Perspectives on the future of manufacturing and quality

Keynote presentation

June 2023
Major shaping forces have mostly been consistent; however, not all have been consistent in how they shaped the industry
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i.e., expectations for best quality at the right time and at low cost.
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- **Opportunities and complexities of global supply chains**
  i.e., new sources of supply, access to new markets and improved supply configurations
Leaders have responded by delivering significant performance on patient outcomes

Key outcomes benchmarking for the last 8 years (data indexed to 100 for base year)

Delivery outcomes¹
OTIF vs confirmed (%, POBOS)

```
100 106
```

+6%

Cost outcomes¹
Labor productivity (Mn units/FTE, POBOS)

```
100 118
```

+18%

Quality outcomes²
Inspections resulting in OAI, % (FDA data)

```
100 101
```

+1%

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¹Analysis basis McKinsey’s POBOS benchmarking analysis for repeat samples. N=18 for Asia and N=96 for Global sites
²For quality outcomes, base year data considered as average from 2013-17; latest year data considered as average from 2019-2023 for 4425 global and 442 Indian sites and excluding data from 2021 and 2022 due to COVID impact
Leaders have responded by delivering significant performance on patient outcomes
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<tr>
<td>![Bar chart for Delivery outcomes] 100 (2013) to 106 (2021) +6%</td>
<td>![Bar chart for Cost outcomes] 100 (2013) to 118 (2021) +18%</td>
<td>![Bar chart for Quality outcomes] 100 (2013) to 101 (2021) +1%</td>
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However, as we look ahead, Pharma companies may need to reimagine their operations

Key challenges

- Plateauing performance improvements
- Increasing variable costs
- Need for different and deeper bench of capabilities
- Rising bar on quality & compliance
However, as we look ahead, Pharma companies may need to reimagine their operations.

**Key challenges**

- Plateauing performance improvements
- Increasing variable costs
- Need for different and deeper bench of capabilities
- Rising bar on quality & compliance

**Big opportunity areas**

- Innovation and new emerging modalities
- Advances in digital technology
- Increasing focus on ESG
Six areas PharmaCos can reimagine operations

1. Continued focus on (cost, delivery and) quality compliance & excellence
2. Reimagine supply chain to build agility and resilience
3. Where and how to play in new product technologies/modalities
4. Focus on ESG in the medium term

- At-scale technology adoption as a ‘must-do’
- Win the war for Talent & Capabilities critical to the all the above
Six areas PharmaCos can reimagine operations

At-scale technology adoption as a ‘must-do’
Digital & AA enabled operations is complementing and advancing lean...

Classic smart lean ways of working...

... are being enabled by Ops 4.0 methodologies

Visual management

Digital Performance management

Integrated plant data lake
Digital & AA enabled operations is complementing and advancing lean...

... are being enabled by Ops 4.0 methodologies

Classic smart lean ways of working...

- Visual management
- MIFA (Material and Information Flow Analysis)
- Digital Performance management
- Integrated plant data lake
- Digital twin (of a plant/process)
Digital & AA enabled operations is complementing and advancing lean...

Classic smart lean ways of working...

- Visual management
- Just-in-time, Single Minute Exchange of Die
- Jidoka and autonomination
- MIFA (Material and Information Flow Analysis)

... are being enabled by Ops 4.0 methodologies

- Digital Performance management
- Integrated plant data lake
- Advanced Analytics based yield optimization and cycle-time reduction
- Digital traceability, ML led deviation management, predictive algorithms, proactive alerts and RCA
- Digital twin (of a plant/process)
... and is ushering in the vision of E2E ‘Digital Production System’

Illustrative/not exhaustive

Manufacturing/production

- AA enabled Machine settings
- Realtime Digital performance boards
- AR guided changeovers
- AA insights to reduce Micro stoppages
- Automatic alerts
- HPLC equipment analytics
- AR guided test instructions
- Live tracking test statuses
- Dynamic QC scheduling
... and is ushering in the vision of E2E ‘Digital Production System’

Illustrative/not exhaustive

Warehouse ➔ Manufacturing/production ➔ Plant support (QA, Engg., SC)

- E2E material traceability
- Material flow dashboards
- AA enabled Machine settings
- Automatic alerts
- Realtime Digital performance boards
- AR guided changeovers
- AA insights to reduce Micro stoppages
- Quality Control Lab
- HPLC equipment analytics
- AR guided test instructions
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- Predictive maintenance through AA based insights
- AI powered root-cause analysis
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Warehouse ➔ Manufacturing/production

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- **Material flow dashboards**
- **Quality Control Lab**
  - AA enabled Machine settings
  - Automatic alerts
  - HPLC equipment analytics
  - AR guided test instructions
  - Live tracking test statuses
  - Dynamic QC scheduling

- **Workforce Management**
  - Dynamic work allocation

- **Realtime Digital performance boards**
- **AR guided changeovers**
- **AA insights to reduce Micro stoppages**

