

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.

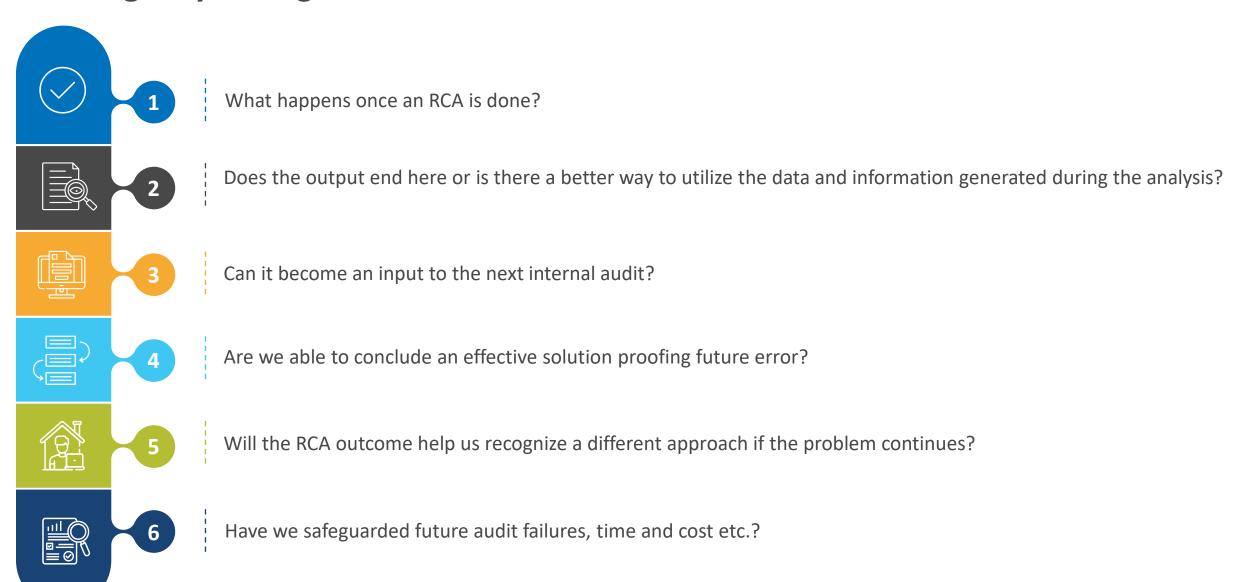
- A. Yes
- B. No



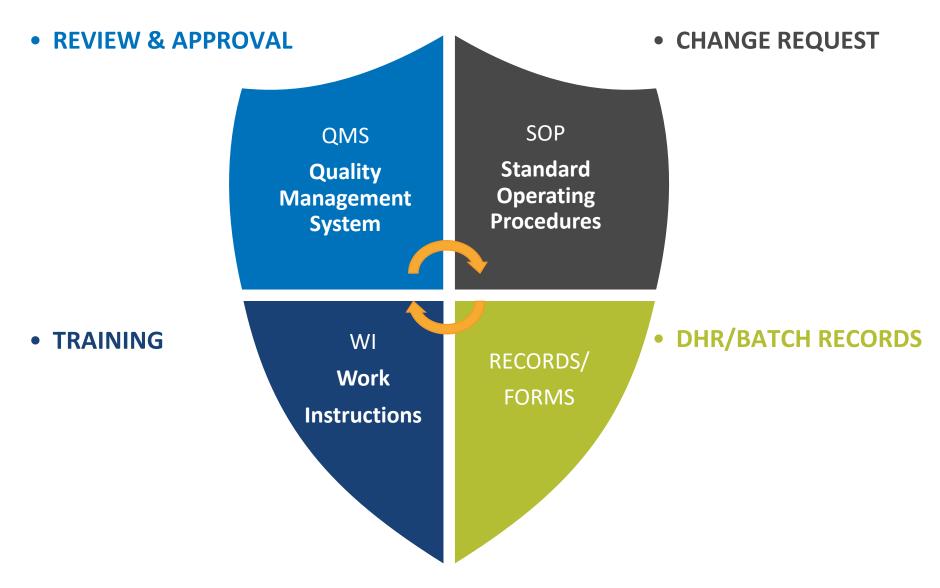
Let's begin by asking a few questions

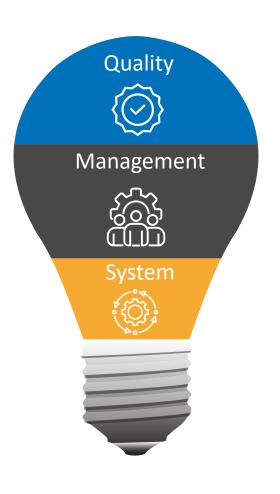


Let's Begin by Asking a Few Questions



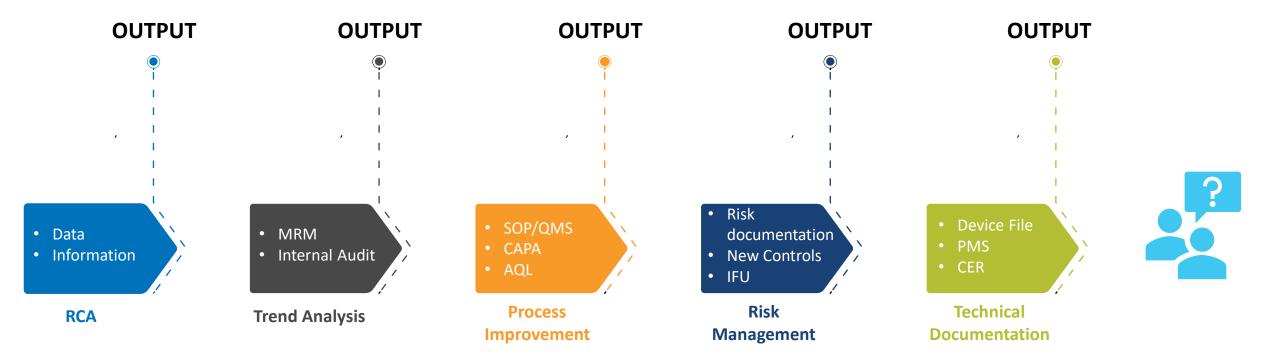
Updating Process or System







