

# Advancing Quality & Compliance

## HARNESSING GENERATIVE AI TO DIGITIZE YOUR QUALITY MANAGEMENT SYSTEM

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# What are we seeking to transform

## QMS Workflows - examples



Corrective & Preventive Action



Nonconformance Management



Internal Audit



Change Control



Complaint Processing

## Process Activities



Quality Record Creation



Failure Investigation



Bounding & Traceability



Document Writing



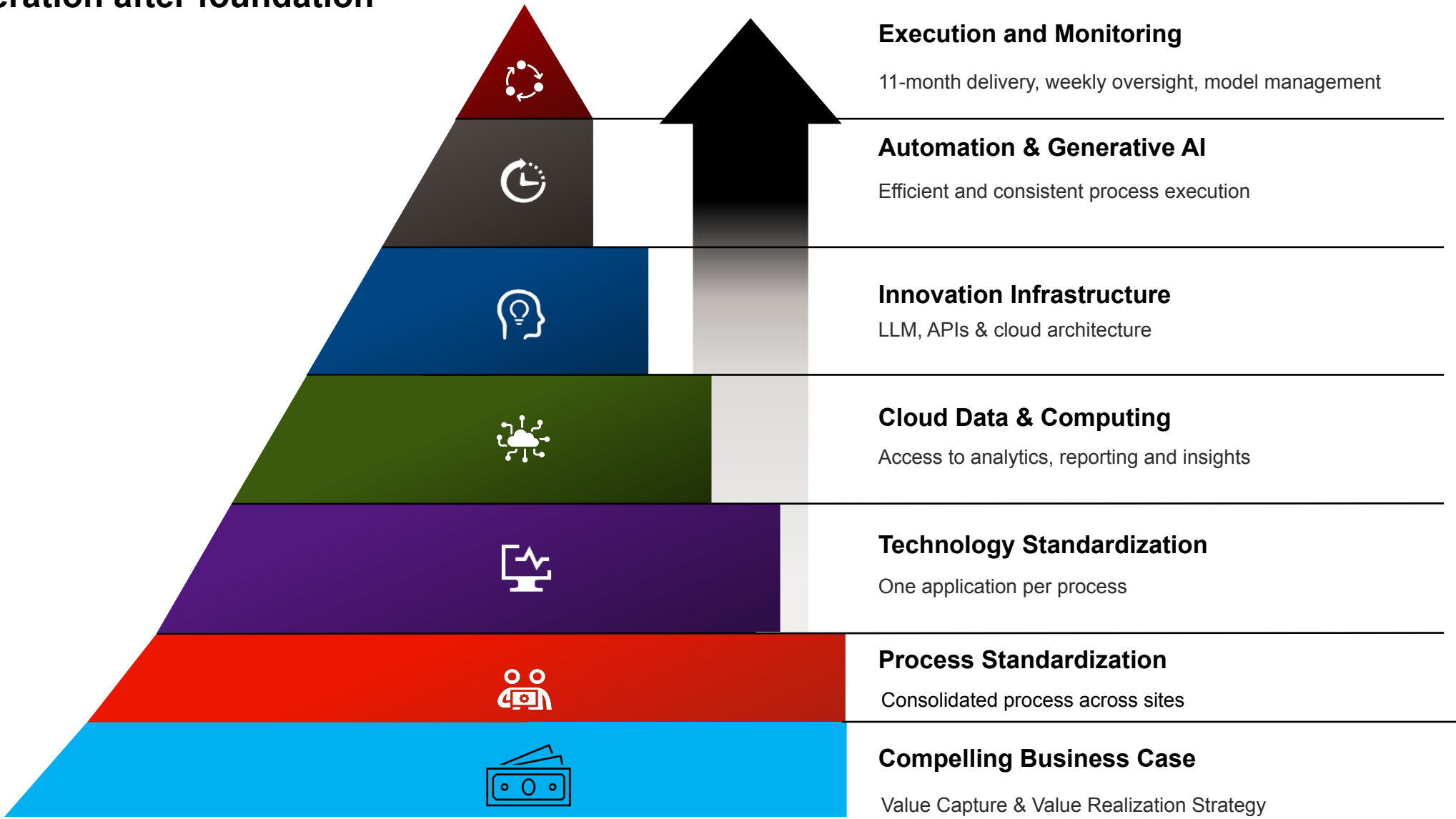
Trends & Reports



## Regulations & Oversight

# QMS Digitalization Transformation Fundamentals

Acceleration after foundation

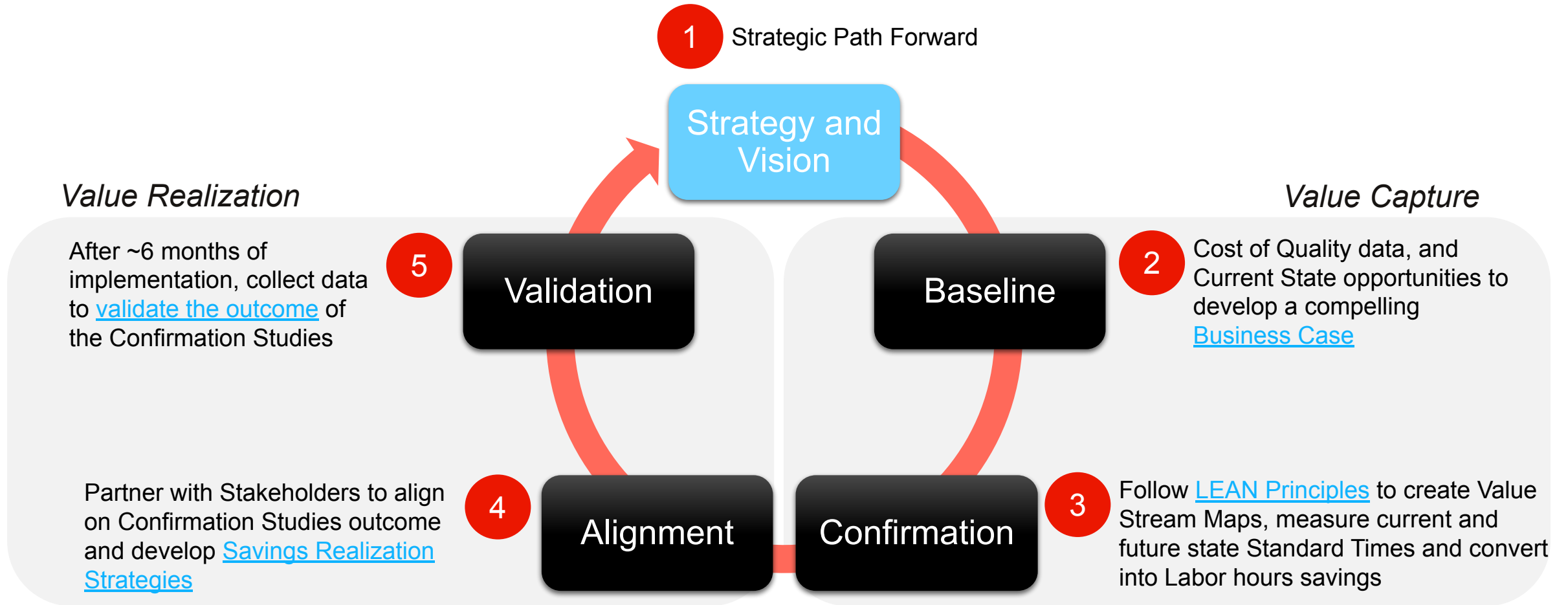


# Why

***“Productivity is being able to do things that you were never able to do before.”***  
Franz Kafka

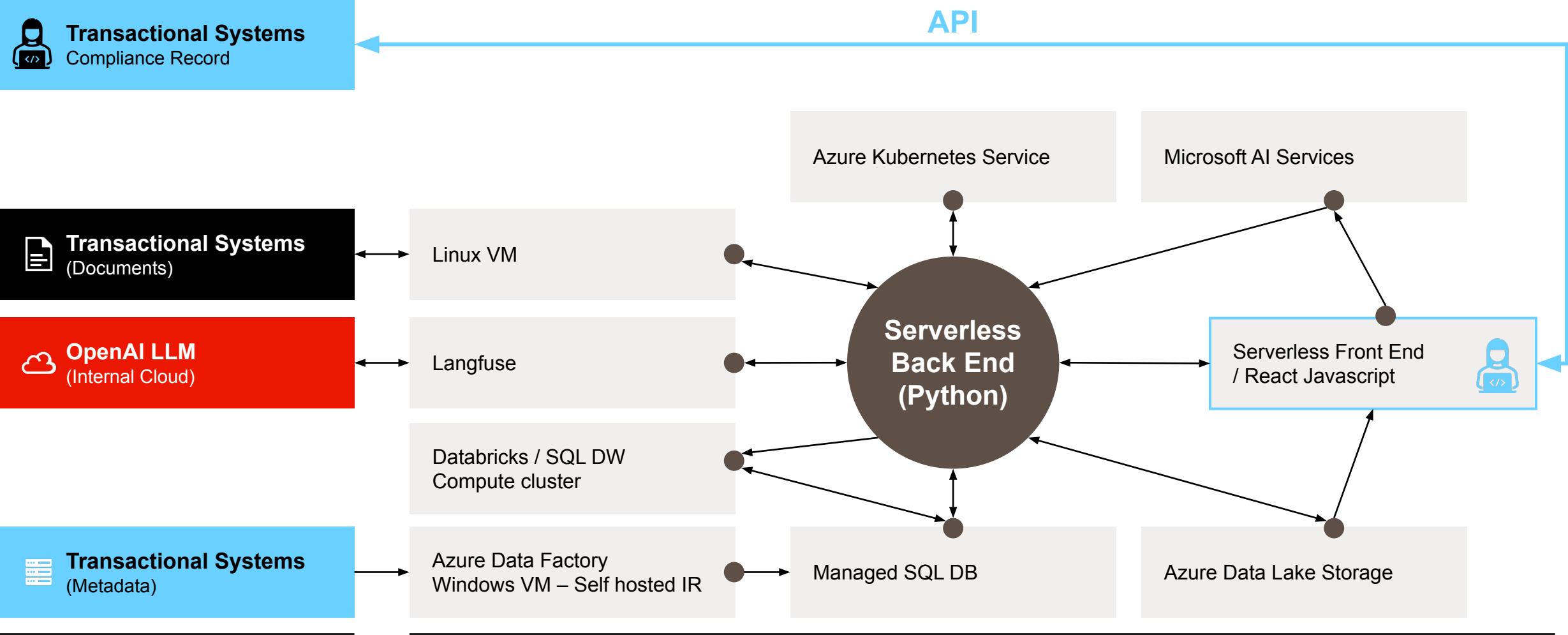
# Agile Business Case -Value Framework

Goal: Operationalize Digitized QMS



# Digital QMS Infrastructure

## High level architecture diagram



Company Intranet

Azure Cloud- VPCx

J&J MedTech

Quality & Compliance

# Innovative Approach

Valuing the experts through efficiency

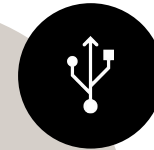
**Technology reduces non-value added time and complexity to execute quality and compliance processes**

## LLM Capabilities

Text generation, entity extraction and **process specific prompt -Reduce execution time.**



