Inspection Readiness

A Pathway for Patient Health Webinar

August 30, 2023

www.Pathway4PH.org

Pathway's Mission:

- To help the industry achieve a quality breakthrough
- So companies can scale quality across their entire organization
- Because the next catastrophic defect could happen today
- And we believe every patient's life matters

So the time to take action is NOW!

The Chief Quality Officer Team

	**Beverly Bates** P&G		**Tracy Founds** Glaukos		**Tony Mire-Sluis** AstraZeneca
	**Brian Molloy** Alexion/AZ		**Karen Netherton** Seqirus/CSL		**Johna Norton** Eli Lilly
	**Maire O'Reilly** Elanco		**Anil Sawant** Merck		**Brian Schultz** Fisher & Paykel Healthcare
	**Peter Shearstone** Thermo Fisher		**Andrew Wirths** AstraZeneca		**Gary Workman** Illumina

Pathway CQO Forum

A Team
in Action!

Quality Science Education Program

University Relations
to Reach Your
Target Schools

Preparing the
Next Generation

Mobilizing Your Success Every Step of the Way

Education Access to
Upskill Every Employee

Hiring Platform
Access to QSE
Students

New "Badges"

Data Integrity, CAPA Mastery, Software Design Controls, **Inspection Readiness**

Inspection Readiness Badge

Available Soon!

- **Class 1:** Regulator's Authority and What to Expect
- **Class 2:** Know Your Current State
- **Class 3:** What are They Looking For?
- **Class 4:** Setting up and Running the Back Room
- **Class 5:** Front Room Plan
- **Class 6:** Responding to the Investigator
- **Class 7:** Outcomes and Responses – Part 1
- **Class 8:** Outcomes and Responses – Part 2

Dave Elder
Greenleaf Health
Former FDA

Tracey Harris
Baxter
Former FDA

Steve Niedelman
King & Spalding
Former FDA

Yenny Ocampo
Baxter

Blaine Spangler
Baxter

Expert Presenters

Steven Niedelman
Lead Quality System/Compliance Consultant, King & Spalding
Former
FDA Deputy Associate Commissioner

Marla Phillips, Ph.D.
CEO/President, Pathway for Patient Health
Former
Merck Site Quality Head

Today's Agenda

1. Role Play
2. Breakout Sessions
3. Key Inspection Readiness Actions

Be ready to engage with your peers!

Role Play

Start date: 15/09/2018

Title: Synthesis of Diethylbenzylphospho

Reaction scheme: $P(OEt)_3$

C_7H_7Br
MW: 171.03

References: 1) SOP NO: 135 (Purification)
2) June, M. et al synthesis of
1993, 34, P. 250-295

Materials:

Substance	Qty	MW ($g mol^{-1}$)
Diethylbenzylphosphonate	14ml	228.22
Benzylbromide	42ml	171.03

Calculations:

Density of diethylbenzylphosphonate = mass

Apparatus: 50 mL RB flask, magnetic st

Hazard note: • By product high sensitive

Role Play #1

Version 1

- Steve (Investigator)
- Marla (Manufacturing Supervisor)

Background: Steve is conducting a General GMP Inspection at a medical device manufacturing plant. Steve is out in the manufacturing area looking through batch records.

- Steve notices that one of the batch record pages is missing.
- Marla indicates she is aware of the issue, and explains that something was spilled on the batch record.
- Your thoughts on how Marla handled the situation?
- Add to the Chatbox: What else do you think Marla needed to do?

Role Play #1 - Debrief

Analyze Marla's actions:

- Good that she knew about the situation, instead of being surprised.
- Had a reasonable explanation, since accidents do happen.
- But…she didn't conduct an investigation, document the issue, determine if this has happened in other areas, improve the procedures to indicate how to handle this.

So how does Steve respond?

- Concern that this is possibly a wide-spread practice of throwing away GMP documents! Yikes! He will want to see MANY other documents.
- Ask to speak to other manufacturing operators, supervisors, lab techs, lab supervisors to see what they say about how to handle these situations.

Key Takeaway?

- Recognize the importance of documenting situations that occur, determine wider impact (always!), and put meaningful corrective actions in place.

Role Play #2

Version 2

- Steve (Investigator)
- Marla (Manufacturing Supervisor)

Background: Steve is conducting a General GMP Inspection at a medical device manufacturing plant. Steve is out in the manufacturing area looking through batch records.

- Steve notices that one of the batch record pages is missing.
- Marla indicates that she wasn't aware of the issue. She checks into it, and finds that a mistake was made, so the page was discarded.
- Your thoughts on what Steve should do next?
- Join a breakout room to discuss how you think Steve might react.

