PDA Regulatory Conference 2025

Achieving CGMP Excellence: Sustainable Compliance Across the Lifecycle
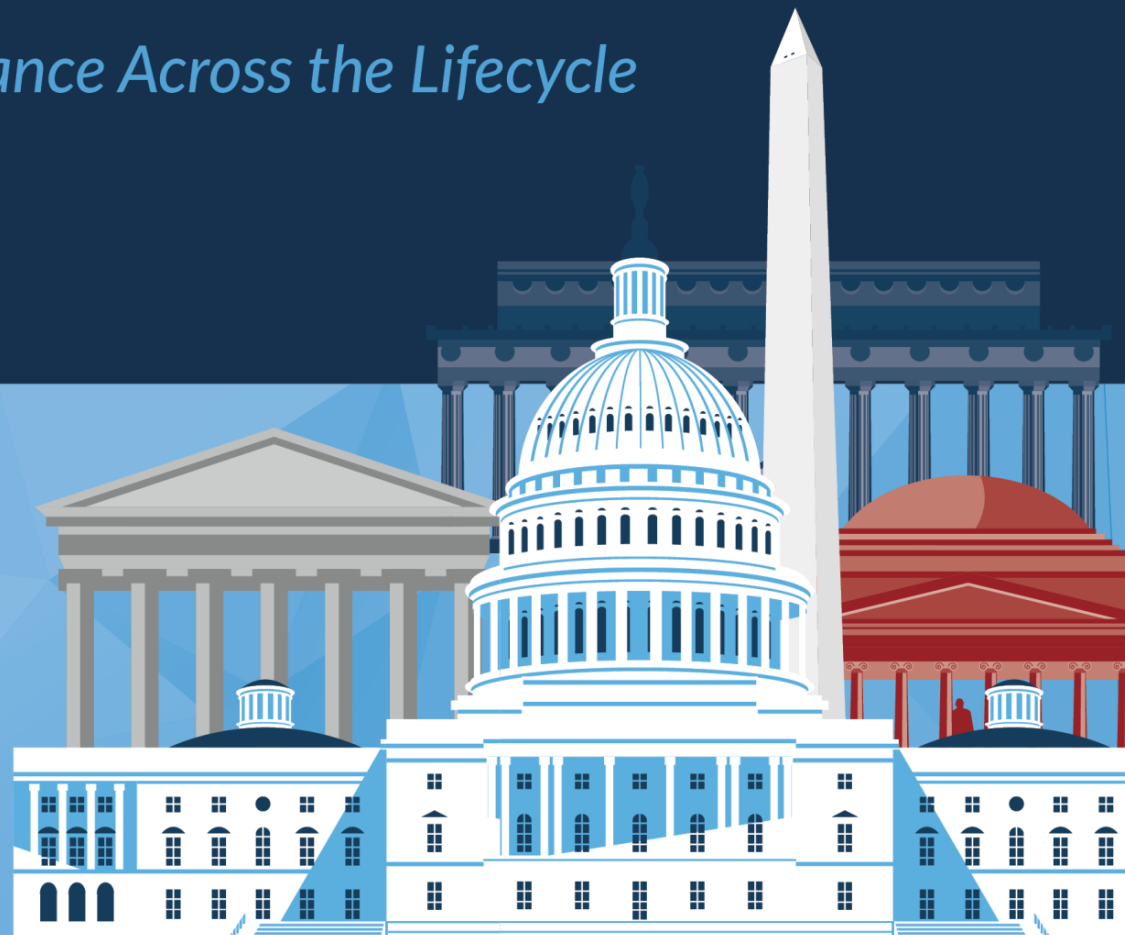
08-10 September | Washington, DC
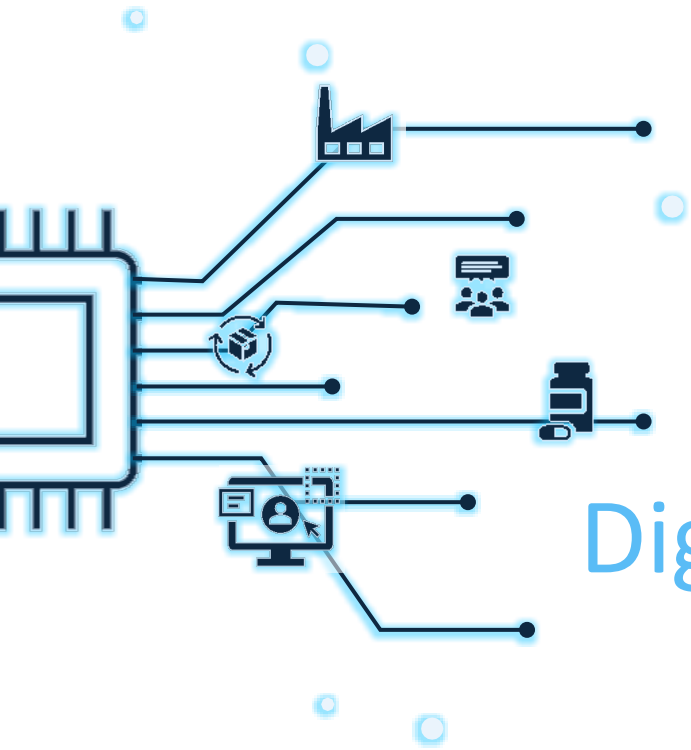
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Guardians of Quality: Digital Tools and AI in the Era of Complex Supply Networks

