervisor). Interview by David Levin. Notes, September 9, 2014.

A-DP4-b

INT. VANESSA'S OFFICE, DAY

After reviewing batch documents, Aseem notices some errors in LORENZO's work. It's become a pattern--so he decides to seek advice from his colleague in QA.

NARRATOR

You decide to check in with Vanessa Clark, the head of the Quality unit. She'll know what to do.

Aseem knocks on VANESSA's door.

ASEEM

Hey, there.

VANESSA

Hey. What brings you up here?

ASEEM

I need some of your sage advice.

VANESSA

What's up?

ASEEM

You know I've been having some problems with Lorenzo lately, right?

VANESSA

Yeah. His documentation?

ASEEM

Yep. He's been making a lot of the same mistakes. Leaving out units and things. It's all minor, but it adds up.

VANESSA

Right...

ASEEM

So, I guess what I'm wondering is, how do I deal with this? I've tried dropping hints.

VANESSA

Hints aren't going to cut it. He's got an academic background, right?

ASEEM

Yeah. Whiz kid in the lab, but I don't know if he's cut out for a GMP environment.

⁸⁴VANESSA

Sounds like you've got to work with him on it. We can figure out some focused training or something... But step one is to bring it up with him directly.

ASEEM

Yeah. But...

VANESSA

I know you're not big on conflict. But you still need to help him understand why it's so important.

ASEEM

(considers this idea)

I guess so.

VANESSA

Look, try putting it this way: As far as the FDA is concerned, if you don't document your work the right way, it's like it never happened. We'd have no clue what went on during production... and It'd be illegal for us to sell that batch, even if it was totally fine.⁸⁵ We'd be completely hosed.

ASEEM

That's a good way of putting it..

VANESSA

(Shrugs and smiles)
It IS my job...

⁸⁴ Crawford, Jim. Phone call: Jim Crawford. Interview by David Levin. Audio, Notes, July 30, 2014.

⁸⁵ Ngan-Woodward, Vivian, Jeanette Mowery, and Lisa Seidman. Kickoff meeting / brainstorm session for "Making the Call: Quality in Biomanufacturing." Interview by David Levin, Anthony Manupelli, and Julie Benyo. Audio, Notes, March 24, 2014.

NARRATOR

You think through what Vanessa told
you. And then, later that week....

[VIDEO cuts to A-DP4-a]

A-DP4-c

INT. ASEEM'S OFFICE, AFTERNOON

Aseem is reviewing documents and notices that one of his team members' batch records are consistently sloppy. He flips from page to page, shaking his head.

NARRATOR

This work just isn't going to cut it. But Lorenzo is a good kid--you figure you'll just help him out and make few corrections.

Aseem pores over LORENZO's documentation, adding bits and pieces of missing info.

ASEEM

(poring over
documentation)

Oh *man*, Lorenzo. Okay - that should be ten *grams*... And 3.3 *liters*.

NARRATOR

No big deal, right? It's just a few small tweaks. But a few days later...

INT. Aseem'S OFFICE. DIFFERENT DAY

VANESSA knocks on the door.

ASEEM

Hey, Vanessa. What's up?

VANESSA

Uh... (Holds up documentation)
Isn't this *your* handwriting?

VANESSA is holding the documents Aseem sent in a few days earlier. She flops them down on Aseem's desk.

ASEEM

Oh. Uh, yeah, I guess it is.

VANESSA

Aseem! You can't just correct these mistakes...

ASEEM

It wasn't a correction. I was adding the units for clarity.

VANESSA

Same difference! I'm gonna need you to verify these units with Lorenzo. Unless he writes the units, it could be 3.3 *bushels* for all we know.

ASEEM

Yeah, but I **saw** him add the right amount. He just wrote it wrong. Simple mistake.

VANESSA

(exasperated)

Aseem... Look. I know you like this kid. He's great. But don't let that cloud your judgment. This is... It's just... You can't DO that!

ASEEM

Look - can't we just...

VANESSA

What, look the other way? Come on, - you know I can't do that. This is serious. It's falsifying records.

It starts to dawn on Aseem that he might have screwed up BIG.

VANESSA (CONT'D)

I'm going to have to bring this to management.

VANESSA starts to get up and leave.

ASEEM

(flustered)

What? Wait! This is... I mean, I've never...

VANESSA

I know. You've got a good track record. But this is completely against FDA regulations! It could cost us our jobs.⁸⁶

⁸⁶ Tetzlaff, Ron. Phone interview. Interview by David Levin. Audio, Notes, June 6, 2014.

VANESSA stops as she walks out the door and looks over her shoulder.

VANESSA

(sadly)

I'll... I'll put a good word in for you. But I *have* to report this.

She walks out, leaving a shell-shocked Aseem at his desk. What has he done?

NARRATOR

That's not good. If you find a problem in someone's documentation, *never* change it yourself. Even a small tweak is considered falsifying documents----and *that's* illegal. Instead, record that you found an error, and start an investigation before doing anything else.⁸⁷

Video returns automatically to A-INTR1

⁸⁷ Ibid.

A-DP5

[SCENE DELETED]

A-INST1 (interstitial)

[SCENE DELETED]

A-DP6

INT. PRODUCTION SUITE, SEED BIOREACTOR, DAY

The batch is up and running. You and Corinne need to add more media to the seed bioreactor. When you scan the barcode on a bag from the raw materials department, though, it comes up as "pending release" rather than "released".

NARRATOR

A week has gone by. You've already inoculated the seed bioreactor, and today, your team needs to add more media to keep it going strong.

ASEEM

Okay, almost ready. Can you grab the media?

CORINNE is already pushing the media bag over on a wheeled cart.

CORINNE

Way ahead of you.

ASEEM

Awesome. Is it scanned in?

CORINNE

Uh, one sec.

CORINNE picks up a handheld scanning unit and passes it over the barcode on the bag. It beeps, and she looks confused at the result on her display.

CORINNE

Hmm.

CORINNE scans the bag a second time. Again, it beeps.

CORINNE (CONT'D)

That's weird. It keeps coming up as "pending release."

ASEEM

Really? Let me see.

Aseem takes a look at the display, and shakes his head.

ASEEM (CONT'D)

It must be a glitch. We're not supposed to have anything that's pending.

CORINNE

Yeah, but can we afford to wait for more? You know they're slow to deliver.

NARRATOR

She's right - the materials department could take forever to get you another bag of media... And you need to feed the bioreactor *now*. What should you do?⁸⁸

(A) Tell your team to document the issue and use it anyway.

[Go to A-DP6-a] ⁸⁹

(B) Call the materials release coordinator to find out what the problem is. ⁹⁰

[Go to A-DP6-b]

⁸⁸ Ducoat, Raymond. Tour of Merck, West Point PA - Ray Ducoat. Audio, Notes, September 9, 2014.

⁸⁹ Ibid

⁹⁰ Ibid

A-DP6-a

INT. PRODUCTION SUITE, DAY

Aseem's team scans the barcode on a bag of media from the raw materials department. It comes up as "pending release" rather than "released".

NARRATOR

You decide you can't wait for more media.

ASEEM

(to Corinne)

Just go ahead and use this for now. It's got to be a glitch.

NARRATOR

You figure you were left with no choice--your team needed the media **now**. Besides, you've never had a problem with materials in the past. So you document your reasoning and move on.⁹¹ But later that afternoon...

INT. PRODUCTION SUITE, WORKBENCH (GEN. PURPOSE), DAY

Phone rings in the production suite. Aseem answers.

ASEEM

Production, this is Aseem.

MATERIALS COORDINATOR (V.O.)

Hey, Aseem - it's Mark from materials.

ASEEM

Yeah?

MATERIALS COORDINATOR (V.O.)

Listen, That media we delivered today--it shouldn't have been released.

ASEEM

What?

⁹¹ Meighan, Kelly. Tour of Merck, West Point PA - Kelly Meighan. Interview by David Levin. Audio, Notes, September 9, 2014.

