

A vibrant, futuristic cityscape at night, illuminated by blue and orange lights. In the center, a massive, metallic robot with glowing red eyes and a chest stands prominently. The sky is filled with several flying saucers emitting beams of light. In the foreground, a chaotic street scene unfolds with people running, falling, and cars in motion, suggesting a state of panic or conflict. The overall atmosphere is one of high-tech dystopia.

AI is Coming!

AI Demystified: How to Effectively Use AI to Improve Your Quality Management System

Presenter: Mark Cooksey
ISO 13485 Quality Leader, Norton Healthcare
Mcooksey6@gmail.com



Leveraging AI in HTM Quality Management Systems

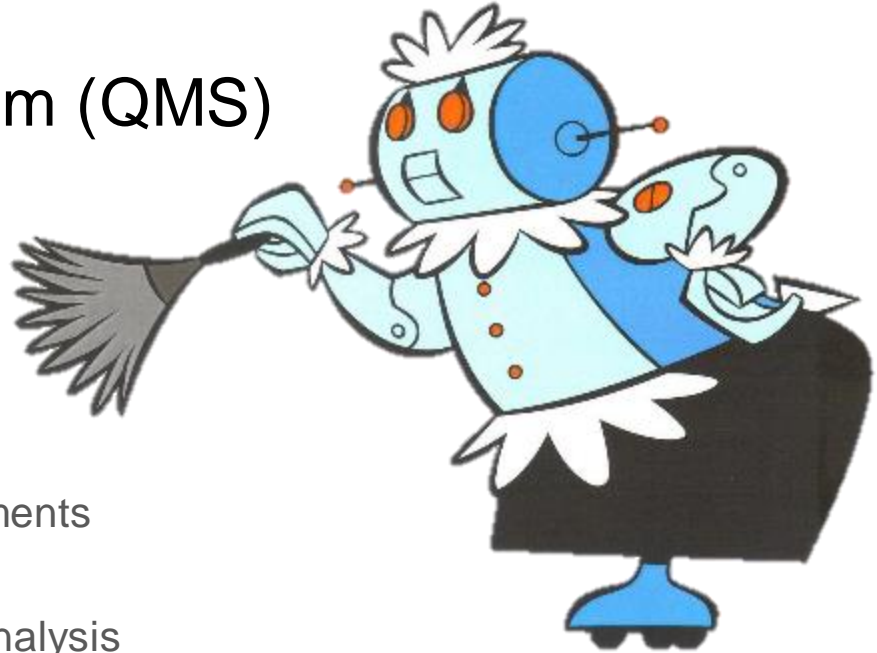
- AI Is here!
- What it can do and Why it's needed
- How to use AI effectively
- Examples of AI Assistance
 - Resolving ISO 13485 Audit Non-Conformities
 - Performing Risk Assessment
 - QMS Documentation Simplification
 - Amazing Presentation Automation
 - Just for Fun

Have you used AI?



AI can improve your Quality Management System (QMS)

- **Creative Collaborator**
 - Brainstorm Ideas
 - Refine details
- **Proofreader**
 - Improved communication
 - Simplify & consolidate documents
- **Problem Solver and Coder**
 - Perform statistical and risk analysis
 - Create VB and HTML Code:
 - Generate Powerpoint presentations
 - Create Excel process map
 - Websites



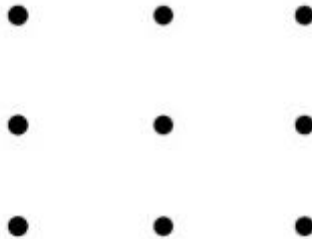


VS.



Can you connect all the dots with only 4 continuous straight lines?

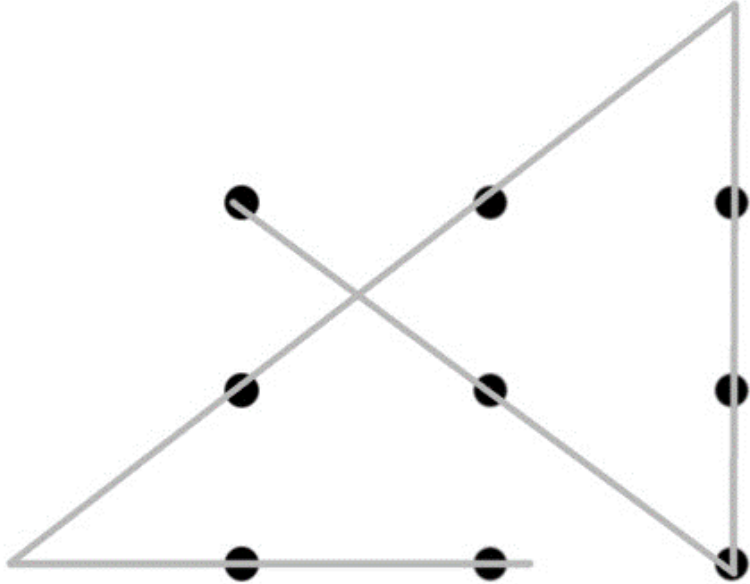
- (You) Search commercial websites
- (You) Read the documentation
- (You) See if it solves your problem
- (You) Keep searching other sites



- (AI) Generates a solution
- (AI) References websites
- (AI) Checks to see if it works
- (AI) Revises the solution as needed

Hint: the lines can go **outside the box**

Connect all the dots by drawing
4 straight continuous lines.