Michael Grischeau

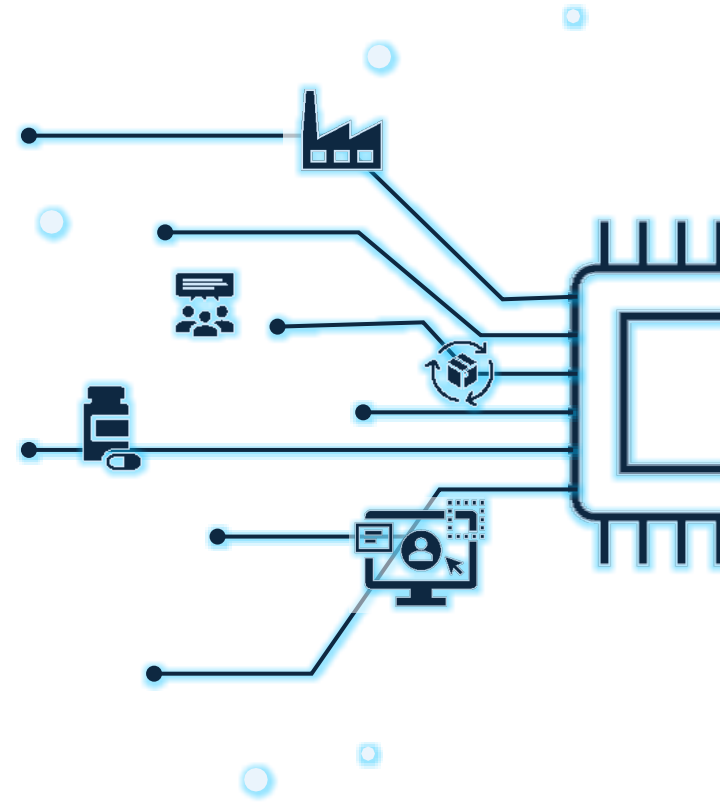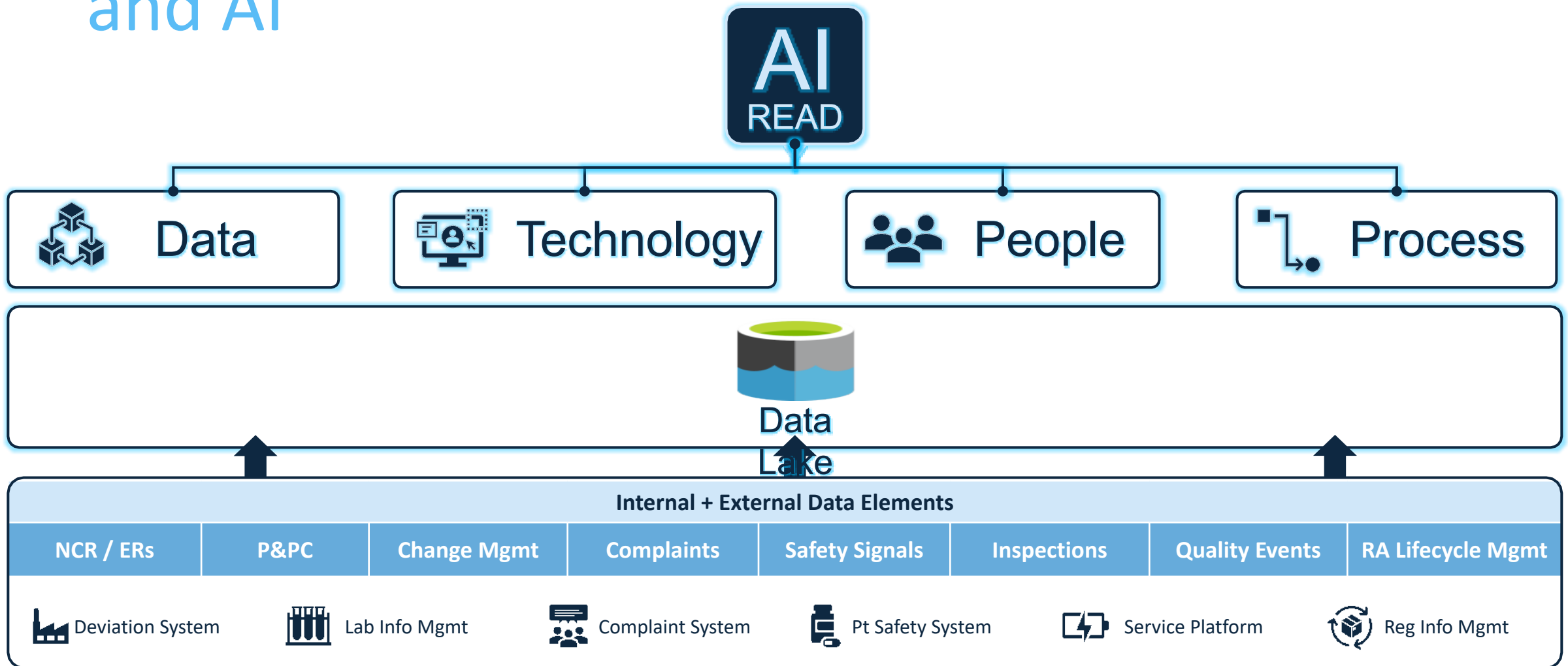*Director of Data Analytics and Management Review*