MATERIALS COORDINATOR
It's not cleared. We're trying to figure out how it got to you. But you didn't use it, did you?

ASEEM
Uh...

Aseem realizes he's made a big mistake.

NARRATOR
Uh, oh. You should have called the materials department when you saw the alert.⁹²

B-ROLL of Aseem going over documentation, looking worried, making phone calls.

NARRATOR (CONT'D)
You start a process deviation,⁹³ but it's already too late. Within a few days it's clear that the media wasn't fit to use... and now the batch is ruined. Your mistake costs you your job.

If there's ever any question about your materials, it's essential to bring your concerns to supervisors and QA.

Game over.

Video returns automatically to A-INTR1

⁹² Ibid.

⁹³ Ibid.

A-DP6-b

INT. PRODUCTION SUITE, SEED BIOREACTOR, DAY

Aseem's team scans the barcode on a bag of media from the raw materials department. It comes up as "pending release" rather than "released".

NARRATOR

You decide not to chance it.

ASEEM

(sighs)

We can't use this.

CORINNE

Do we have time to wait for a new one, though?

ASEEM

I'll have to check. Let me make a few calls.

INT. PRODUCTION SUITE, WORKBENCH (GEN. PURPOSE), DAY

Aseem walks over to the phone and dials the materials department.

ASEEM

Hey, Mark - it's Aseem down in production. Yeah. So we just scanned a bag of media you guys delivered, and it's coming up as "pending release".

Aseem checks the tag on the media.

ASEEM (CONT'D)

Looks like... SQ14ME dash 1026.

A beat. Aseem glances over at the bag, surprised.

ASEEM (CONT'D)

Wait - seriously? Yeah. Okay. I'll send somebody up.

CORINNE

What was that all about?

ASEEM

Looks like there was a screwup on their end. This wasn't supposed to be released.

CORINNE

Really?

ASEEM

Yeah. It went through QC, but wasn't in the system for some reason.

NARRATOR

Good thing you checked. You should never use raw materials until they're approved. If there's ever any doubt about them, make sure you call the appropriate department. Click "next" to continue.⁹⁴

[NEXT] (BUTTON TAKES USER TO SCENE A-DP7)

⁹⁴ Ibid.

A-DP7

INT. PRODUCTION SUITE, SEED BIOREACTOR, DAY

Lorenzo is jotting some notes down in a logbook in the production suite.

NARRATOR

Later that month...

Lorenzo suddenly hears an alarm sound from the seed bioreactor. He rushes over to investigate.

LORENZO

Aw, man.

Aseem walks over while Lorenzo is checking out the alarm. He looks at the display screen to see what's going on.

ASEEM

Hey. So what's going on?

LORENZO

I don't know. Process air flow seems normal, but I keep getting a foam alarm.

ASEEM

Let me see.

Aseem looks at the control panel and LORENZO's documentation to verify.

ASEEM (CONT'D)

Looks like you set this up right. Flow meter looks normal, too. Did you look in the tank?⁹⁵

LORENZO

Yeah - it's foaming a little, but doesn't look that bad. It's weird.

NARRATOR

Lorenzo did everything by the book. What could be causing the foam-up? You wonder if the alarm is just a glitch. But if there *is* foam in the

⁹⁵ Ducoat, Raymond. Tour of Merck, West Point PA - Ray Ducoat. Audio, Notes, September 9, 2014.

bioreactor, you can't ignore it.
What do you do next?

(A) Stop and troubleshoot the alarm
now.

[Go to A-DP7-c]

(B) Ignore the alarm. It's probably
a malfunction.⁹⁶

[Go to A-DP7-b]

(C) Improvise and add more anti-
foaming agent.⁹⁷

[Go to A-DP7-a]

⁹⁶ Armstrong, Patrick. Phone interview - Patrick Armstrong, BMS.
Interview by David Levin. Audio, Notes, June 27, 2014.

⁹⁷ Menard, Jon. In-person followup. Interview by David Levin. Audio,
Notes, December 8, 2014.

A-DP7-a

INT. PRODUCTION SUITE, SEED BIOREACTOR, DAY DAY

Lorenzo and Aseem find a foam alarm going off on the seed bioreactor. The pair decide to add more anti-foaming agent.

NARRATOR

You're still not sure exactly what's causing the foam, but you decide you can't ignore it.

ASEEM

Okay, let's get some anti-foam in there.

LORENZO

How much?

ASEEM

Try 20 mils.

LORENZO

Got it. What do you think's causing it?

ASEEM

Not sure. But the antifoam should take care of it.

NARRATOR

Lorenzo adds antifoam according to procedure----and it seems to help. So you record the event in the batch record, and move on with your day. But a week later...

INT. PRODUCTION SUITE, SEED BIOREACTOR, DIFFERENT DAY

The foam alarm goes off again, and LORENZO yells over to Aseem.

LORENZO

Hey, Aseem - it's foaming again.

ASEEM

Really?

LORENZO

Yeah, the alarm just went off. I don't know what's up with this.

NARRATOR

You don't know, either----he's following procedures to the letter. Adding more antifoam now could damage the cells and put the batch out of spec. Looks like the real problem was something else. Try that again.⁹⁸

RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR SCENE A-DP7. ANY CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.

⁹⁸ Ibid.

A-DP7-b

INT. PRODUCTION SUITE, SEED BIOREACTOR, DAY

Lorenzo and Aseem find a foam alarm going off on the seed bioreactor.

NARRATOR

You decide it's probably a glitch.

ASEEM

You guys did everything by the book. It shouldn't be foaming up.

LORENZO

Weird. What do you think it is?

ASEEM

Could be a bad sensor. We've had that happen in the past.

Aseem scans the control panel for a moment, considering this idea.

ASEEM (CONT'D)

Yeah. Just ignore it for now and keep an eye on the tank.

LORENZO

Sure.

NARRATOR

For a few hours, that seems to work. Until...

INT. PRODUCTION SUITE, DAY (DIFFERENT ANGLE)

Lorenzo calls Aseem back into the production suite.

LORENZO

(urgently)

Hey, Aseem... Aseem!

Aseem comes running in.

ASEEM

What? What is it?

LORENZO

I don't know. We're getting some really weird readings.

ASEEM

Like what?

LORENZO

High pressure, low flow rate. Just... weird. And the foam is getting pretty high.

ASEEM

(looks at control panel)
How long has it been like *this*?

LORENZO

I don't know. I just noticed it.

ASEEM

Did you get any more foam alarms?

LORENZO

Yeah, a second one popped up a few minutes ago - I figured you should know.

ASEEM

(worried)
Oh, man. We've gotta get the pressure down fast or...

Suddenly, the pair hear a loud "pop" followed by a splash of liquid.

⁹⁹NARRATOR

The emergency pressure release just blew... and now the batch is leaking all over the floor. Looks like the alarm wasn't a glitch after all. Foam had been building up in the bioreactor all day, until it finally blocked the vent filter - letting pressure inside rise to dangerous levels. Guess you should have troubleshoot that sooner.

100

⁹⁹ Mardirosian, Dan, and Chris Bellerive. WPI Followup Visit, March 4, 2015.

¹⁰⁰ Ducoat, Raymond. Tour of Merck, West Point PA - Ray Ducoat. Audio, Notes, September 9, 2014.

Video returns automatically to A-INTR1

A-DP7-c

INT. PRODUCTION SUITE, SEED BIOREACTOR, DAY

Lorenzo and Aseem hear a foam alarm going off on the seed bioreactor. Aseem decides to call in the facilities team to troubleshoot ASAP.

NARRATOR

You decide you'd better troubleshoot *now*. The problem could be serious.

ASEEM

(to LORENZO)

I don't like this.

LORENZO

Me neither. What do you think we should do?

ASEEM

(gleefully)

Well... We play detective. Narrow things down!

Aseem looks excited by this prospect.

LORENZO

You sound like that's a good thing.

ASEEM

It is! Well - okay, not *good* good. But this is the fun part!

LORENZO

Process alarms?

ASEEM

No, *problem solving*. Come on. Let's put our heads together! ¹⁰¹

LORENZO

You got it.