AI can help
you think
**outside the
box** for *new*
solutions

Norton's Challenge : Two ISO Certifications

ISO 9001 CERTIFIED



LEGACY APPLICATIONS
SUPPLY CHAIN
CORPORATE POLICIES
SOPs

CLAUSE 4.0
QUALITY
MANUAL
DOCUMENT
CONTROL



CLAUSE 5.0
MANAGEMENT
RESPONSIBILITY



CLAUSE 6.0
HUMAN
RESOURCES



CLAUSE 7.0
PRODUCT / SERVICE
DEVELOPMENT



CLAUSE 8.0
QUALITY
IMPROVEMENT



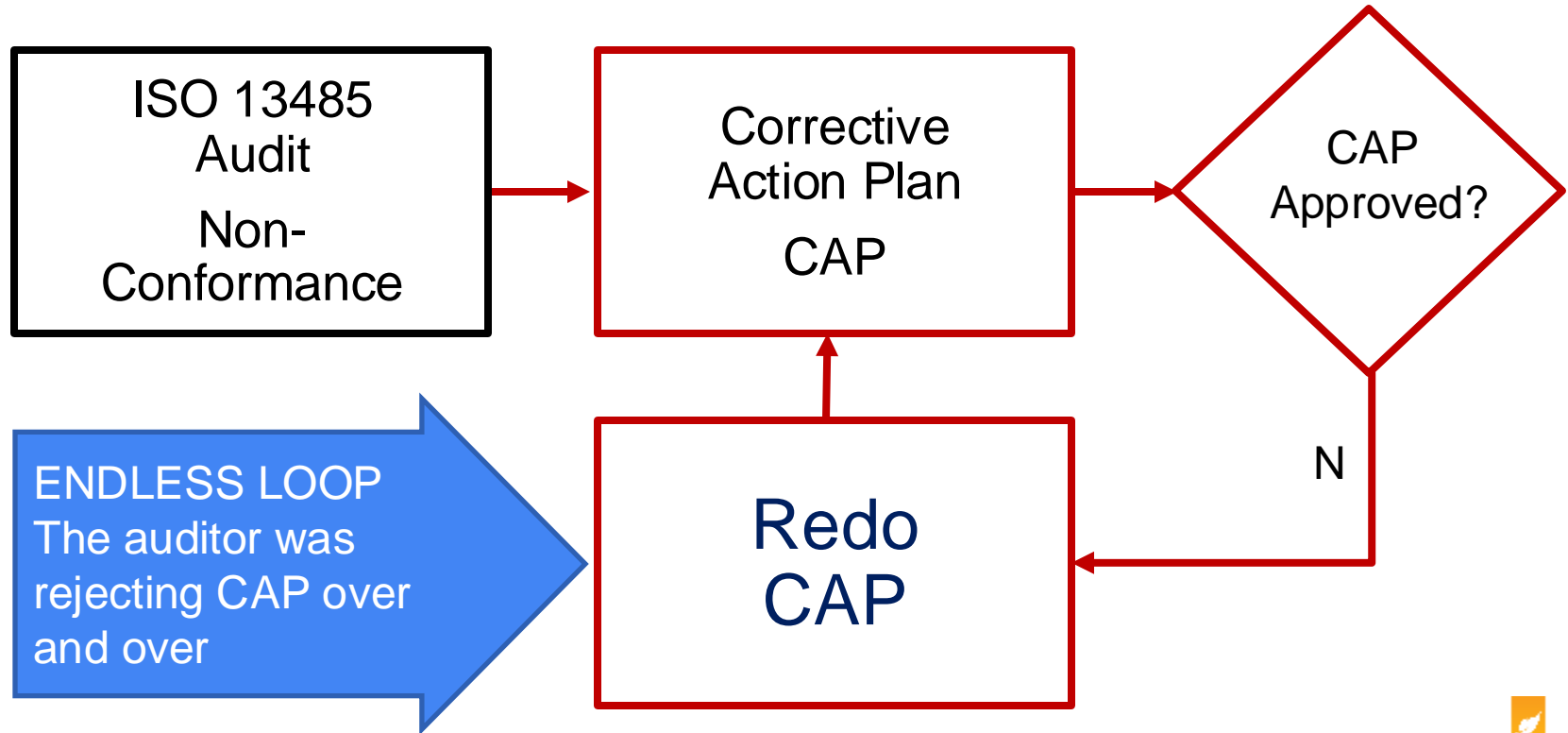
ISO 13485 CERTIFIED



Challenge #1:
Close out ISO 13485 audit
non-conformances



The Problem: Auditor Endless Loop



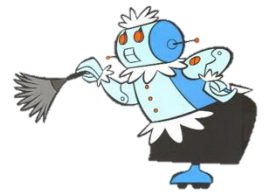
Reasons for the Auditor CAP Rejections

Auditor: “Clinical Engineering has failed to:”

- **Complete** the CAP form correctly.
- **Demonstrate** understanding of the ISO 13485 standard
- **Identify** the root causes of the Non Conformance (NC)
- **Define** Short and Long Term Solutions
- **Explain** how the solutions address the root causes



Help! Effective AI prompts



- **Provide context:** Give background information or perspective.
- **Be specific:** Clearly define what you need AI to do.
- **Set expectations:** Ensure the AI can achieve the desired outcome.
- **Evaluate Output:** Compare AI results to your expectations and experience
- **Dialogue:** Provide feedback to AI to adjust accordingly.

