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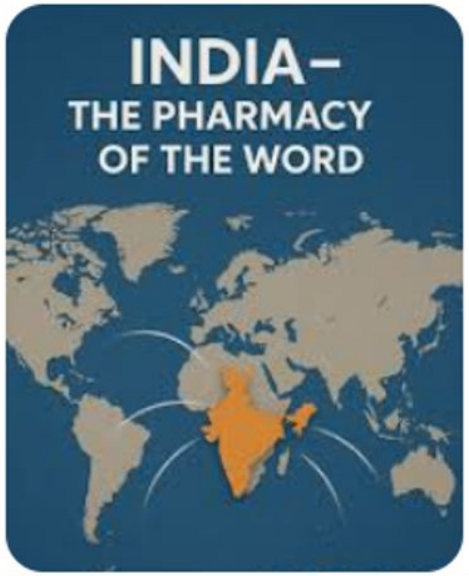
TRUST, TRACEABILITY AND
TRANSFORMATION

What the next era of AI means for GMP Pharma

Anil Chandrupatla

The Pharma Industry at a Crossroads

From Manual Compliance to Digital Intelligence: The Next Leap for Indian Pharma



Indian pharma leads globally in scale but faces increasing complexity in regulatory, operational, and data management processes.

Pharma companies that industrialize AI use cases across their organizations have the potential to double their operating profit

AI use cases in operations account for 39% of the impact by boosting efficiency on the production, material, and supply chain costs

R&D accounts for 26% of the impact, followed by commercial at 24%, with AI increasing efficiencies in developing new medicines and opening up new ways of interaction

Pharma's enabling functions contribute 11%, with AI increasing the speed and efficiency of supporting processes such as IT, finance, HR, and legal and compliance

In total, pharma companies could gain an additional $254bn in annual operating profits worldwide by 2030, assuming a high degree of industrialization of AI use cases

Source: Re-inventing Pharma with Artificial Intelligence – PwC Study

"AI-driven automation is no longer optional — it's the competitive advantage."

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Unlocking Value in GMP Operations

Aligning AI Use Cases to Industry's Highest Value Operations

Regulatory Agility (Continuous compliance)	Plant Optimization (Maximizing Yield & Output)	Productivity & Performance (Operational Efficiency)
Rapid Audit Response Instant data retrieval for auditor queries	**Yield Optimization** Principal Component Analysis (PCA) to maximize output	**Employee Productivity** Track operator efficiency & training gaps
Automated Reporting APR/PQR & Management Reviews	**Material & Vendor Intelligence** Automate raw material reconciliation and AI-driven Supplier Quality Risk Scoring	**Predictive Maintenance** Analyze downtime patterns (Machine Productivity)
OOS Investigation Support AI-driven root cause analysis	**Environmental Monitoring** Automate trending to predict risk	**Right-First-Time (RFT) Analytics** Eliminate recurring data discrepancies and rework

The Vision & Challenge

- The Vision for the Indian Pharma is clear - Be the undisputed quality leader for the world
- But this vision is threatened by a fundamental problem ...

... and the challenge is not the challenge of expertise, it's the challenge of visibility, the **dark data** problem!

Do you know what your factory is telling you?

80%

of GMP-critical data is dark - Locked in PDFs, SOPs, handwritten logs, emails

Handwritten Logs

SOP (PDF)