¹⁰¹ Seidman, Lisa, Vivian Ngan-Woodward, and Jeanette Mowery. Script Review meeting. Interview by David Levin, February 19, 2015.

NARRATOR

You alert your manager and the engineering department, and together, you all try to figure out the problem.

CUT TO: MONTAGE OF TROUBLESHOOTING WITH THE ENGINEERING AND PRODUCTION TEAM. Aseem AND TEAM ARE CROSSING ITEMS OFF A WHITEBOARD; PORING OVER DOCUMENTS, TAKING READINGS FROM CONTROL PANELS.

NARRATOR (CONT'D)

Within a few hours, the team finds a bad flow sensor in the process air line¹⁰². Extra air had been bubbling through the bioreactor, causing the foam-up. Good thing you found it early! If you'd waited, you could have ruined the batch. Be sure to investigate every issue until you know exactly why it happened. ¹⁰³Click "next" to continue.

[NEXT] (BUTTON TAKES USER TO SCENE A-DP8)

¹⁰² Mardirosian, Dan, and Chris Bellerive. WPI followup visit/interview. Audio, Notes, September 2, 2014.

¹⁰³ Ibid.

A-DP8

[SCENE DELETED]

A-DP9

NOTE: this scene's dialogue mirrors parts of CORINNE scene C-DP8.

INT. PRODUCTION SUITE, FLUID TRANSFER PANEL, DAY

Corinne has just finished a steam in place procedure of the harvest transfer line.

NARRATOR

A week later, you're almost ready to harvest the batch. The lines coming out of the bioreactor have been sterilized, and you're keeping them pressurized until they're ready to use. Your team just needs to make a few more tweaks...

Corinne approaches the transfer panel. There are already a few "hoses" in place with triclamps.

CORINNE

Let's see here... line three goes to the point 5 filter, so...

Corinne starts to remove the elbow from one of the ports by loosening the tri-clamp holding it in place. As soon as she does, she hears a loud hissing sound, which startles her.

CORINNE (CONT'D)

Aggh!...

She immediately tightens the knob again.

CORINNE

Hey, Aseem? Listen, um - I think I might have done something wrong here.

ASEEM

(Rushes over)
What do you mean?

CORINNE

I was about to hook up a filtration chain, and I'm pretty sure I let pressure out on one of the lines...

ASEEM

Which one?

CORINNE
 (pointing to a different
 port)
 Uhhh... I think it was that one.

ASEEM
 You sure? These lines go to totally
 different places. One of them's the
 main transfer.

Corinne checks her documentation, then the lines, then the
 documentation again, unsure.

CORINNE
 Yeah... It was number four.
 Definitely.

NARRATOR
 Hmm. If Corinne is right, there's
 no real problem. But she doesn't
 sound certain. If she *did* open the
 main transfer, it might not be
 sterile anymore. What do you do?

(A) Follow up with her and ask her
 to show you the valve she hit.

[Go to A-DP9-a]

(B) Re-steam the transfer line as a
 precaution.

[Go to A-DP9-c]¹⁰⁴

(C) Dismiss the error and move
 ahead as planned.

[Go to A-DP9-b1]¹⁰⁵

¹⁰⁴ Meighan, Kelly. Tour of Merck, West Point PA - Kelly Meighan.
 Interview by David Levin. Audio, Notes, September 9, 2014.

¹⁰⁵ Armstrong, Patrick. Phone interview - Patrick Armstrong, BMS.
 Interview by David Levin. Audio, Notes, June 27, 2014.

A-DP9-a

INT. PRODUCTION SUITE, FLUID TRANSFER PANEL, DAY

Aseem decides to follow up on CORINNE's claim that she opened the wrong valve.

ASEEM (CONT'D)

Okay - just one more time, walk me through exactly what happened.

CORINNE

Well, I was going to hook up the filtration assembly for steaming...

ASEEM

Yeah?

CORINNE

So I went over to the panel... And started taking the tri-clamp off here.

Corinne points to the elbow on the #4 line.

ASEEM

Then what?

CORINNE

I heard a hissing sound, so I tightened it again.

ASEEM

Wait, you had pressure on number *four*?

CORINNE

Yeah. Totally.¹⁰⁶

NARRATOR

You have a feeling that Corinne is remembering wrong. But then again, she's usually pretty good about these things... What if *you're* wrong? What else could you do?

¹⁰⁶ Meighan, Kelly. Tour of Merck, West Point PA - Kelly Meighan. Interview by David Levin. Audio, Notes, September 9, 2014.

[RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR SCENE A-DP9. ANY CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.]

A-DP9-b1

INT. PRODUCTION SUITE, FLUID TRANSFER PANEL, DAY

Aseem decides that based on CORINNE's description, the error wasn't serious.

NARRATOR

Corinne is usually pretty reliable.
So you decide to trust her on this.

Aseem thinks for a second, then shrugs.

ASEEM

Well, if it was number four,
there's no problem. We're gonna
steam that tomorrow anyway.

CORINNE

(relieved)

Okay, great. I was worried for a
sec.

ASEEM

Nah, I think we're good.

NARRATOR

A few days later, your team
harvests the batch normally, and
sends it on to downstream
production. Now that it's out of
your hands, you're starting to
relax a bit. But then...

A-DP9-b2

INT. ASEEM'S OFFICE. DAY

The phone rings.

ASEEM

Production, Aseem here.

INT. PRODUCTION SUITE, WORKBENCH (GEN. PURPOSE), DAY

KEVIN

Hey, Aseem. It's Kevin. Listen - I
think we've got a problem.

Conversation cuts back and forth between production suite and Aseem's office.

ASEEM

What do you mean?

KEVIN

I mean I'm getting a hit on your seed culture. Looks like endotoxins.

ASEEM

(suddenly concerned)

Are you sure? Maybe the sample got contaminated or something.

KEVIN

We thought of that. But the downstream samples are showing endotoxins, so we know *something* got in.

ASEEM

(worried)

Bacteria?

KEVIN

Yeah. We haven't ID'd the strain yet.

ASEEM

(sighs)

I don't understand. We didn't see anything wrong on our end.

Aseem picks up the documentation on his desk, glances at it, and tosses it down again.

KEVIN

Maybe it happened during harvest. Either way, we'll need to investigate. My boss just asked me to keep you posted.

ASEEM

(takes a deep breath)

Well... Thanks. I guess.

Aseem hangs up the phone and starts massaging his temples.

CUT TO: FOOTAGE OF CORINNE'S MISTAKE

NARRATOR

The investigation that follows eventually leads back to Corinne's mistake. Turns out she *did* open the harvest line, which let air and bacteria inside. Result: low-level contamination. The batch is ruined.
¹⁰⁷If you had followed up with Corinne, or just re-steamed the line, this all could have been avoided. Try again.

RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR SCENE A-DP9. ANY CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.

A-DP9-c

INT. PRODUCTION SUITE, FLUID TRANSFER PANEL, DAY

Aseem decides to re-steam the line after following up with Corinne.

NARRATOR

So...

ASEEM

(to CORINNE)

No offense, but you don't sound too certain.

CORINNE

Well, I mean, I guess there's a *chance* it was that one, but...
(Points to the port next to #4)

ASEEM

But what?

CORINNE

I just--I don't know. It happened really fast. I'm pretty sure, though.

ASEEM

Pretty sure? If there's even a slight chance it was the transfer line, we can't ignore that.

CORINNE

(resigned)

Yeah, I know.

ASEEM

Look, mistakes happen. I'm just glad you told me. We've got some time before harvest, so I think we can re-steam as a precaution. ¹⁰⁸

CORINNE

That's not going to screw up our schedule?

¹⁰⁸ Seidman, Lisa, Vivian Ngan-Woodward, and Jeanette Mowery. Script Review meeting. Interview by David Levin, February 19, 2015.

ASEEM

Nah. There's some wiggle room built in.¹⁰⁹ Just tell Lorenzo to drop what he's doing and help you. I'll check the work when you're done.