Breakout

How would you expect Steve to react to Marla's response?

- What might he say?
- What might he do?

Group Notetaker:
First Name closest to "A"

Role Play #2 - Debrief

So how does Steve respond?

- Maybe raised eyebrows in disbelief, but he will try to conceal his concern so he can gain more information from Marla.
- Ask about how often and long this has been happening, but do so in a way that makes Marla feel comfortable that her actions are "ok".
- Say something like: yeah, I've seen other companies do that, and sometimes when their data doesn't meet specifications. (see if Marla agrees, or offers similar scenarios, etc.).
- Start diving deeper into batch records, laboratory notebooks, etc.

Key Takeaway?

- Understand why the regulations are in place. What is the harm in throwing away pages from a batch record? Really?
- Use of bound books and sequentially numbered pages (lab notebooks being signed out, etc.) for accountability is absolutely expected.

Role Play #3

- Steve (Investigator)
- Marla (Laboratory Manager)

Background: Steve is reviewing the analytical laboratory notebooks in Marla's lab, during a Pre-Approval Inspection. The data being reviewed is related to the validation studies for the PAI Product.

- Steve notices that one of the laboratory notebook pages does not have the balance number documented.
- Marla responds that she knows the analyst always uses balance 37, and is eager to show Steve the other notebook pages.
- Your thoughts on how Marla handled the situation?
- Add to the Chatbox: What do you think Marla did wrong?

Role Play #3 - Debrief

Marla's response was against what we are taught!

But her actions were right!

- Keep answers simple.
- Don't pull out information they didn't ask for.
- Don't flip through other pages of documents that they didn't review, etc.

So how does Steve respond?

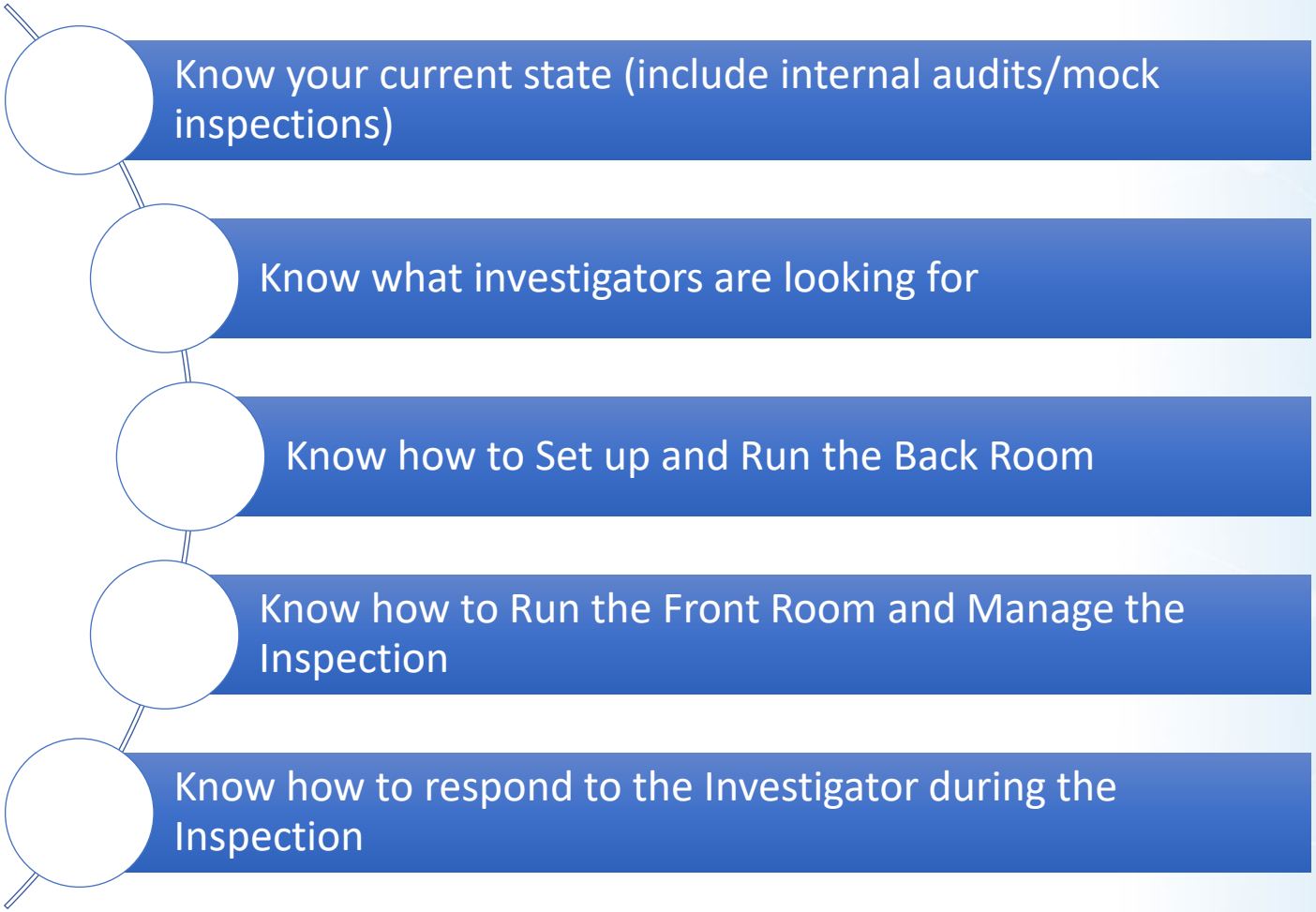
- Marla knew for sure what she was talking about. She was the Supervisor who had reviewed the notebook.
- Marla was confident and allayed bigger concerns the FDA could have had about laboratory documentation practices.
- Marla suggested excellent next steps she would take, which demonstrated that she understood the bigger picture.

