HOP Integration in Biopharma (or any) Manufacturing

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THE TYPICAL TERRAIN

Recent performance issues have created an opening to try something new

Your sponsor is ready…..but will be gone in 2 to 4 years

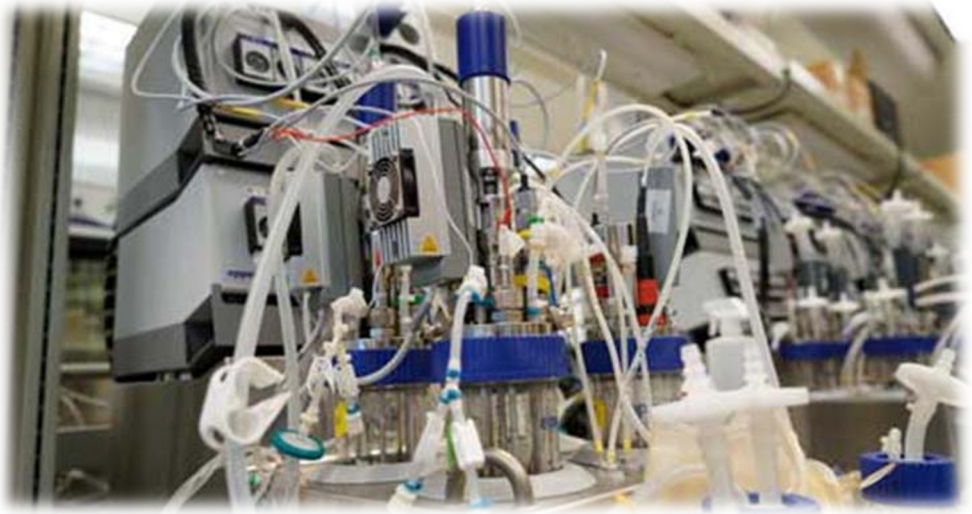
Most leaders think HOP is something for workers only

