From Scale to Science:
Building AI-enabled BioPharma manufacturing advantage

GPQS

24th February 2026

India's next leap: From pharmacy of the world to a global BioPharma manufacturing hub

PHARMACY of the world

40%
Volume of drugs sold in the US

20%
Volume of drugs sold globally

30%+
Lower costs vs. US and Europe

700+
FDA-approved sites – highest in a country

BIOPHARMA powerhouse ?

70%+
Global mortality burden is NCDs where Bio is central to care

~50%
of innovative drug pipeline

~50%
New capacity addition announcements

Source: Future of India Pharma Operations, Global Business Reports, WHO,. Fortrea

Operations performance: Key differentiator in Biologics

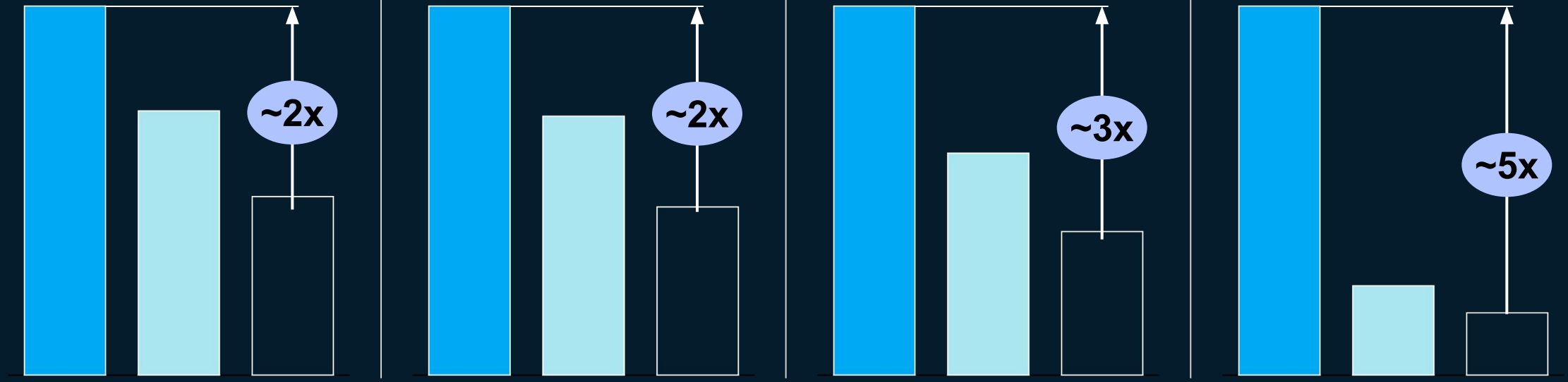
Productivity unit/FTEs[1]

Top quartile | Median | Bottom quartile

Chemical

Biologics

API	Solids	Sterile liquids	Drug Substance
Output PER FTE	'000 Units PER FTE	'000 PUs PER FTE	Batches PER 100 FTEs



