

Rewards of Managing Risk in Manufacturing

CIEHF – January 2024

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www.doqualitydifferently.com

OUR BEGINNINGS: A SNAPSHOT OF BIOPHARMA INDUSTRY DESIGN



Paper Records



Tablets to Access Procedures



Automation HMI

THE REALITIES OF COMPLEXITY AND VARIABILITY



Large Scale Stainless Steel

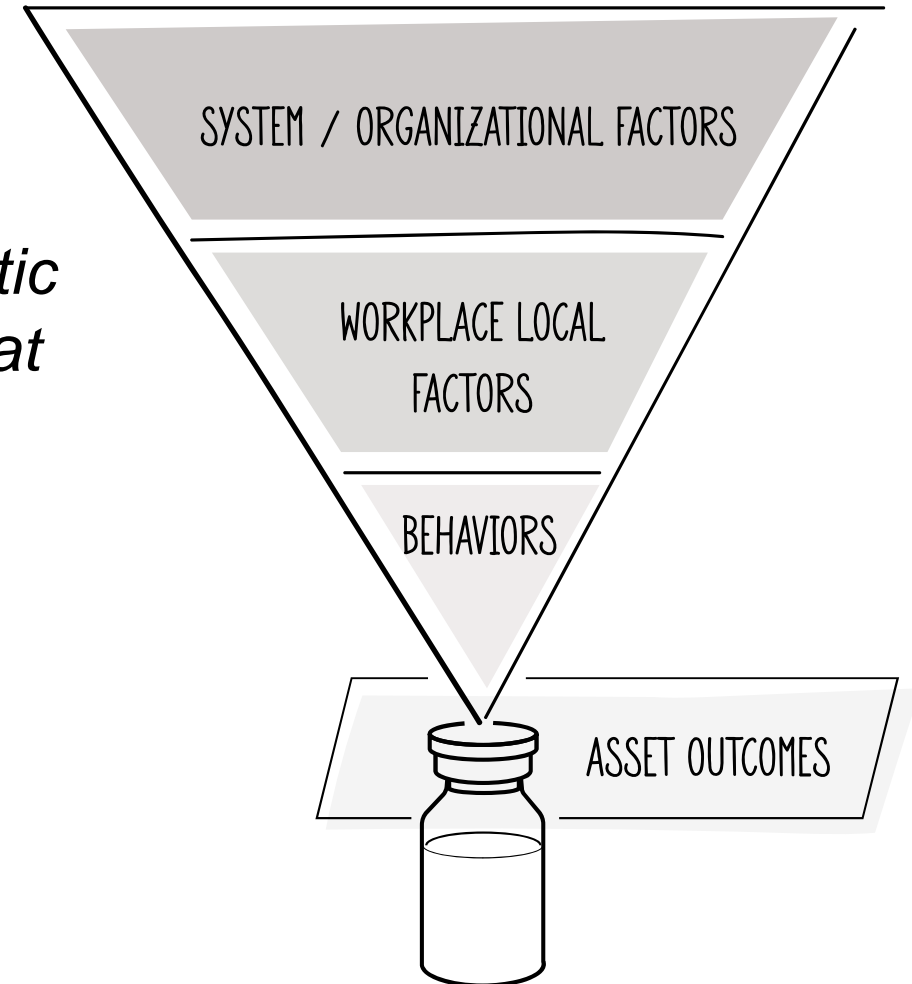


Single-Use

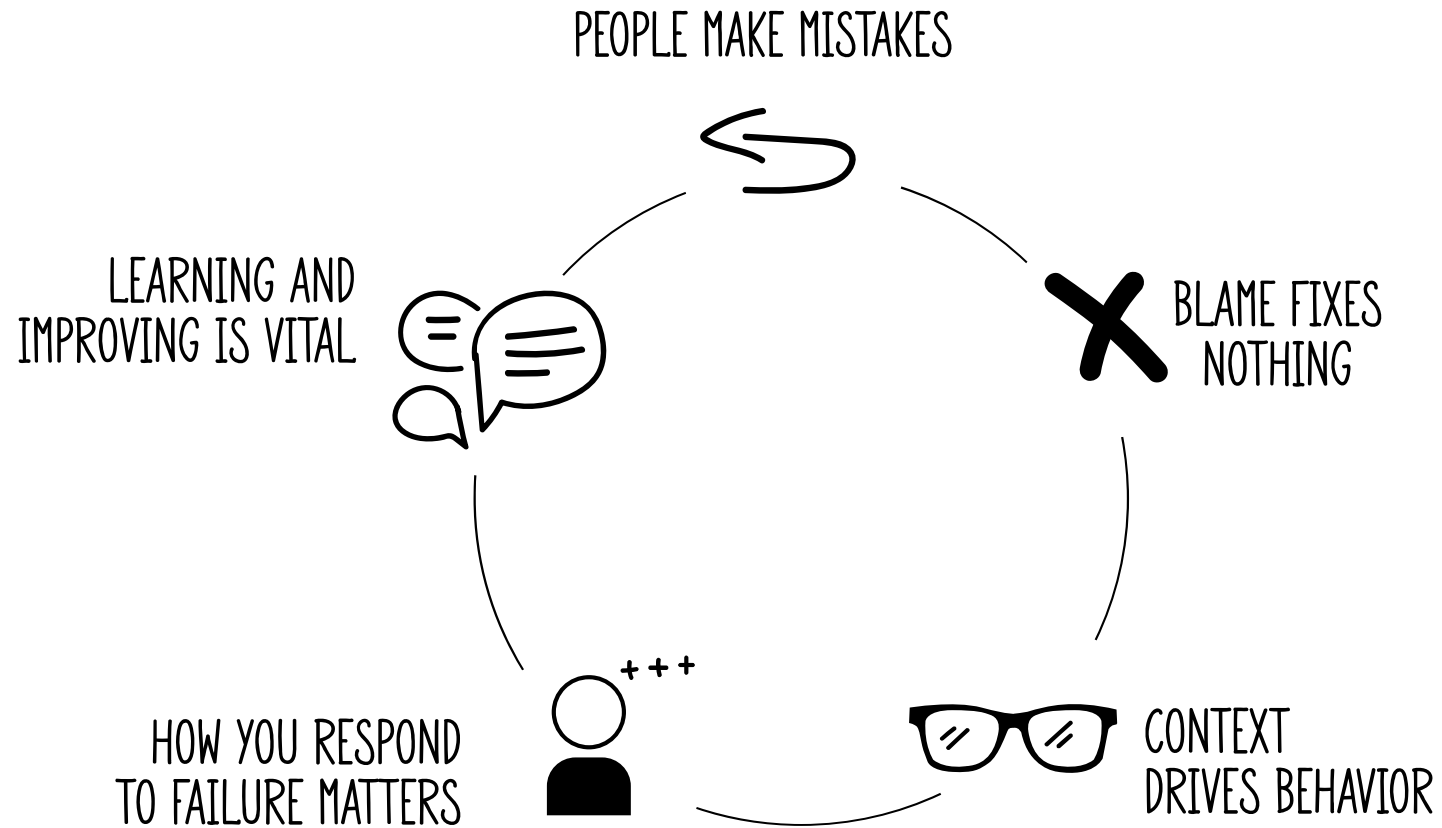
HUMAN AND ORGANIZATIONAL PERFORMANCE

