



HOP Integration in Biopharma (or any) Manufacturing

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www.doqualitydifferently.com

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

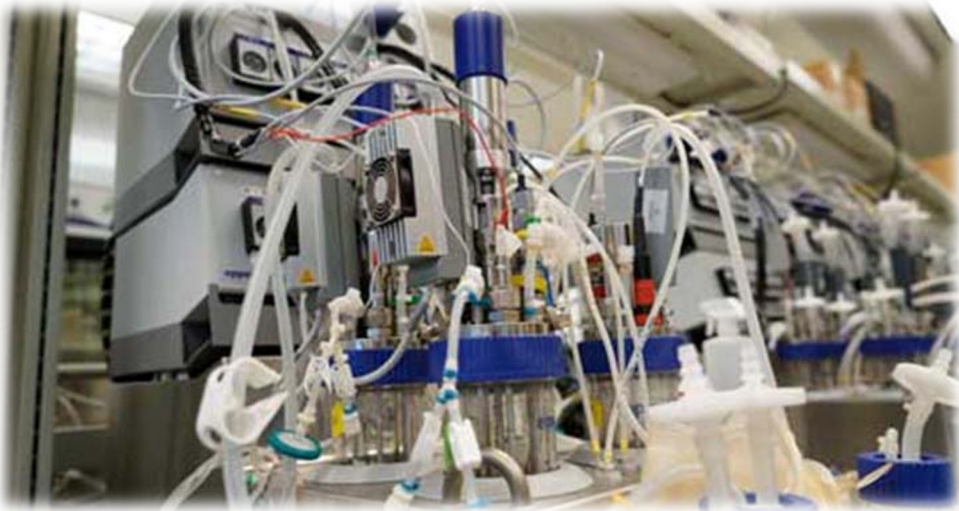
Most leaders think HOP is something for workers only

People with roles in Operational Excellence will feel threatened

MISSING REGULATORY EMPHASIS



VS



 **U.S. NRC**

 **U.S. FOOD & DRUG
ADMINISTRATION**

LEAN IS EVERYTHING THAT IS GOOD

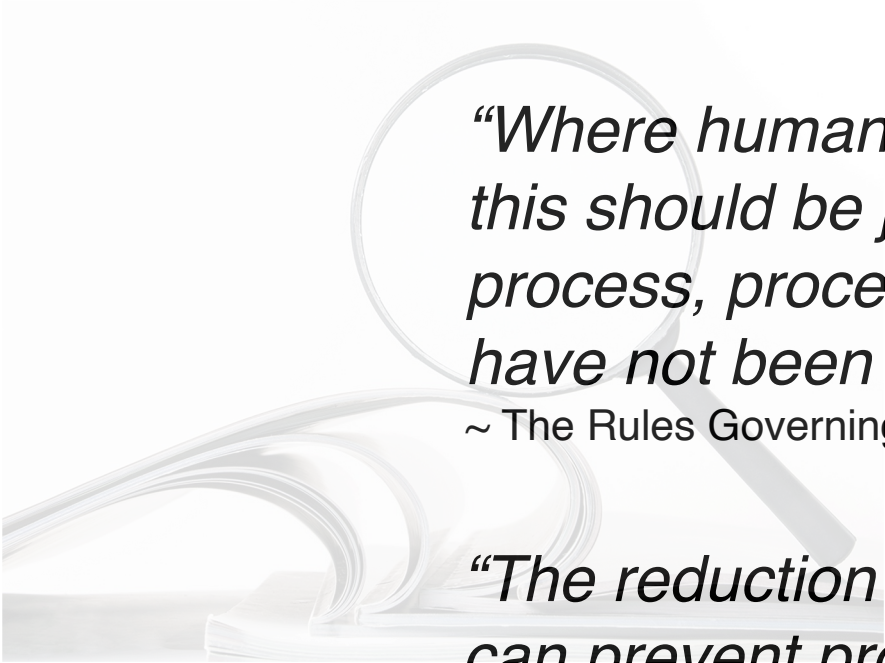
71.6% of 1,100 companies surveyed had implemented Lean practices in their operations, 58.2% of the companies are using Six Sigma, and certainly a high percentage are using both.¹

“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'

A magnifying glass is positioned over an open book, symbolizing investigation or scrutiny. The magnifying glass's lens is focused on the text below it.

