

AI AND ADVANCED ANALYTICS IN QUALITY & MANUFACTURING

Adoption pathway, assurance strategy and use cases for a futuristic smart pharma enterprise

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Disclaimer

1

Knowledge sharing only

Prepared solely to share knowledge and best practices based on practical experience. Not created with intent to harm, injure or defame any person, association or company.

2

Apply with due diligence

These ideas may be referred to; participants should carry out their own due diligence and detailed risk assessment before applying them at their workplace.

3

Not a substitute for guidelines

The contents cannot replace or substitute regulatory guideline requirements. Refer to the current version of the applicable guidelines during implementation.

4

Personal opinion

The contents of this presentation represent the presenter's personal opinion only.

Digital Transformation Journey

DIGITIZATION

Converting data, documents and processes from paper / analog to digital

Functional software

Receives and processes data from instruments.

Transactional software

Data feed is given manually by the operator.

Functional systems:
PLC | SCADA | HPLC | GC | UV
| IR

Transactional systems:
ERP | DMS | QMS | AMS | LIMS
| LMS

DIGITALIZATION

Using digital technologies to change business model, operations and processes, bringing efficiency and quality

DATA

VISUALIZE

ANALYZE

Data visualization is part of digitalization: representation of data through common graphics, such as charts, plots, infographics and animations.

DIGITAL TRANSFORMATION

Integrating digital technologies into all aspects of business operations

- Use technologies to deliver new products and services, improve existing products and services, and streamline processes.
- AI / ML helps understand, compare and analyze structured data and can support predictive analysis to improve business processes and Quality.

AI / ML • IoT • Connected Intelligence

From digital records → connected data → intelligent decisions

Digital transformation in the Pharma Industry is no longer optional

Digital tools, including automated data capture, help ensure data integrity, traceability, and compliance with regulations.

Growing Regulatory Complexity

Increasing Research and Development (R&D) Speed and Success

AI and machine learning allow for the rapid analysis of vast datasets to identify promising drug candidates, significantly speeding up the research phase and lowering failure rates in clinical trials.

Intensifying Competition and Cost Pressures

Achieving Operational Excellence

Adapting to Disruptive Global Events

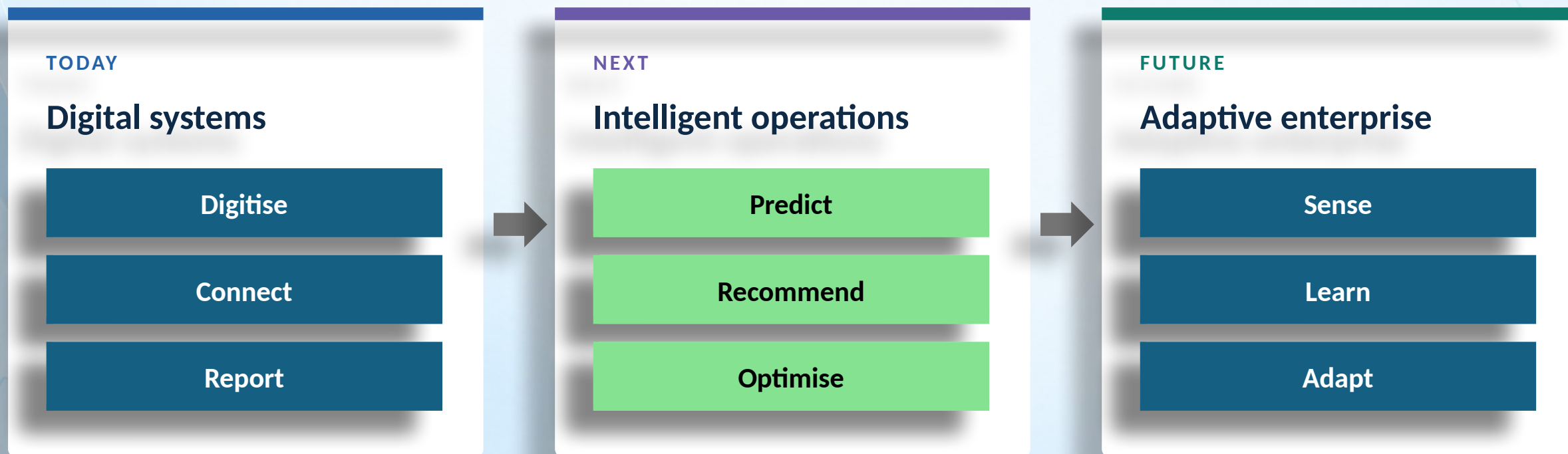
Digital technologies, like artificial intelligence (AI) and automation, accelerate drug discovery, optimize manufacturing, and streamline clinical trials.