Provide Context



“You are the auditor. See the attached non-conformance for context.”



Response:

AI summarizes and confirms its understanding based on its own research and your attached information.

AI asks: what do you want to do?

Provide Context



you are an ISO 13485 auditor who recently conducted a recertification audit at Norton Healthcare, an in-house servicer of medical equipment. YOU issued 6 minor non-conformances and 1 major citing items from a previous audit were not effectively resolved because some issues remain. You have rejected the response to RA-07. here is your email exchange: Hello Mark,

Thank you for your prompt response. Please do amend the finding detail form for this non-conformity and address the major finding. Once I receive the updated form, I will review.



Set expectations



“Let’s make sure the CAP meets ISO 13485 requirements.”



Response:

- AI completes an ISO compliant CAP)
- Generates a letter to the auditor (Iris)

Subject: Revised Corrective Action Plan for Non-Conformity RA 07

Dear Iris,

I hope this message finds you well. Following our recent correspondence regarding Corrective Action Plan RA-07, I have revised the CAPA documentation to address the major finding identified during the audit. Thank you for your guidance and patience throughout this process.

Here is a summary of the revised Corrective Action Plan:

1. **Root Cause Analysis:**

- The root cause of the non-conformity is identified as inadequately protected fields in the CAPA form, leading to accidental deletion of crucial information. This oversight persisted due to the continued use of the modified form without detection.

2. **Correction Actions:**

- **Review Controlled Form:** We will review the current controlled revision of "Form 8.5-2-1 Corrective and Preventive Action Record Rev 2" to ensure it includes the necessary language regarding the assessment of impact on the performance of medical devices and regulatory requirements.
- **Immediate Form Restoration:** Restore the original verbiage of the CAPA form and investigate methods to protect critical fields to prevent accidental deletion or modification of essential information.

3. **Corrective Actions:**

- Create a CAPA for Finding #2024-RA-07.
- Form Validation/Protection Mechanism: Implement a protection/validation mechanism within the CAPA form to ensure the completeness and integrity of entered data.

Evaluate Output



“This looks pretty good. I took the CAP and made a few Changes for clarity. How does this look?”

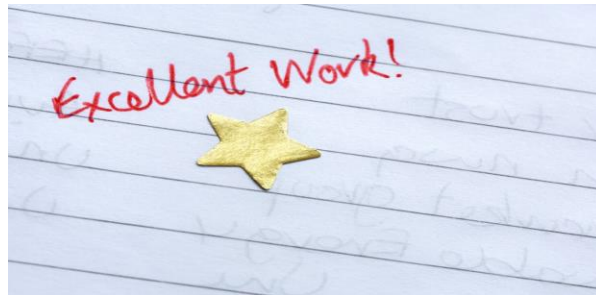


Response:

AI evaluates my work and offers suggestions for clarity.

AI Strengths – what it does well

- Can decipher meaning
- Has access to expanse of information
- Take an outline and create a book
- Take a book and create an outline



Challenge #2: Performing Risk Assessment



Risky Business

- After COVID restrictions, patient census skyrocketed.
- Clinical Engineering was denied access to beds for PM.
- Bed PM completions metrics tanked.
- AI used to evaluate the **risks of changing from OEM to AEM PM.**

What are the **risks** of changing PM?



create an RPN score for each item of the PM of the Versacare bed (RPN = risk priority, each item is rated 1 to 5 for the following risks: severity (5 is highest), detection (5 is highest risk meaning difficult to detect the failure, frequency (5 is for high occurrence failure)

Cancel

Send



Creating an RPN (Risk Priority Number) for each item in the Preventive Maintenance (PM) of the Versacare hospital bed involves assigning ratings for three factors: Severity, Detection, and Frequency, with each factor rated from 1 to 5. The RPN is calculated by multiplying these three ratings (RPN = Severity x Detection x Frequency). A higher RPN indicates a higher priority for addressing that specific item in the PM plan. Below, I'll provide a hypothetical example of how you might assign ratings to various maintenance items:

Item 1: Electrical Components

- Severity (5): Electrical failures can lead to patient safety issues.
- Detection (3): Electrical issues are relatively easier to detect through routine inspections.
- Frequency (4): Electrical components may have moderate failure rates due to frequent use.