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



- Update risk documentation
- Residual Risk
- New Controls
- Label/IFU



- Procedures/ SOP/WI
- Validations
- Design changes





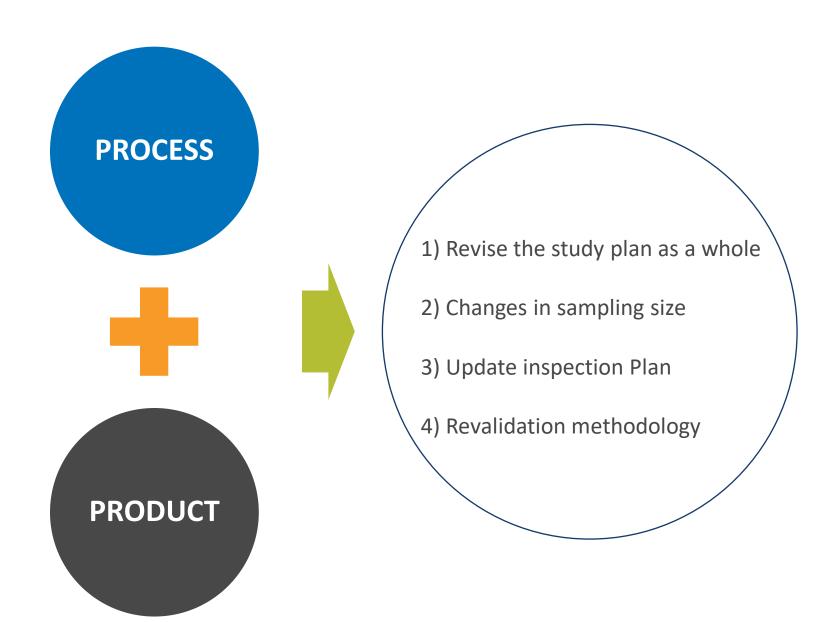
- Risk information
- Quality Inspections
- CAPA



- Customer Feedback
- Complaints
- CAPA
- Product Failures
- Registry/Recall database