Machine Learning helps for early failure prediction, quick investigations, process optimization, right first time etc.

The COVID-19 pandemic highlighted the critical need for digital readiness. It accelerated the shift towards decentralized clinical trials and remote collaboration,

What a futuristic smart pharma looks like

The enterprise becomes a system that senses, learns and improves continuously



The destination is not “more AI”. It is a more intelligent enterprise.

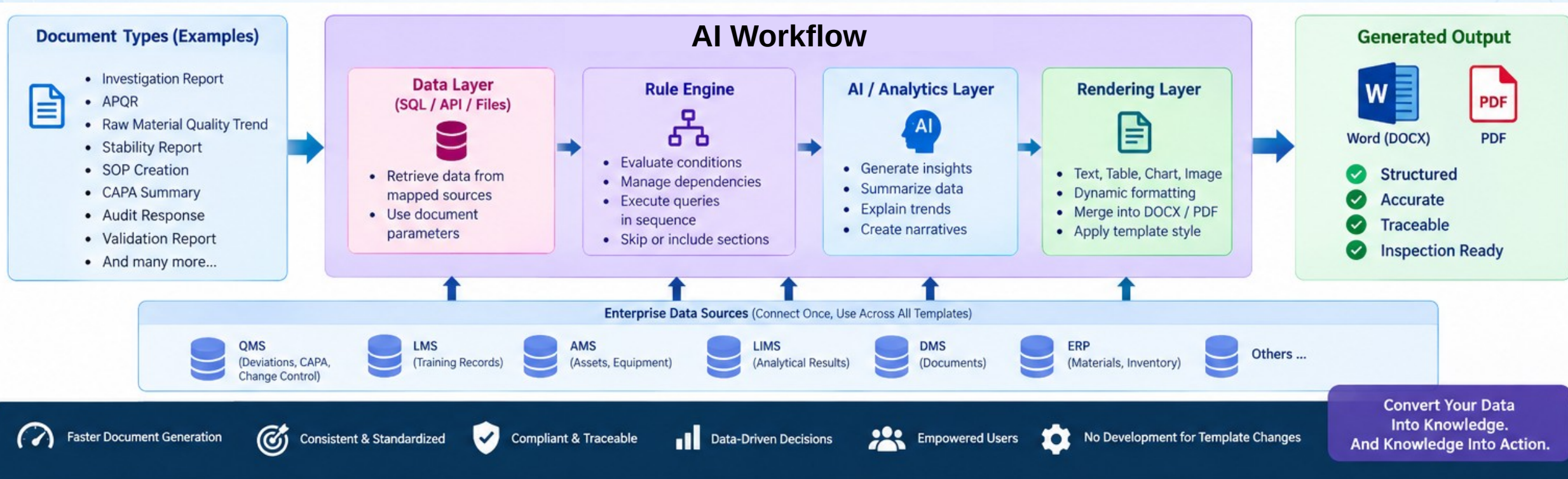
Futuristic Quality

