Moving your organization to more effective post-event learning - a biopharma perspective

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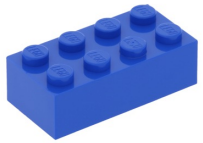
YOUR ORGANIZATION'S CURRENT EFFECTIVENESS

What gets in the way of learning what needs to be learned as part of post-event learning?

What is currently helping your post-event learning to be effective?

WE FAIL SOMETIMES



Deviation Initiation

		Deviation Number	23-0147
General Information			
Event Observer	Emmet Jones	Department	MFG
Dated of Occurrence	24Apr23	Date of Discovery	05May23
Deviation Description			

On 05May23 during data review, a Lego Sciences Engineer identified that the Lego pipeline assembled on 24Apr23 did not begin and end with white bricks and the middle brick was not blue.

Per MFG-SOP-0046, Lego Pipeline Construction, Rev,09 for Batch No. LEGO-MFG-1251-01, white bricks are required to begin and end the pipeline, and a blue block is positioned in the middle of the pipeline.

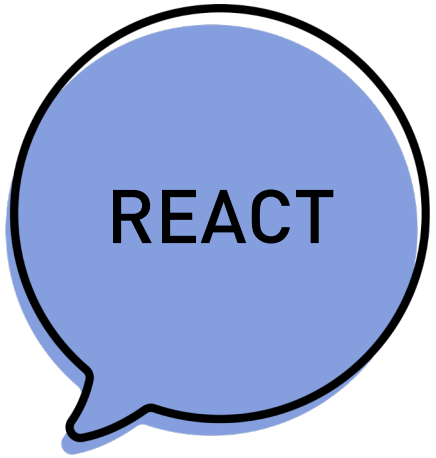
THE ALL TOO COMMON KICK-OFF

SITE SENIOR LEADER

“I’ve just learned that batches 19 and 21 may need to be discarded. Manufacturing Technicians, the Performer and Witness, (fill in the blank), and then the mistake was missed by both the Manufacturing Supervisor and QA page reviews.

We need corrective actions by Friday.”

WHAT DO YOU OFTEN HEAR AS AN INITIAL REACTION?



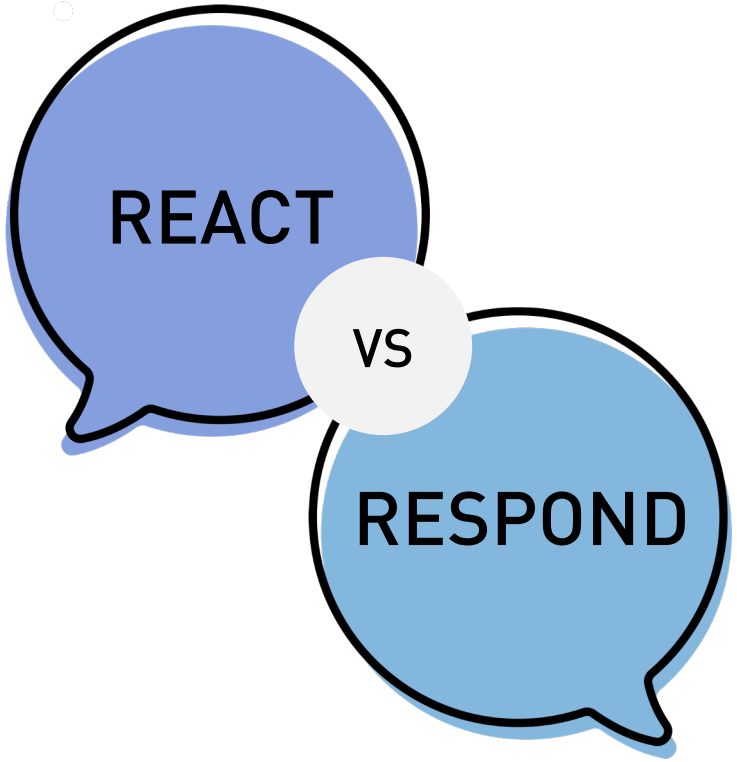
Who was involved?

Didn’t this happen before? How could they not be more careful?

Procedure requirements are clear. This is another example of people just being complacent.

What can you do to help your leadership respond in a manner that better ensures effective learning?

HOW WE RESPOND MATTERS: A BETTER PLACE TO START



How are the people and the facility?