AbbVie

Contents

- Approach to Transformative Tools and AI
- Contextualizing the Pharmaceutical Supply Chain
- Use Cases and Examples

Practical Approach to Transformative Tools and AI

AI READ

Data	Technology	People	Process

Data Lake

Internal + External Data Elements

NCR / ERs	P&PC	Change Mgmt	Complaints	Safety Signals	Inspections	Quality Events	RA Lifecycle Mgmt
Deviation System	Lab Info Mgmt		Complaint System	Pt Safety System		Service Platform	Reg Info Mgmt

Suppliers

Contract Manufacturing Quality

AI READ

Data • Technology • People • Process

Data Lake

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| NCR / ERs | P&PC | Change Mgmt | Complaints | Safety Signals | Inspections | Quality Events | RA Lifecycle Mgmt |

Deviation System · Lab Info Mgmt · Complaint System · Pt Safety System · Service Platform · Reg Info Mgmt

Contract Manufacturing Quality

Objective

Automate Contract Manufacturing Organization (CMO) performance monitoring to drive quality improvements

- Risk-based
- Define critical elements
- Assign scoring and weighting
- Establish thresholds
- Consider relationship factors

Deliverables

- Automated dashboard leveraged globally by external product QA Elimination of manual data processing
- Operationalized for internal and external business reviews

Contract Manufacturing Quality

Performance Management Automation

Metric	CMO 1	CMO 2	CMO 3	CMO 4
Total	92	100	70	85
Product	0	0	-10	-10
Compliance	0	0	-10	-5
Timeliness	-8	0	-10	0