People with roles in Operational Excellence will feel threatened

MISSING REGULATORY EMPHASIS

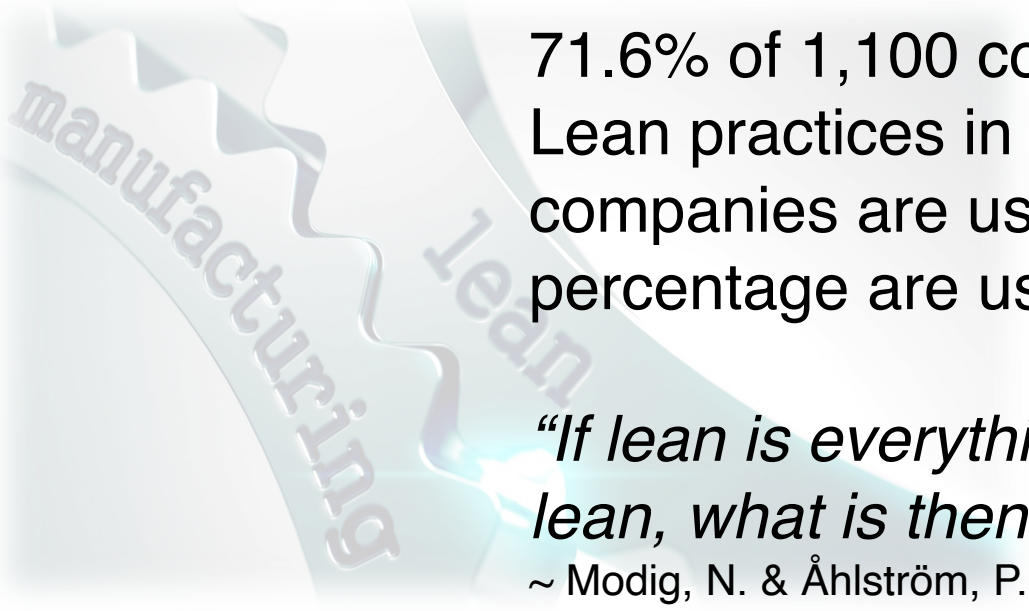
U.S.NRC

VS



FDA U.S. FOOD & DRUG ADMINISTRATION

LEAN IS EVERYTHING THAT IS GOOD



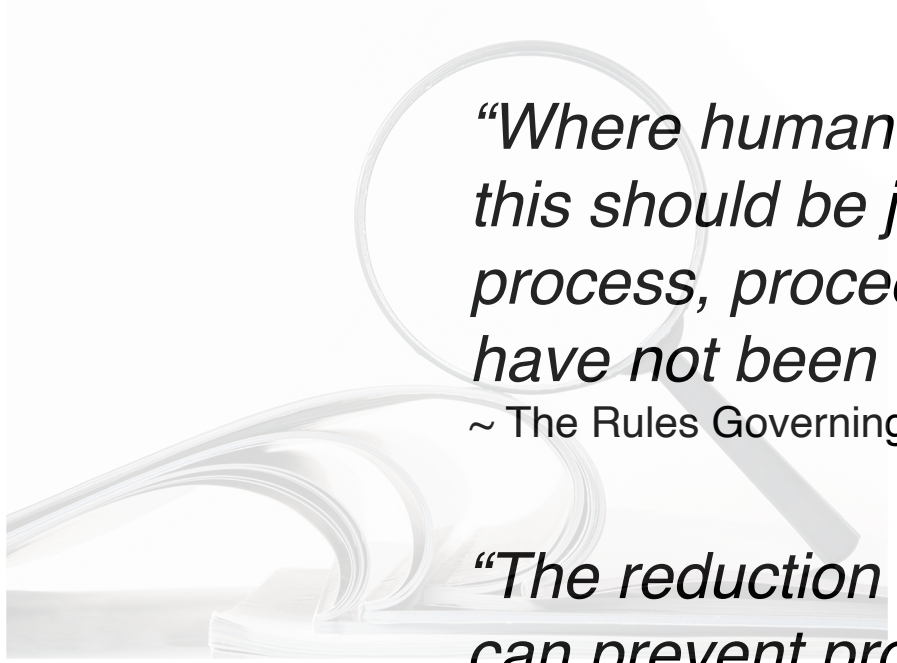
71.6% of 1,100 companies surveyed had implemented Lean practices in their operations, 58.2% of the companies are using Six Sigma, and certainly a high percentage are using both.[1]

“If lean is everything that is good, and everything good is lean, what is then the alternative?”

~ Modig, N. & Åhlström, P. (2012) This is lean: resolving the efficiency paradox

1 - https://supplychainminded.com/most-companies-are-using-lean-but-not-always-so-well/

PROBLEMATIC BELIEFS ABOUT 'HUMAN ERROR'