How can I help support activities for return to operations?

How can I help ensure we learn what we need to learn?

A REVIEW OF THE INSTRUCTIONS

Batch Record Part 1

	Step Description	Performer	Witness
1.0	Obtain baseplate and orient bottom in parallel to work surface. **NOTE:** Skewness of the baseplate against the work surface cannot exceed 0.5 mm	/	/
1.1	Document the room number: _____	/	/
1.2	Log item number for pipeline bricks: _____	/	/
1.3	Build lego brick pipeline per MFG-SOP-0046, Lego Pipeline Construction	/	/

A REVIEW OF THE INSTRUCTIONS

MFG-SOP-0046, Lego Pipeline Construction
Version 9.0
Effective 23May23

SCOPE
This SOP describes the construction of lego pipelines for any customer in small scale, large scale, and flexible volume facilities.

PROCEDURE

1.1 Obtain bag of legos

1.2 Empty bag of legos on work surface

NOTE: If building in the large scale facility, use a bin to hold the legos while constructing

1.3 Arrange the legos by color and size

1.4 Build from left to right, in a straight line.

1.5 Do not use red bricks smaller than size 6. Use all black bricks provided, if any. If green bricks are used and one is early in the pipeline, a green block cannot be near the end of the pipeline. Begin the pipeline with a white brick. The middle of the pipeline should have a blue brick. The end of the pipeline cannot be yellow and needs to have a white brick.

HOW WORK IS DONE

- What percentage of your deviation investigations include going to watch how the work is performed?
- How do you decide when going to watch work is necessary?