AI-assisted quality, automated compliance and built-in risk mitigation

Futuristic QA Organogram



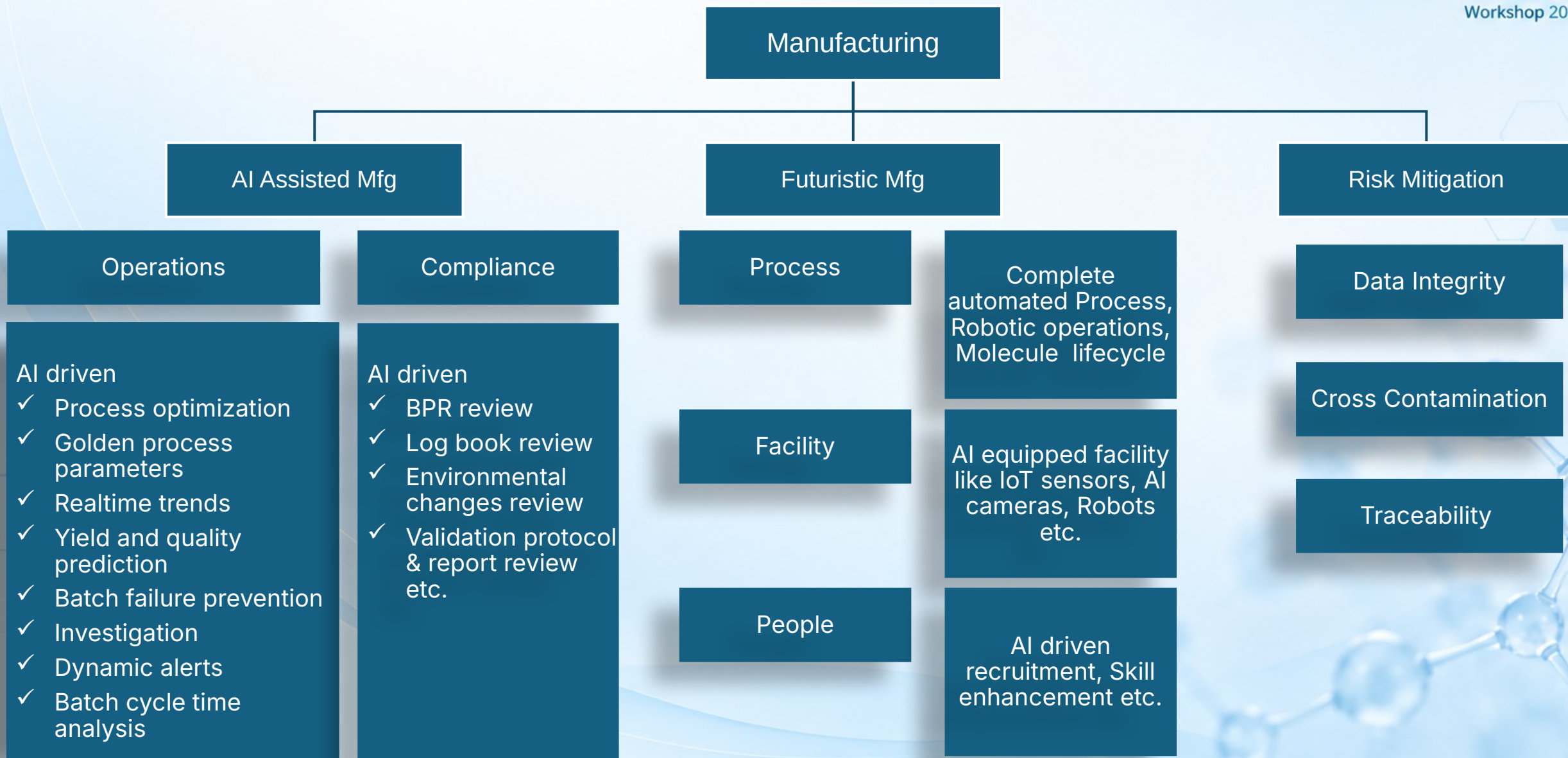
AI workflow



Futuristic Manufacturing

Predictive operations, golden process parameters and automated review

Futuristic Manufacturing Organogram



AI / ML model benefits in Manufacturing

What the models deliver across data, investigation and process

Quick data accessibility

- Access hundreds of batch records in one place
- Both electronic and PDF data
- Tabulated for quick comparison