CORINNE

Okay. Thanks, Aseem.

INT. PRODUCTION SUITE, WORKBENCH (GEN. PURPOSE), DAY

Aseem pores over documentation and seems pleased.

NARRATOR

The next morning, you check Corinne and Lorenzo's documentation. Looks like they re-steamed the transfer line according to procedure, so you're ready to harvest.

It's better to be safe than sorry—especially on something as important as the harvest. Nice job.

[VIDEO CUTS TO A-OUT1]

¹⁰⁹ Menard, Jon. In-person followup. Interview by David Levin. Audio, Notes, December 8, 2014.

A-OUT1

PRODUCTION SUITE: MID-SHIFT; DAY

SHOT: MONTAGE OF DOWNSTREAM PROCESSING

NARRATOR

Finally, your team harvests the bioreactor. You've made it through another batch. The cells you created will be sent downstream, where other technicians will collect the valuable proteins they make. Those will be purified and packaged, and in a few weeks, a new shipment of Squabanin will be out the door... Right on schedule.

CUT TO: ASEEM, CORINNE, AND LORENZO WORKING TOGETHER IN THE PRODUCTION SUITE.

NARRATOR (CONT'D)

Congratulations. You've become a respected supervisor. Under your lead, your team followed current good manufacturing practices. You've got an eye for quality.

You can go back and explore other outcomes for this character, or choose another character to play. Click next to continue.

[NEXT] (BUTTON TAKES USER TO MENU-1)

K-INTR1

INT. QC LAB, DAY

MS Kevin Turner working under the Bio Safety Cabinet (BSC).

NARRATOR

This is you. Kevin Turner.

NARRATOR

A QC Analyst at Franklin. You're relatively new to the company - but you've made a lot of friends here, and you love working with them.

INT. QC LAB, DAY

Kevin, Kendra, and John are all hard at work in the QC lab.

NARRATOR (CONT'D)

You especially love working with microbes. That was your passion in college, but you had a hard time turning it into a paycheck. So you went back to community college for extra training. Now you have a steady job with lots of hands-on work. Plus, you're making a difference--the therapies your company makes save hundreds of lives every year.

[VIDEO CUTS DIRECTLY TO K-DP1]

K-DP1

INT. CORPORATE LOBBY

Kevin and Aseem are walking into Franklin and run into each other outside the front door.

NARRATOR

Another Monday.

ASEEM

Hey, Kev! Glad you could make it last night.

NARRATOR

Aseem Komani. He's a production supervisor at Franklin. But to you, he's a friend and mentor.

KEVIN

Of course! I love seeing your family.

KEVIN

(laughs)

But what about *you*? Everything okay? You seemed kind of preoccupied.

ASEEM

Oh. Yeah. Lot of things up in the air, You know.

KEVIN

Like what?

Aseem stops and pulls Kevin aside.

ASEEM (CONT'D)

Well... you know there's a huge batch of Squabanin coming up, right? Tight turnaround?

KEVIN

Yeah, so?

ASEEM

So... The CEO said if anything got screwed up, Stilton Pharmaceuticals could pull their contract.¹¹⁰

KEVIN

Are you kidding? They're our biggest client!

ASEEM

For now.

KEVIN

But they've worked with us for years. Why would they drop us?

ASEEM

New leadership. The CEO just retired, so they're shaking things up.

KEVIN

Jeez. But that would mean...

ASEEM

(finishes KEVIN'S thought)

Budget cuts. Layoffs.

KEVIN

Wow.

ASEEM

Yeah. So... You can understand I'm a little stressed out.

KEVIN

Wow. Yeah.

The pair reach a hallway that branches off from the main corridor.

ASEEM

Thanks. This is me.

Aseem starts to turn down the side hallway.

¹¹⁰ Crawford, Jim. Phone call: Jim Crawford. Interview by David Levin. Audio, Notes, July 30, 2014.

NARRATOR

That got your attention. The stakes are normally high at Franklin-- losing a batch could cost the company millions. Even harm patients. Click "next" to continue.

[NEXT] (BUTTON TAKES USER TO SCENE K-DP2)

K-DP2

INT. QC LAB, BIO SAFETY CABINET, DAY

KEVIN is working in a bio safety cabinet (BSC), preparing samples for testing.

NARRATOR

Your conversation with Aseem is still rattling around in your head. It's a little tough to concentrate, especially when you have *other* distractions.

JOHN MASON

Hey, Kev--what's the story with these samples? Are you gonna process them?

NARRATOR

Like your coworker, John Mason. He's been doing QC at Franklin for years. He's a bit of a talker.

KEVIN

Sure, say 20 minutes? Just gotta finish this...

KEVIN's cell phone goes off. He instinctively reaches over to turn off his phone, then goes back to his work in the BSC before he realizes what he's done. He looks at his phone, then at his gloves, and sinks somewhat.

KEVIN (CONT'D)

(quietly)

Tsk ugggh.

NARRATOR

You have a sinking feeling you might have contaminated the samples. Once you're gloved up, you need to keep your hands inside the BSC--and you defintietly can't touch your cell phone. It's crawling with bacteria. What should you do?¹¹¹

¹¹¹ Platco, Sheryl. Tour of Merck, West Point PA - Cheryl Platco (QC Supervisor). Interview by David Levin. Notes, September 9, 2014.

(A) Document the error, change your gloves, and keep working with the sample.¹¹²

[Go K-DP2-a]

(B) Throw the plates away, change your gloves, and start over with the remaining sample fluid.¹¹³

[Go K-DP2-b]

¹¹² Ibid.

¹¹³ Ibid.

K-DP2-a

INT. QC LAB, BIO SAFETY CABINET, DAY

KEVIN has absentmindedly grabbed his cell phone while working in the BSC. He puts fresh gloves on while the narrator voices over:

NARRATOR

Good call. The plates you already processed *could* be contaminated - but starting over isn't an option. You might not have enough sample fluid left to re-do the procedure... So you'll have to document the error, and wait to see if it's going to be an issue. After all, you won't know if the plates are *really* contaminated until you incubate them. Click "next" to continue.¹¹⁴

[NEXT] (BUTTON TAKES USER TO KEVIN SCENE K-DP3)

¹¹⁴ Ibid.

K-DP2-b

INT. QC LAB, BIO SAFETY CABINET, DAY

KEVIN has absentmindedly grabbed his cell phone while working in the BSC. He puts fresh gloves on while the narrator voices over:

NARRATOR

You decide the samples might be contaminated. When you touched your phone, you could have picked up bacteria on your gloves--and that may have contaminated the plates. So you toss the ones you've processed and start over.

KEVIN eyeballs the remaining sample fluid, and considers how much is left.

CUT TO A DIFFERENT ANGLE OF KEVIN IN THE BSC. TIME HAS PASSED.

NARRATOR (CONT'D)

Later that day, you're almost done with the new plates. And then...

KEVIN goes to pull more sample fluid into his pipette, and realizes that he's run out. He looks dejected - things are not going his way today.

NARRATOR (CONT'D)

...You've run out of fluid from the micro sample. Great. Now you can't finish, and you'll have to start a deviation with QA.¹¹⁵

You should have hung onto the original plates until you were sure if they were contaminated or not.

Now, you're in a bind.

¹¹⁶

Try that again.

**RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR KEVIN SCENE K-DP2.
ANY CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.**

¹¹⁵ Ibid.

¹¹⁶ Ibid.

K-DP3

INT. QC LAB, BIO SAFETY CABINET, DAY

KEVIN absentmindedly grabs his cell phone while working in the BSC. He decides he should hang onto the plates he's processed if there's a chance his error contaminated them. He wonders if he should tell someone.

NARRATOR

You decide to put a note about your error on the documentation before you incubate the plates. And then...¹¹⁷

INT. QC LAB, INCUBATOR

Kevin is putting plates into the incubator when John, who is working nearby, walks up and starts to chat.

JOHN

So, you got your review scheduled yet?

KEVIN looks up suddenly.

KEVIN

What?