Paper BPR

Risk

Operational Blindspot

Not an IT Problem

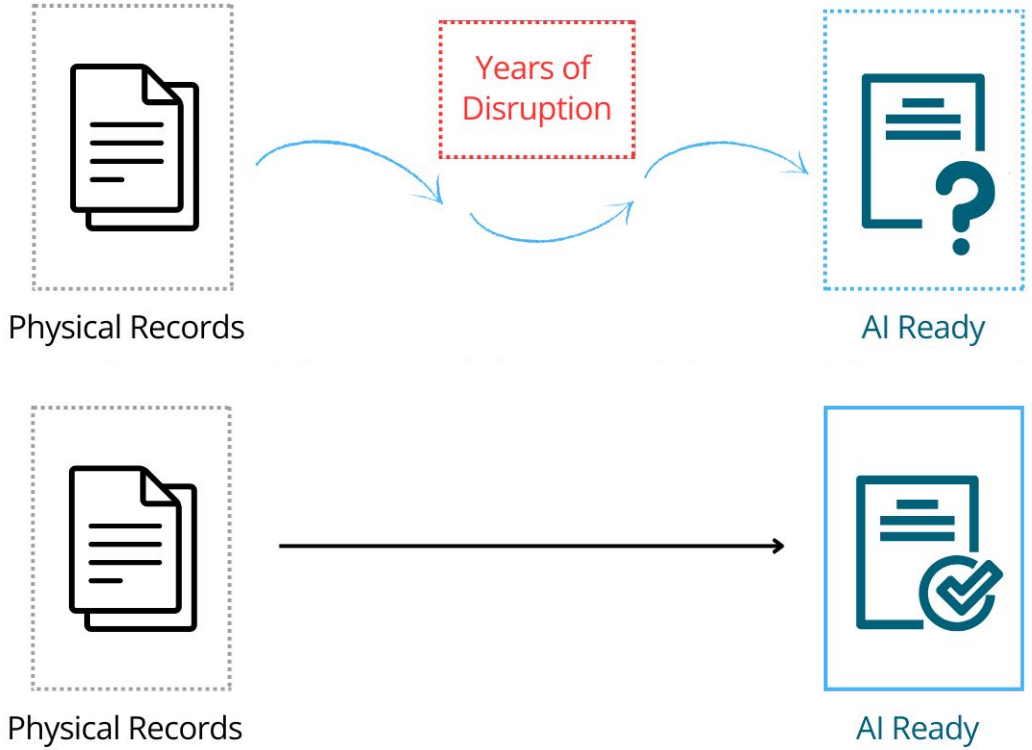
Do you really need to go Digital before going AI?

The Old way

Digitizing records is not the same as creating intelligence. Its slow, disruptive, and locks you into rigid processes

The New way

Modern AI adapts to your reality - Paper or Digital - to deliver insights in days!

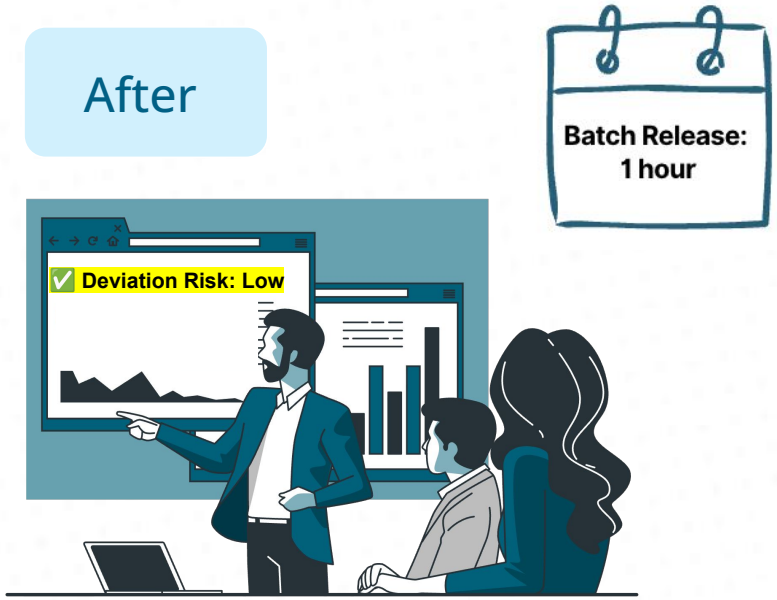


A day in the life: From firefighting to forecasting

Before

QA teams buried in stacks of paper, looking stressed. A calendar shows "Batch Release: 5 Days

