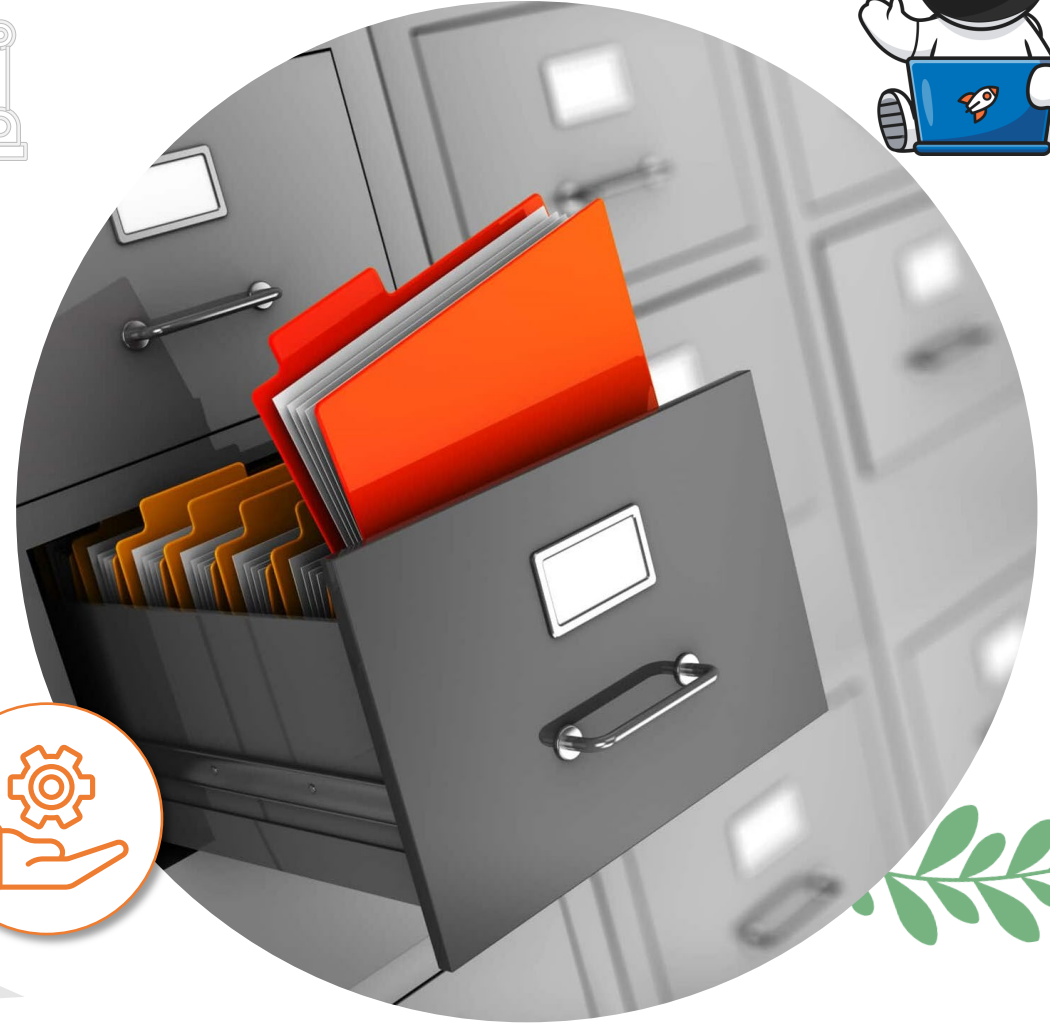
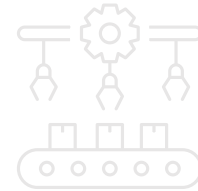
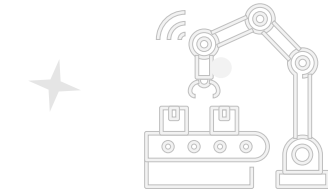


You've Completed Your Root Cause Analysis, Now What?

Presented by | Sundeep Agarwal



Speaker Introduction

SUNDEEP AGARWAL

Medical Device Expert & Consultant



An expert in medical and IVD devices & life sciences, Mr. Sundeep Agarwal is a speaker, trainer and consultant in the field of Quality Assurance, Regulatory Affairs, QMS, GMP, Software Validation, SaMD, Artificial Intelligence, Combination Devices, GCP, Design & Development, Risk Management and Industrial Manufacturing. He is a lead auditor for medical devices and has expertise in ISO 13485, EU MDR, IVDR, CE Certification, CER, PMS, USFDA, 510(K), ISO 14971, MDSAP.



Take Away:



POLL 1

After an effective RCA, I am aware of what to do with the data and information resulted from RCA.