- Scoring starts at 100
- Deductions based on each subgroup
- Subgroup is a compilation of elements (e.g., Product = Initiated NCRs, Effectiveness, etc.)
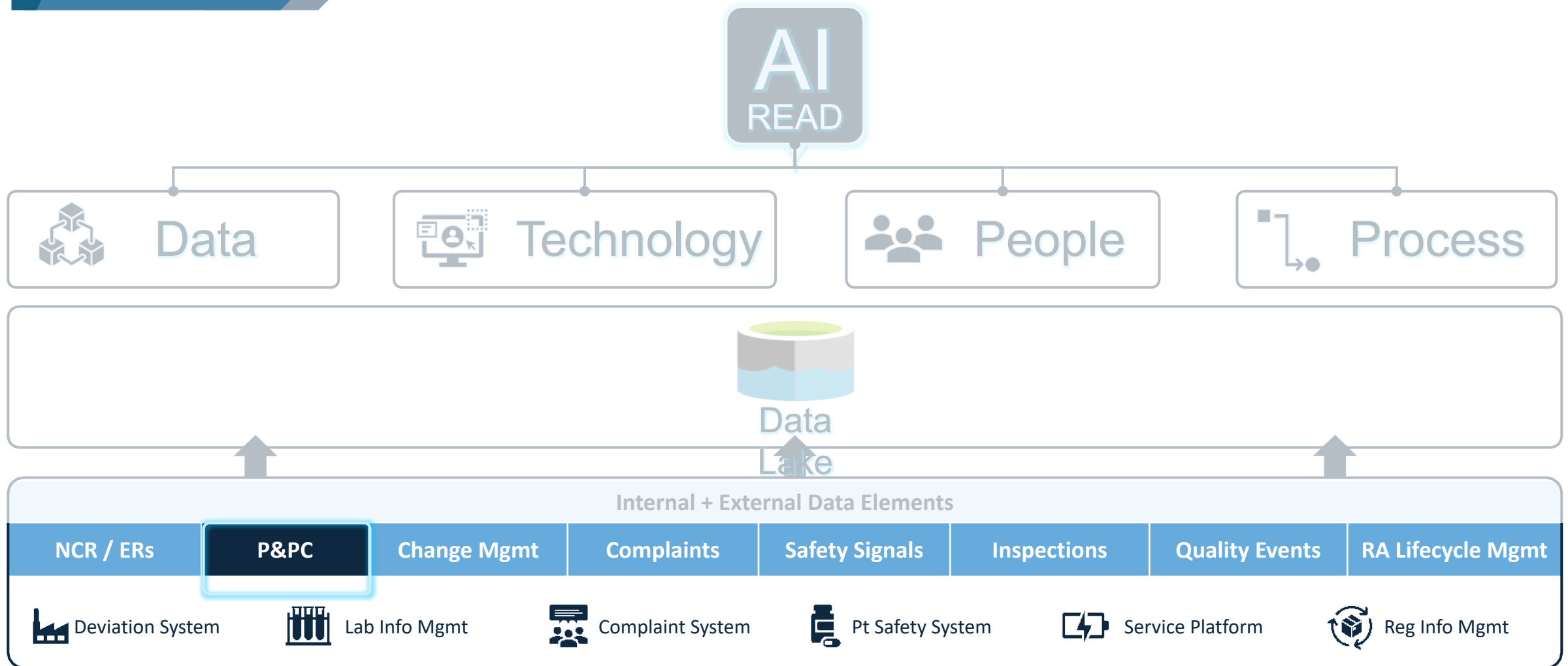- Subgroups assigned maximum deduction

Results & Business Value

✓ Automation leading to accelerated decision making and escalation

✓ Objective approach aligned cross-functionally

✓ Transparency with CMOs for relationship management

Manufacturing & Distribution

Process & Product Performance

AI READ

Data | Technology | People | Process

Data Lake

Internal + External Data Elements

NCR / ERs	P&PC	Change Mgmt	Complaints	Safety Signals	Inspections	Quality Events	RA Lifecycle Mgmt
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Process & Product Performance

Objective

Digitize Supplier Certificates of Analysis (CoAs) for automated trending

- Enable access to data, accelerate ingestion, and standardize product data across CMOs
- Feed data to common data model in lake
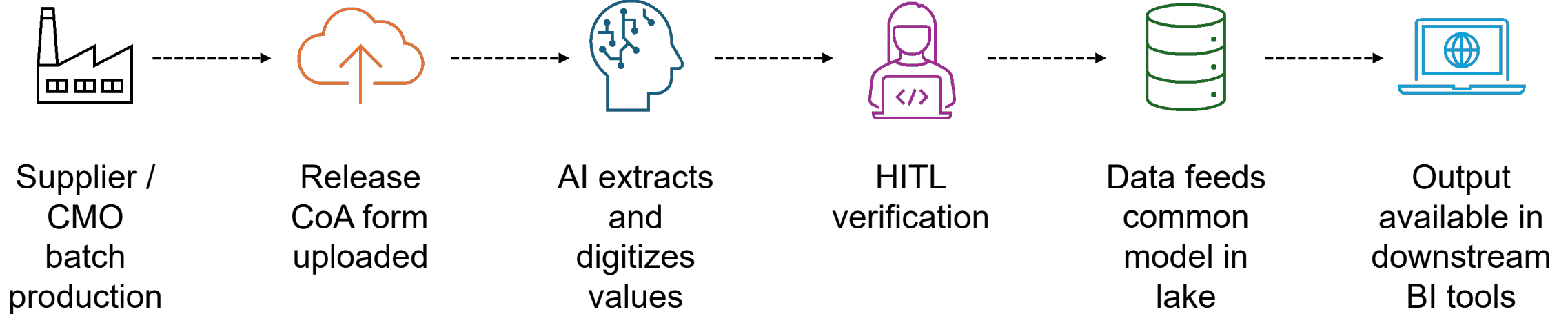- Keep Human In The Loop (HITL) verification