After



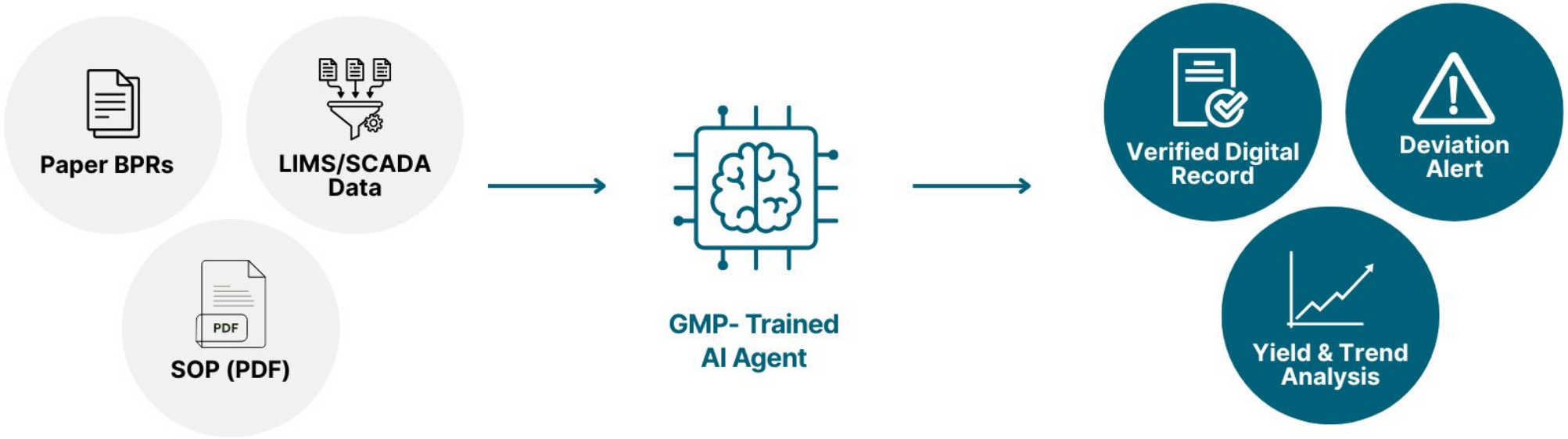
The dashboard shows "Deviation Risk: Low." The calendar shows "Batch Release: 1 hour.

How it works - AI Agents for GMP Compliance

AI agents read and understand your GMP documents and data

They are anchored on your site-specific SOPs and MBRs.

They verify data in real-time, flag potential deviations, and uncover hidden trends



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Building Trust: Reliability & Oversight by Design

Human Oversight is Critical. Uncertain outputs are automatically flagged for human review.

No "Black Boxes." Every AI output is traceable to the source data.

Designed for Your Next Inspection. Immutable audit trails clearly separate human vs. AI actions.