A. Yes

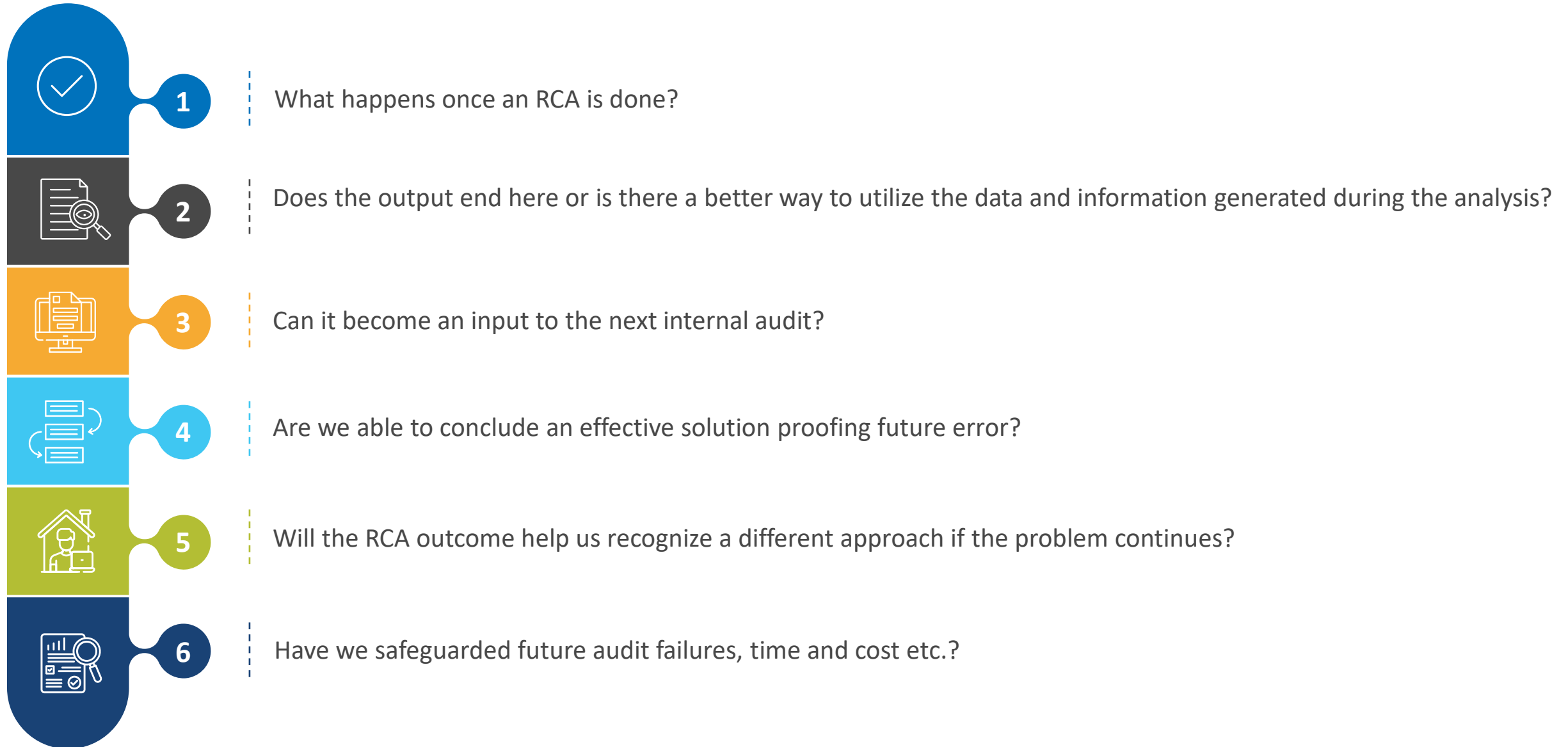
B. No



Let's begin by asking a few questions

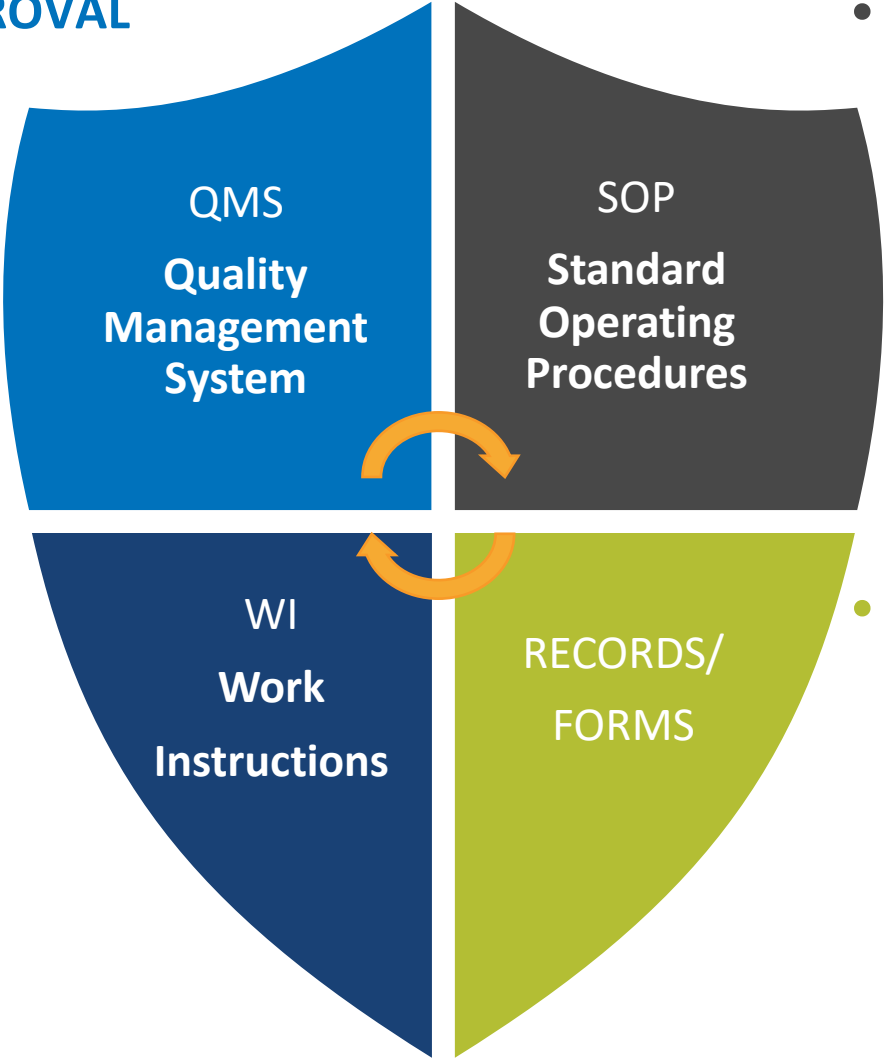


Let's Begin by Asking a Few Questions



Updating Process or System

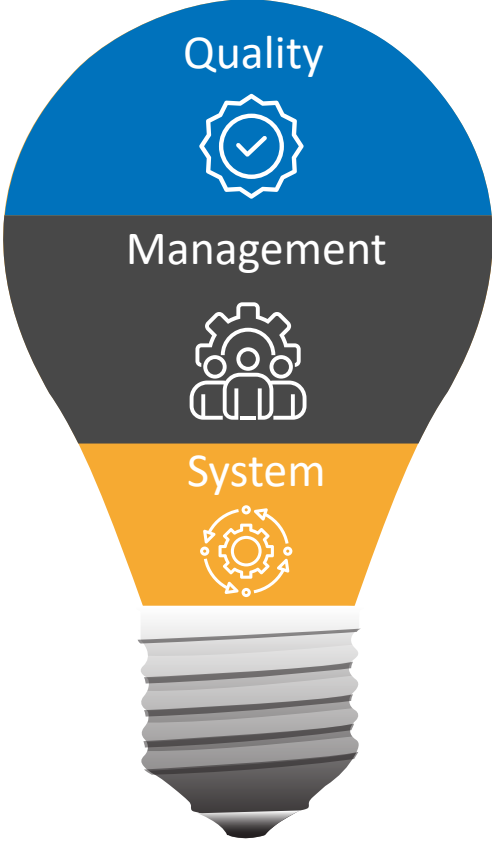