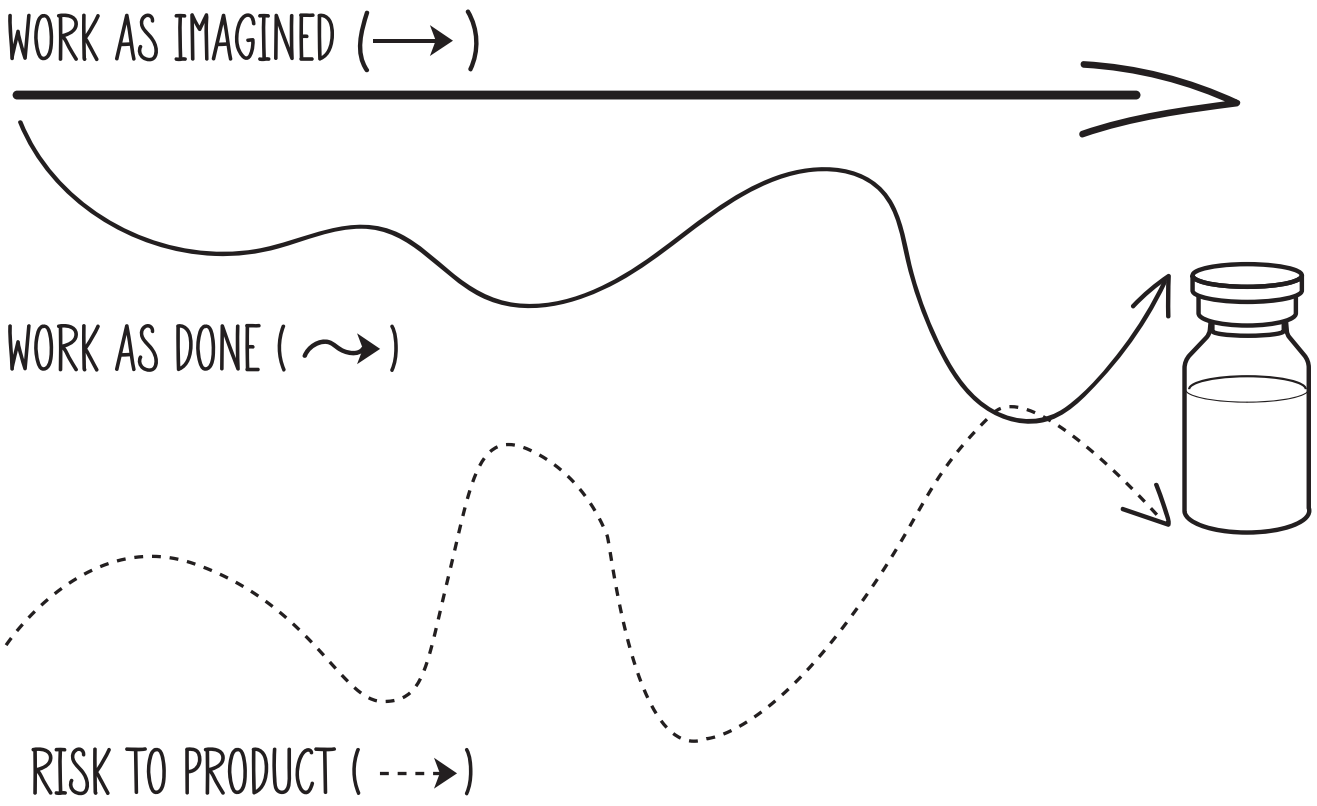
THE QUESTION

Is the *"direct cause"* known?

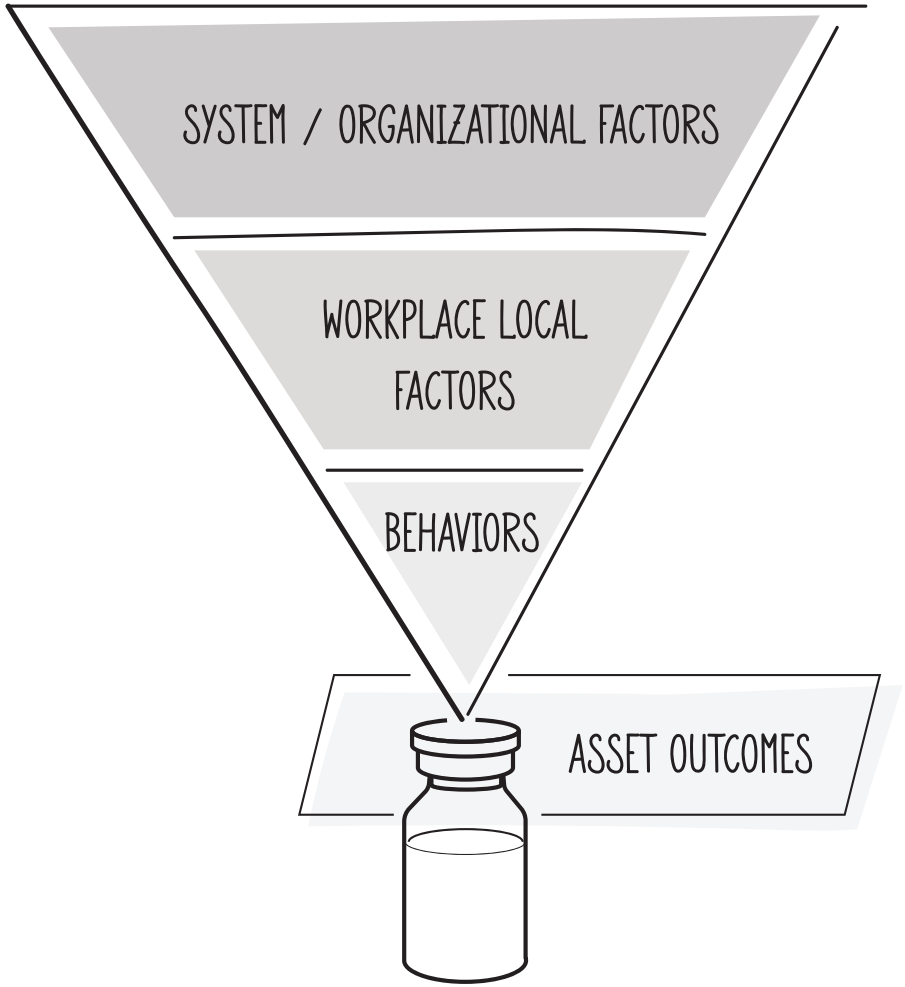
NO… perhaps begin with Kepner-Tregoe Problem Analysis