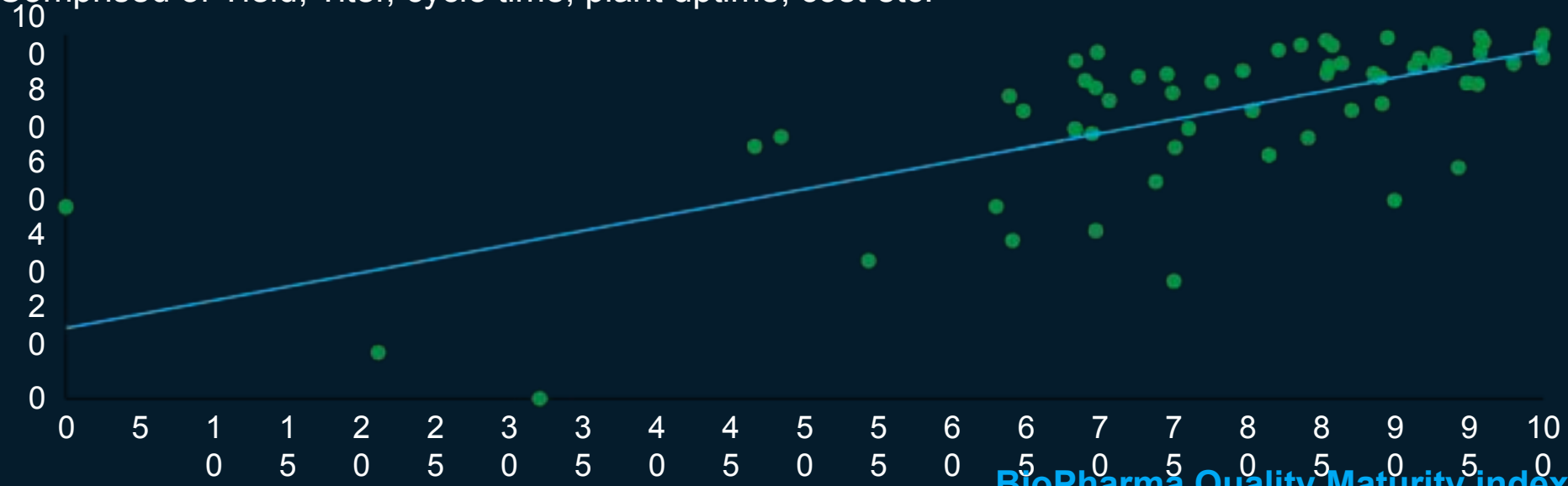
1. Productivity units are not comparable between technologies

Source: McKinsey POBOS

Quality Matters: Plants with highest Quality standards outperform in Operations performance

Correlation of Operations performance with Quality maturity[1,2]
n=58 BioPharma sites

BioPharma Performance index
Comprised of Yield, Titer, cycle time, plant uptime, cost etc.



BioPharma Quality Maturity index
Based on OOS rates, deviation rates

BioPharma leaders outperforming on both quality & operating performance

Quality is not just 'hygiene', but a **driver of performance and a core differentiator**

1. Data transformed using reverse min-max normalization (min: 100, max: 0)
2. Quality maturity index calculated using deviations per batch; Performance index calculated using unit cost blending yield, cycle time, titer efficiencies

Source: McKinsey POBOS

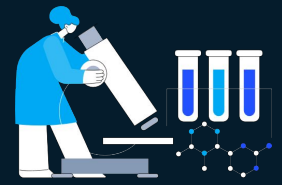
Scientific complexity: BioPharma manufacturing has different set of challenges vs. traditional pharma

While foundations of good quality remain same…

… these complexities make it difficult to do this consistently

Much higher variability

Living cells grow unpredictably, even under seemingly similar conditions



Complex interdependencies

Performance relies on much more interdependent parameters

Extreme sensitivity

Small shifts drive significant fluctuations in performance

Long cycle times

Hard to monitor variables real-time. Small deviations drive substantial impact on key attributes

AI advantage: Rewiring manufacturing processes with AI is key to success in Biomanufacturing

Traditional approaches can achieve median performance		‘Rewiring’ with AI can drive top-decile performance
 Process engineering & DOEs	→	**Digital twins** for in-silico modeling for product development, tech transfer
 Offline testing & analysis	→	**AI soft sensors and deep-learnings PAT** for continuous visibility into CQAs
 Golden batch analysis	→	**Self-optimized closed loop control** for real-time batch steering
 Root cause investigation	→	**GenAI Copilots** for deviation triage, evidence synthesis and documentation
 Shopfloor data systems	→	**Agentic AI for end-to-end orchestration** of manufacturing operations