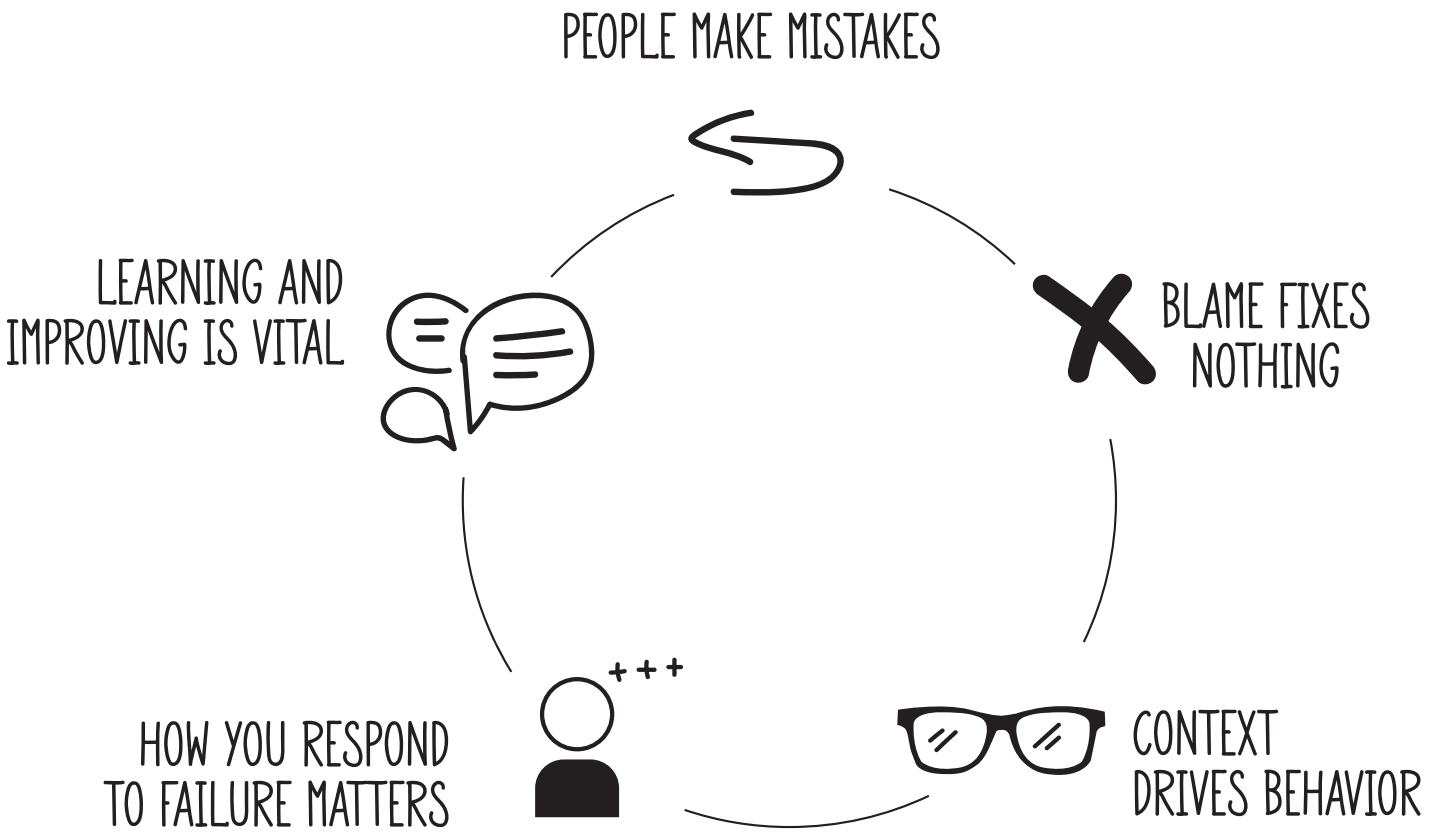
"Where human error is suspected or identified as the cause, this should be justified having taken care to ensure that process, procedural, or system-based errors or problems have not been overlooked, if present."

~ The Rules Governing Medicinal Products in the European Union (European Commission)

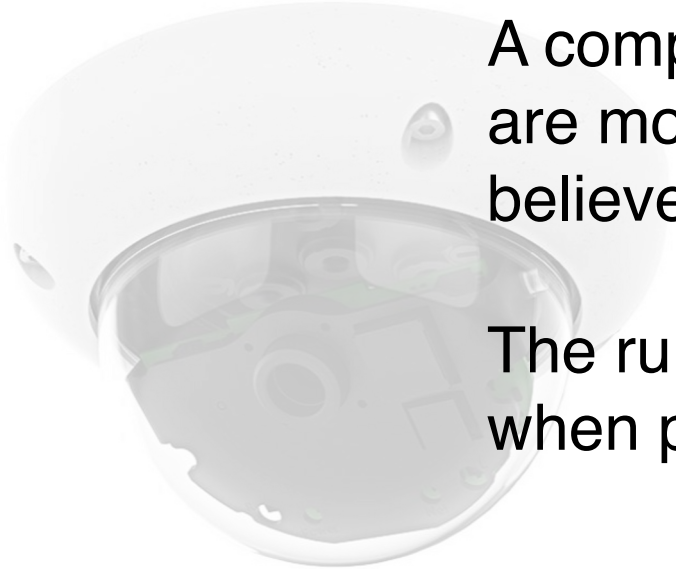
"The reduction of human error can lead to a system that can prevent problems before they occur."