“Human and organizational performance is a holistic application of human factors and system safety that improves the management of risk in operations.”

~ Berry, C. & Wilson, A.D. (2023) Do Quality Differently



HOP PRINCIPLES PUT INTO PRACTICE IMPROVE MANAGEMENT OF RISK



OPERATIONALIZING: PEOPLE MAKE MISTAKES

1 Talk about Workplace Local Factors and System / Organizational Factors...

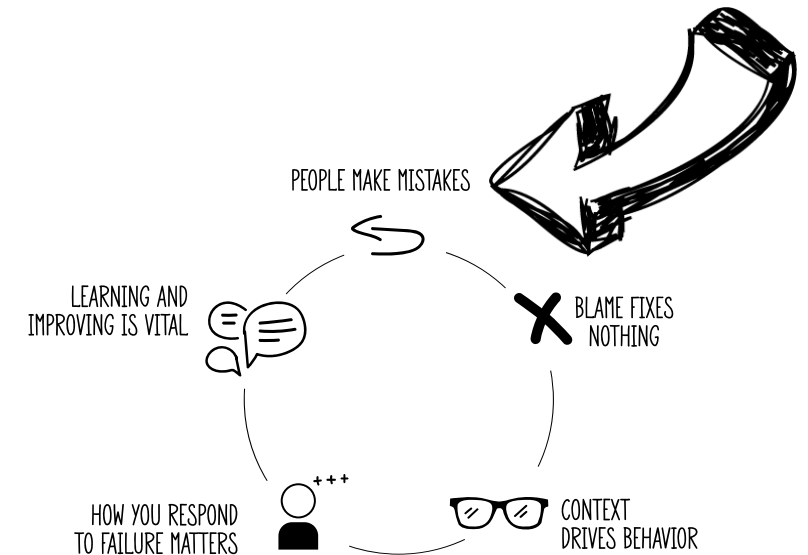
and do not focus solely on Behaviors (and Mindset), which ignores what is influenced by the workplace