Deliverables

- Scalable solution for adoption across Operations
- Cross-functional collaboration to define the data model and critical datapoints for downstream teams
- Standardization of datapoints across internal and external manufacturing
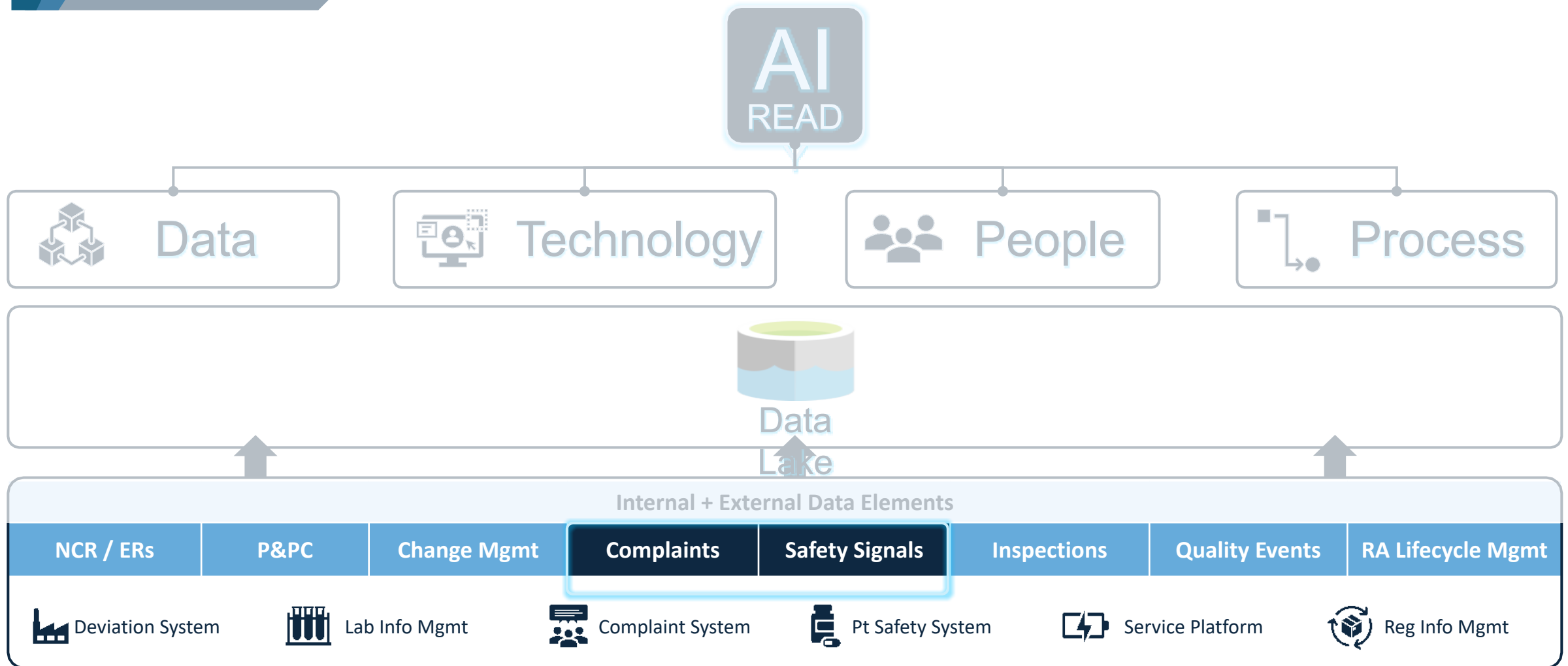
Process & Product Performance