~ Drug Shortages: Root Causes and Potential Solutions (FDA)

HOP PRINCIPLES ARE A MUST



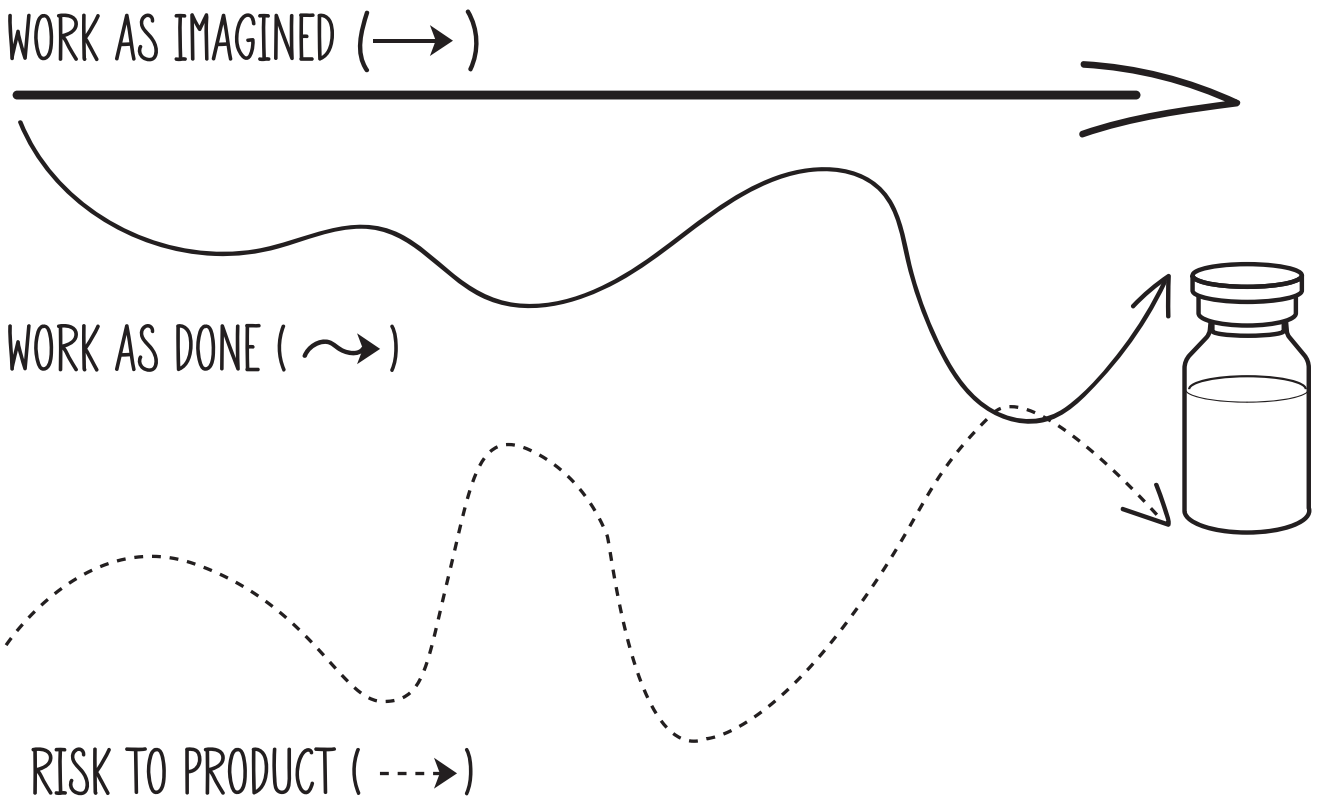
THE DARK SIDE OF COMPLIANCE MINDSET



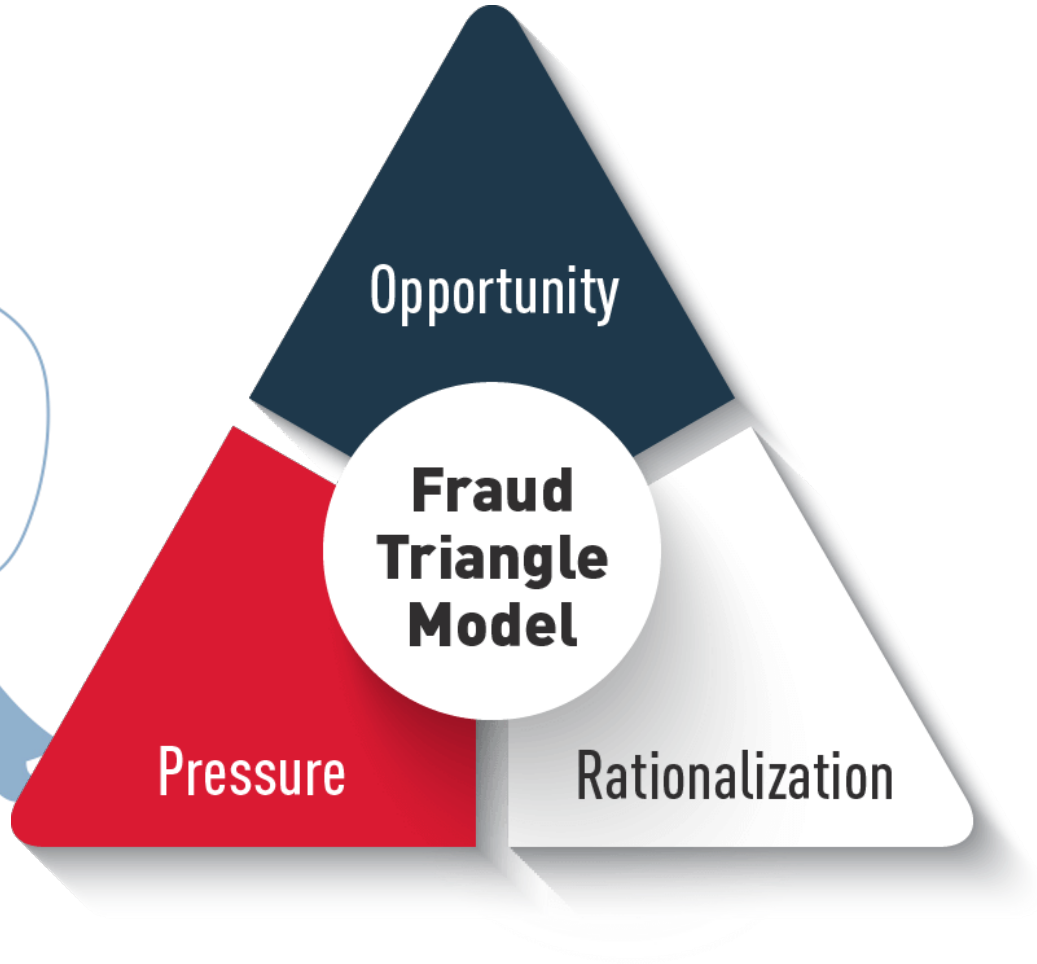
A compliance mindset is deficit-oriented where actions are motivated to meet written or espoused requirements believed to be perfect.

The rules and systems have worked very well to date, so when people fail it is because of non-compliance.