- REVIEW & APPROVAL



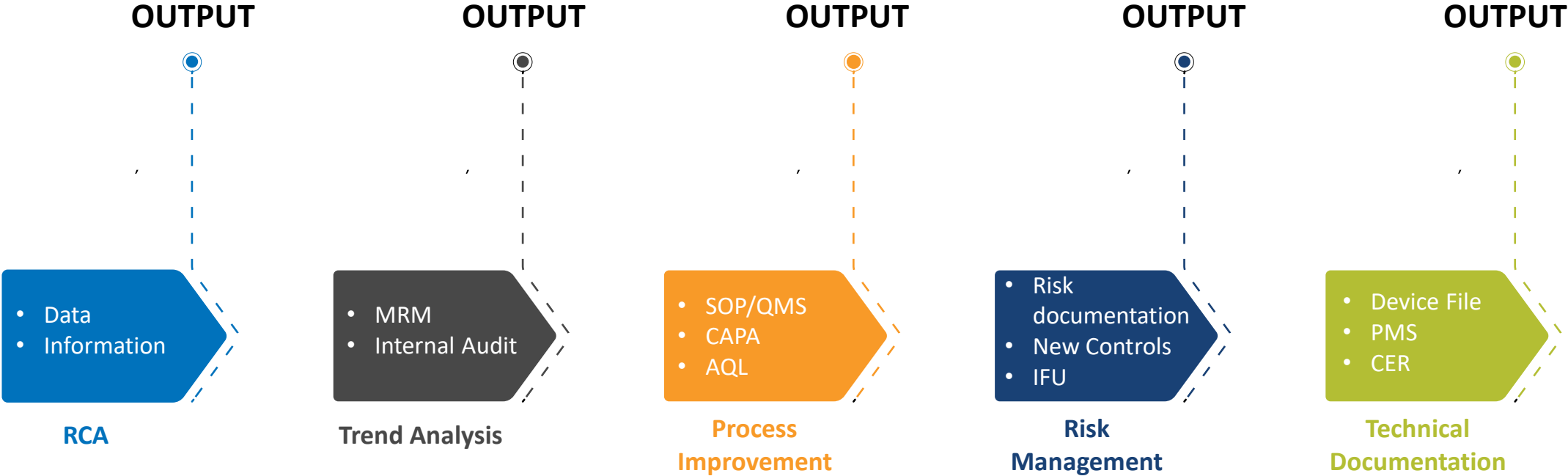
- CHANGE REQUEST

- TRAINING

- DHR/BATCH RECORDS



Correlation Between Processes




MRM and Internal Audit



INTERNAL AUDIT:

Are we ensuring the information being utilized during internal Audit?