RPN for Item 1 = 5 (Severity) x 3 (Detection) x 4 (Frequency) = 60



- A failure of the side rail latching mechanisms can lead to
 - unintended patient falls
 - entrapment between the side rails,
- Severity (5):

Side rail Latching Mechanisms

- Caster braking system failures make it difficult to secure the bed causing:
 - impact patient safety and mobility.
 - unintentional bed movement
 - patient falls
 - Difficulty securing the bed in a fixed position.
- Severity (4):

Caster Braking Systems

- Electrical System Component failures can lead to
 - power outages
 - malfunctioning bed adjustments
 - unexpected movements
 - danger to patients or caregivers.
- Severity (5):

Electrical System Components

Versacare Bed Sub Systems

Item	Severity	Detection	Frequency	RPN
Side rail Latching Mechanisms	5	1	3	15
Caster Braking Systems	4	1	3	12
Electrical System Components	5	1	3	15
Electrical Power Cords	4	1	2	8
Control Return to Neutral	3	1	3	9
Controls/Cabling Entanglement	4	1	2	8
Lockout Controls	3	1	2	6
Sleep Surface	4	1	3	12
Head Angle Display (if applicable)	3	1	2	6
VersaCare Bed Main Battery	4	1	3	12



“Help me calculate the RPN based on Severity, Detection, and Frequency of Malfunction.”

AI evaluated RPN
Bed PM changed to AEM
Severity may be **high**
Detection of failure is **easy**
Frequency of failure is **low**

Bed PM changed after AI Risk Assessment

Challenge #3: AI Simplifies QMS Documentation



CE Legacy

- CE Policies
- SOPs
- HTM Practices
- Leadership Training
- The Joint Commission
- Vendor Status Quo
- Disconnected Documents
- Performance Tracking
- CMMS

70 Legacy
CE SOPs

350



CE SOPs

Hundreds of NHC Policies and Procedures

>1000



NHC ISO 9001

**NHC
QMS**

New ISO 13485

- Quality System Procedures
- QSPs
- Lean 6 Sigma Quality Tools
- Staff Training
- DNV ISO Audits
- Active Vendor Assessment
- Integrated ISO Documentation
- QMS Review
- Audit Records

50 ISO 13485
QSPs, Forms

200



CE ISO 13485



You

i want to simplify our quality manual. I'm sendin you 2 - 3 pieces of it.

here's the 1st. Quality Manual

Manual #: QM-01

Revision #: 2

Approvals:

Scott Skinner: _____ Date:

System Director, Clinical Engineering

Mark Cooksey: _____ Date:

Management Representative



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can you put all this together?



NHC Clinical Engineering Quality Management System (QMS) Documentation Overview

1. QMS Documentation

NHC Clinical Engineering's QMS documentation comprises:

- **Quality Manual (QM)** including Quality Policy and Objectives;
- Documented procedures per ISO 13485 requirements;
- Department-required documents for effective process control;
- Quality records as per ISO 13485;
- Documentation specified by national or regional regulations.

2. Extent of Documentation

The extent of QMS documentation depends on:

- Practicality and applicability;
- Process complexity and interaction;
- Personnel competence



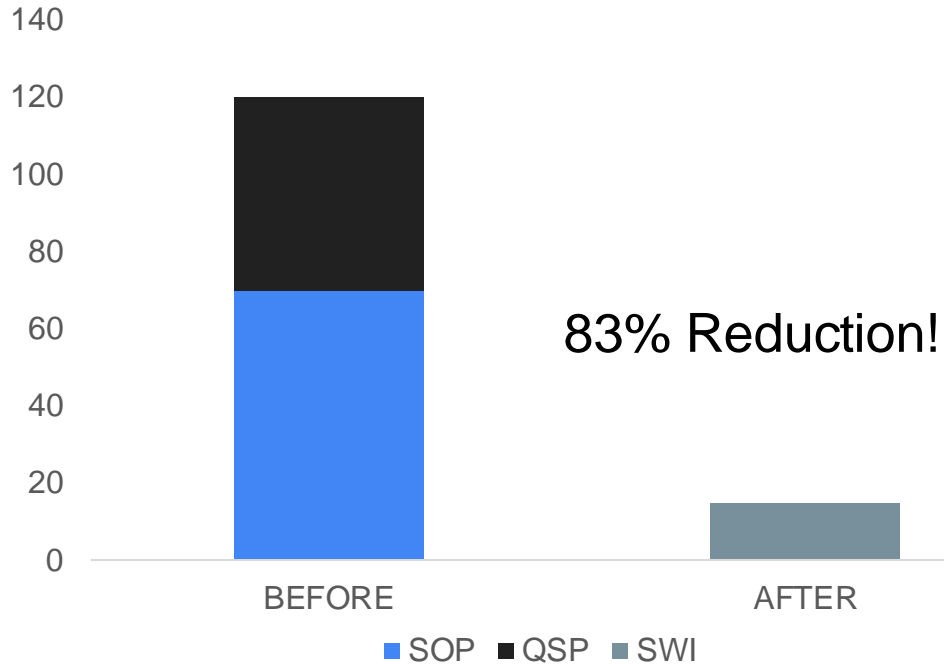
Message ChatGPT



ChatGPT can make mistakes. Check important info.



AI Simplifies CE QMS Documentation



Integrated ISO 13485 with ISO 9001

AI Generates MRI Repair Policy



lets' search for some complex repair verbiage for MRI and then give a simple step by step instruction for PM.