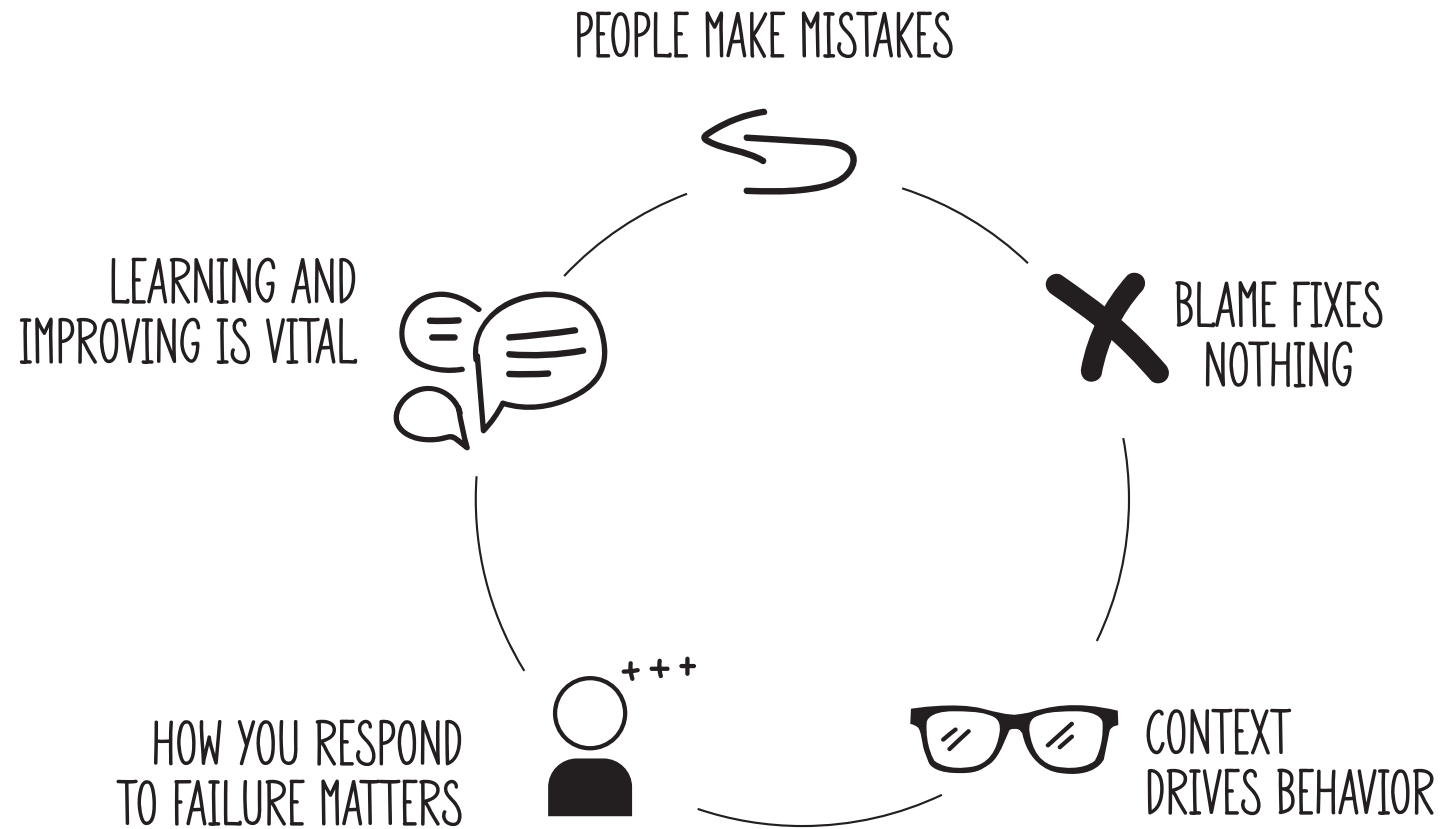
“Where human error is suspected or identified as the cause, this should be justified having taken care to ensure that process, procedural, or system-based errors or problems have not been overlooked, if present.”