The Results: Audit Ready, Business-Adapted

95+%
Reduced Batch Review Time: From 5 days to 1 hour

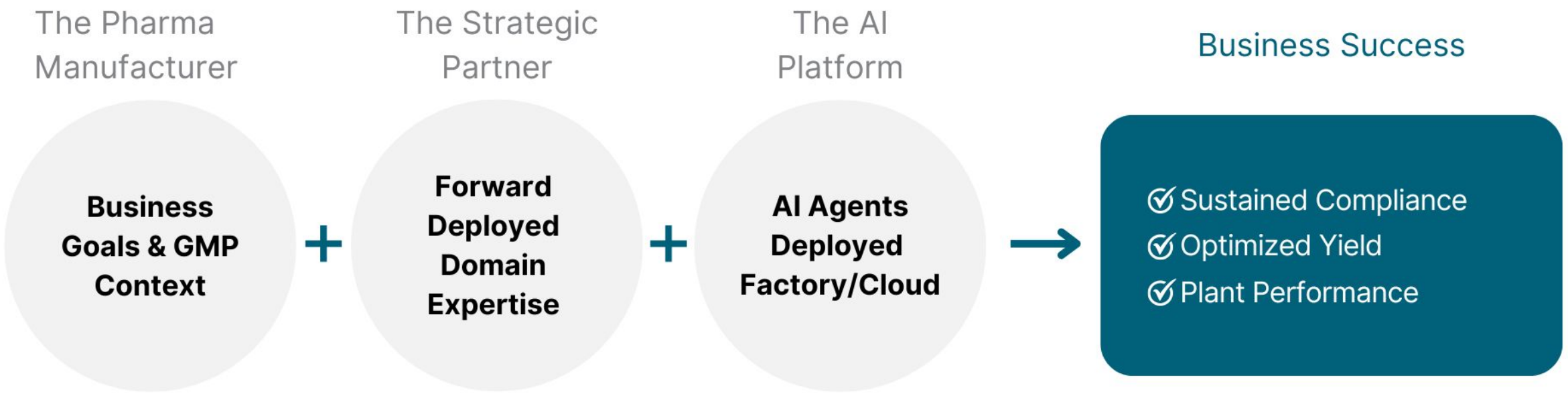
0
Zero
Data Integrity Issues: During internal and external audits

High
Improvement in right-first-time metric

- **Regulator Confidence:** GAMP-aligned, 21 CFR Part 11 compliant, and audit ready by architecture.
- **Business Adaptability:** Deploys in weeks, not years. Works with your existing people and processes

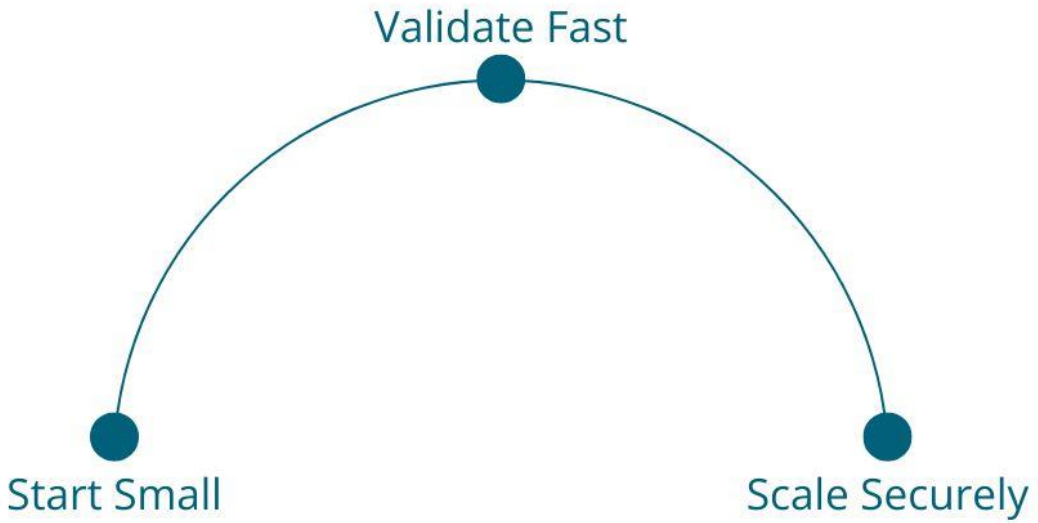
Rethinking Partnership in the AI Era

From IT Services to a Strategic **“Success Trio”**



How to get started?

- AI adoption doesn’t have to be risky all-or-nothing
- Pick solutions that are non-disruptive and give the best ROI
- Start with small wins like compliance, and grow with confidence



The AI factory is here

Build your future on a New Foundation

Audit-Aligned

Quality-First

Yield-Aware

https://forms.office.com/r/PfDRKfJ8XS