Investigation

- Faster investigation and data collation
- Vendor source and material quality evaluation
- Identify the potential cause of failure

Predictive analysis

- Predict yield and quality of a batch
- Enables proactive remedial action

Batch cycle time

- Suggest cycle time reduction
- Without affecting quality and yield

Simple data analysis

- Trends across multiple BPR versions
- Min, max, mean and standard deviation
- Understand variability and x-factors

Exploratory analysis

- Relationship between dependent and independent variables
- Significance to quality and yield

Critical process parameters

- Identify undefined critical parameters
- Assure significance of defined parameters

Golden process

- Identify golden process parameters
- Optimise conditions against them

AI Adoption & Assurance Strategy

Risk-based credibility for a defined Context of Use

USFDA draft guidance interpretation

Risk-based credibility for a specific Context of Use — not technology-based validation

GUIDANCE SCOPE

In scope

AI producing information intended to support regulatory decision-making on safety, effectiveness or quality.

Outside scope

Discovery and operational-efficiency uses that do not affect patient safety, drug quality or study-result reliability.

MODEL RISK

Model influence × Decision consequence

Model influence — contribution of AI evidence relative to other evidence.

Decision consequence — significance of an adverse outcome from an incorrect decision.

FDA SEVEN-STEP CREDIBILITY FRAMEWORK

1

Question of interest

2

Context of Use

3

Model risk

4

Credibility plan

5

Execute

6

Document results

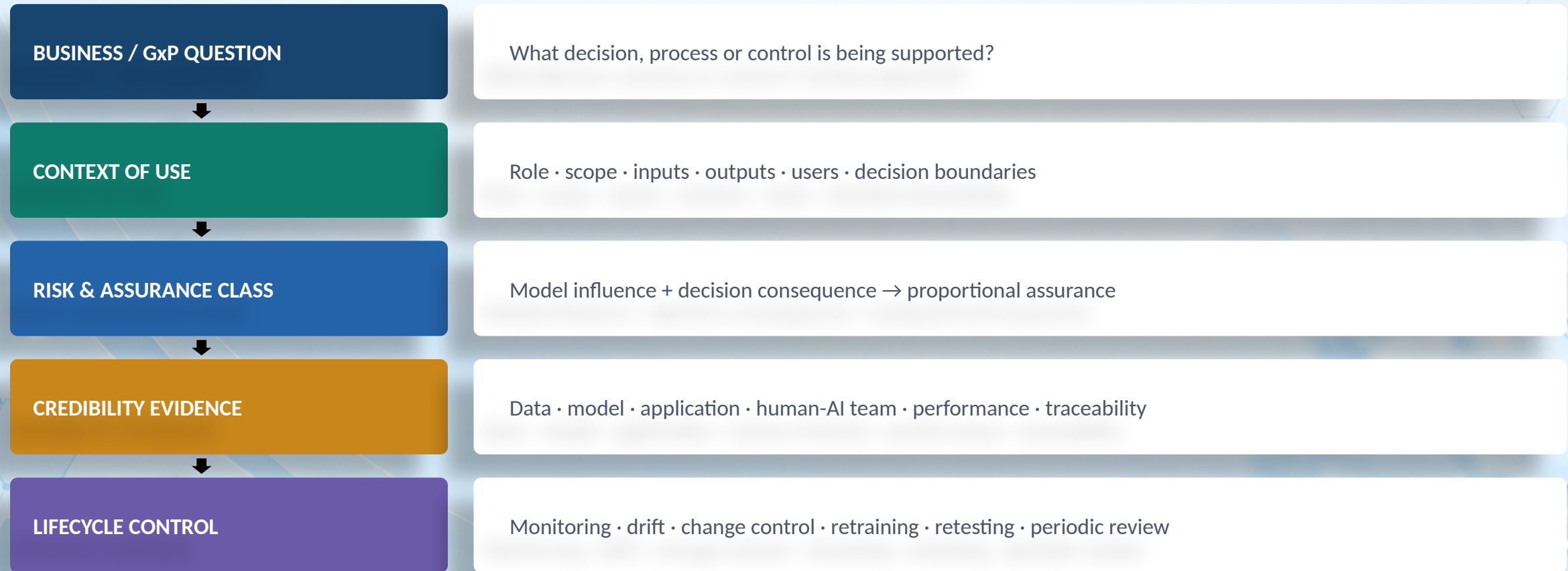
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Adequacy for COU