YES… go watch work

WAI & WAD CONCEPT IS KEY



CHANGE CONVERSATIONS TO INCLUDE COMPLEXITY

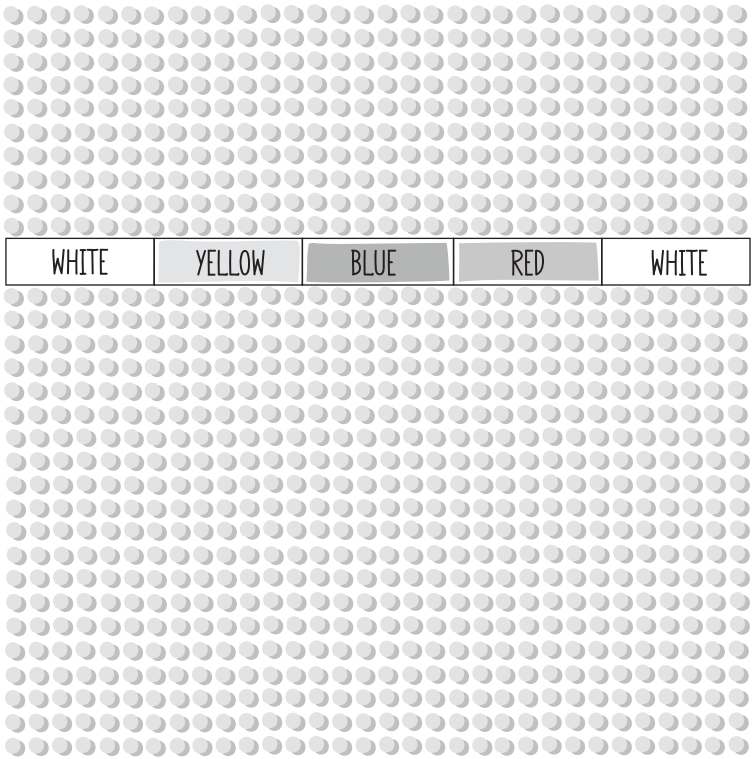


HUMBLE INQUIRY

Edgar Schein

“Humble Inquiry is the fine art of drawing someone out, of asking questions to which you do not already know the answer, of building a relationship based on curiosity and interest in the other person.”

UNDERSTAND THE INFLUENCE OF THE SYSTEM



What does humble inquiry sound like?

What might not sound like humble inquiry?

WHAT WE MIGHT LEARN FROM TALKING WITH THOSE WHO DO THE WORK

We don’t use white legos because they are known to result in air leaking into the pipeline due to a poor sealing surface.

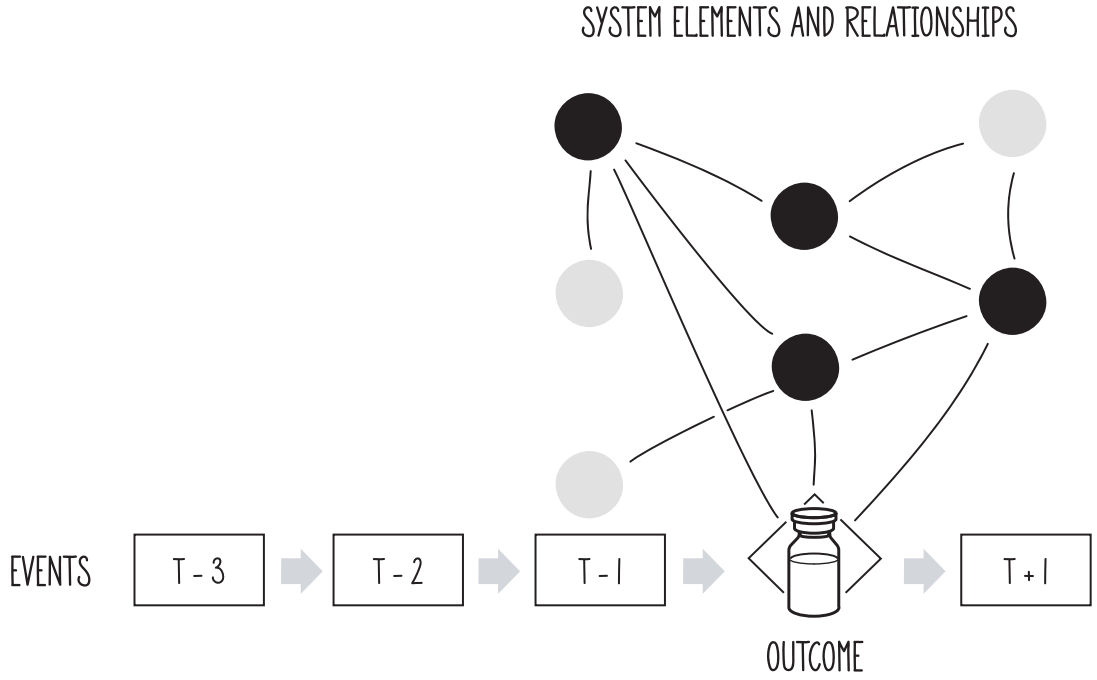
Sometimes the bags of legos do not include blue bricks. We use what we are given for each pipeline.