Complex Repair Verbiage for MRI

Complex Document: MRI repair documentation often includes highly technical language and detailed procedures. For example:

- **Pulse Sequence Parameters:** "Appropriate annotation should include the type and times of the pulse sequence, the number of signals averaged or added (NSA), the size of the reconstructed region, the size of the acquisition matrix in each direction, and the slice thickness."
- **Magnetization Coherence:** "Loss of phase coherence of the spins results in a decrease in the transverse magnetization and hence a decrease in the MR signal. In the quantum mechanical description of magnetic resonance, coherence refers to a transition between different states of the spin system (see multiple quantum coherence)." ¹

AI Generates MRI Repair **Procedure** from Policy



Simplified Step-by-Step Instructions for MRI Preventive Maintenance (PM)

1. Preparation:

- **Gather Tools and Materials:** Ensure you have all necessary tools, including cleaning supplies, calibration devices, and safety equipment.
- **Review Safety Protocols:** Familiarize yourself with the MRI safety zones and ensure all personnel are trained and aware of the safety procedures.

2. Initial Inspection:

- **Visual Check:** Inspect the MRI machine for any visible signs of wear or damage.
- **Environment Check:** Ensure the MRI room is clean and free of any metallic objects that could interfere with the magnetic field.

AI Generates MRI Repair **Checklist** from Procedure



Step	Action	Completed
Preparation	Gather Tools and Materials	<input type="checkbox"/>
	Review Safety Protocols	<input type="checkbox"/>
Initial Inspection	Visual Check	<input type="checkbox"/>
	Environment Check	<input type="checkbox"/>
System Calibration	Magnet Calibration	<input type="checkbox"/>
	RF Coil Check	<input type="checkbox"/>
Software Updates	Check for Updates	<input type="checkbox"/>
	Run Diagnostics	<input type="checkbox"/>
Cleaning and Maintenance	Clean the Bore	<input type="checkbox"/>
	Inspect and Clean Filters	<input type="checkbox"/>
Functional Testing	Run Test Scans	<input type="checkbox"/>
	Review Results	<input type="checkbox"/>
Documentation	Record Maintenance Activities	<input type="checkbox"/>
	Report Issues	<input type="checkbox"/>

Challenge 4: Automate Powerpoint Creation from AI Outline



MDEXPO
New England • October 8-10, 2024



Help me generate VB code to automatically create a PowerPoint Presentation from the Outline you created. Here is the outline. Slide

1: Title Slide

Title: AI Demystified: How to Effectively Use AI to Develop or Improve Your Quality Management System

Speaker: Mark Cooksey, DME Quality Engineer, Norton Healthcare

Slide 2: Introduction

Introduction of Mark Cooksey

Objective of the presentation

Importance of AI in QMS

Slide 3: Overview of AI

Definition of Artificial Intelligence (AI)

Types of AI: Narrow AI, General AI

Examples of AI in everyday life

Slide 4: Understanding QMS and ISO 13485

Definition of Quality Management Systems (QMS)

Key components of ISO 13485

Importance of ISO 13485 in HTM



Here's a Visual Basic for Applications (VBA) code that will create a PowerPoint presentation based on the outline you provided:

vba

Copy code

```
Sub CreateAIPresentation()  
    Dim pptApp As Object  
    Dim pptPres As Object  
    Dim slide As Object  
  
    ' Create a new PowerPoint application  
    Set pptApp = CreateObject("PowerPoint.Application")  
    pptApp.Visible = True  
  
    ' Add a new presentation  
    Set pptPres = pptApp.Presentations.Add  
  
    ' Slide 1: Title Slide  
    Set slide = pptPres.Slides.Add(1, 1) ' ppLayoutTitle = 1  
    slide.Shapes.Title.TextFrame.TextRange.Text = "AI Demystified: How to Effectively Use AI"  
    slide.Shapes.Placeholders(2).TextFrame.TextRange.Text = "Mark Cooksey, DME Quality Eng"
```





“Here are the instruction to use the VB code to create your Powerpoint Presentation.”

1.Enable the Developer Tab:

- Open PowerPoint.
- Go to File > Options.
- In the Customize Ribbon section, check the box for Developer and click OK.

2.Open the Visual Basic Editor (VBE):

- Press Alt + F11 to open the VBE.
- Alternatively, you can click on the Developer tab and then click Visual Basic.

3.Insert a New Module:

- In the VBE, right-click on VBAProject (YourPresentationName).
- Select Insert > Module. This will create a new module where you can paste your VBA code.

4.Copy and Paste the VBA Code:

- Copy the VBA code you want to use.
- Paste it into the new module window that opened in the VBE.

5.Run the VBA Code:

- Close the VBE and return to PowerPoint.
- To run the code, you can press Alt + F8, select the macro you want to run, and click Run.