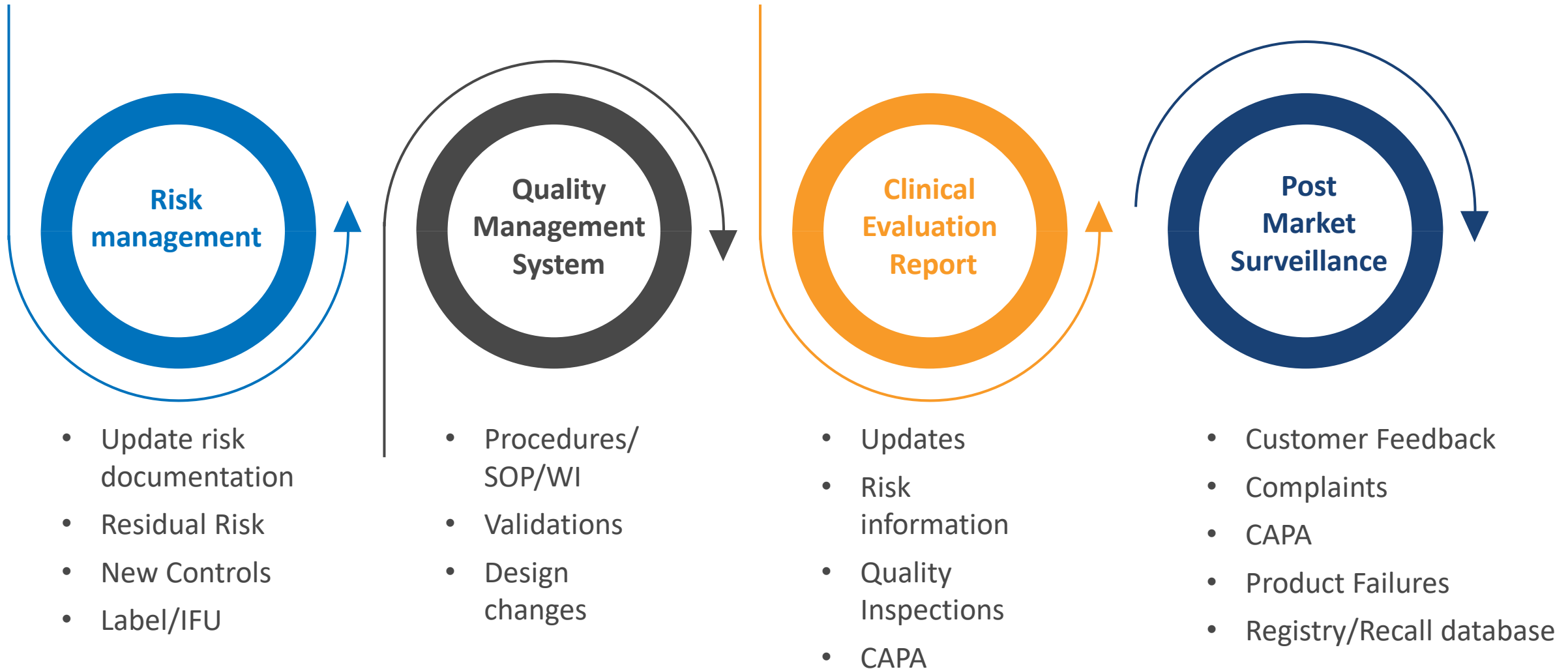


MANAGEMENT REVIEW MEETING:

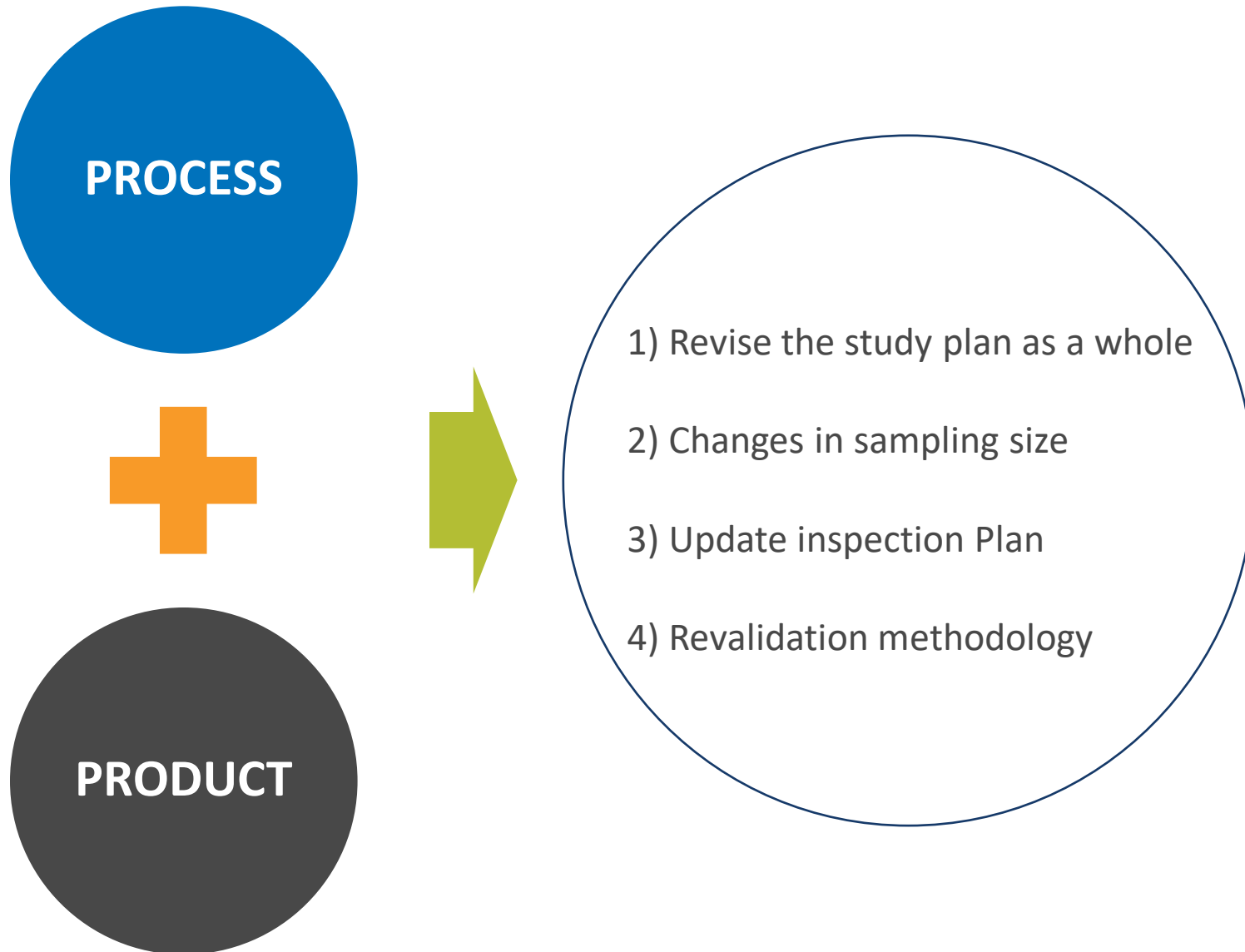
Are we ensuring the information being discussed in a management review meeting