THE PROBLEM WITH FIVE-WHYS

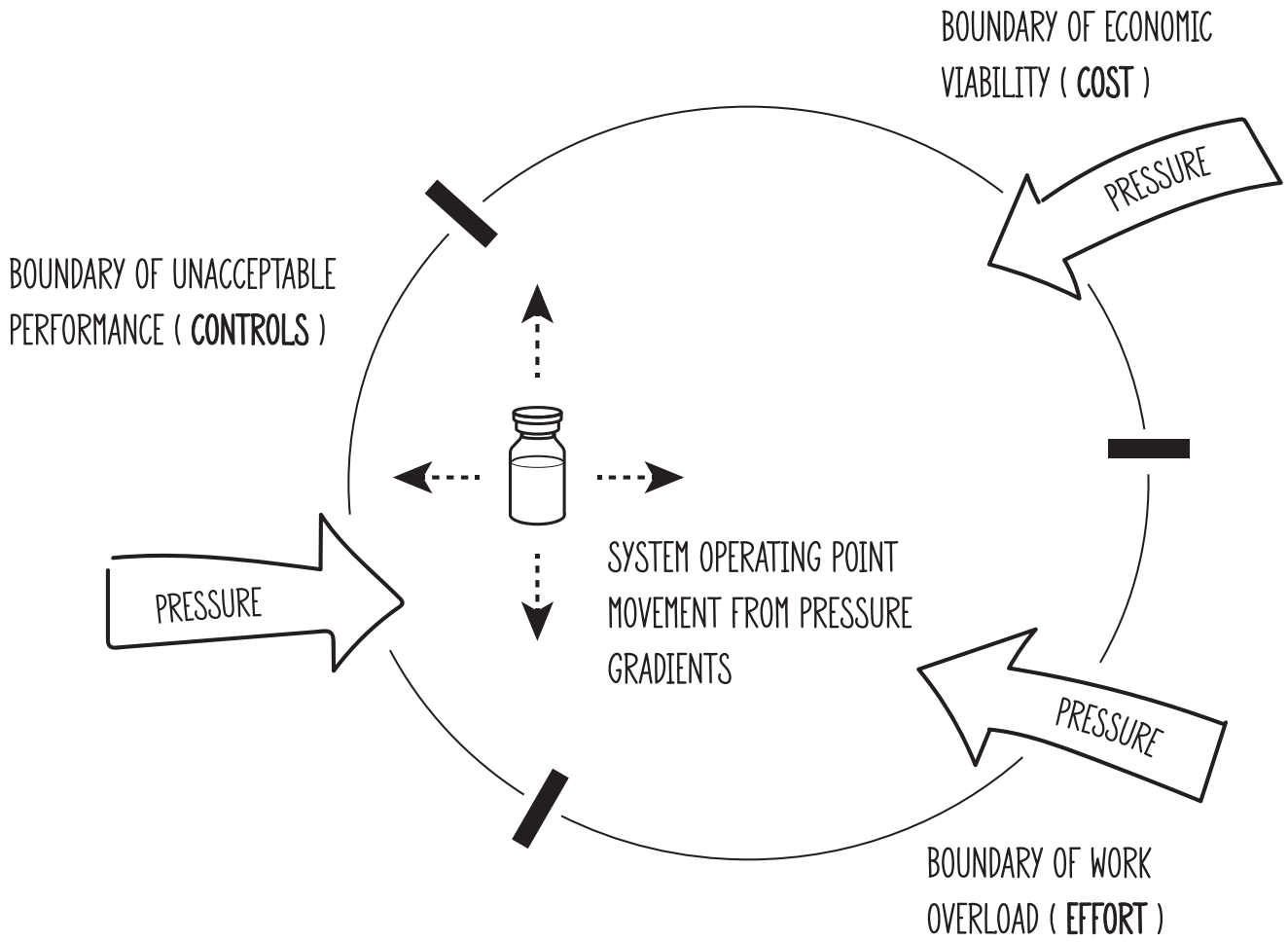
There are likely multiple conditions, each necessary but only jointly sufficient.