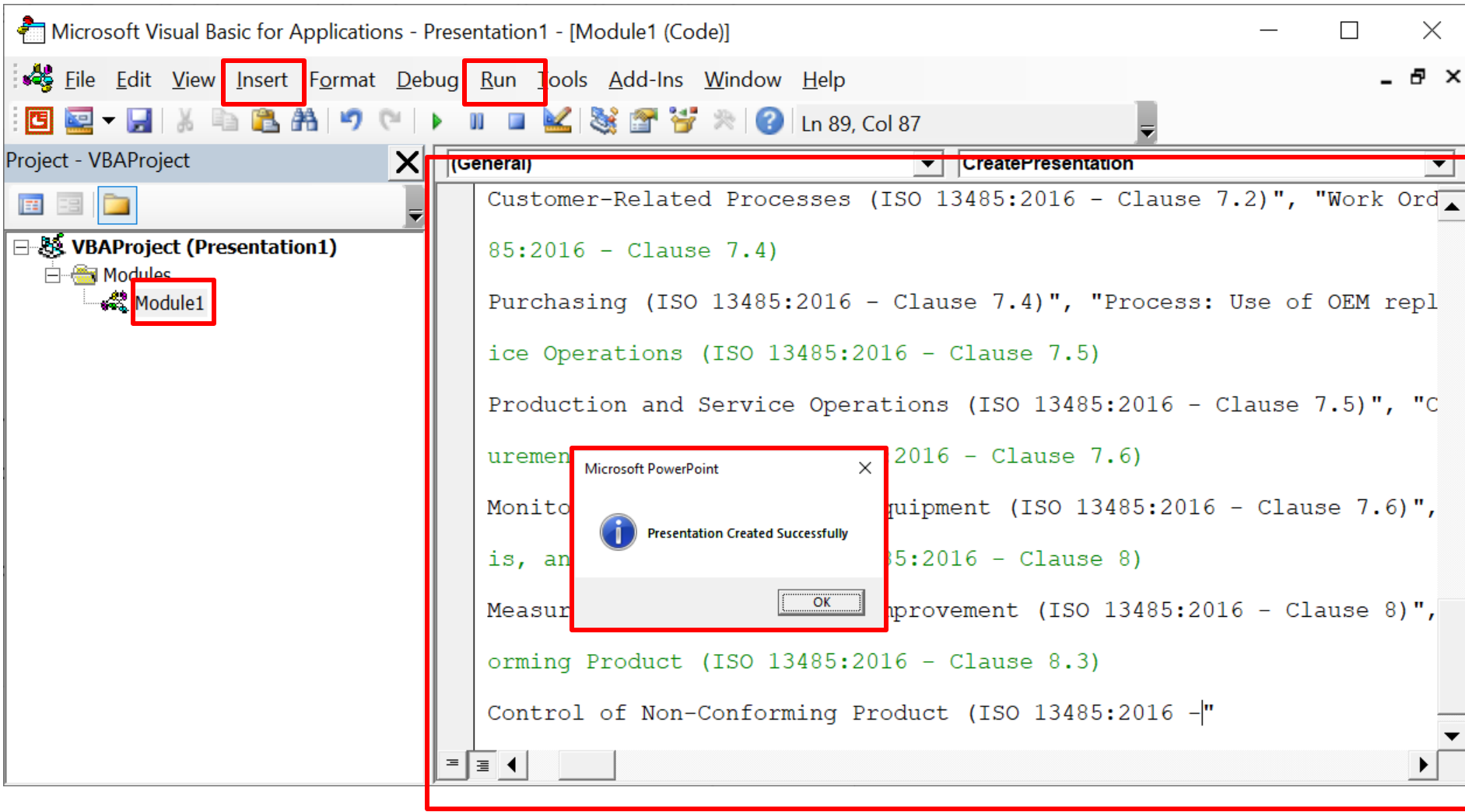
Visual Basic
Macros
Macro Security
Code
Add-Ins
PowerPoint Add-Ins
COM Add-Ins
Add-Ins
A
Properties
View Code

SUBSCRIPTION CANCELLED On Sunday, December 1, 2024, most features of PowerPoint will be disabled. Reactivate

1

Click to add title

Click to add subtitle



Microsoft Visual Basic for Applications - Presentation1 - [Module1 (Code)]

File Edit View **Insert** Format Debug **Run** Tools Add-Ins Window Help

Ln 89, Col 87

Project - VBAProject

VBAProject (Presentation1)

Modules

Module1

(General) CreatePresentation

```
Customer-Related Processes (ISO 13485:2016 - Clause 7.2)", "Work Ord  
85:2016 - Clause 7.4)  
Purchasing (ISO 13485:2016 - Clause 7.4)", "Process: Use of OEM repl  
ice Operations (ISO 13485:2016 - Clause 7.5)  
Production and Service Operations (ISO 13485:2016 - Clause 7.5)", "C  
urement (ISO 13485:2016 - Clause 7.6)  
Monitor (ISO 13485:2016 - Clause 7.6)",  
is, an (ISO 13485:2016 - Clause 8)  
Measur (ISO 13485:2016 - Clause 8)",  
orming Product (ISO 13485:2016 - Clause 8.3)  
Control of Non-Conforming Product (ISO 13485:2016 -"
```

Microsoft PowerPoint

Presentation Created Successfully

OK



AI Demystified: How to Effectively Use AI to Develop or Improve Your Quality Management System

Mark Cooksey, DME Quality Engineer, Norton Healthcare



Introduction

- Introduction of Mark Cooksey
- Objective of the presentation
- Importance of AI in QMS



Overview of AI

- **Definition of Artificial Intelligence (AI)**
- **Types of AI: Narrow AI, General AI**
- **Examples of AI in everyday life**

Understanding QMS and ISO 13485



- Definition of Quality Management Systems (QMS)
- Key components of ISO 13485
- Importance of ISO 13485 in HTM



Challenges in QMS Development

- Complexity of QMS development
- Resource intensity
- Interpretation of standards
- Maintaining compliance



This works great! How much time would I have spent to draft this outline and create a rough draft Powerpoint. Compare to your (AI) time to develop and calculate the % reduction in development time.