Key Takeaway?

- Being Inspection Ready every day means – know what is going on in your operation…every day!

Key Steps for Inspection Readiness

Our Inspection Readiness Badge goes into all the details!



Always be Inspection Ready!

Quiz Time!

True or False – Are regulators allowed to do the following during an inspection (answer in chat box)

	True?	False?
Take pictures of internal operations?	✓	
Access financial data?		✓
Access a firm's computers?		✓
See Internal Audit records	✓	

Unique Data Requests

Request Type	Expectation
Photographs	Inspectors are allowed take photographs of the facility as objective evidence. • The firm should always take the same photo for their records. • If the equipment used to take the photo is not allowed into a controlled room, then the firm should work with the regulator to determine how to obtain the picture.
Financial/Research Data	Regulators are restricted from accessing financial, sales, pricing, personnel, or research data.
Computer Viewing	Inspectors may request to see data/objective evidence/electronic systems in real-time on a firm's computer. • An employee from the firm must be the individual that is navigating on the computer while the inspector is viewing it. • An inspector should never be given log-on credentials/password for a personal computer from the firm. • An inspector should not be given unsupervised access to a firm's computer and/or electronic database
Internal Audit Results	The regulators may request to see that internal audits have been performed. While regulators do have the authority to review internal audit results, they have a policy that indicates they will not review them as they do not want to discourage firms from thoroughly self auditing themselves. Any CAPA's resulting as an outcome may be reviewed.

If in doubt, you can ask for a moment to confer with your management (and legal) team

Today's Agenda

- Role Play
- Breakout Sessions
- Key Inspection Readiness Actions

But, before we go!

Inspection Readiness Badge

Available Soon!

- **Class 1:** Regulator's Authority and What to Expect
- **Class 2:** Know Your Current State
- **Class 3:** What are They Looking For?
- **Class 4:** Setting up and Running the Back Room
- **Class 5:** Front Room Plan
- **Class 6:** Responding to the Investigator
- **Class 7:** Outcomes and Responses – Part 1
- **Class 8:** Outcomes and Responses – Part 2

Dave Elder
Greenleaf Health
Former FDA

Tracey Harris
Baxter
Former FDA

Steve Niedelman
King & Spalding
Former FDA

Yenny Ocampo
Baxter

Blaine Spangler
Baxter

Pathway CQO Forum

A Team
in Action!

First Ever!

Quality Operations Forum

PURPOSE

$150/year

To support site and corporate quality professionals in proactively implementing successful practices gained through a vibrant network of global peers collaboratively addressing contemporary and complex challenges.

60+
Live Meetings
Each Year

Live External Intel

- Quarterly live meetings
- Trends, insights and intel
- Regulator activity and expectations
- Global resources to improve your operations

Live World Cafe

- Weekly live meetings with forum members
- Challenging topics for site operations
- Realtime collaboration to gain insights
- Successful practices shared

Live Network

- 24/7 access to your global peers
- Engage in online dialog
- Invite your peers to join initiatives that matter to you

Join Today!

https://www.pathway4ph.org/site-quality-officer-forum

Pathway for Patient Health

Register Today!

Pathway for Patient Health

QMS Agility Model: In-depth “How to” Workshop

October 12, 2023
10:00am – 2:00pm Eastern

QMS Agility Initiative

Thank You!

Marla A. Phillips
CEO and President
Pathway for Patient Health
Marla.Phillips@Pathway4PH.org

www.Pathway4PH.org