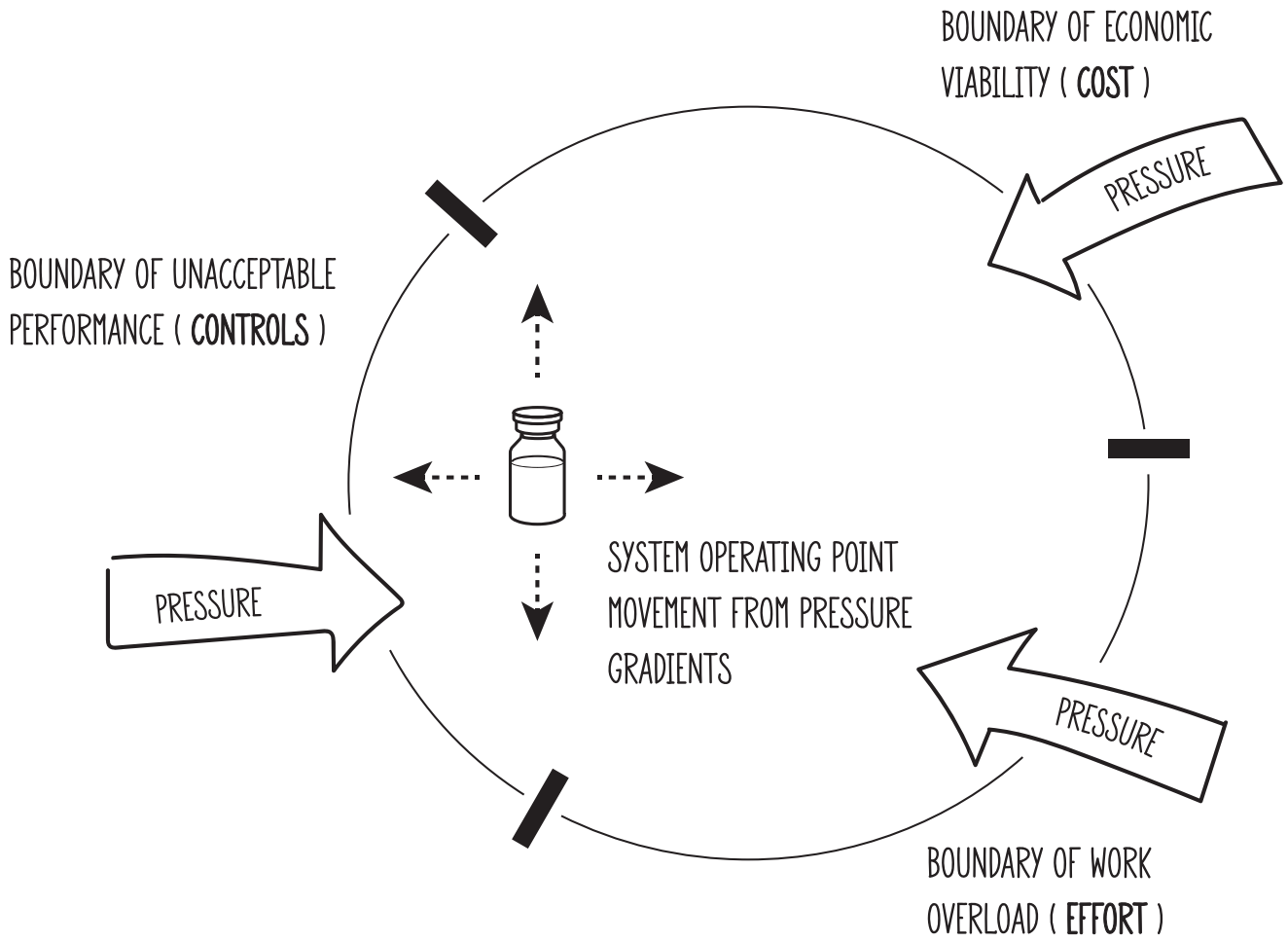
WAI & WAD CONCEPT IS KEY



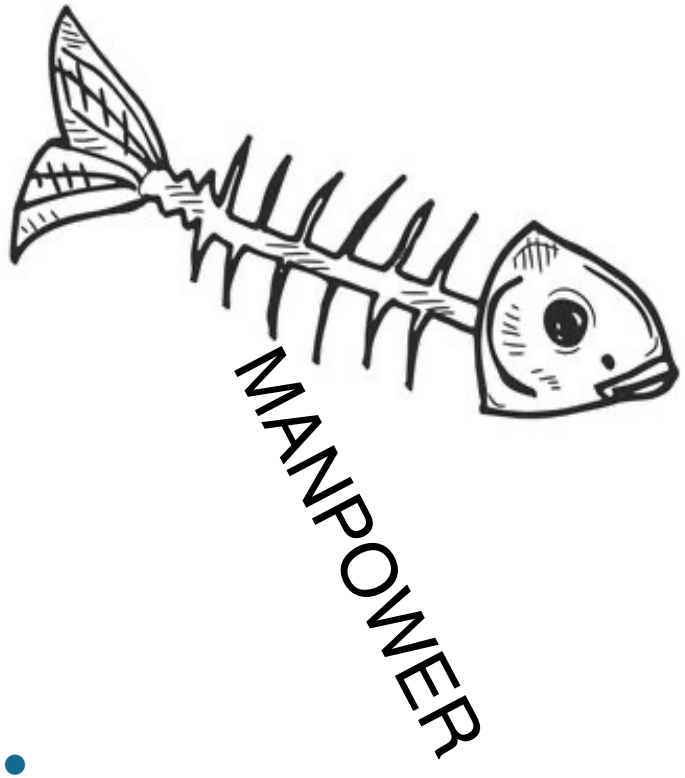
CRESSY FRAUD TRIANGLE = SUSPICIOUS MINDS