**GenA**  
|



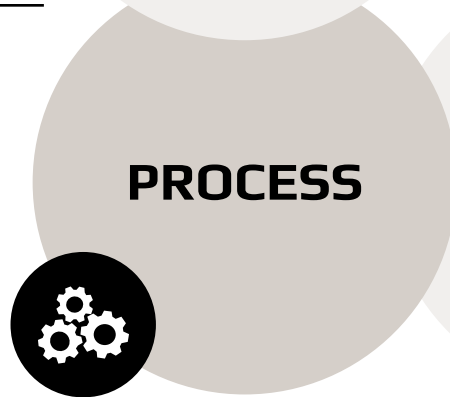
**AP**  
|

## Automated System Entry

Multiple systems and **data accessibility** add **complexity** addressed by **APIs.**

## Technology Enabled Compliance

Procedure based UI/UX ensuring all **actions complete the first time.**



**PROCESS**

**DATA**



## Access & Reports

Requesting data and tracking reports from multiple sources in **one interface**








# Regulatory Compliance & Controls Monitoring

# Current Regulatory landscape

Regulation, Standard or Guidance	Region	Type
The EU AI Act ((EU) 2024/1689)	EU	Act
UK (MHRA) Guidance - Software and AI as a medical device	UK	Guidance
U.S. FDA Draft Guidance: AI-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations	U.S.	Draft Guidance
U.S. FDA Guidance: Marketing Submission Recommendations for a Predetermined Change Control Plan for AI-Enabled Device Software Functions	U.S.	Guidance
U.S. FDA Digital Health and AI Glossary	U.S.	Guidance
ISO/IEC 42001:2023, Information technology — Artificial intelligence — Management system	Global	Standard

# LLM/GenAI Metrics, Controls and Monitoring

## Generation & Classification

METRICS	Criteria	Coherent 	Relevant 	Grounded  	Concise  	Accurate 
	Focus	Grammar, structure, readability, appropriateness	Aligned to the task and user input	Connected and limited to source data inputs	To the point without embellishment	Most relevant categories, labels and groupings
CONTROLS	Technical	System & User prompts	<ul style="list-style-type: none"> <li>• System &amp; User prompts</li> <li>• Task based user inputs</li> <li>• Internally sourced data</li> </ul>		System & User prompts	<ul style="list-style-type: none"> <li>• System &amp; User prompts</li> <li>• Explanation and rationale</li> </ul>
	Process	Human in the loop				
PERFORMANCE	Validation	<ul style="list-style-type: none"> <li>• Quantitative measure baseline established via technology (e.g. accuracy, response time, user satisfaction, usage, user behavior)</li> <li>• Subject matter expert review and approval of LLM / GenAI output</li> </ul>				
	Production	<ul style="list-style-type: none"> <li>• Quantitative monitoring against established baseline via technology (e.g. trend analysis, pattern recognition and anomaly detection)</li> <li>• Standard process monitoring and auditing</li> </ul>				

**Generation:** Text writing and content creation  
(e.g. ChatGPT)



**Classification:** Grouping and labeling inputs  
(e.g. Spam Filter)



# Digital QMS

## Simplification & Optimization of QMS through Digital Transformation by Citizen Developers

**Gartner**: 80% of technology solutions will be built by professionals outside of IT by 2024

**McKinsey**: Organization that empowers citizen developers score 33% higher on Innovation



Citizen Developers – Business & Process Owners, Domain Experts, Functional Leaders

# Innovation Success Factors

Collective ownership and iterative progress are critical

## Change Management

Grow Digital  
Acumen

Change  
Agents

Leadership  
Engagement

Adoption  
Metrics

## Project Philosophy

Progress Over Perfection

Product Backlog

Implement at Scale

## Project Management

Business & Technology members



## Business Representation

Highly technical  
business organization  
co-developing in some cases

## Technology Representation

Business knowledgeable  
technology organization with clear  
process understanding

# Outcomes

What advancing innovation looks like



01.

02.

03.

04.

05.

06.

More time for experts to innovate and improve –  
**Proactive Quality**

Data-based process monitoring

Measures of usage to drive adoption

Validated LLM consistency and ownership

Business ownership of LLM performance

Trust in Technology to improve outputs



# THANK YOU