Revalidation



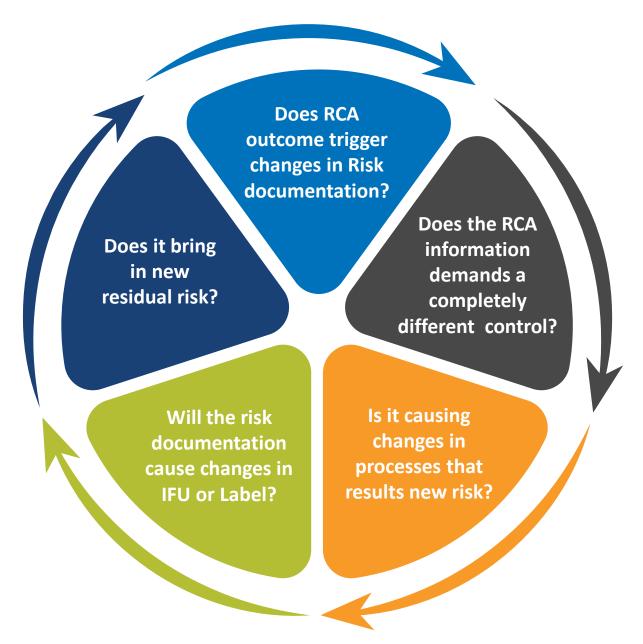


POLL 2

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

- A. Yes
- B. No

Risk Profile and Management





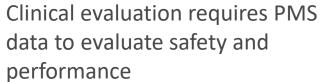


Post Market Surveillance and Clinical Evaluation



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





Predictive Preventative Actions



Outputs from RCA



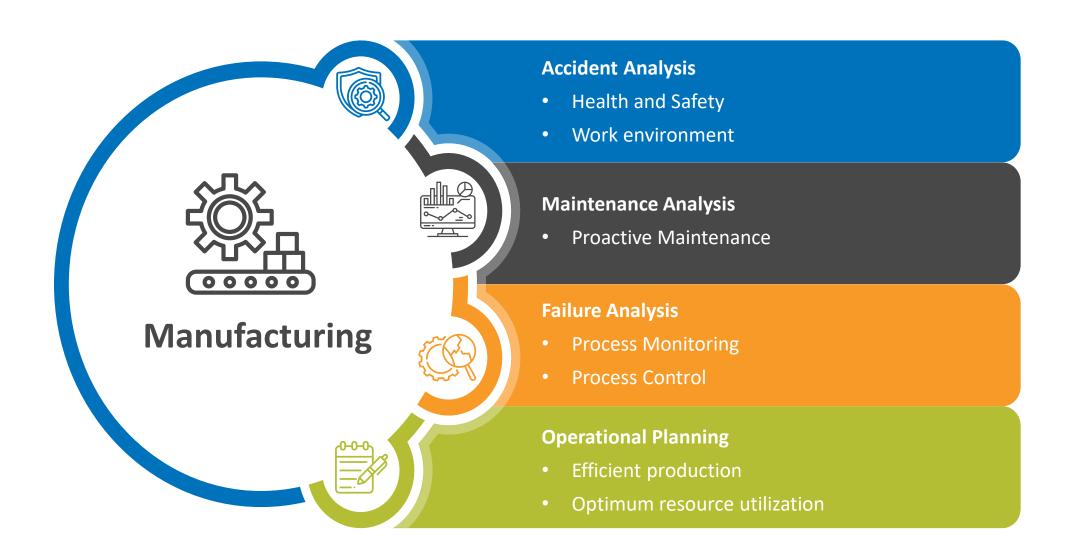
Predict the most accurate actions required