2 Don't Allow People to Settle on Human Error as an Explanation...

Ask questions about work context, how people's assessments and actions made sense to them at the time, and how things go right most of the time

3 Design Systems for People and for When They Fail...

because they will fail, and so controls that detect and mitigate failure are essential



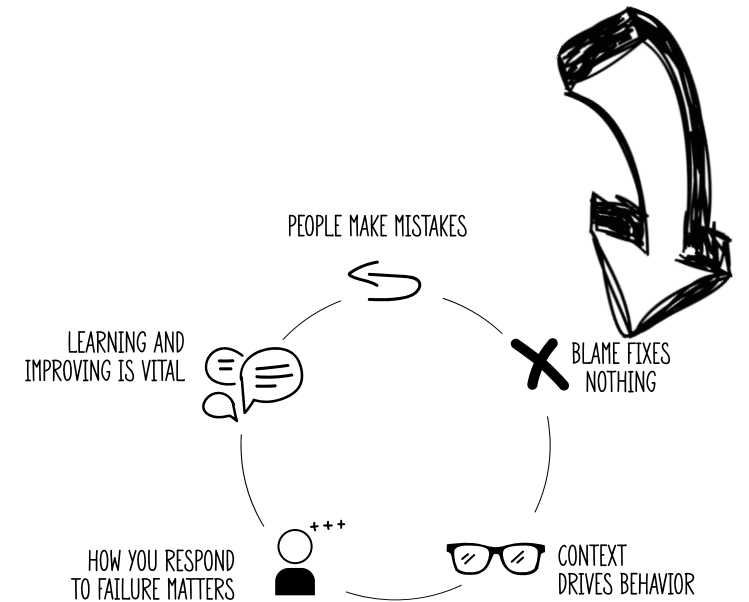
OPERATIONALIZING: BLAME FIXES NOTHING

4 End the Practice of Tying Blame & Discipline to Failure...

The attributes of Accountability are respect, trust, inquiry, curiosity, and mutualness

5 Elevate Psychological Safety...

People will speak up with questions, admit mistakes, and express ideas and concerns when they do not fear negative consequences



OPERATIONALIZING: CONTEXT DRIVES BEHAVIOR

6 Go Watch Work and Learn About the System...

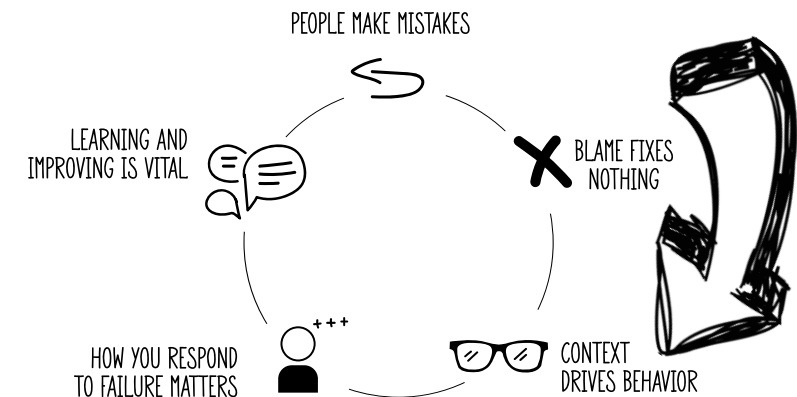
The conditions and factors that are associated with failure are present in success

7 Listen to the Stories of Workers...

The people who perform the work are smart and know where the risk is in the process