Success Stories: Examples of highest-impact AI applications

1

IN SILICO product development

30%+ ↓
development TAT & costs

40%+ ↓
physical experimentation

2

AI GUIDED tech transfers

30-50%+ ↓
tech transfers timelines

25-40% ↑
first-time-right scale-ups

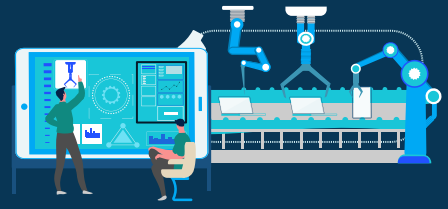
3

REAL-TIME steered batch operations

20-50% ↑
Yields and titers

50% ↓
Batch failure / OOS / OOT

4



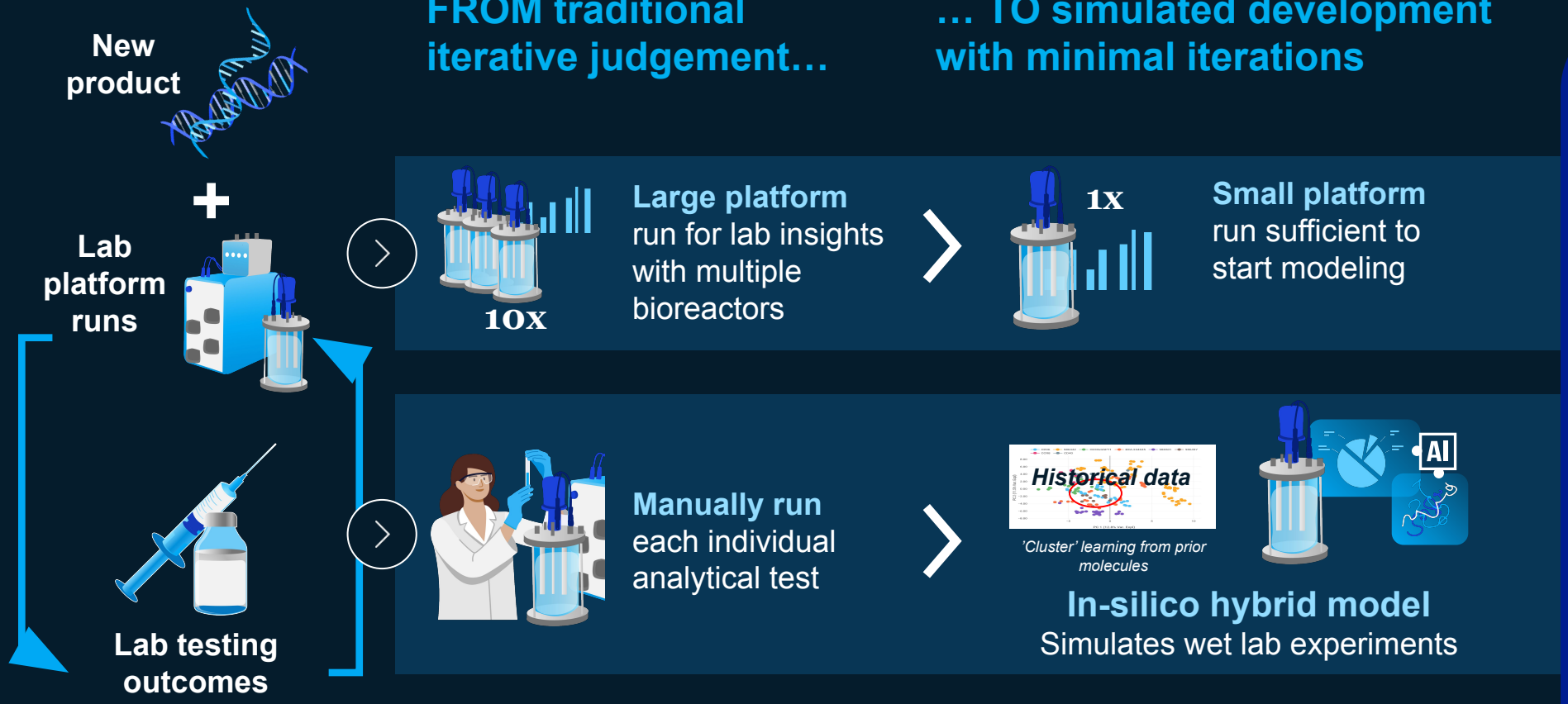
ALWAYS-ON 'Zero Error' oversight

80% ↓
Repeat non-conformances

40%+ ↑
Speed of error resolution

Source: McKinsey analysis

1. IN SILICO Process Development: Hybrid models enabled speed and efficiency



~30% ↓
Product development timelines

~40% ↓
Iterations / physical experimentation

~50+% ↓
FTE requirements per project

Results in

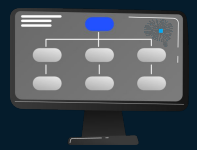
10x iterations
Manual bioreactor experiments (limited by capacity)

6x iterations
Automated and very targeted confirmatory runs

Source: McKinsey analysis

2. AI GUIDED Tech transfers – integrated suite of use cases plugged interface leakages across the tech transfer value chain

GenAI-based documentation | Agentic AI-enabled business process | AI/ ML-based modeling

Pre-initiation	Initiation Phase	Planning Phase	Execution Phase	Launch
 **1. Predictive in-silico models** for scale-up	 **2. Facility-fit analysis**	 **4. Smart RFP** generation	 **6. Real-time batch analyzer** for Eng / PpQ	 **8. Automated report and submission authoring**
	 **3. Material planning** & supply assurance	 **5. Governance process accelerator**	 7. **Process execution Agent** for decision support	