 ↔ **Plant support** (QA, Engg., SC)

- **AI powered root-cause analysis**
- **Predictive maintenance though AA based insights**
- **Digital enabled learning/e-learning on-the-go**
This has the potential to unlock significant performance

1

**Productivity improvement**

- **30-40%**
  Increase in capacity of bottleneck equipment

- **30%+**
  Increase in overall OEE/asset productivity

- **20-30%**
  Increase in people productivity

Source: McKinsey White paper – “What’s now and next in analytics, AI, and automation”
This has the potential to unlock significant performance

1
Productivity improvement
- 30-40% Increase in capacity of bottleneck equipment
- 30%+ Increase in overall OEE/asset productivity
- 20-30% Increase in people productivity

2
Quality excellence/improvement
- 30-50% Reduction in deviations
- 20-30% Reduction in OOS
- 200%+ Increase in product robustness

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This has the potential to unlock significant performance increase.

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### 3. Conversion Cost Optimization
- **20-35%**
  - Reduction in conversion cost
- **10-15%**
  - Reduction in manpower cost

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   - 30-50%: Reduction in deviations
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   - 200%+: Increase in product robustness

3. Conversion Cost optimization
   - 20-35%: Reduction in conversion cost
   - 10-15%: Reduction in manpower cost
   - 15-20%: Increase in Commit vs. Actual (OTIF)

4. Service level optimization
   - 15-20%: Decrease in logistics cost

Source: McKinsey White paper – “What’s now and next in analytics, AI, and automation”
Digital adoption has accelerated significantly; India exhibits leadership

132 advanced 4IR lighthouses identified globally

19 global lighthouses from pharmaceuticals and medical devices

2 lighthouse sites from India

Six areas PharmaCos can reimagine operations

Continued focus on (cost, delivery and) quality compliance & excellence
While the industry has demonstrated a strong trajectory, much remains to be done to achieve quality excellence

Significant progress made on quality over last 8+ years ...

Inspections resulting in OAI, % (FDA data)

- Global
- Asia

<table>
<thead>
<tr>
<th>Year</th>
<th>Global</th>
<th>Asia</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015-17</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>2018-23</td>
<td>101</td>
<td>70</td>
</tr>
</tbody>
</table>

Source: Data sourced from USFDA inspections database for drug-quality inspections. Data from 2021 and 2022 not considered due to paucity of USFDA audits post COVID-19. Based on the inspection of a total of 4425 unique PharmaCos globally and 442 unique Indian PharmaCos in the last 8 years.
While the industry has demonstrated a strong trajectory, much remains to be done to achieve quality excellence.

Significant progress made on quality over last 8+ years …

Inspections resulting in OAIAs, % (FDA data)

- Global
- Asia

2015-17: 100, 70
2018-23: 101, 70

+1% increase
-30% decrease

… however, much more needs to be done to achieve quality excellence.

+35% increase in OAIAs as % of USFDA inspections in India

~70% of OAIAs in 2022 were from top Pharma companies in the country (part of IPA group).

Source: Data sourced from USFDA inspections database for drug-quality inspections. Data from 2021 and 2022 not considered due to paucity of USFDA audits post COVID-19. Based on the inspection of a total of 4425 unique PharmaCos globally and 442 unique Indian PharmaCos in the last 8 years.
Leading PharmaCos have already started to think about this
Survey of top 10 PharmaCos globally, 2022

Q: What are your biggest priorities to make your Quality function more resilient?

<table>
<thead>
<tr>
<th>Priority</th>
<th>% of respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improve risk identification</td>
<td>55</td>
</tr>
<tr>
<td>New tools and capabilities for resilience</td>
<td>52</td>
</tr>
<tr>
<td>Strategic investments to prepare for adverse events</td>
<td>48</td>
</tr>
<tr>
<td>Integrate resilience into operating model</td>
<td>34</td>
</tr>
<tr>
<td>Assess scenarios to anticipate impact</td>
<td>34</td>
</tr>
</tbody>
</table>

Q: What are the biggest moves you are looking to make in the next 2-3 years on quality?

<table>
<thead>
<tr>
<th>Move</th>
<th>% of respondents</th>
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<tbody>
<tr>
<td>Digital/AA enabled Quality processes</td>
<td>62</td>
</tr>
<tr>
<td>Predictive quality</td>
<td>55</td>
</tr>
<tr>
<td>QMS redesign and digitization</td>
<td>48</td>
</tr>
<tr>
<td>E2E connection of product data</td>
<td>45</td>
</tr>
<tr>
<td>Automated inline testing</td>
<td>28</td>
</tr>
</tbody>
</table>

Source: McKinsey survey of Top10 PharmaCos globally, 2022
5 pillars of Quality excellence of the future – “Smart Quality”

Quality controls optimized, Automated, Digitized, and Integrated into product development and supply chain workflows