I'm glad the code worked well for you!

Let's break this down:

Manual Time Estimation:

1. Drafting the Outline:

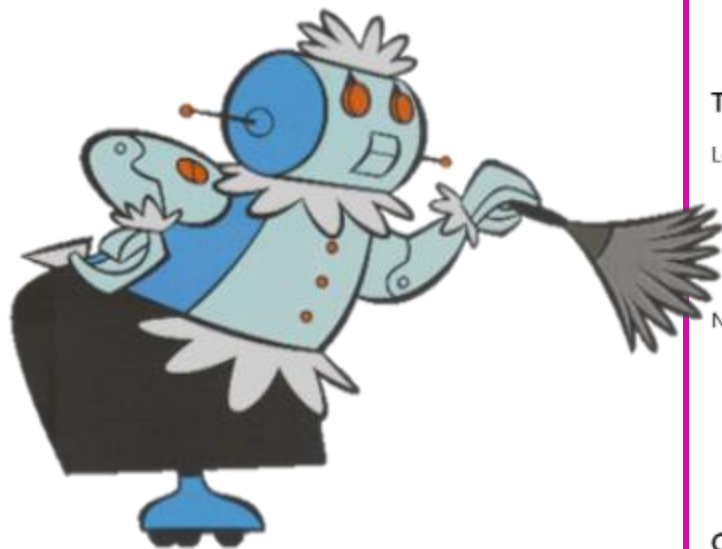
- Depending on your familiarity with the topic, drafting an outline with 21 slides, including bullet points, could take about **2 to 4 hours** (research, structuring content, and drafting).

2. Creating the PowerPoint:

- Manually creating each slide, typing in titles and bullet points, and formatting the presentation might take about **1.5 to 2 hours**.



AI does the math!



Total Estimated Time:

- 3.5 to 6 hours manually for both the outline and creating the rough draft PowerPoint.

AI Time Estimation:

- Using AI, the outline was generated and structured in a couple of interactions, and the VBA code to automate PowerPoint creation was provided in a matter of **minutes**.
- Assuming **10 to 15 minutes** for outline generation and code development with AI.

Time Savings Calculation:

Let's assume a **manual effort of 5 hours (average)** vs. **15 minutes** using AI.

1. **Manual time:** 5 hours = 300 minutes
2. **AI time:** 15 minutes

Now, let's calculate the percentage reduction in development time:

$$\text{Time reduction} = \frac{(\text{Manual time} - \text{AI time})}{\text{Manual time}} \times 100$$

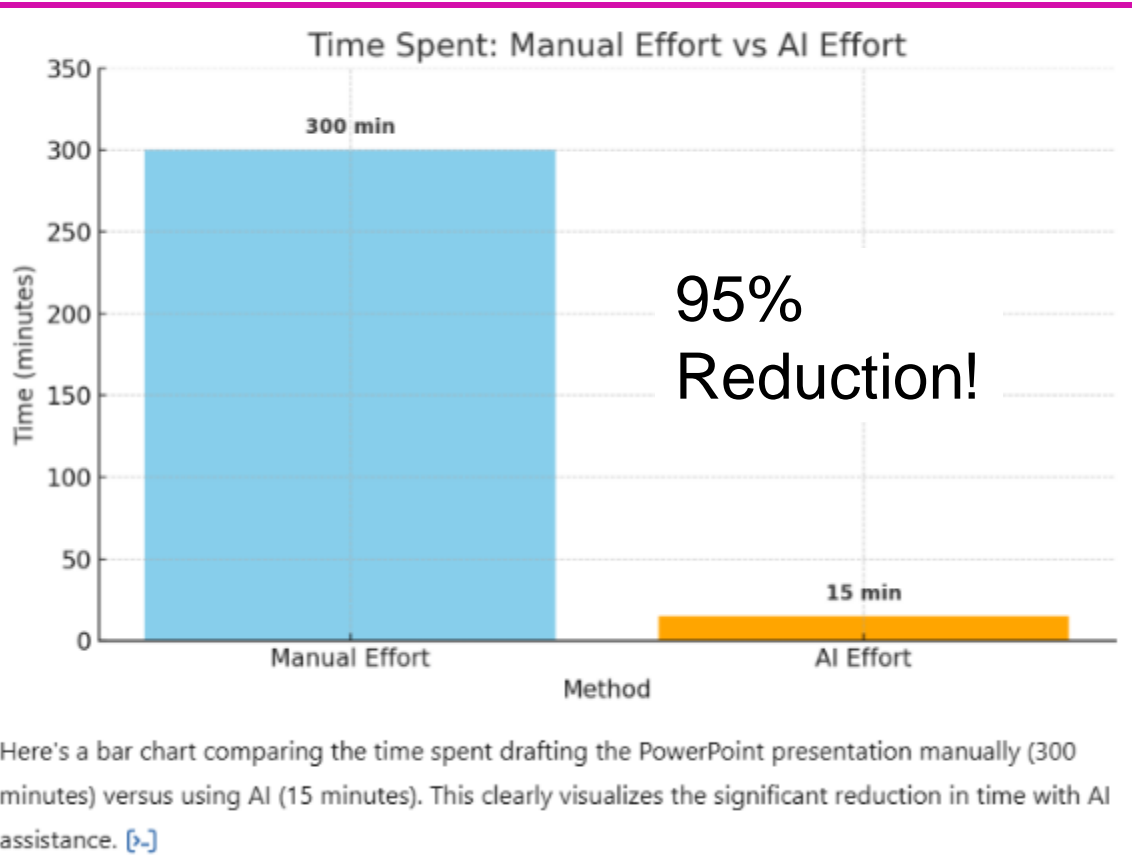
$$\text{Time reduction} = \frac{(300 - 15)}{300} \times 100 = \frac{285}{300} \times 100 \approx 95\%$$