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

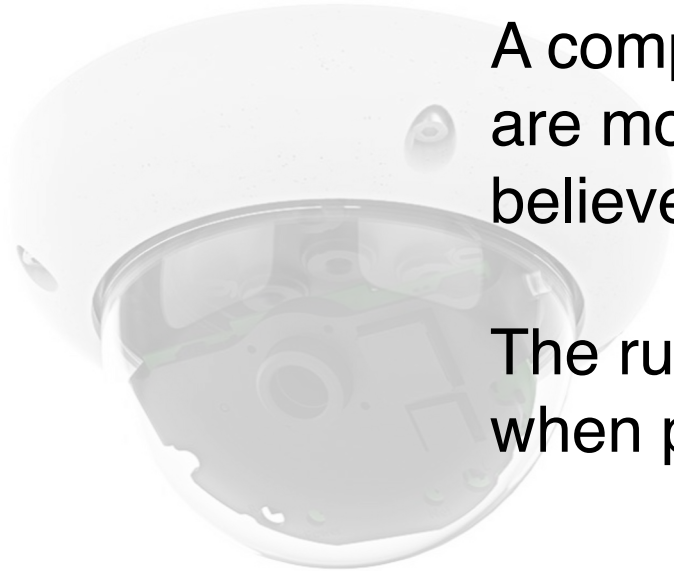
“The reduction of human error can lead to a system that can prevent problems before they occur.”