JOHN

(Sarcastically)

Mine's next week. Can't wait...

NARRATOR

Oh, right. You forgot about your review. You're worried that if your supervisor learns about your mistake, it won't look good. Then again, maybe you *should* tell her now. Do you...

(A) Tell your supervisor about the cell phone.

¹¹⁸**[Go to K-DP3-a]**

¹¹⁷ Tetzlaff, Ron. Phone interview. Interview by David Levin. Audio, Notes, June 6, 2014.

¹¹⁸ Platco, Sheryl. Tour of Merck, West Point PA - Cheryl Platco (QC Supervisor). Interview by David Levin. Notes, September 9, 2014.

(B) Keep things quiet. Putting a note on the official worksheet should be enough.¹¹⁹

[Go to K-DP3-b]

¹¹⁹ Menard, Jon. In-person followup. Interview by David Levin. Audio, Notes, December 8, 2014.

K-DP3-a1

INT. QC LAB, INCUBATOR, DAY

KEVIN has absentmindedly grabbed his cell phone while working in the BSC. He's preparing to incubate his plated samples to find out if they're contaminated, and decides to tell his coworkers about the situation.

NARRATOR

You decide to ~~document and~~ tell your supervisor about the cell phone. If the plates *are* contaminated, she needs to know so it doesn't cause a problem later.

KEVIN

Hey, Kendra?

Kendra walks over from her station across the room as John looks on.

KENDRA

What's up?

KEVIN

These in-process samples? So... my cell phone started ringing when I was in the BSC, and I grabbed it to turn it off----I wasn't even thinking.

KENDRA

(calmly)

Uh, oh. Did you change your gloves?

KEVIN

(sheepishly)

Yeah. I realized it a second later. But I'd already handled the samples.

KENDRA

You put a note in the documentation?

KEVIN

Yep.

KENDRA

Okay, good. Just keep an eye on those plates when they're incubating. If they come up positive, let me know.

KEVIN

(a little concerned)
Will do. I don't know how I flaked like that... I just----

KENDRA

Happens to the best of us. But don't sweat it. If the plates come up clean, there's no problem.

KEVIN

Right... Thanks.

NARRATOR

Good call. If there's even a *chance* you contaminated a sample, you need to document the error and tell your coworkers right away.

INT. QC LAB, INCUBATOR, DAY

KEVIN is checking up on the incubated samples.

NARRATOR

Later that week, you check on the plates, and...

KEVIN

(to KENDRA and JOHN)
Hey, guys? So - I'm getting a hit on these. Something must have gotten in there after all.

KENDRA

(sighs)
Okay. Let's start an investigation, then. You got the procedures? ¹²⁰

KEVIN

Yep.

¹²⁰ Tetzlaff, Ron. Phone interview. Interview by David Levin. Audio, Notes, June 6, 2014.

KENDRA

It's probably from handling, but we need to verify that. And try to keep your cell phone *off* next time, ok?¹²¹

NARRATOR

Good thing you told Kendra - if you hadn't warned her about the contamination, it might have caused a false alarm.¹²² Once you investigate, though, it looks like the micro samples are clean after all... Close call. Click next to continue.

[B-Roll: Kevin documenting work].

[NEXT] (BUTTON TAKES USER TO K-DP4)

¹²¹ Platco, Sheryl. Phone interview re: QC micro. Interview by David Levin. Audio, Notes, September 9, 2014.

¹²² Ibid.

K-DP3-b

INT. QC LAB, INCUBATOR, DAY

KEVIN has absentmindedly grabbed his cell phone while working in the BSC. He decides he shouldn't tell his co-workers about the incident.

NARRATOR

~~Your annual review is coming up...~~
So you decide to keep your mistake to yourself, and quietly add a note to the documentation. But later that week...

JOHN opens up the incubator and notices a colony forming unit on one of KEVIN's plates.

JOHN

(concerned)

Hey, Kevin - these are your plates, right?

KEVIN

(hesitantly)

Uh... Yeah. Why?

JOHN

Looks like there's something growing in two of them. See?

JOHN points out a tiny colony on two plates.

JOHN (CONT'D)

We've got to let QA and the upstream guys know about this...

KEVIN takes a closer look. Something's there, all right. He looks worried. This was probably caused by his error, but he can't be sure... And now, he can't stay quiet about the incident any longer.

KEVIN

Oh. Well, uh, listen, I was meaning to tell you guys... (KEVIN trails off)

KENDRA

(enters conversation)

Tell us what?

KEVIN

Uh... My cell phone went off when I was working with these, and I kind of grabbed it for a second. I wasn't even thinking.

KENDRA gives him a shocked and quizzical look.

KENDRA

While you were handling samples? Why didn't you tell me?

KEVIN

I... sorry, I mean, you looked really busy on Monday! I just thought you'd see it in the documentation.

KENDRA

Kevin, if there's *any* chance of contamination, I need to know *immediately*! The last thing we want is to be caught off guard.¹²³

KENDRA pauses. She's still annoyed but collects herself.

KENDRA

Look. Either way, we're going to have to make sure this stuff came from your phone, not from the batch. I need you to start an investigation, okay?¹²⁴

KEVIN

(sheepishly)

Sure - I'm on it.

NARRATOR

If you think you contaminated a sample, you need to document the error immediately and let your supervisor know. *[Click here to continue]*¹²⁵

¹²³ Platco, Sheryl. Tour of Merck, West Point PA - Cheryl Platco (QC Supervisor). Interview by David Levin. Notes, September 9, 2014.

¹²⁴ Ibid.

¹²⁵ Tetzlaff, Ron. Phone interview. Interview by David Levin. Audio, Notes, June 6, 2014.

**RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR KEVIN SCENE K-DP3.
ANY CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.**

K-DP4

INT. QC LAB, BIO SAFETY CABINET, DAY

KEVIN is getting ready to transfer samples under the hood, when his coworker JOHN strikes up a distracting conversation.

KEVIN
(tallying up his
equipment in the BSC)
Ok. Cups... Filters... plates...
pipette...

KEVIN eyes the pipette, and realizes he's running out of fresh tips.

Hmm. Hey, John, do you have any
more pipette tips? This box is
almost out.¹²⁶

JOHN
(checks for tips on the
shelf in front of him)
Uh... I think that's the last one.

KEVIN
Ok - I should have enough for this.
It'll be close, though, and--ah,
man!

Kevin turns while he's talking, and as he does, knocks over a bottle in the BSC with his pipette.

JOHN
What?

KEVIN
Nothing. I just knocked something
over.

NARRATOR
You think your pipette tip might
have hit the jars. If it did,
you'll need a fresh one, but you're
running out of extras. What do you
do?

¹²⁶ Platco, Sheryl. Phone interview re: QC micro. Interview by David Levin. Audio, Notes, September 9, 2014.

(A) Ignore it and keep working.
[Go to K-DP4-a1]¹²⁷

(B) Ask John to grab more tips so
you can replace yours.¹²⁸
[Go to K-DP4-b]

¹²⁷ Kneller, Elizabeth. Phone interview: Elizabeth Kneller. Interview by David Levin. Audio, Notes, July 31, 2014.

¹²⁸ Platco, Sept. 9, 2014.

K-DP4-a

INT. QC LAB, BIO SAFETY CABINET, DAY

KEVIN wonders if he hit his pipette tip on a sealed jar in the BSC. He decides not to change the tip, figuring it's probably fine.

NARRATOR

There are only a few fresh pipette tips left in the box. You figure this one is probably okay. And besides - the BSC is one of the cleanest areas in the whole building. But then...

INT. QC LAB, INCUBATOR, DAY

KEVIN pulls the samples out, and stares at them. At least one is contaminated, and shows a colony-forming unit.

KEVIN

Oh, man. (Sighs). Hey, John? I think we've got something here.

JOHN comes over to the incubator, where KEVIN is holding a few plates.

JOHN

Uh, oh. Where are these plates from?

KEVIN

In-process micro samples. I don't think it's a problem with the batch, though...

JOHN

What do you mean?