8 Ask Better Questions...

Use Humble Inquiry to ask better questions and learn more



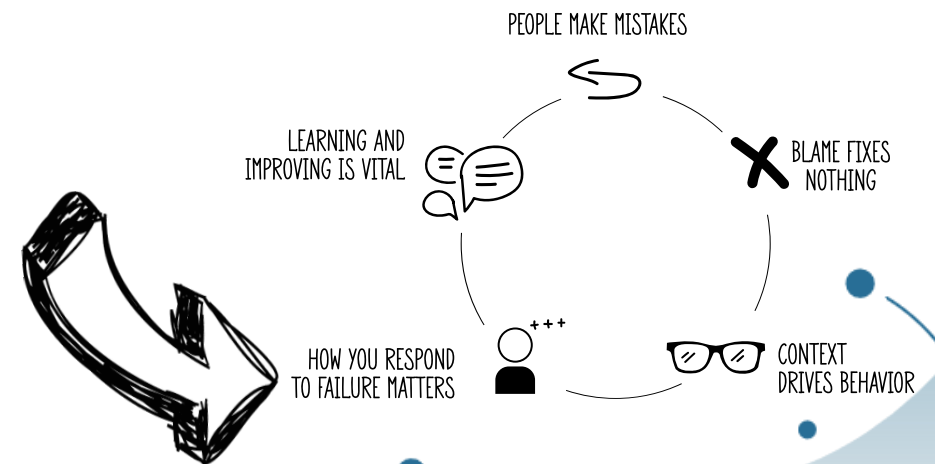
OPERATIONALIZING: HOW YOU RESPOND TO FAILURE MATTERS

9 Respond to undesired outcomes with questions based upon caring & support...

How are people and the facility? How can I support activities for return to service? How can I help ensure we learn what we need to?

10 Avoid asking “why?” ...

Use “How” instead – this will result in richer responses and prevent people from feeling blamed



OPERATIONALIZING: LEARNING AND IMPROVING IS VITAL

11 Drive Investigation Conversation toward Conditions & Factors, and Away from Cause Codes provided by Quality Management Systems...

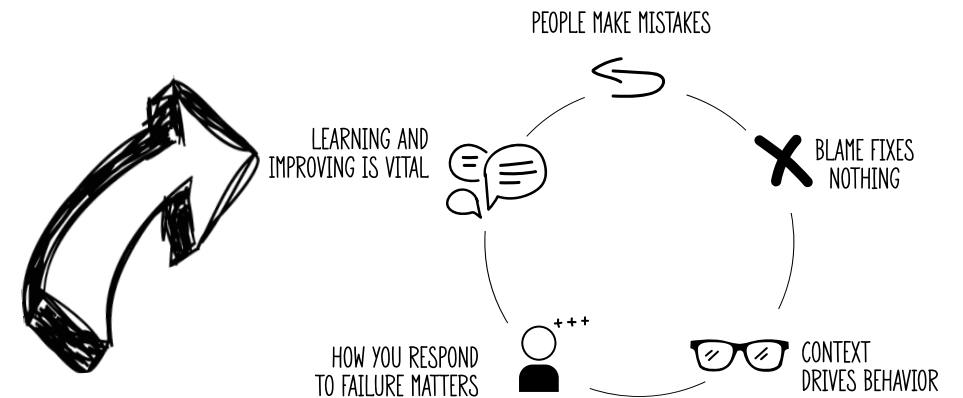
Taxonomies promote convergent thinking and constrain learning

12 Use alternative investigation approaches since 6M Fishbone and 5-Why will not always Reveal Conditions that need Adjustment...

Mechanistic / linear thinking does not help solve complex adaptive systems problems

13 Promote After Action Reviews...

Institutionalize structures that provide focus on continuous learning and improvement



CASE STUDY: THE FEED LINE MIXUP

A Senior Manufacturing Technician cut the feed / drain line for the in-use media tote connected to an in-service bioreactor, resulting in a batch loss.