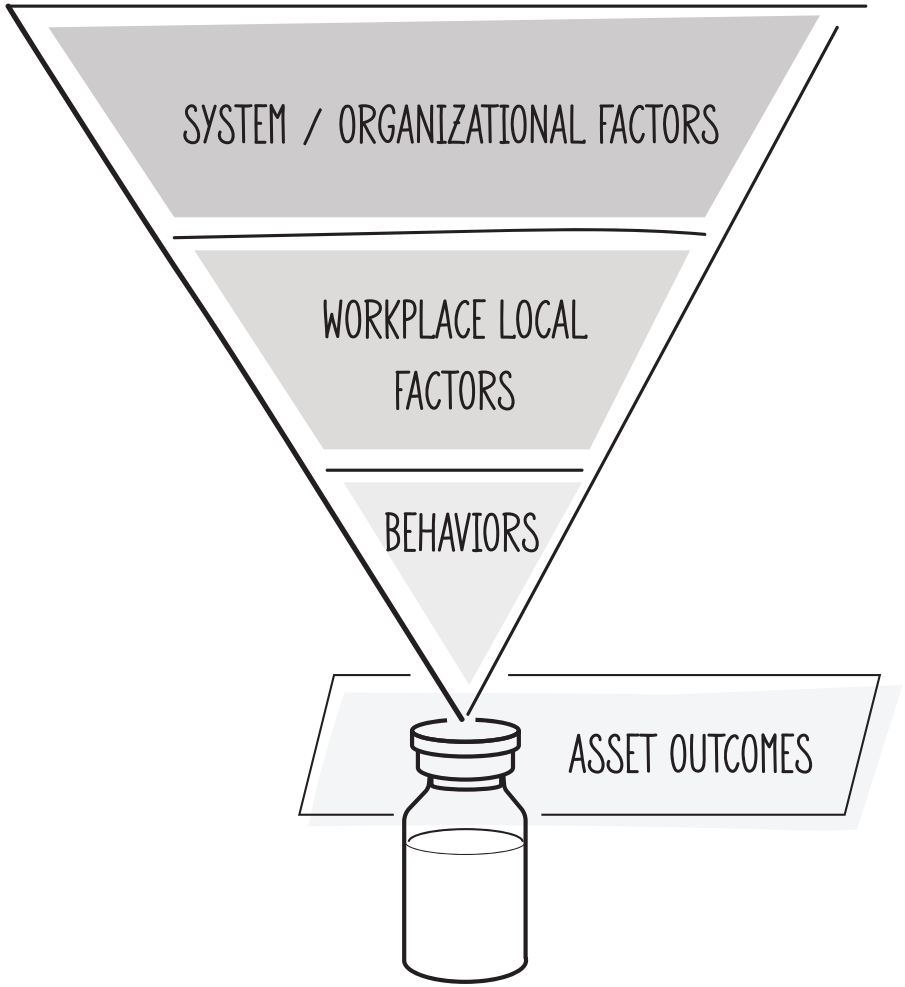
SHIFT TALK TO SYSTEM & CONTROLS



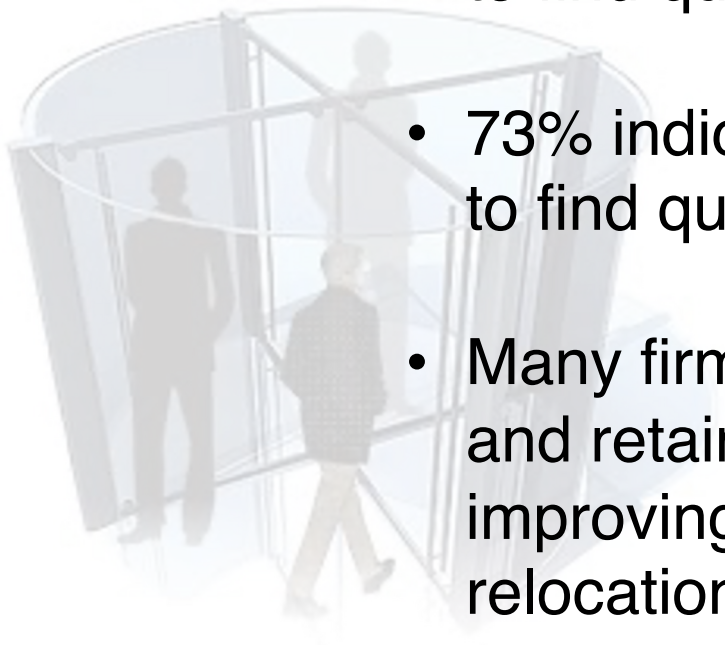
THE LOVE AFFAIR WITH SIMPLE IDEAS



CHANGE CONVERSATIONS TO INCLUDE COMPLEXITY



REVOLVING DOOR OF TALENT



- 94% reported some level of hiring difficulty when trying to find qualified candidates for nonentry-level roles.
- 73% indicated some level of hiring difficulty when trying to find qualified entry-level candidates.
- Many firms are employing creative ways of attracting and retaining talent, including increasing wages, improving benefits packages, adding tuition and relocation assistance, and offering remote work options.