Impacting Technical Documentation



Revalidation



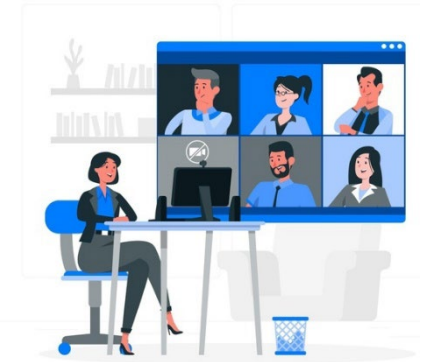
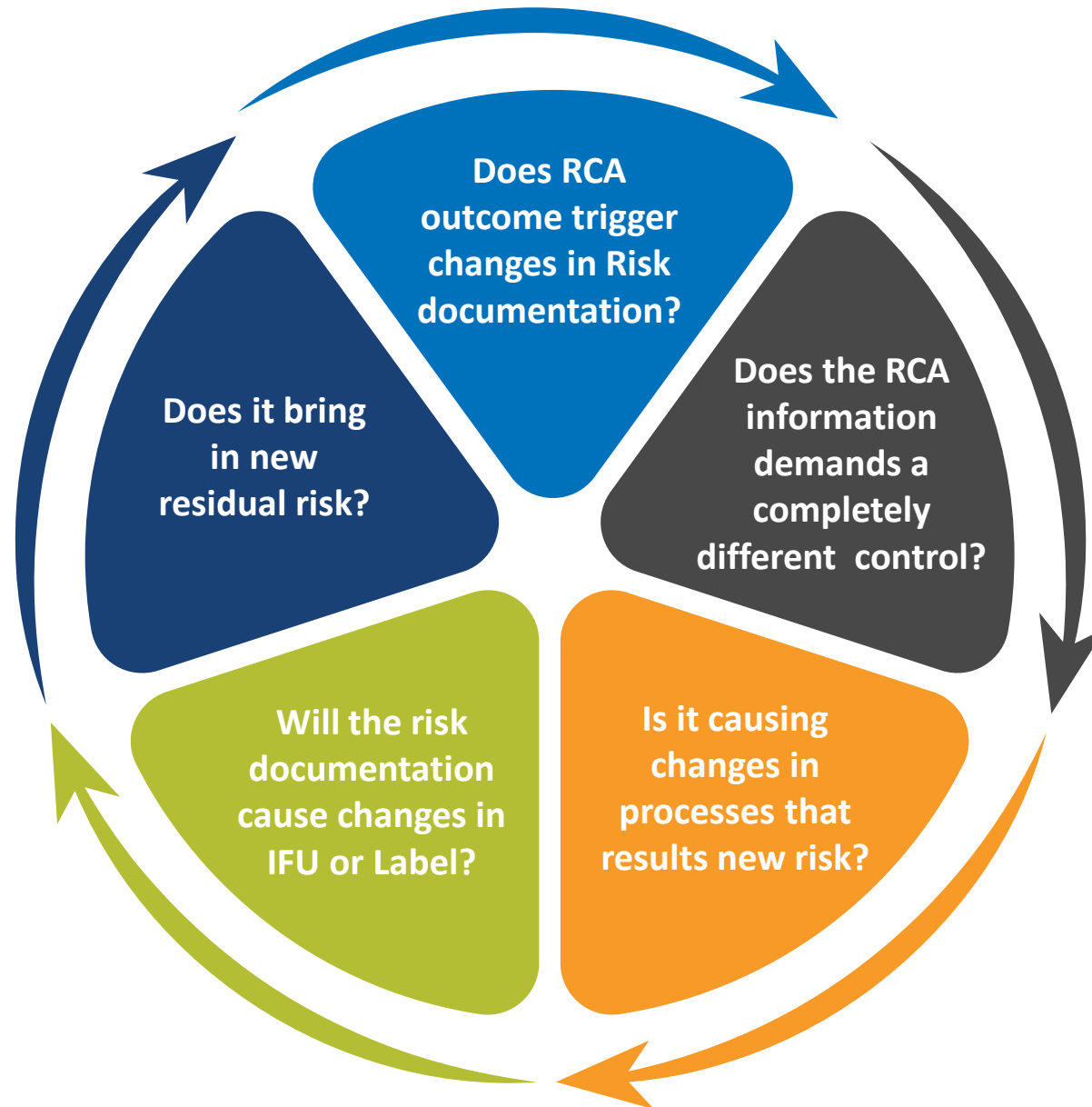
POLL 2

I understand digitalization and EQMS will automate our processes and reduce inefficiencies?