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

HOP PRINCIPLES ARE A MUST



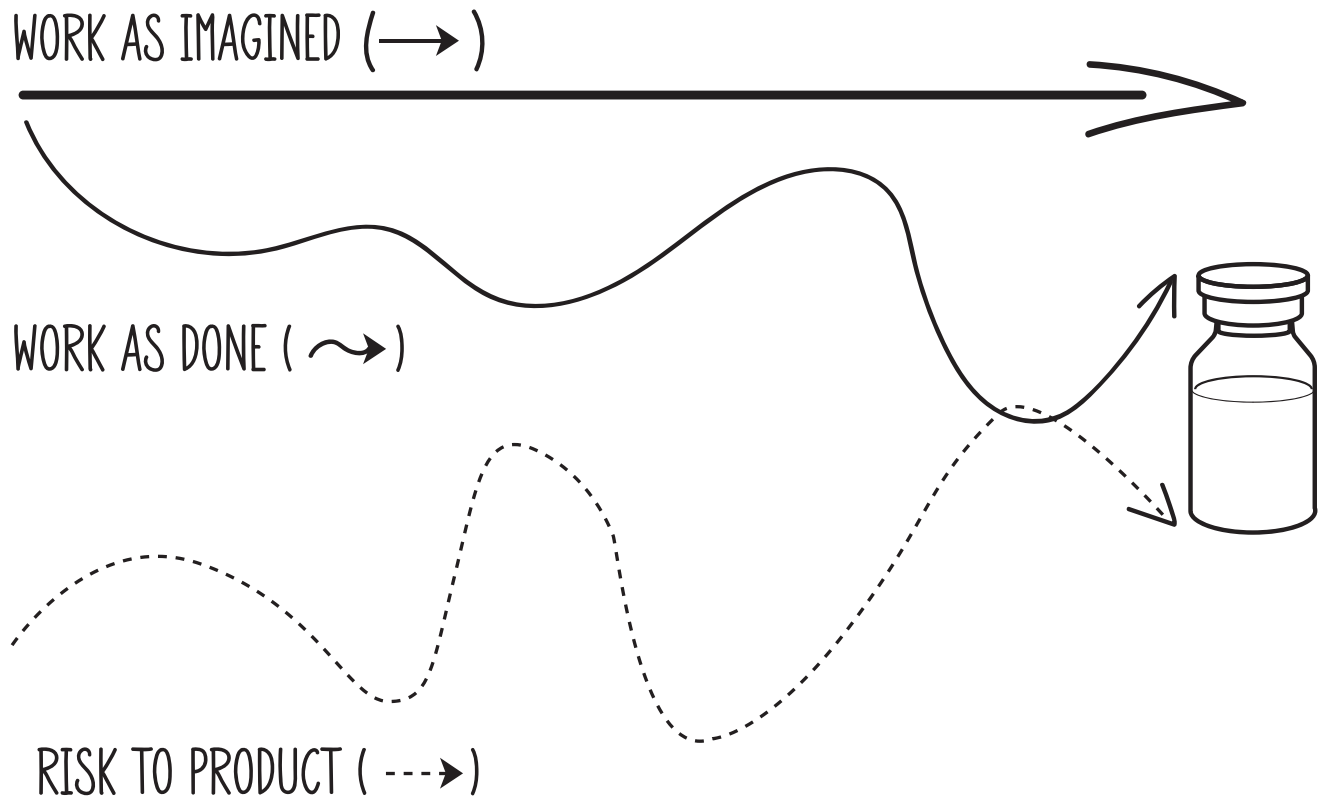
THE DARK SIDE OF COMPLIANCE MINDSET



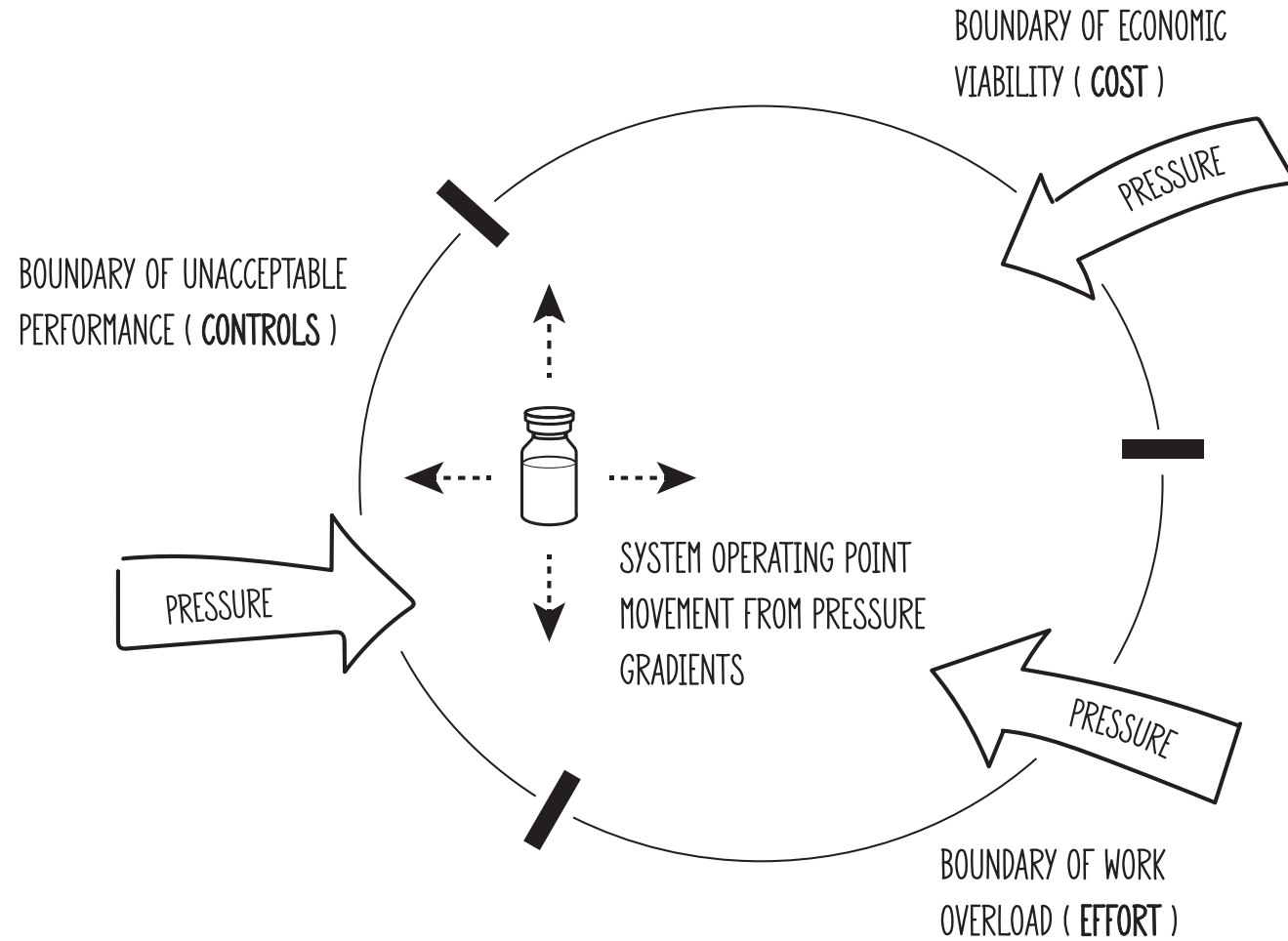
A compliance mindset is deficit-oriented where actions are motivated to meet written or espoused requirements believed to be perfect.