CONTENT

TIPS ON MAKING HOP STICK BETTER

BUILD NEW HELPFUL SHARED BASIC ASSUMPTIONS

‘Human Error’ is not a cause

HOP is necessary to improve the management of risk (not ‘Human Error’)

Going to Gemba includes watching work to learn from the experts

Different types of problems require different analysis methods

Cause codes are not causes

Undesirable events will happen and we will get better only if we improve our systems and controls

IN A WAY THAT YOUR ORGANIZATION WILL BE WILLING

‘Human Error’ is not a cause

What about accountability?

HOP is necessary to improve the management of risk (not ‘Human Error’)

But corrective actions are more complex

Going to Gemba includes watching work to learn from the experts

We already do walkthroughs

Different types of problems require different analysis methods

That sounds complicated

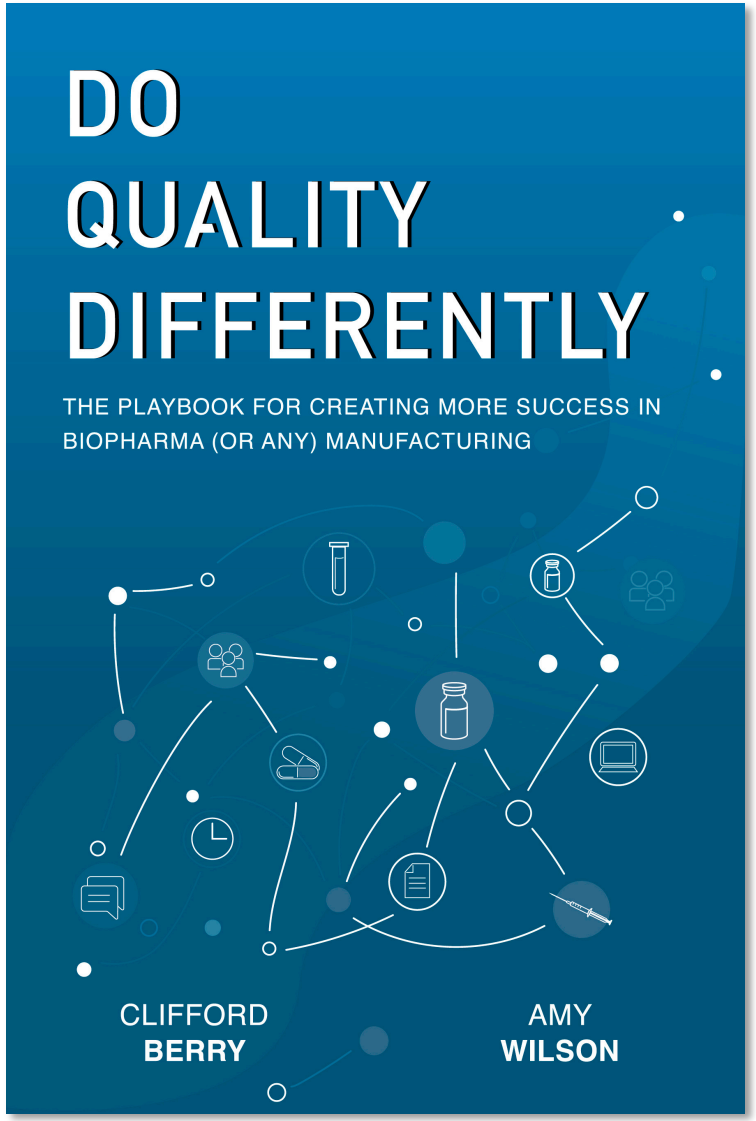
Cause codes are not causes

Those are the causes allowed by the SOP.

Undesirable events will happen and we will get better only if we improve our systems and controls

But we won’t have any more human error, right?

THANK YOU



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