“Smart” Quality Controls
5 pillars of Quality excellence of the future – “Smart Quality”

Quality Management Systems and processes reimagined with design thinking approach, enhanced with automation
5 pillars of Quality excellence of the future – “Smart Quality”

“Smart” Quality Controls

“Smart” Quality Assurance

Process and product mastery

Direct sources of value

Enablers

Advanced analytics and risk based decision making to predict and prevent quality issues
5 pillars of Quality excellence of the future – “Smart Quality”

- “Smart” Quality Controls
- “Smart” Quality Assurance
- Process and product mastery
- Pan-Enterprise collaboration and quality capability building built into day-to-day work
- “Smart Quality” ways of working

Direct sources of value
Enablers
5 pillars of Quality excellence of the future – “Smart Quality”

“Smart” Quality Controls

“Smart” Quality Assurance

Process and product mastery

“Smart” compliance foundation

“Smart Quality” ways of working

Joint innovation with regulators focused on process and system maturity

Direct sources of value

Enablers
Six areas PharmaCos can reimagine operations

Focus on ESG in the medium term
ESG is becoming important for doing business today; even more important in future

Strong investor appetite

$17T

of assets managed by ESG investors

1. Total U.S.-domiciled sustainably invested assets under management, both institutional and retail; 2. % who consider a company’s social and environmental commitments when deciding where to work; 3. From 2013 to 2018, based on analysis of sustainability-marketed products in US CPG market, compared to conventional counterparts

Source: CNBC article, “Sustainable investing’ is surging, accounting for 33% of total U.S. assets under management’ (Dec 2020); McKinsey Quarterly, ‘Five ways that ESG creates value’ (2019); NYU Stern’s Center for Sustainable Business, ‘Sustainable Share Index™: Research on IRI Purchasing Data’ (2019); CDP, ‘Climate Change’ Report (2019); Cone Communications, ‘Millennial Employee Engagement Study’ (2016); Forbes article, ‘A Fifth Of World’s Largest Companies Committed To Net Zero Target’ (March 2021); Energy and Climate Intelligence Unit & Oxford Net Zero, ‘Taking Stock’ Report (2021); McKinsey analysis
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**Shifting customer expectations**

>6x

growth in sustainability CPG products

50%

of CPG growth came from sustainability-marketed products

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**Strong investor appetite**

$17T of assets managed by ESG investors

**Shifting customer expectations**

>6x growth in sustainability CPG products

50% of CPG growth came from sustainability-marketed products

**Talent attracted to sustainable firms**

76% of millennials attracted towards sustainable companies

Aspirational target setting

>20% of world’s largest public companies have committed to net-zero as of today.

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GSH goes beyond ‘just’ compliance; there is real value opportunity

1. Sustain market share
2. Mitigate potential cost and supply risks
3. Increase operations efficiency
4. Green business building
5. Lower cost of capital
6. Value for investors
7. Employee productivity and morale uplift

7 drivers of value
# The ESG near-term potential and vision in Pharmaceuticals

## Environment

<table>
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<th>2030</th>
<th>Vision</th>
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<td><strong>50% reduction</strong></td>
<td><strong>NET ZERO</strong> with</td>
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<td>reduction of total carbon footprint¹; Carbon neutral for scope 1 &amp; 2</td>
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1. Including Scope 3
2. Type II diseases have a substantial proportion of their cases in low & middle income countries. Type III diseases are those that are overwhelmingly or exclusively incident in low & middle income countries. Type III diseases are currently researched 8 times less than type I diseases burdening mostly high income countries

The ESG near-term potential and vision in Pharmaceuticals

2030

Environment

50% reduction
reduction of total carbon footprint;
Carbon neutral for scope 1 & 2

Social

100% availability
priority treatments in portfolio
accessible and affordable to all
patients worldwide

Vision

NET ZERO with
- Decarbonization along the value chain
- Waste elimination

Reduce global disease burden
- Maximize access & equity
- Invest and innovate to address true unmet needs


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The ESG near-term potential and vision in Pharmaceuticals

**2030**

**Environment**

- **50% reduction**
  - Reduction of total carbon footprint¹; Carbon neutral for scope 1 & 2

**Social**

- **100% availability**
  - Priority treatments in portfolio accessible and affordable to all patients worldwide

**Governance**

- **100% reporting of self**
  - Sustainability reporting for own operations certified by independent 3rd party

**Vision**

**NET ZERO** with
- Decarbonization along the value chain
- Waste elimination

**Reduce global disease burden**
- Maximize access & equity
- Invest and innovate to address true unmet needs

**Full ESG transparency** and clear communication – internal and external

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In conclusion – 3 questions you can reflect on to ensure the future of your operations strategy

1. What forces do you foresee that your organization needs capitalize upon ... or safeguard against?

2. Will your current strategic vision for operations allow you to do this effectively?

3. What are some near term moves for you to make?