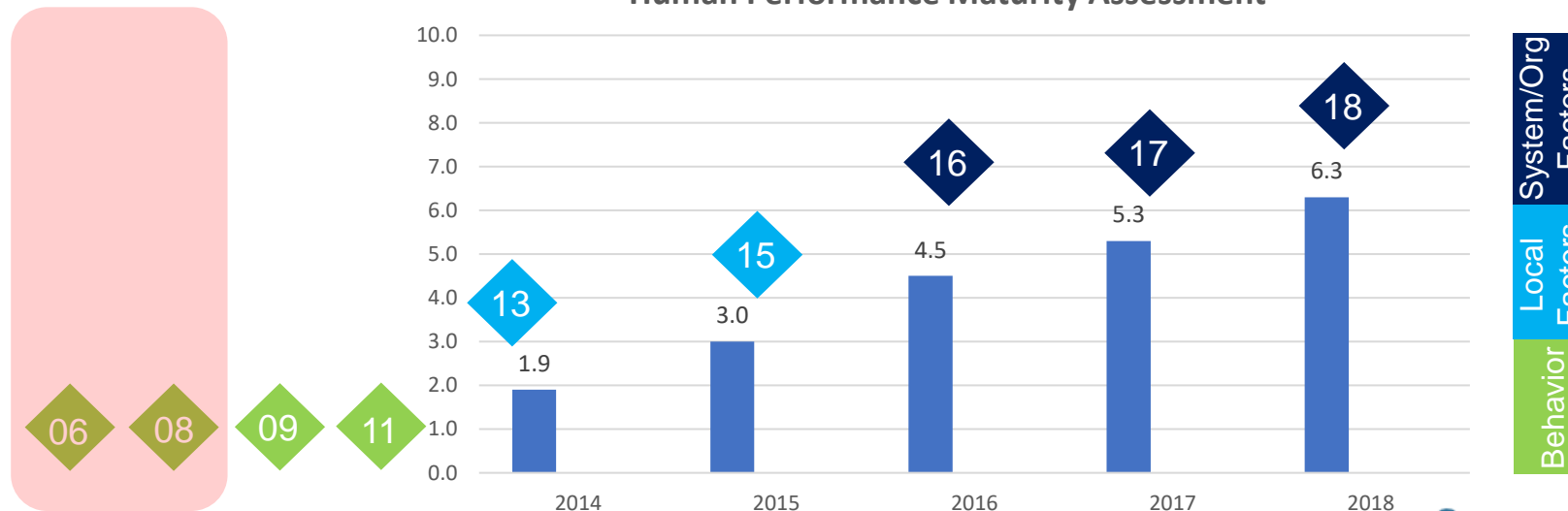
750L Tote Bag Removal

- NOTE:** Before opening any tote check the WIT, sight holes, and signage to ensure the tote is empty.
- 13.15.1. Contact technician in RM 104, confirm tote to be drained has been flushed off and the tubing put in the iris valve. If tubing has already been pulled through iris valve, proceed to Step 13.15.3
 - 13.15.2. Open the iris valve and remove colder connection and tubing. Close iris valve after removal.
 - 13.15.3. Ensure that the iris valve is closed. Direct the colder connection to drain ensuring tubing is not kinked. Utilize a "Wet Floor" sign to indicate the tubing is on the floor.
 - 13.15.4. Open the colder connector over the drain by depressing the button and engaging the plastic head. Open clamp on tubing to allow media to drain out of the bag.
 - 13.15.5. Confirm the media bag has been drained by using the tote's WIT and the sight holes next to the door.
 - 13.15.6. Follow the tubing back from the drain to the drained tote. Have this step verified by a co-worker prior to performing Step 13.15.7
 - 13.15.7. Close the clamp on the tubing and cut the tubing just below the clamp.
 - 13.15.8. Empty the remaining media in the cut tubing into the drain prior to discarding.
 - 13.15.9. Visually verify that tote is empty using WIT and sight holes next to door. Open tote. Remove and discard bag.
 - 13.15.10. Clean the tote per *SOP-049532*.
 - 13.15.11. Close the doors of the tote after cleaning and label tote with "Empty" sign.

CASE STUDY: LEARNING CHANGES ACROSS HOP MATURITY

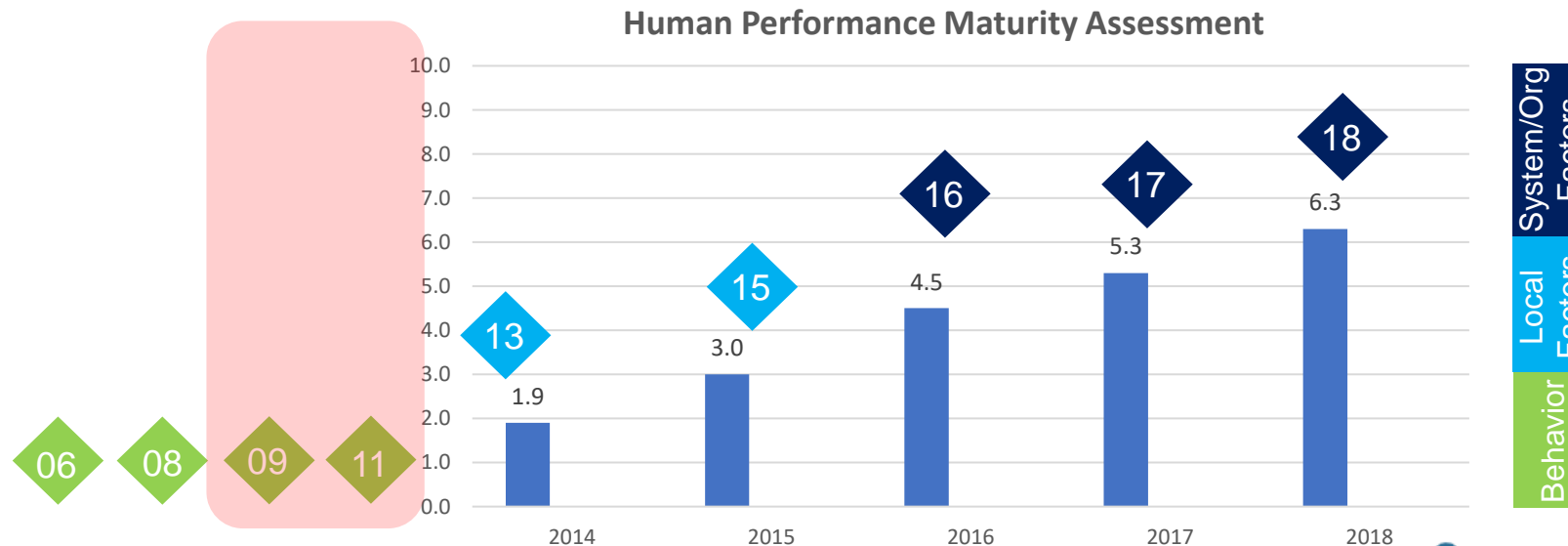
Date	What happened	Cause(s)	CAPA
Q3 2006	Calculation error (multiplication versus division)	Calculation error	Awareness CAPA
Q3 2008	Actual added exceeded target by 3.8%	Personnel	None
Q3 2008	Actual added exceeded target by 3.1%	Personnel	Procedure revision and awareness CAPA