A. Yes

B. No

Risk Profile and Management



Post Market Surveillance and Clinical Evaluation



RCA outcomes will suggest update in Risk Management, Quality Inspections, CAPA, IFU, Label



PMS results new data that includes safety reports, results from published literature, registries, PMCF studies, and other data about device usage

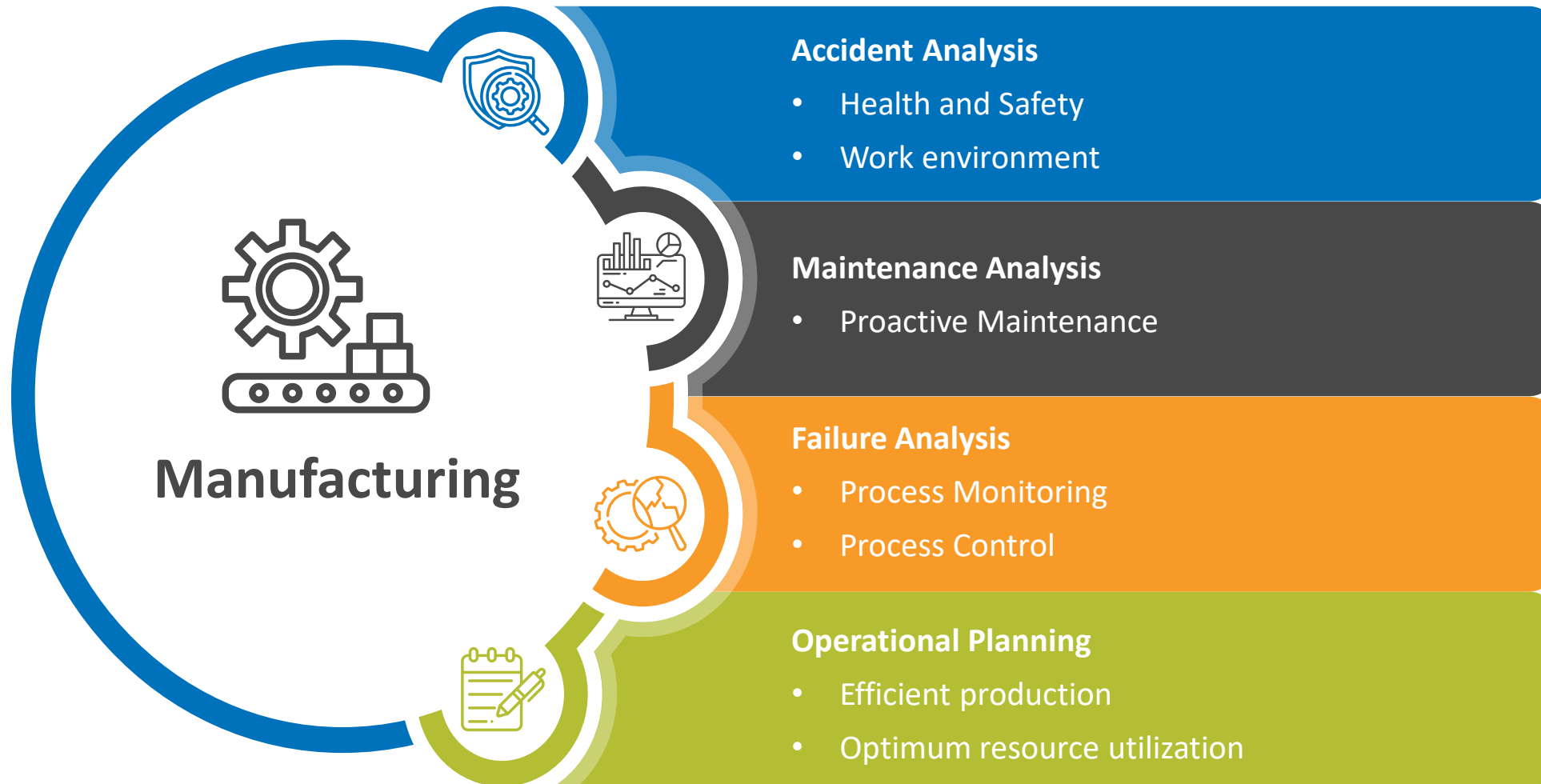


Clinical evaluation requires PMS data to evaluate safety and performance

Predictive Preventative Actions



On the Manufacturing Floor



Automation Towards Solution

Data > Learning >

Updating > Automation >

Predictive Actions >

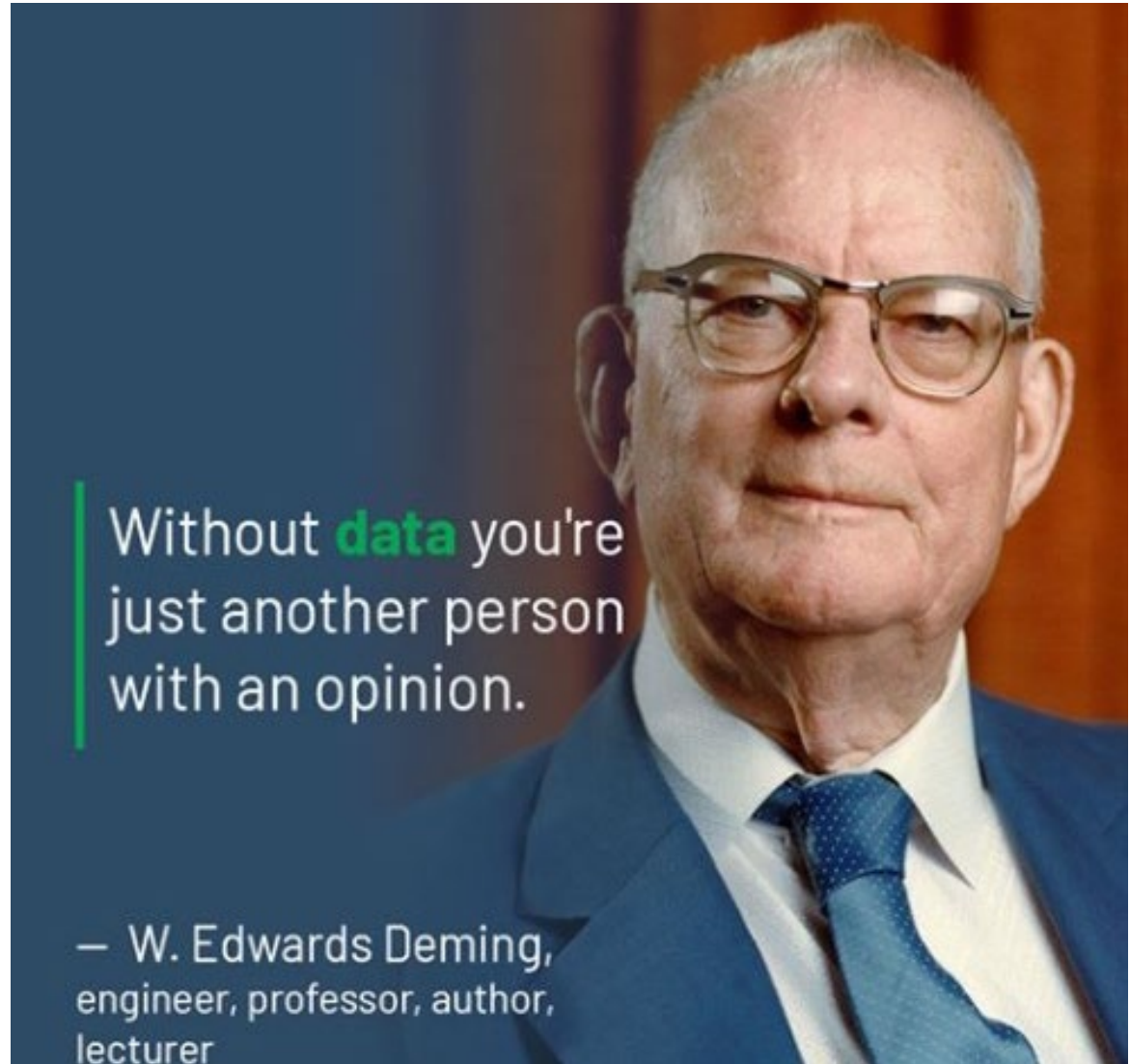