Supports planning & maintenance



On the Manufacturing Floor





Automation Towards Solution

Data > Learning >

Updating > Automation >

Predictive Actions >

Failure Prevention >

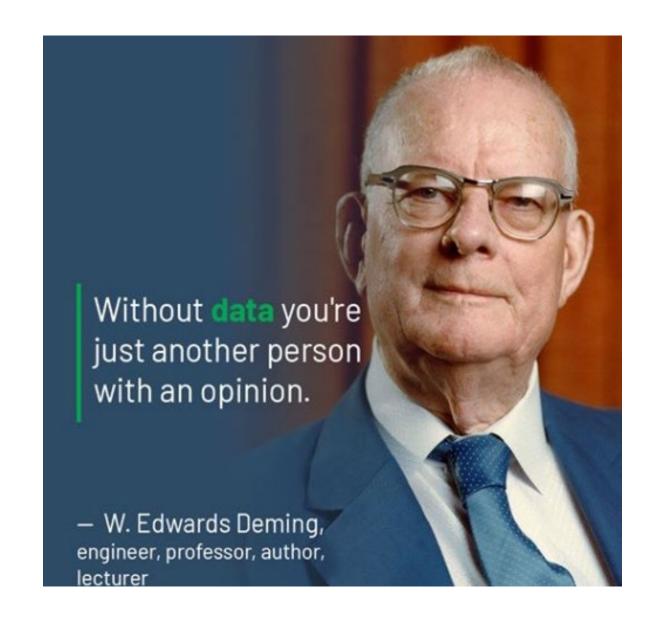
Save cost > Save Time





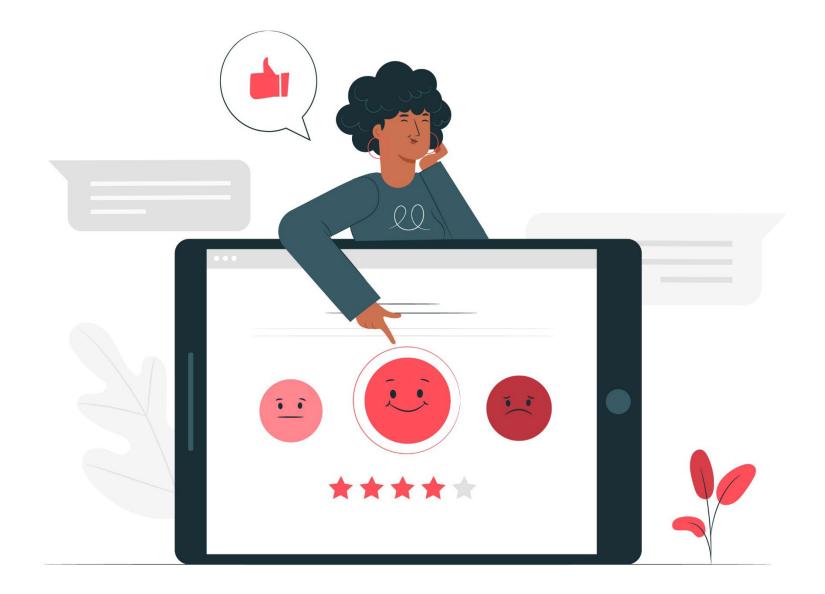
Winding up!

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





Feedback





About ComplianceQuest



Al-powered cloud platform for Clinical, Quality and Safety management solutions

INTEGRATIONS

CRM

EBR

ERP

HRMS

LIMS

MES

MOM

PLM

RIMS

Others



Clinical

CLINICAL MANAGEMENT

- · Clinical Trial Operations
- Study Start-Up
- CTMS
- eTMF
- EDC
- Safety & Pharmacovigilance
- Decentralized **Clinical Trials**



MARKET SURVEILLANCE

- Complaint Management
- Regulatory Assessment
- Regulatory Reporting
- MDR eGateway
- Field Service Connector



QUALITY MANAGEMENT

- Audit CAPA
- 5 Why RCA
- Change Control
- Deviation
- Equipment
- Investigation
- NC
- OOS/OOT
- Product Inspection



EQMS

SUPPLIER MANAGEMENT

- Audit
- On/Off-**Boarding**
- Accreditations
- Deviations
- SCAR
- 5 Why RCA
- Supplier Central
- Inspections
- PPAP
- Document Exchange
- Supplier Ratings
- Score Cards
- Permit to Work

RISK MANAGEMENT

- Audit
- Risk Register
- Process Inspection
- JSA
- · Permit to Work
- Investigation



WORKFORCE **DIGITALIZATION**

- Document Management
- SOP Enforcement
- Training
- Change
- Learning Portal



EHS

HEALTH AND SAFETY

- · Injuries, Vehicle, Security, Property
- Claims Management
- Safety Observations
- Near Miss
- Investigation
- 5 Why RCA
- Regulatory **Forms**
- Inspections
- JSA
- Permit to Work
- Management of Change
- Toolbox Talk



ENVIRONMENT & SUSTAINABILITY

- Spills and Releases
- Sustainability
- Permits
- Regulatory Library
- Notice of Violation
- Audit























MANAGEMENT REVIEW





Dashboards, Reports



Collaboration





Communication



Mobile



Validation



Intelligence

PLATFORM POWERED BY









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