KEVIN

Remember when I knocked over those jars? I think that might have contaminated the plates. ¹²⁹

JOHN

I thought you changed your pipette tip?

KEVIN

(sheepishly)

No, I was running out. I... I figured the BSC is already clean, so...

JOHN

Yeah, but the jar you hit might not have been. I mean, that might have contaminated a bunch of stuff.

KEVIN

(embarrassed)

I know, I know. I should have changed it.

JOHN

(sighs, resigned)

Well, we won't know for sure until we incubate all of them. Either way, you'd better let Kendra know.¹³⁰

Kevin nods. He's not looking forward to this. He picks up the phone, and dials Kendra's number. We see Kevin on the phone, looking worried.

NARRATOR

In a production environment, it's important to do things right the first time... But mistakes do happen. If you think you messed up, document it and alert your supervisor right away. Click "next" to continue.

[NEXT] (BUTTON TAKES USER TO K-DP5)

¹³⁰ Mardirosian, Dan, and Chris Bellerive. WPI Followup Visit. Interview by David Levin, March 4, 2015.

K-DP4-b

INT. QC LAB, BIO SAFETY CABINET DAY

KEVIN thinks he might have accidentally hit his pipette tip in the BSC.

NARRATOR

So you decide to change the tip, and ask John to scrounge up some extras for you. After all--the BSC is clean, but that jar you hit might *not* be.¹³¹

KEVIN

(to JOHN)

Hey, man - I'm almost out of pipette tips. Any chance you could call the materials department for me?

JOHN

Yeah, hang on a sec.

JOHN picks up the phone and dials the materials department.

JOHN (CONT'D)

Hey, Mark. Yeah, it's John. Listen, we need some pipette tips *now*. Can I stop in to grab a couple boxes? Uh huh. Great, thanks.

JOHN hangs up the phone.

JOHN

(To KEVIN)

Figures. They've been sitting on them all morning. I'll grab 'em.

KEVIN

Awesome - thanks, man.

NARRATOR

Good call. You should never chance contaminating a sample¹³². If your hands are full, you can always ask a coworker for help. Remember:

¹³¹ Crawford, Jim. Phone call: Jim Crawford. Interview by David Levin. Audio, Notes, July 30, 2014.

¹³² Ibid.

communication and teamwork are essential for making a quality product. Click "next" to continue.

[NEXT] (BUTTON TAKES USER TO K-DP5)

K-DP5

INT. QC LAB, WORKBENCH (DISSECTING SCOPE) DAY

KEVIN notices his coworker John jotting data on post-it notes then adding it into his documentation later.

NARRATOR

A few days later...

JOHN is working at a dissecting microscope, looking at environmental samples. He has a stack of plates by his side, and notes/documentation spread all over the workbench.

JOHN

(muttering softly to himself)

Okay, plate 14SQ-10-05A... clear. - 05B... clear. -05C...

As JOHN goes through the plates next to him, we see him write something down--though from this angle, it's unclear what he's writing on.

KEVIN

Man, you're really cruising through those.

JOHN

(without looking up)

Yeah, 15 years of practice pays off. -05D... Clear.

We see what JOHN is writing on now. It's a yellow post-it note.

KEVIN

Wait - is that a post-it?

JOHN

It's just for a rough tally.¹³³

KEVIN

But - what about the documentation?

JOHN

I'm just checking the numbers here so I don't screw them up on the

¹³³ Kneller, Elizabeth. Phone interview: Elizabeth Kneller. Interview by David Levin. Audio, Notes, July 31, 2014.

form. I'll add it all to the record later.

KEVIN
(skeptical)
Really? That's--

JOHN
(cuts KEVIN off)
Look, I kind of have to concentrate here, okay?

NARRATOR
John has a lot more experience than you do... But you still know that jotting things down on scrap paper is against procedure¹³⁴. He needs to use the official documentation. What do you want to do?

(A) SCENE DELETED

(A) Press the issue with John.
[Go to K-DP5-b]

(B) Quietly inform your supervisor.
[Go to K-DP5-c]

(C) Ignore it. He hasn't caused any problems so far.
[Go to K-DP5-d]

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¹³⁴ Ibid.

¹³⁵ Ibid.

K-DP5-a

[SCENE DELETED]

K-DP5-b

INT. QC LAB, WORKBENCH (DISSECTING SCOPE) DAY

KEVIN spots JOHN jotting notes down on a post-it instead of the official documentation.

NARRATOR

You decide to push the issue with John.

KEVIN

Come on, man - you know that won't fly.

JOHN

Kevin, I've been doing this for years. I can keep track of things just fine.¹³⁶

KEVIN

Yeah, I'm sure. But it's still against procedure...

JOHN

Look, it's just more convenient to get the count right first.

KEVIN

But that makes the *post-it* your primary document... right? It's the first record you made. Come on, man.¹³⁷

JOHN

(sighs, irritated but giving in)
Okay, I'll do it on here if makes you feel better. (Holds up the documentation). But I'm telling you, I haven't made a mistake yet.¹³⁸

NARRATOR

Hmm. John seems to be caving this time, but you have a feeling he'll

¹³⁶ **Ibid.**

¹³⁷ **Ibid.**

¹³⁸ **Ibid.**

try this again. You may have to go
over his head. So...

[VIDEO CUTS DIRECTLY TO KEVIN SCENE K-DP5-c]

K-DP5-c

INT. KENDRA'S OFFICE, DAY

NARRATOR
That afternoon...

KEVIN knocks on KENDRA's office door.

KEVIN
Hey. You got a minute?

KENDRA puts down the document she was reading and looks up.

KENDRA
Sure... Is something wrong?

KEVIN
(hesitantly)
Not exactly. I just kind of have a
question about... Uh... Well, about
John.

KENDRA smiles slightly and braces herself for this - what's
JOHN up to now? She knows he can be a little hard to take
sometimes.

KENDRA
Ah, yes. What about him?

KEVIN
Well - so, I know he's been here
forever, and he *really* knows his
stuff...

KENDRA
(smiles expectantly)
But...?

KEVIN
But I saw him writing documentation
on a post-it. I mean, is that
kosher?

KENDRA sighs. She's been down this road before.

KENRDA
You know it's not.

KEVIN

Yeah. Well... I mentioned that to him, but he didn't really want to hear it.

KENDRA

Okay, I'll talk to him. I mean, he's good, but sometimes he falls into bad habits when he's stressed out.

KEVIN nods and leaves the office. Camera stays on Kendra making a phone call, as audio ducks under narrator.

NARRATOR

Good call. If someone isn't following current good manufacturing practices, it could pose a big problem. Your supervisor should know, so they can help the employee improve. ¹³⁹

**[NEXT] (BUTTON TAKES USER TO KEVIN
SCENE K-DP6)**

¹³⁹ Torres, Francis. Tour of Merck, West Point PA - Francis Torres. Audio, Notes, September 9, 2014.

K-DP5-d

INT. QC LAB, WORKBENCH (DISSECTING SCOPE) DAY.

KEVIN is at work in the QC lab, and eyes JOHN from across the room, doing his thing with the post-its.

NARRATOR

You know John isn't doing things *exactly* by the book, but he's been doing this job longer than you. So you decide to ignore his mistakes. Then, a few weeks later...

INT. KENDRA'S OFFICE, DAY

Kevin knocks on the doorway.

KEVIN

Hey. You wanted to see me?

KENDRA

Yeah, have a seat.

Kevin sits.

KEVIN

What's up?

KENDRA

...So, we've been seeing some problems with John's documentation. Have you noticed anything unusual while you were working with him?

KEVIN

(nervously)

Oh. Uh... Off the record? I *did* see him writing some stuff on post-its once or twice.

KENDRA

Really. I was afraid of that.

KEVIN

You were?

KENDRA

When John is stressed out, he can... Well... Take some liberties.

KEVIN

Hmm.

KENDRA

We're setting up a counseling session to address that. And you're going too.

KEVIN

Me?

KENDRA

Yes! If you knew about this, why didn't you say anything?