Cross cutting

9. **Tech Transfer decision orchestration agent**

10. **Digital thread/platform** for process, product, and plan data

30-50% ↑
tech transfer speed

0
Interface leakages and unplanned failures

25-40% ↑
first-time-right scale-ups

Source: McKinsey analysis

3. REAL-TIME steered batch operations: Real-Time Process Simulation and Prediction

FROM judgement-based manual steering of batches …

… TO ML-guided, real-time and automated batch steering

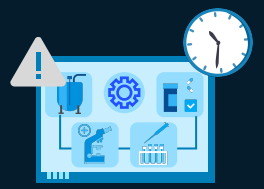
A

Experience-led process given **complex, interdependent bioreactor variables**

AI guided process setpoints to inform / guide process runs

B

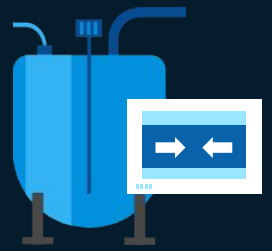
Resource-intensive and fragmented process optimization



Real time ML models continuously predict and optimize parameters

C

Any schedule changes manually communicated to operations



Schedule dynamically adjusted (steered) to reflect most optimal changes

AI models continuously refined with every new batch data

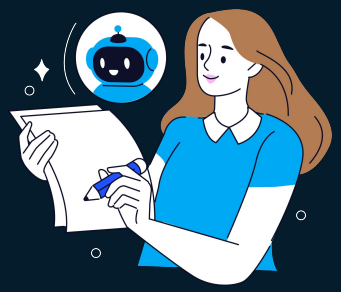
30%+ ↑
reactor occupancy

20%+ ↑
yield / tier

80% ↓
in CQA variability

Source: McKinsey analysis

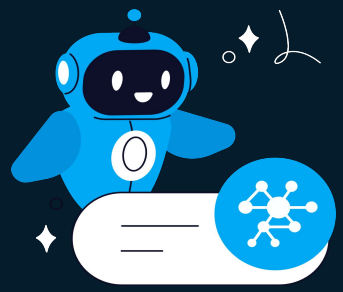
Key takeaways: Learnings for BioPharma leaders



1

BOLD AMBITION

Strive to achieve top-decile operations & quality performance



2

AI-FIRST APPROACH

Reimagine shopfloor end-to-end processes with AI

3

REWIRE FOR SCALE

Talent, Data & Tech, Partnerships, Change management

THANK YOU

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