Human Performance Maturity Assessment



CASE STUDY: LEARNING CHANGES ACROSS HOP MATURITY

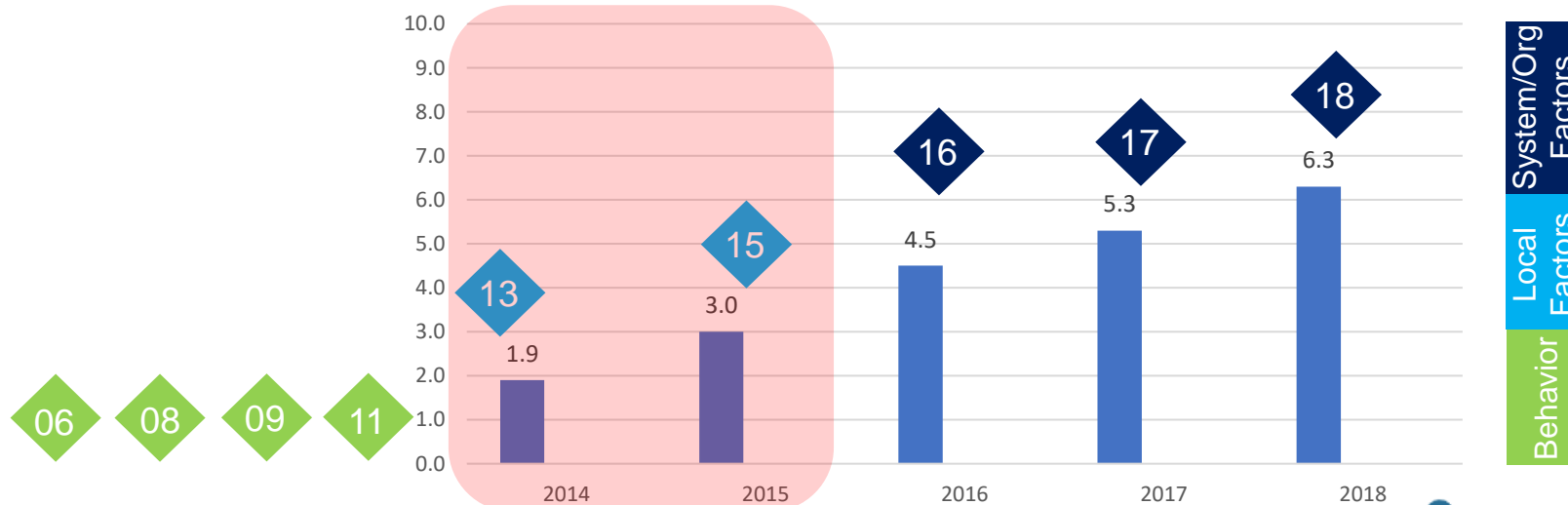
Date	What happened	Cause(s)	CAPA
Q1 2009	Batch record followed to calculate amount rather than PE in place for batch	Calculation error (Document)	None
Q1 2011	Out of range UF pool concentration	Out of range result cause unknown; Personnel cause assigned to not recognizing out of range result	Awareness CAPA