Our work systems are complex, not linear.

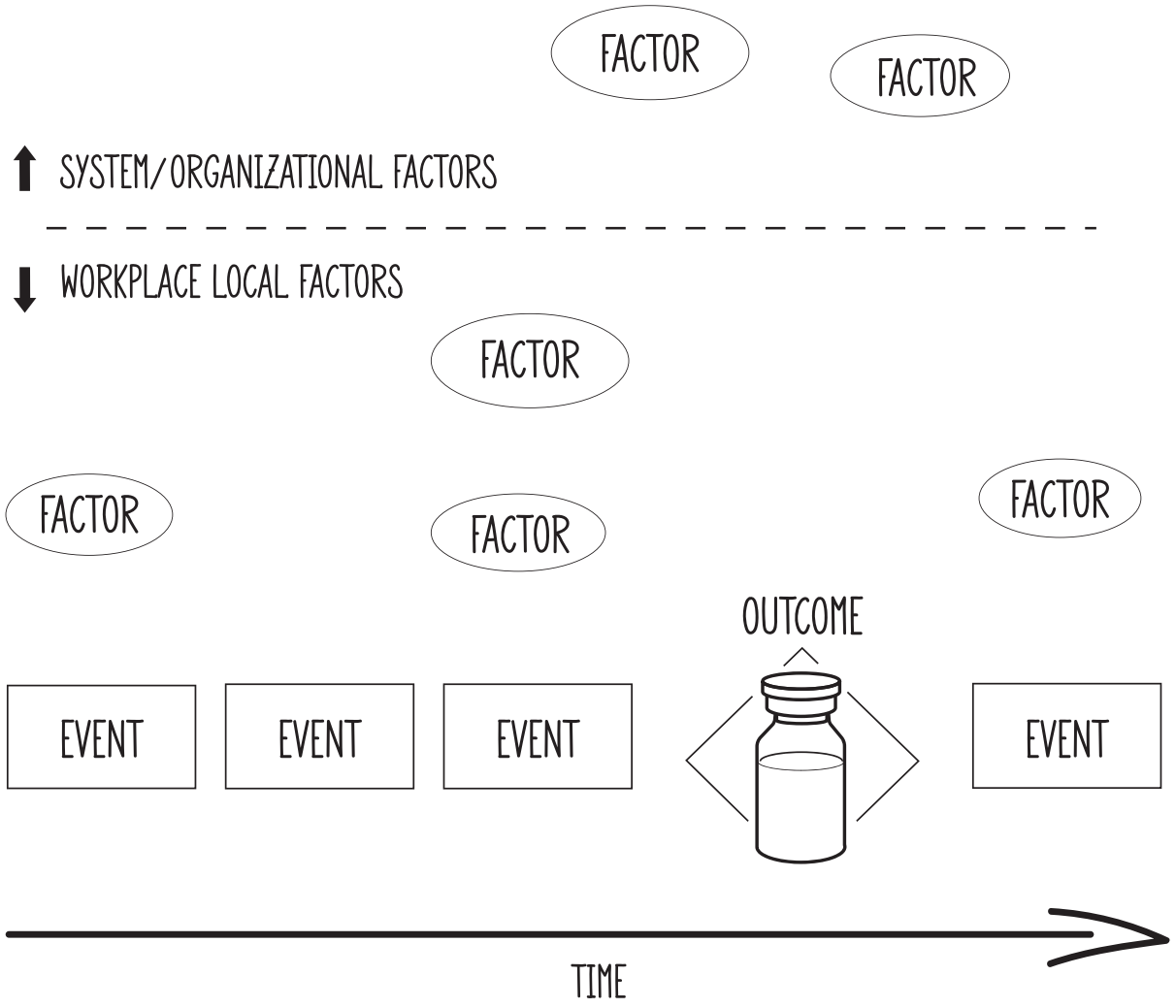
We may need to learn about the relationship between elements, not a broken element.