Digitized CoA

Supplier / CMO batch production	Release CoA form uploaded	AI extracts and digitizes values	HITL verification	Data feeds common model in lake	Output available in downstream BI tools

Results & Business Value

- ✓ Seamless and automated process and product performance monitoring
- ✓ Common datapoints for manufacturing data, regardless of internal or external site
- ✓ Accelerate CMO onboarding through standardized cross-functional datapoints

Post Market Surveillance

Patients & Consumers

AI READ

| Data | Technology | People | Process |

Data Lake

Internal + External Data Elements

| NCR / ERs | P&PC | Change Mgmt | **Complaints** | **Safety Signals** | Inspections | Quality Events | RA Lifecycle Mgmt |

Deviation System · Lab Info Mgmt · Complaint System · Pt Safety System · Service Platform · Reg Info Mgmt

Post Market Surveillance

Objective

GenAI powered process with customer complaint coding

- Automated coding upon intake
- Identification and risk-ranking of priority complaints
- Use to assist with investigation
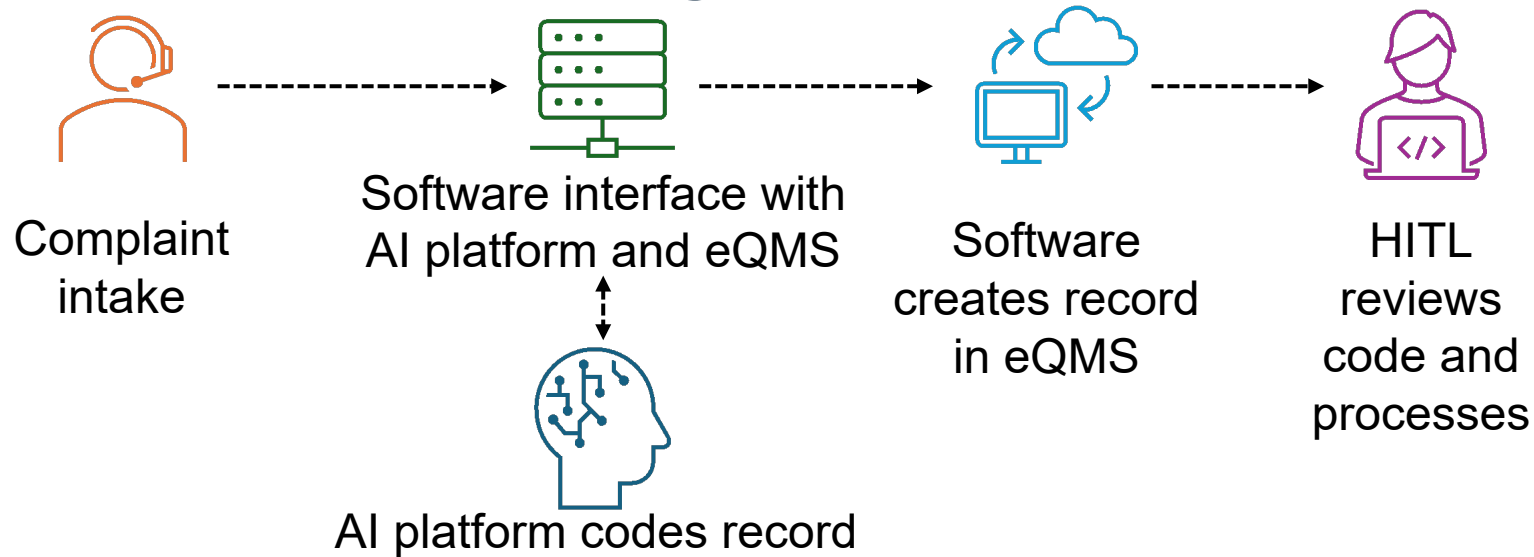- Keep Human In The Loop (HITL) for verification and next actions

Deliverables

- Compliant and responsible AI with HITL and conformance to internal guidance
- Monitoring plan to measure defined business value metrics with coding and performance
- Scalable solution for strategic adoption of AI within complaint management processes

Post Market Surveillance

Coding Automation

Complaint intake

Software interface with AI platform and eQMS

Software creates record in eQMS

HITL reviews code and processes

AI platform codes record

Results & Business Value

- ✓ Improved "right first time" coding
- ✓ Move from minutes to seconds in coding at intake
- ✓ High-priority complaints identified at receipt for accelerated investigation with CMO

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Guardians of Quality