CASE STUDY: LEARNING CHANGES ACROSS HOP MATURITY

Date	What happened	Cause(s)	CAPA
Q1 2013	Addition target exceeded	Pump speed in procedure not adequate for small volumes	Procedure revision
Q4 2013	Too little added due to incorrect unit conversion	Personnel	BPR and procedure revisions
Q2 2015	In process test out of specified range (too much added)	Instructions and stock solution prepared incorrectly	Procedure revision

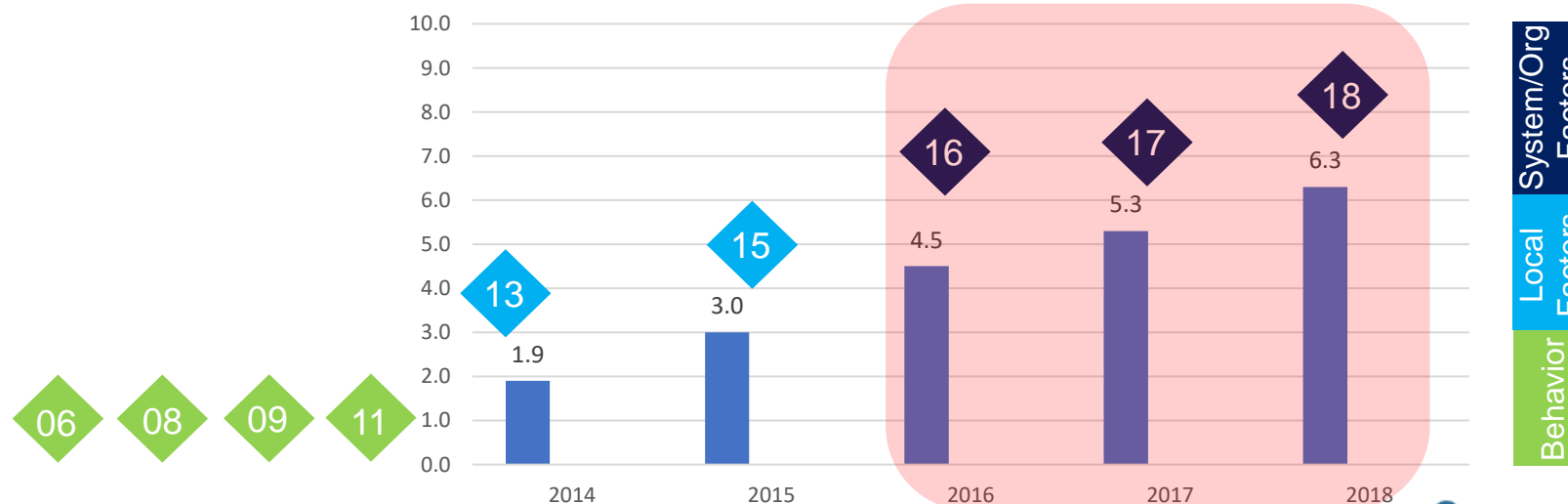
Human Performance Maturity Assessment



CASE STUDY: LEARNING CHANGES ACROSS HOP MATURITY

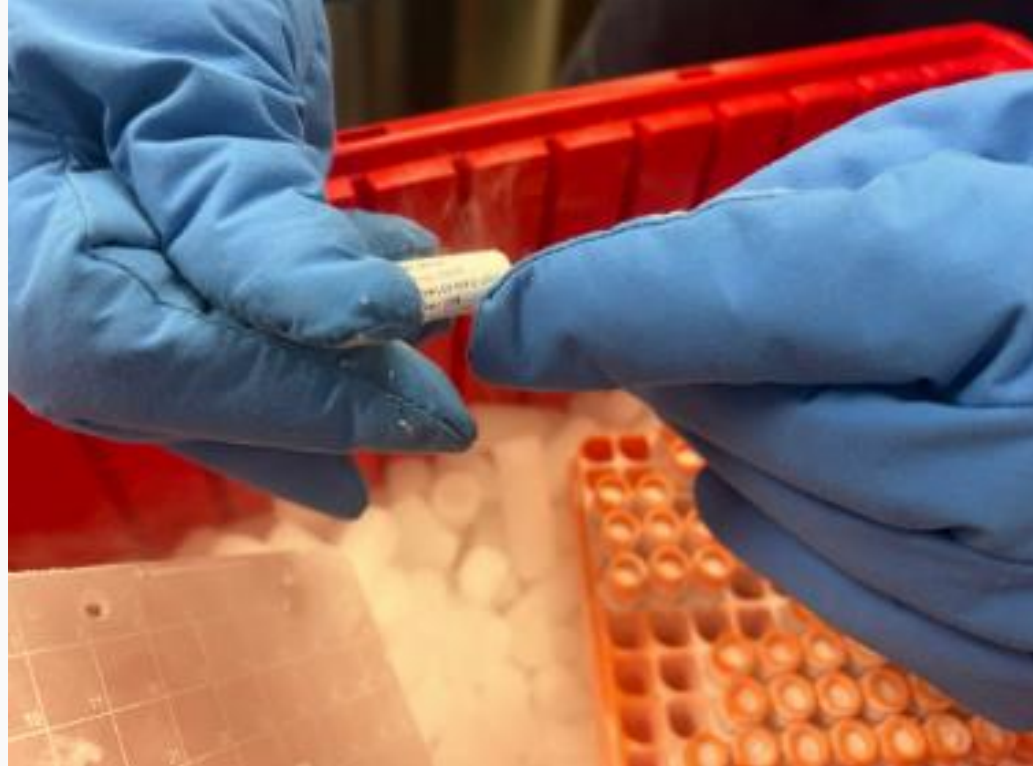
Date	What happened	Cause(s)	CAPA
Q4 2016	Actual amount added exceeded target (pump)	Equipment design (pump robustness)	New pump head for small volume additions