SHIFT TALK TO SYSTEM & CONTROLS



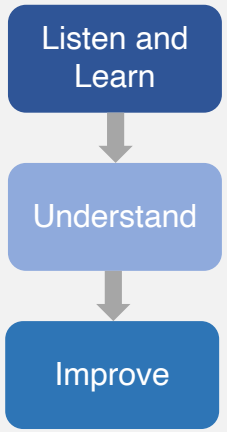
LET'S PRACTICE:
EVENT & CAUSAL FACTOR CHARTING



ANOTHER APPROACH: LEARNING TEAMS

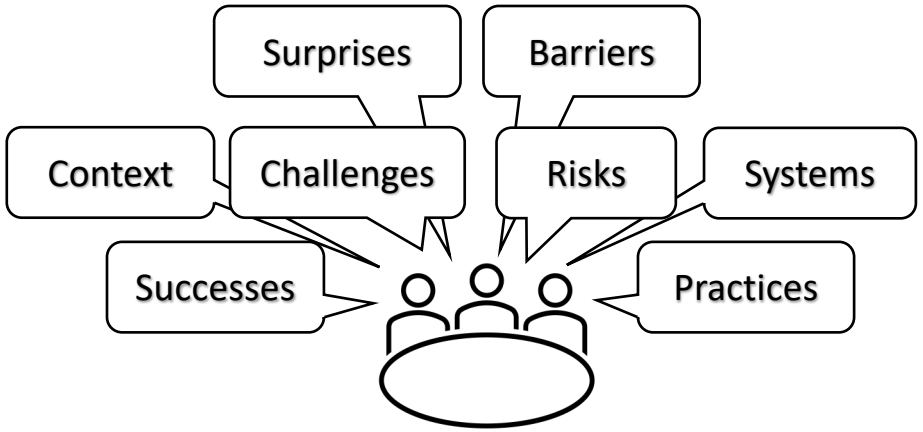
What is a Learning Team?

A Learning Team is a facilitated, open discussion that engages both those who perform a work activity and those who design the work.



Uses Humble Inquiry

Open-ended questions and leader support are used to create a psychologically safe space for discussion. This allows for a candid and context-rich dialogue, which enables effective operational learning and improvement.



AN EXAMPLE LEARNING TEAM PROCESS AND QUESTIONS

- Leader Kick Off
- Brief Overview of Task or Event
- Discuss Task in Detail
- Conditions Associated with the Event
- Ideas for Improving the System

Learning Teams are great for rapidly learning about context, decisions, or complex situations

Credit to Ashley Waddey for process and question descriptions

THE OCCASIONAL ENDING

SITE SENIOR LEADER

“I agree that we need changes made to this work process. Let’s get those done.

But ultimately, this event would not have happened if a Performer and Witness had done their jobs correctly. We also need some accountability.”

GROUP DISCUSSION

How would you respond to this senior leader's assertion about accountability?

THE BRIGHT SIDE

Your better questions and approaches will be driving real improvement…

…and be the beginning of driving new conversations with real learning

ANOTHER WAY TO LEARN: AFTER ACTION REVIEWS

4 Basic, but powerful questions:

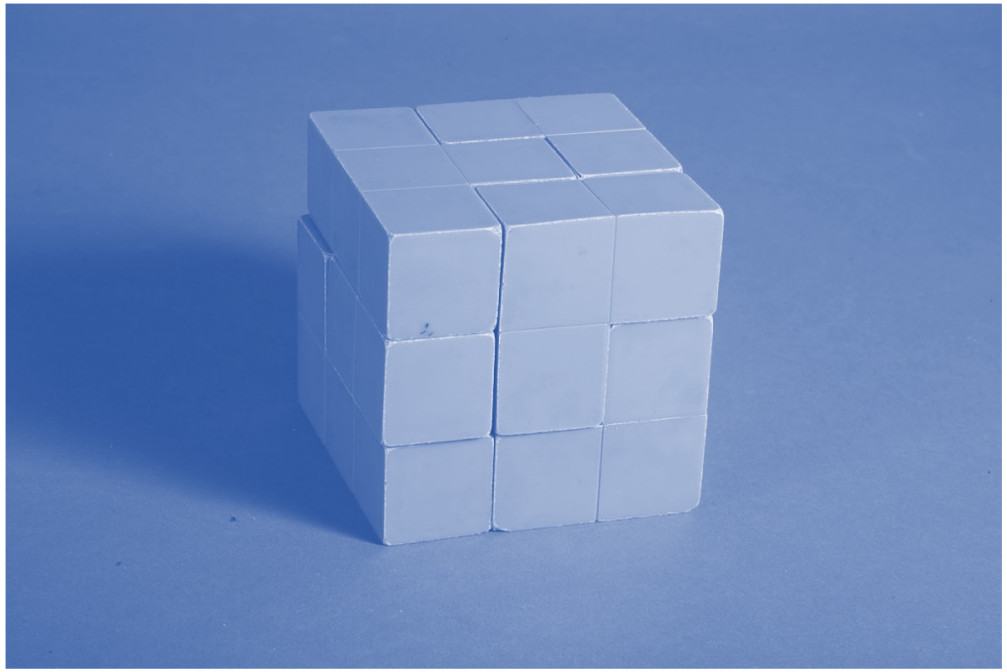
1. What did we set out to do?
2. What actually happened?
3. How did it happen?
4. What are we going to do next time?