KEVIN

Well, I... I guess I didn't want to get him in trouble.¹⁴⁰

KENDRA

Very noble. But if you see stuff like this happening, you need to tell me, okay? He could miss something big. Or just write it down wrong.¹⁴¹ Either way, it's against procedure.

KEVIN

(nodding slowly)

Gotcha.

Audio ducks out. Kevin and Kendra continue talking visually (ad lib dialogue) as Narrator voices over.

NARRATOR

Hmm. That didn't turn out so well. If you see someone going against procedure, your supervisor needs to know. Quality is everyone's responsibility. Try that again.

RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR KEVIN SCENE K-DP5. ANY CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.

¹⁴⁰ Menard, Jon. In-person followup. Interview by David Levin. Audio, Notes, December 8, 2014.

¹⁴¹ NC Community Colleges BioNetwork. "GMP Lab Notes." Interactive. *GMP Requirements*. Accessed September 15, 2014. <http://www.ncbionetwork.org/iet/gmp/>.

K-DP6

INT. QC LAB, WORKBENCH (DISSECTING SCOPE) DAY.

KEVIN is working at a dissecting scope when a temperature alarm goes off on a nearby incubator.

NARRATOR

You've really settled into a groove. As new samples come in, you process them and send the results out like clockwork. But suddenly...

SFX: INCUBATOR ALARM

NARRATOR

...A temperature alarm on the incubator. Those are *John's* samples in there. But *you're* busy dealing with your own work. Should you...

(A) Go over and check it out yourself.

[Go do K-DP6-c]

~~(B) [SCENE DELETED]~~

(B) Ignore it. Not your samples, not your problem.

[Go do K-DP6-a]

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K-DP6-a

INT. QC LAB, WORKBENCH (DISSECTING SCOPE) DAY.

KEVIN is working at a dissecting scope when a temperature alarm goes off on a nearby incubator. He decides to just ignore it - it's not *his* problem.

SFX: INCUBATOR ALARM

NARRATOR

The sound is irritating, but you figure John should be the one to deal with the alarm. Not your samples, not your problem.

JOHN eventually runs in to deal with the alarm.

JOHN

Hey! How long has this been going off??

KEVIN

Couple of minutes, I think.

JOHN

And you're just *standing* there?

KEVIN

Well, I had my hands full with *these*.

JOHN

Come on. It's not like you're in the BSC. You couldn't get up for two seconds?

KEVIN

(embarrassed)

No, I... I just got wrapped up. Sorry.

JOHN

(visibly irritated)

It's... fine. But if the alarm goes off again, can you just get up and check it? If anything happens to these samples, we'll lose a week's work.¹⁴³

¹⁴³ Ibid.

JOHN walks out of the lab in a huff.

NARRATOR

He's right. Quality is everyone's job. You should always check an alarm immediately, document it, and tell your supervisor if the procedure calls for it. It might have serious consequences. Try again.

¹⁴⁴**RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR KEVIN SCENE K- DP6. ANY CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.**

¹⁴⁴ Platco, Sheryl. Phone interview re: QC micro. Interview by David Levin. Audio, Notes, September 9, 2014.

K-DP6-b

[SCENE DELETED]

K-DP6-c

INT. KENDRA'S OFFICE, DAY

KENDRA picks up the ringing phone in her office (scene cuts back and forth between office and QC lab).

KENDRA
Kendra here.

KEVIN
Hey, it's Kevin.

KENDRA
What's up?

KEVIN
Listen - I'm getting a temp alarm on one of the incubators.

KENDRA
Which one?

KEVIN
Number two. It's running low.

KENDRA
Hmm. Did you reset it?

KEVIN
Yeah, to 37 degrees.

KENDRA
Nice catch. Can you document that and keep an eye on it?¹⁴⁵ I'll get facilities to take a look as soon as they can.¹⁴⁶

KEVIN
Sure, I'll be here.

KENDRA
Thanks. I'll let them know it's urgent.

¹⁴⁵ Ibid.

¹⁴⁶ Ibid.

NARRATOR

Good job. If you hadn't checked on the incubator, the colder temperature would have affected the samples inside. Quality is *everyone's* job--even if the samples aren't yours.¹⁴⁷ If you see a problem, follow procedures and document it immediately. Click *next* to continue.

[NEXT] (BUTTON TAKES USER TO K-DP7)

¹⁴⁷ Ibid.

K-DP7

INT. QC LAB, WORKBENCH (LAL TEST), DAY.

As upstream production moves along, it's time to inoculate the seed bioreactor from a set of spinner flasks. Before that happens, you have to test the flasks for endotoxins.

NARRATOR

Later that week, you're working with samples from the seed culture. The production team needs the culture to scale up the batch. But first, you have to test it for endotoxins--molecules made by certain kinds of bacteria. They're poisonous to humans... so If you find them, it could mean the culture was contaminated.

KEVIN is conducting an LAL Gel clot test. We see him checking small test tubes one by one.

KEVIN

SQ14-203 is... good. -204... Good. 205...

JOHN

Endotoxin tests?

KEVIN

Yeah - they're about to scale up to the seed reactor... Just got to make sure the cultures look good good first.

JOHN

I guess they're farther along that I thought.

KEVIN

Smooth sailing as usual. Seems like overkill to test at this point.¹⁴⁸

JOHN

Maybe. But if it's in the procedure...

¹⁴⁸ Menard, Jon. In-person followup. Interview by David Levin. Audio, Notes, December 8, 2014.

KEVIN

Yeah, I know. I'm just saying-- seems like there's other stuff we could be doing.

JOHN

Better safe than sorry. Endotoxins could kill somebody. Would *you* want to mess with them?¹⁴⁹

KEVIN

Fair point. -206... Good...

KEVIN (CONT'D)

207... huh.

KEVIN squints at one of the tubes as he holds it. At the bottom, a clear gel-like substance seems to stick to the glass.

NARRATOR

Suddenly, something catches your eye. A positive hit for endotoxins. They're in the sample after all! But... You've never found them before. Maybe *you* messed up the test. What do you do next?

(A) Find the procedure for a positive test result. That'll tell you what to do.¹⁵⁰

[Go to K-DP7-a2]

(B) Alert the production staff to the issue.

[Go to K-DP7-c]¹⁵¹

(C) Redo the test. You must have made a mistake somewhere.^{152 153}

[Go to K-DP7-b]

¹⁴⁹ Carta, Giorgio, and Alois Jungbauer. *Protein Chromatography: Process Development and Scale-Up*. Weinheim: Wiley-VCH, 2010.

¹⁵⁰ Tetzlaff, Ron. Phone interview. Interview by David Levin. Audio, Notes, June 6, 2014.

¹⁵¹ Platco, Sheryl. Tour of Merck, West Point PA - Cheryl Platco (QC Supervisor). Interview by David Levin. Notes, September 9, 2014.

¹⁵² Ngan-Woodward, Vivian, Jeanette Mowery, and Lisa Seidman. Kickoff meeting / brainstorm session for "Making the Call: Quality in Biomanufacturing." Interview by David Levin, Anthony Manupelli, and Julie Benyo. Audio, Notes, March 24, 2014.

¹⁵³ Menard, Dec. 8, 2016.

(D) [SCENE DELETED]

K-DP7-a1

[SCENE DELETED]

K-DP7-a2

INT. QC LAB, WORKBENCH (LAL TEST), DAY

NARRATOR

You decide to check the procedure.
Sure enough, it tells you to alert
Kendra... And a few minutes later,
she comes by to take a look.-

Kevin nods, considering this.

KENDRA (CONT'D)

Okay, walk me through exactly what
you did.

KEVIN

Well... I put 100 mils of reagent
into-

¹⁵⁴KENDRA

No, no. Start at the beginning.

KEVIN

Oh. I, uh... grabbed all the
materials?

KENDRA

From where?

KEVIN

Pipette tips from here... tubes
from here... reagent from over
here...

He grabs a bottle of reagent from the shelf. JOHN, who is
across the room, suddenly pipes in.

JOHN

(interjecting)

Wait - *that's* what you used?