Q2 2017	Actual amount added exceeded target (calculation error)	Calculation error/BPR calculations not human factored	BPR updates and a CAPA to explore improved addition methods
Q1 2018	Amount added resulted in concentration exceeding action limit	Overall process design (manual, no secondary verification, instructions, etc.)	New pump implementation, new procedure

Human Performance Maturity Assessment

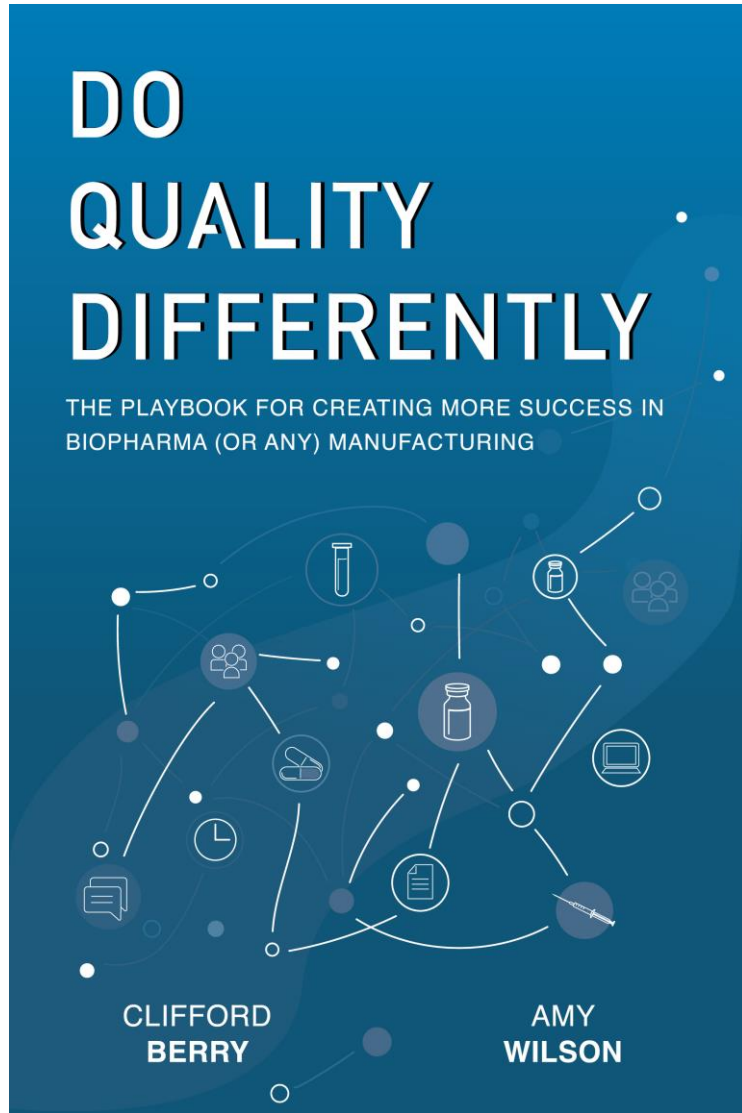


CASE STUDY: WRONG WCB CRYOVIALS

A Senior Manufacturing Technician picked the wrong cell bank cryovials for a thaw, and coworker acting as Witness missed the mistake.



THANK YOU



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