After Action Reviews are a great way to extend learning from when things go wrong to successes too

SETTING UP YOUR AAR FOR SUCCESS

- Purpose
- Ground Rules
- Inclusive
- Empathy
- Psychological Safety
- How, Not Why

LET'S PRACTICE:
AFTER ACTION REVIEW



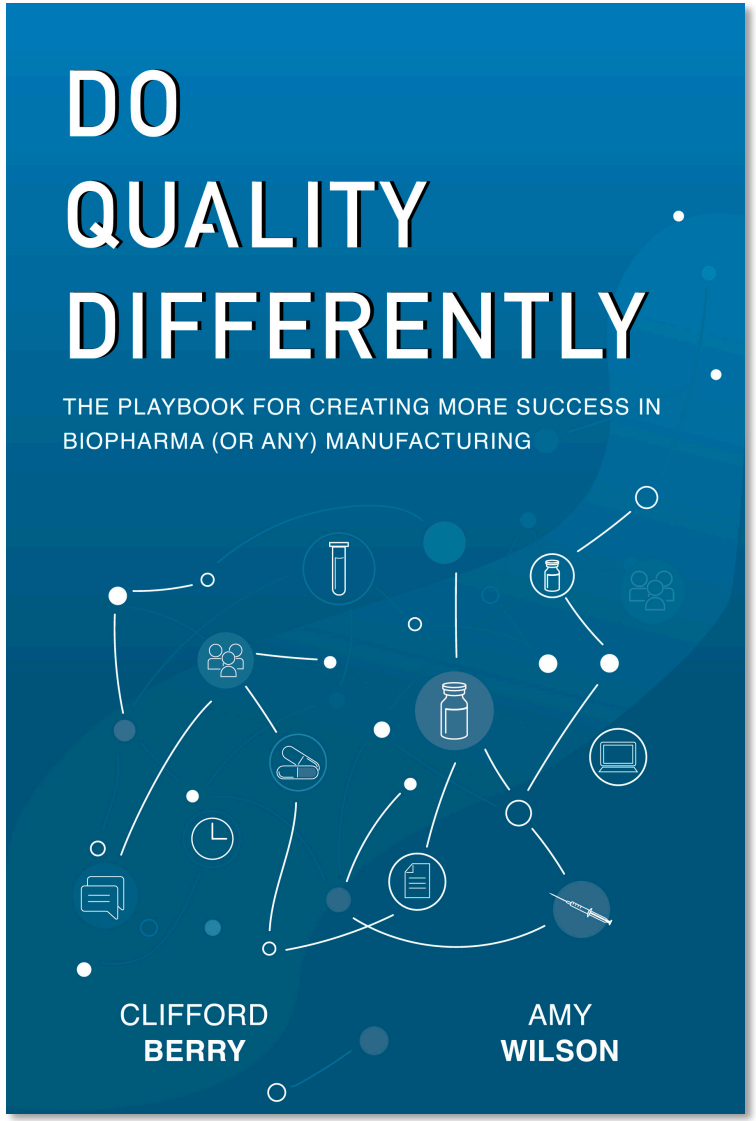
GROUP DISCUSSION

What are your experiences and questions related to learning?

“It is not the answer that enlightens, but the question.”

Eugene Ionesco

THANK YOU



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