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

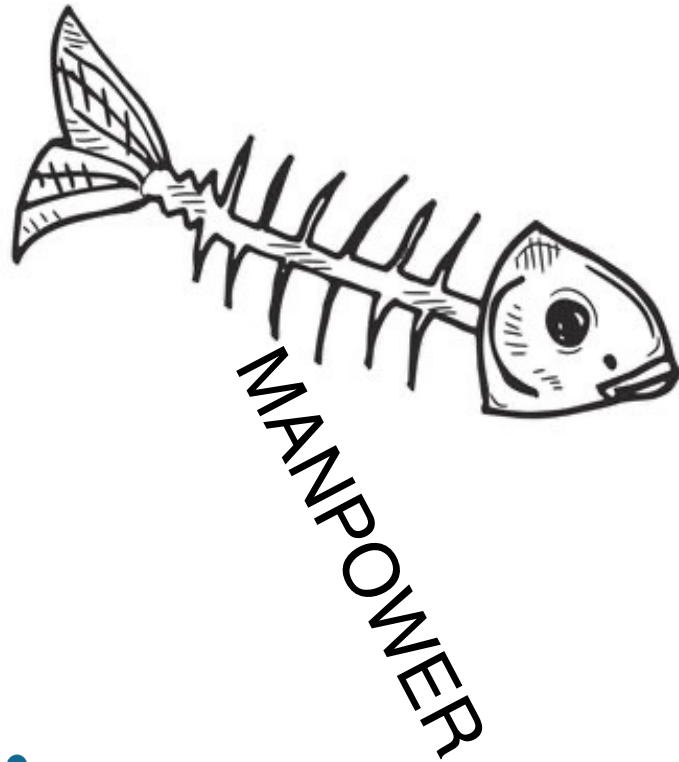
WAI & WAD CONCEPT IS KEY



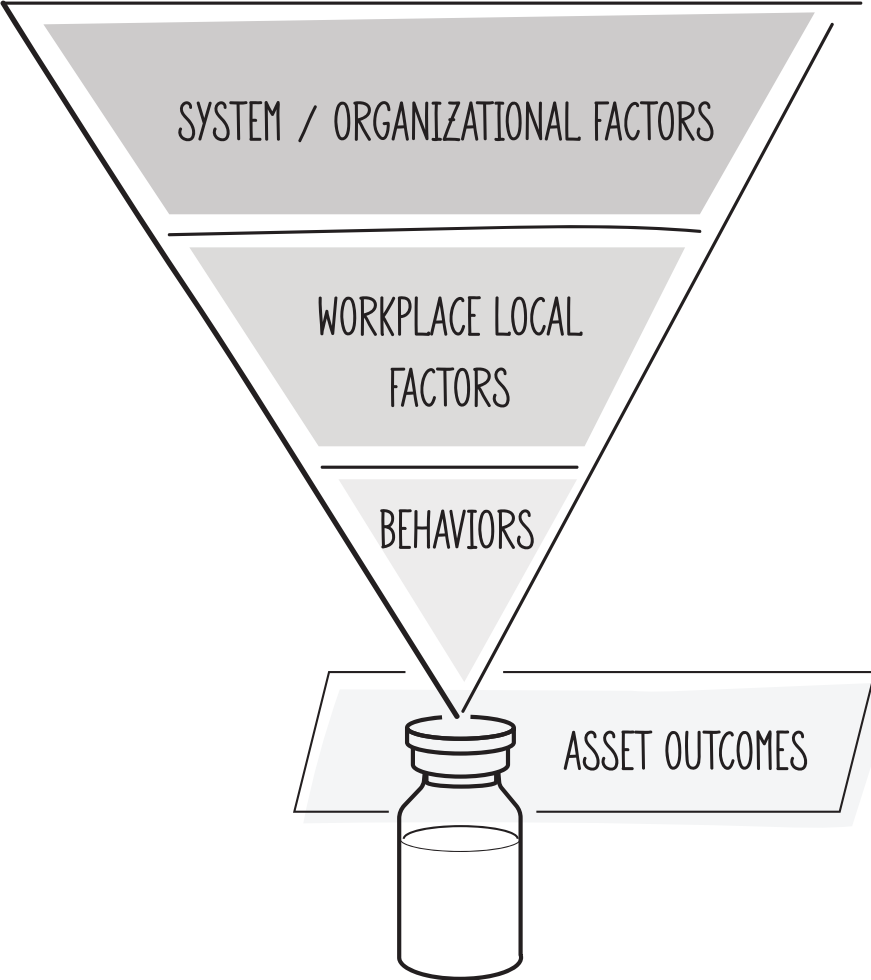
SHIFT TALK TO SYSTEM & CONTROLS



THE LOVE AFFAIR WITH SIMPLISTIC IDEAS



CHANGE CONVERSATIONS TO INCLUDE COMPLEXITY



BUILD NEW HELPFUL SHARED BASIC ASSUMPTIONS