Failure Prevention >

Save cost > Save Time

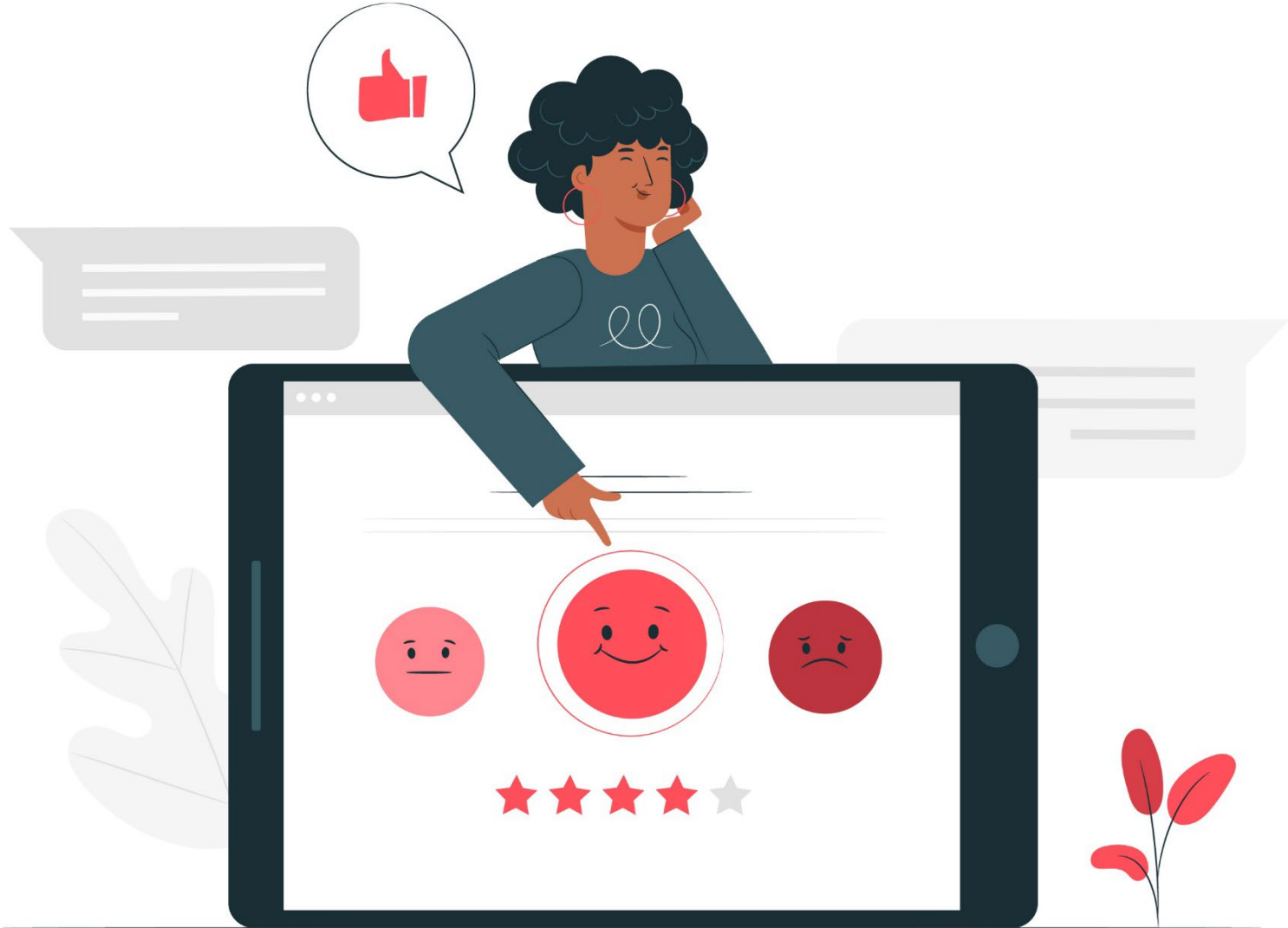


Winding up!

“Data driven decision tends towards a solution, else its merely just another discussion”



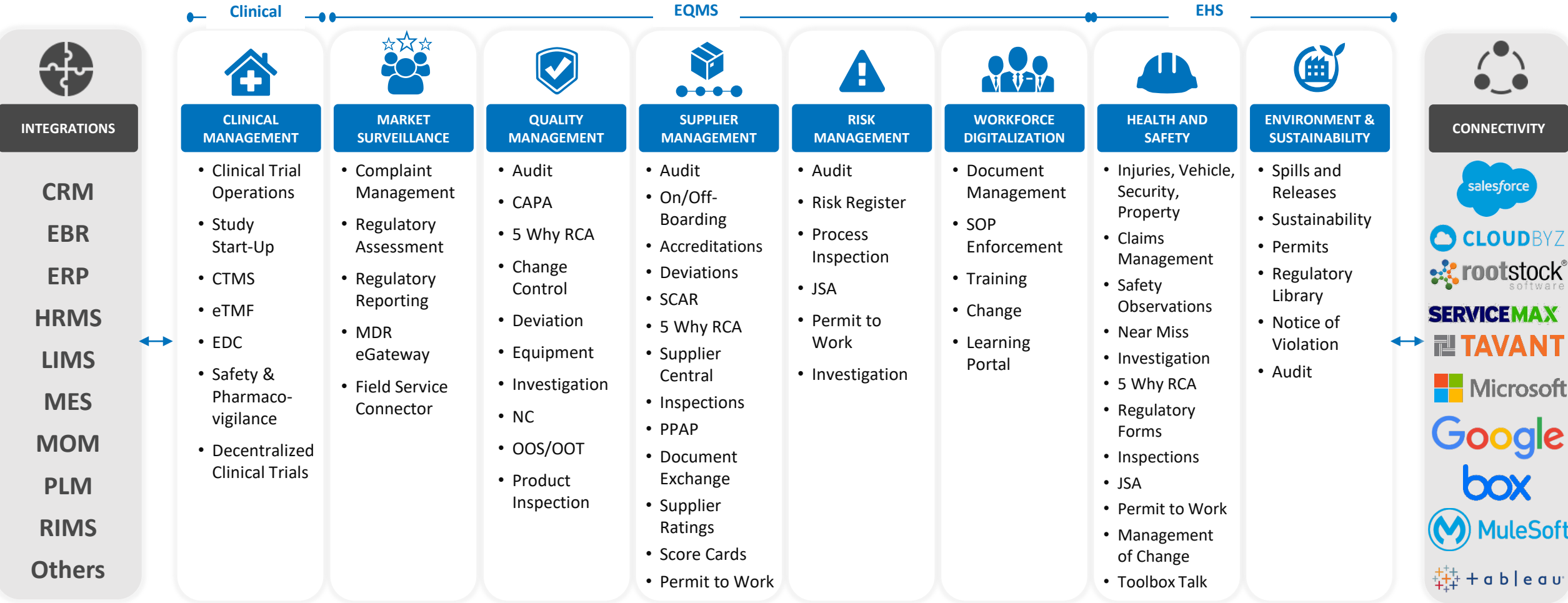
Feedback



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