Conclusion:

By using AI, you achieved a **95% reduction in development time** compared to manually drafting the outline and creating the PowerPoint presentation.



can you generate a bar chart showing the improvement in time?



Challenge # 5: AI Just for Fun





COPILOT



NOTEBOOK



You

create a Marvel like superhero that repairs MRI scans



Copilot

Sure, let's create a Marvel-like superhero! How about we call them **"ScanGuard"**?

ScanGuard

Real Name: Dr. Alex Carter



Origin Story: Dr. Alex Carter was a brilliant radiologist working at a cutting-edge medical research facility. One day, while experimenting with a new type of MRI machine designed to detect and repair cellular damage, an unexpected power surge caused the machine to malfunction. The resulting explosion fused Dr. Carter's DNA with the machine's advanced technology, giving them extraordinary abilities.

Super Powers:

- MRI Vision:** ScanGuard can see through objects and people, detecting any abnormalities or damage at a cellular level.
- Healing Touch:** By focusing their energy, ScanGuard can repair damaged tissues and organs, effectively healing injuries and illnesses.
- Data Manipulation:** They can interface with any digital system, allowing them to correct errors in medical scans and other digital data.
- Electromagnetic Pulse (EMP):** ScanGuard can emit a controlled EMP to disable electronic devices or disrupt harmful technologies.

Costume: ScanGuard's suit is sleek and metallic, with glowing blue lines that mimic the look of MRI scan images. The suit is equipped with various medical tools and gadgets, including a portable scanner and a healing device.

~~**Mission:** ScanGuard is dedicated to using their powers to advance medical science and save lives. He travels the world, helping hospitals and clinics repair faulty MRI scans, diagnose difficult cases, and heal patients who have no other hope.~~

~~**Catchphrase:** "Let's get to the heart of the problem."~~



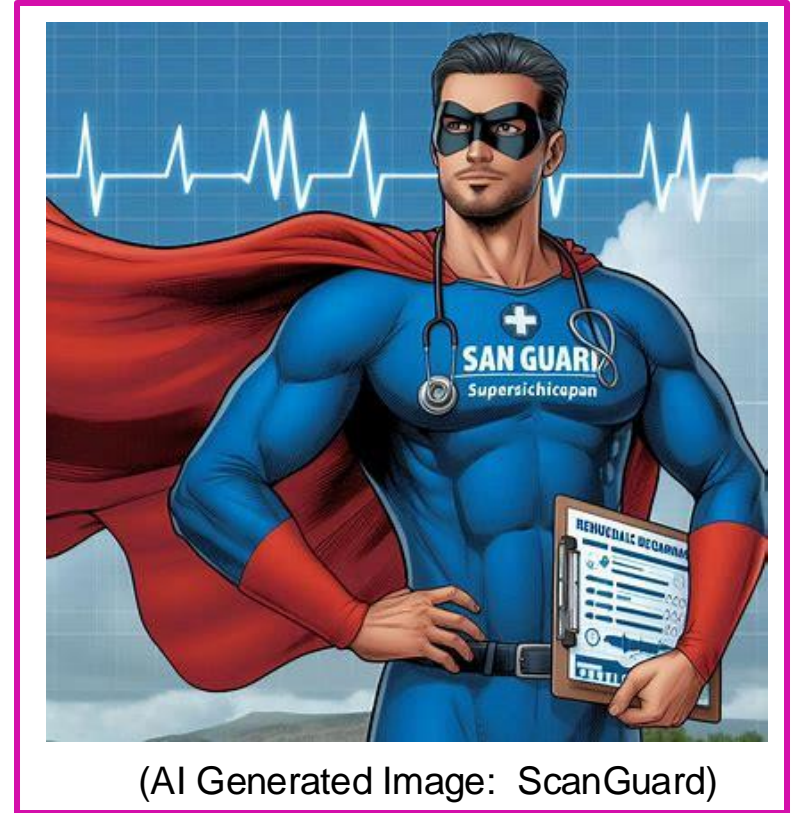
Benefits of AI in HTM

- Develop New Skills
- Improved accuracy
- Increased efficiency
- Better decision-making
- Productivity / Cost savings

Challenges and Considerations

- Data privacy concerns
- Integration with existing systems
- AI is no replacement for human expertise
- Training and skill requirements

- AI Is here
- What it can do
- Why it's needed
- AI Tips
- Examples of AI





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Thank You!

Mark Cooksey

ISO 13485 Quality Leader, Norton Healthcare

Mcooksey6@gmail.com

(502) 554-5206