Our interpretation: start with the decision. Define exactly what AI does and does not do. AI generates the first draft; the user reviews and evaluates before accepting. Human review is a control, not a formality.

Enterprise AI assurance architecture

Applied across LLM / GenAI, agentic AI, RAG and hybrid AI solutions



Core design principle: define the AI role first, then scale assurance to GxP impact, model influence and decision consequence.

Internal AI assurance classification

Organisation-defined risk tiers used to set proportionate assurance — not an FDA classification

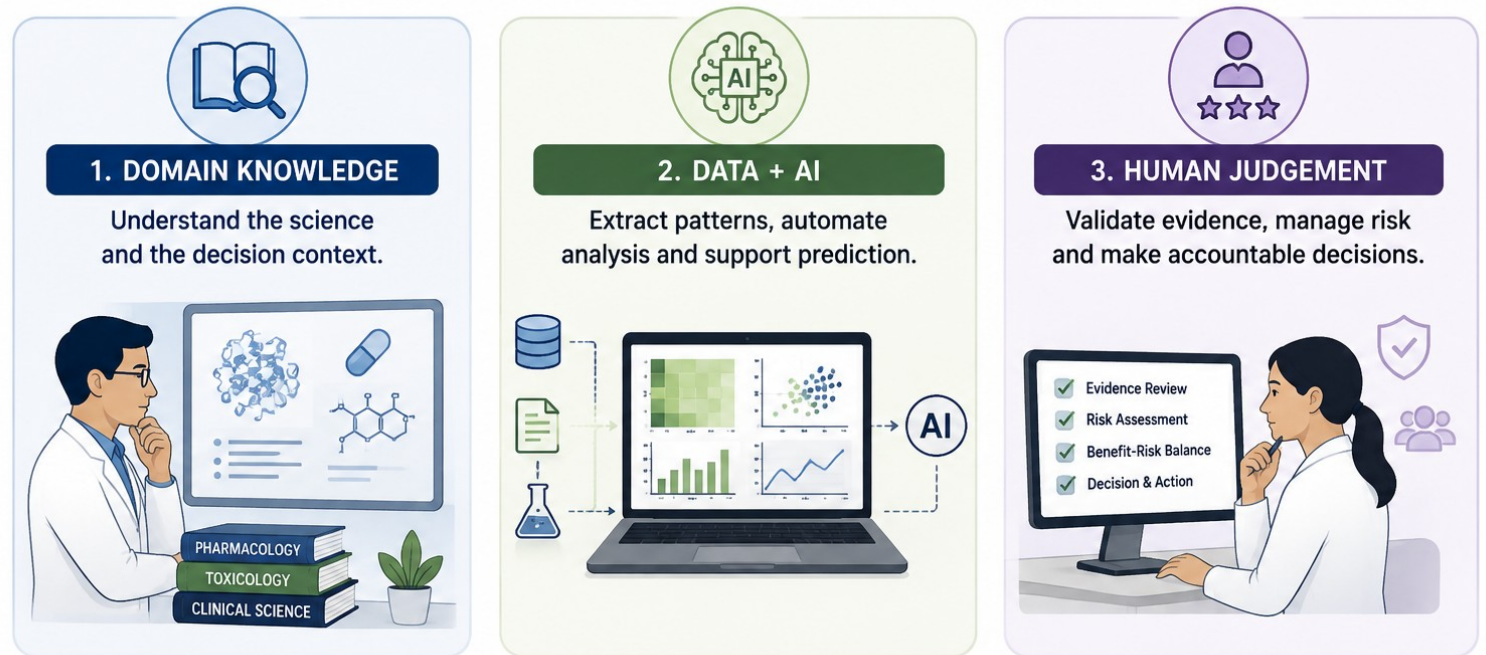
CLASS	EXAMPLE	ASSURANCE
AI-1	Productivity / non-GxP assistance (e.g., meeting summaries, training-material drafting, non-GxP report formatting)	Basic assessment (basic assessment: intended-use check, data/output sanity checks and documented review; formal AI validation is generally not required for non-GxP use)
AI-2	GxP-supporting information and retrieval (e.g., SOP retrieval, regulatory guidance search, batch-record information retrieval)	Risk-based assurance (risk-based assurance: documented risk assessment, source/data controls, retrieval-accuracy testing, access controls and periodic review)
AI-3	GxP decision support — human independently evaluates and decides (e.g., deviation/CAPA trend analysis, OOS evidence review, batch-trend assessment)	Formal AI validation (formal AI validation: approved validation plan/protocol, defined Context of Use, performance testing, acceptance criteria, human oversight and change control)
AI-4	AI influencing critical GxP decisions — human remains accountable (e.g., batch-release risk recommendation, critical-deviation impact assessment)	Enhanced validation (enhanced validation: formal validation plus expanded challenge testing, error/consequence assessment, stronger monitoring, human accountability and tighter change control)
AI-5	Autonomous or automated critical GxP action (e.g., autonomous batch disposition, automatic approval of a critical GxP action)	Highest controls (highest level of assurance: extensive validation/qualification, independent review, rigorous challenge testing, continuous monitoring and strict change control)