KEVIN

Yeah, why?

JOHN

That expired last week.

¹⁵⁴ Lisa Seidman, Vivian Ngan-Woodward, and Jeanette Mowery.
Meeting at ATE Conference. Interview by David Levin. Audio, Notes, October 21, 2014.

KEVIN

(checks label)

What? But... Aw, man. I must have gone on automatic. I didn't even check.¹⁵⁵

KENDRA

Well, in that case, I think we're okay to document it and retest the samples. If we get another hit, let me know and we'll take it from there.¹⁵⁶

KEVIN

Sure - keep you posted.

KENDRA walks out of the room. JOHN looks over at Kevin, who is mortified. He smiles and shakes his head.

JOHN

Hey, at least we figured it out.

KEVIN

Ugh. Don't even start...

JOHN laughs.

NARRATOR

¹⁵⁵ Menard, Jon. In-person followup. Interview by David Levin. Audio, Notes, December 8, 2014.

¹⁵⁶ Seidman, Ngan-Woodward, Mowery; October 21, 2014.

K-DP7-a3

INT. QC LAB, WORKBENCH (LAL TEST) DAY

KEVIN retests the samples for endotoxin as directed by KENDRA. John is working in the background.

NARRATOR

Later that day, you retest like Kendra asked. But something looks off... Again.

Kevin holds up a test tube and squints at it, concerned. It looks like a positive test result.

NARRATOR (CONT'D)

You thought the reagent was the problem... but maybe this is real contamination after all. So you ask Kendra to take another look.

KENDRA enters. JOHN and KEVIN are standing over the workbench, examining a test tube.

KENDRA

Another hit??

KEVIN

See for yourself.

KENDRA looks at the test tube, then flips through the documentation.

KENDRA

Hmm. This looks legit. ...I think we've got the real thing here.¹⁵⁷

KEVIN

So... now what?

KENDRA

We let production know. Call Aseem and fill him in... he's going to have to trash that flask.

KEVIN

Sure.

¹⁵⁷ Platco, Sheryl. Tour of Merck, West Point PA - Cheryl Platco (QC Supervisor). Interview by David Levin. Notes, September 9, 2014.

KENDRA

Nice work, you two. I think we caught this early.

NARRATOR

Good work. When a test result flags a problem like this, you need to follow the right procedures and talk to your supervisor. ¹⁵⁸If you didn't, that flask could have contaminated the rest of the batch. Click "next" to continue.

[NEXT] (BUTTON TAKES USER TO K-OUT1)

K-DP7-b

INT. QC LAB, WORKBENCH (LAL TEST), DAY

KEVIN decides he must have caused the contamination.

NARRATOR

You figure you *must* have done something wrong. All the *other* samples were fine. So you mark them as clear on the lab form, and move on.¹⁵⁹ [Long beat] Then, a few weeks later...

INT. QC LAB, WORKBENCH (GEN PURPOSE), DAY

JOHN is doing some endotoxin tests. He seems concerned by what he sees.

JOHN

Hey, Kendra I think you should take a look at this.

KENDRA

What's up?

JOHN

I'm getting a positive hit on this endotoxin test...

KENDRA

From the seed reactor?

Kendra looks at endotoxin test vial.

KENDRA

Hmm. Might be low-level contamination. Nothing showed up before now...¹⁶⁰

KENDRA reads over the lab worksheet. She looks over at Kevin, who now is stirring in his seat.

¹⁵⁹ Menard, Jon. Script Review comments. Interview by David Levin. Audio, Notes, June 15, 2015.

¹⁶⁰ Platco, Sheryl. Phone interview re: QC micro. Interview by David Levin. Audio, Notes, September 9, 2014.

KEVIN
Uh... Yeah. Sort of.

KENDRA
What do you mean, "Sort of"?

KEVIN
Well... I Messed up one of the samples when I was testing it, but it turned out to be fine.

KENDRA
You can't just make that call! We have procedures!¹⁶¹

KEVIN
But... I'm *sure* I messed up somewhere. In school, we retested all the time if we made a mistake, so...

KENDRA
This isn't school, Kevin. You can't just retest until you get the result you want. There are serious regulations against that!

¹⁶²KEVIN
But, I... I mean...

KENDRA fumes for a moment, glaring at Kevin.

KENDRA (CONT'D)
Come up to my office. We need to talk about this.

KENDRA starts to leave the room. KEVIN looks at JOHN pleadingly, but he avoids eye contact.

KENDRA (CONT'D)
NOW, Kevin.

KEVIN follows Kendra out of the room, dejected.

NARRATOR
She's right. In order to retest, there has to be a documented lab error that would invalidate the original test.

¹⁶¹ Tetzlaff, Ron. Phone interview. Interview by David Levin. Audio, Notes, June 6, 2014.

¹⁶² Kneller, Elizabeth. Phone interview: Elizabeth Kneller. Interview by David Levin. Audio, Notes, July 31, 2014.

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In the investigation that follows, it's clear that a flask you tested really WAS contaminated... And your poor judgment made you miss it. Now the batch is ruined... and you're eventually fired for falsifying records.¹⁶⁴ If anything seems out of the ordinary, you need to document it and follow your lab's procedures to the letter.¹⁶⁵

Game Over.

Video returns automatically to A-INTR1

¹⁶³ Lisa Seidman, Vivian Ngan-Woodward, and Jeanette Mowery. Meeting at ATE Conference. Interview by David Levin. Audio, Notes, October 21, 2014.

¹⁶⁴ Menard, Jon. In-person followup. Interview by David Levin. Audio, Notes, December 8, 2014.

¹⁶⁵ Tetzlaff, Ron. Phone interview. Interview by David Levin. Audio, Notes, June 6, 2014.

K-DP7-c

INT. QC LAB, WORKBENCH (LAL TEST), DAY

After testing samples from Franklin's seed culture for endotoxin, KEVIN notices that one of the samples is contaminated.

NARRATOR

You decide you need to let production know, so you call Aseem and give him the news.

Kevin dials Aseem's number on the phone and talks briefly) (dialogue ad-lib; shot is video only)

NARRATOR (CONT'D)

But later that day...

Kendra enters QC Lab, looking concerned.

KENDRA

Hey, Kevin? ...I just got a call from Aseem in production. He says you told him you found a hit on his micro samples?

KEVIN

Yeah... endotoxins. One of the shake flasks was positive.

KENDRA

(frustrated)

You need to let *me* handle news like that! This could be a false alarm. ¹⁶⁶

KEVIN

Well, I figured production needed to know anyway, so...

KENDRA

But we have procedures for this exact scenario. I need you to *follow* them! First, we figure out if the contamination is real, *then* we tell

¹⁶⁶ Platco, Sheryl. Tour of Merck, West Point PA - Cheryl Platco (QC Supervisor). Interview by David Levin. Notes, September 9, 2014.

production. We don't want to cause
a panic without reason.

KEVIN
Well, yeah, but...

KENDRA
(cuts him off)
No buts. Stick to procedures, okay?

Kendra leaves in a huff.

NARRATOR
She's right. The company has
procedures in place for a reason--
you can't just act on your own. Try
that again.
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**RETURN TO THE "MULTIPLE CHOICE" SCREEN FOR KEVIN SCENE K-DP7.
ANY CHOICES PREVIOUSLY SELECTED ARE GREYED OUT.**

K-DP7-d

[SCENE DELETED]

K-OUT1

QC LAB, WORKBENCH (GEN. PURPOSE), DAY

SHOT: MONTAGE OF QC LAB WORK?

NARRATOR

Congratulations. You caught a major source of contamination before it got into the bioreactor. If it did, it would have ruined the batch, and there could have been dire consequences for the company. Thanks to you, everything is going smoothly.

You're feeling pretty good about your job, and making a name for yourself as a respected analyst with an eye for quality. You'll do well in this field.

[Long beat]

You can go back and explore other outcomes for this character, or choose another character to play. Click next to continue.

[NEXT] (BUTTON TAKES USER TO MENU-1)