‘Human Error’ is not a cause

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

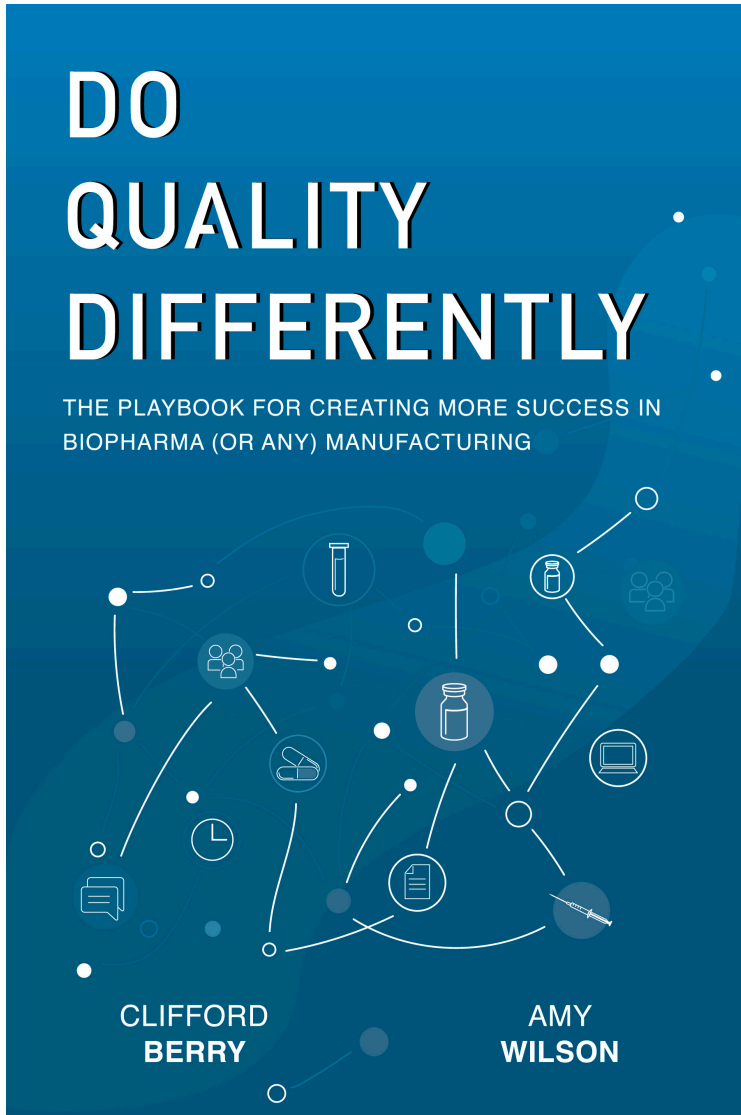
Going to Gemba includes watching work to learn from the experts

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

THANK YOU



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