Three capabilities must grow together

AI alone is not enough; domain knowledge and human judgement create professional value.

- Domain knowledge - understand the science and the decision context.
- Data + AI - extract patterns, automate analysis and support prediction.
- Human judgement - validate evidence, manage risk and make accountable decisions.

AI + EXPERTISE = BETTER DECISIONS



INFORMED INSIGHTS. SMARTER DECISIONS. BETTER OUTCOMES.



From AI Concerns to a Practical Adoption Path

The questions that typically slow AI adoption in Pharma — and how to move from concern to action

WHAT LEADERS ASK

1

Will people accept it?

2

Can we trust it?

3

Where do we start?

A SAFE, FAST, BUSINESS-LED APPROACH

START SMALL

Prioritize high-value,
manageable use cases

PROVE VALUE

Pilot • Measure •
Learn

ASSURE & GOVERN

Context of Use •
Risk • Human oversight

SCALE ACROSS FUNCTIONS

R&D • Manufacturing • Quality • Supply Chain • Engineering

AI BECOMES PART OF THE OPERATING MODEL

4

Is our data ready?

5

How do we control
GxP risk?

6

What value will we
get?

The objective is not to deploy AI everywhere at once — it is to create a repeatable path from VALUE → TRUST → SCALE.

Key Takeaways From This Session

1

Digital transformation would help the organizations to transform the way the R&D, Technology Transfer and Manufacturing operations and bring in more efficiency in the process and quality.

2

AI/ML technology can be adopted by the companies already Digitized and Digitalized the processes as well the organizations operating in a manual way.

3

A high collaboration is required between Industry, Regulators and AI technology providers

4

Three capabilities must grow together

- Domain knowledge
- Data + AI
- Human judgement

5

A definitive regulatory guideline on AI / ML usage in Pharma Industry a need of the hour.

6

Indian organizations should accelerate adoption of AI / ML technologies to improve their processes and quality as well as to reduce the cost of medicines. AI will revolutionize the Pharma industry.

Thank you

Questions and discussion