

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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Increasing bar on patient expectations and outcomes

i.e., expectations for best quality at the right time and at low cost

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Innovation in products and product technologies,

i.e., pace of products and product availability continued to accelerate, e.g., COVID

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Continuous battle for skilled talent more intense and complex

i.e., evolving talent requirements, plus new nature of work and expectations of talent

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Advances in operations technologies

i.e., from new operations and quality management systems to digital and Advance Analytics

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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

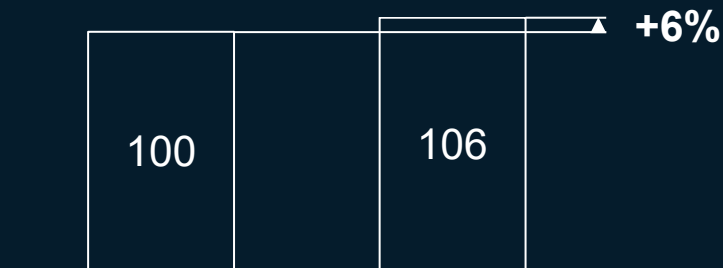
Leaders have responded by delivering significant performance on patient outcomes

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

□ Global

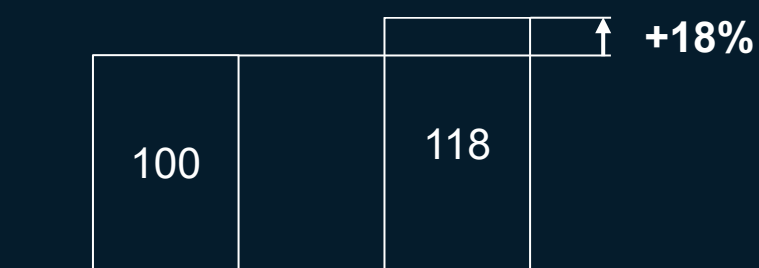
Delivery outcomes¹

OTIF vs confirmed
(%, POBOS)



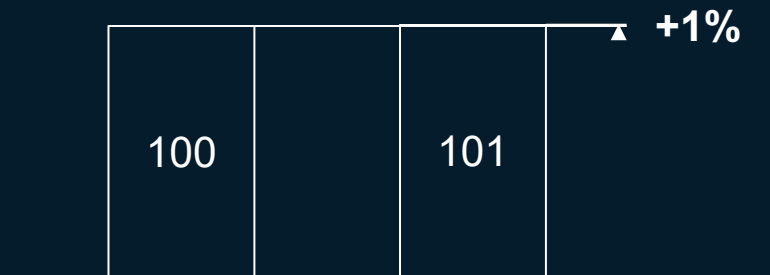
Cost outcomes¹

Labor productivity
(Mn units/FTE, POBOS)



Quality outcomes²

Inspections resulting in OAI, % (FDA data)



1. Analysis basis McKinsey's POBOS benchmarking analysis for repeat samples. N=18 for Asia and N=96 for Global sites

2. For 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

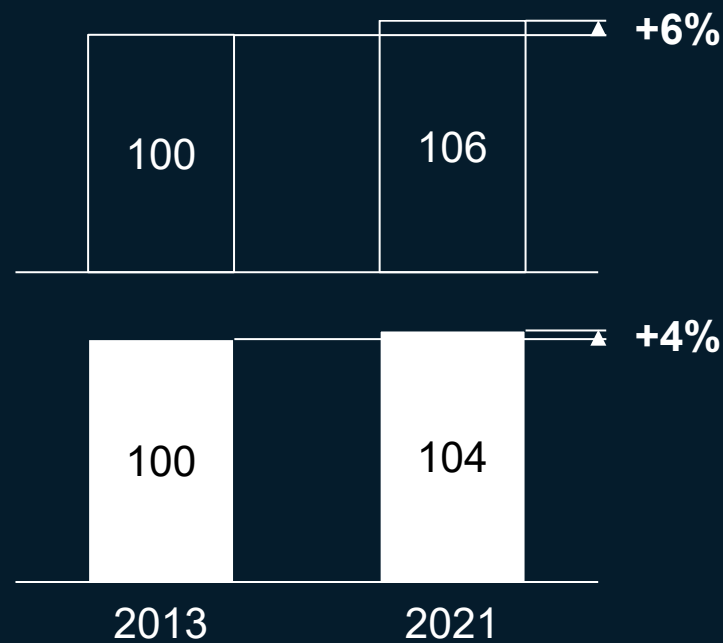
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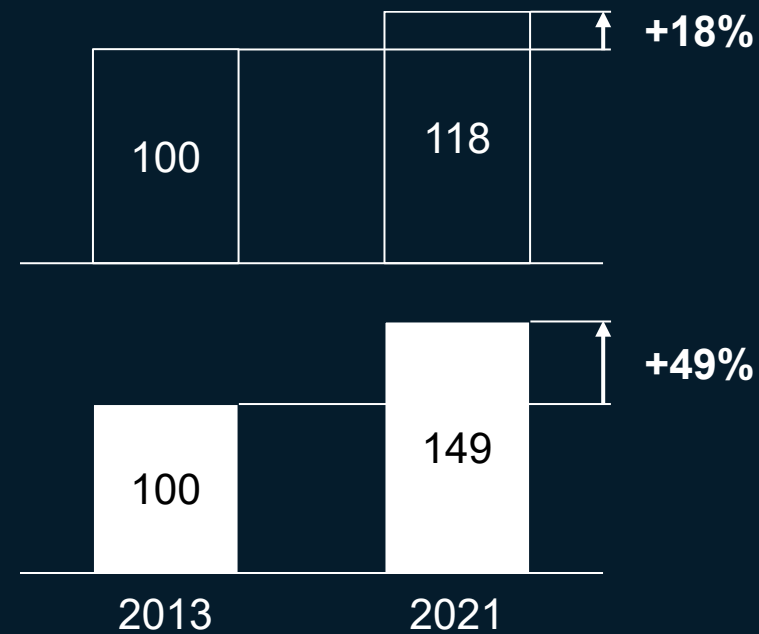
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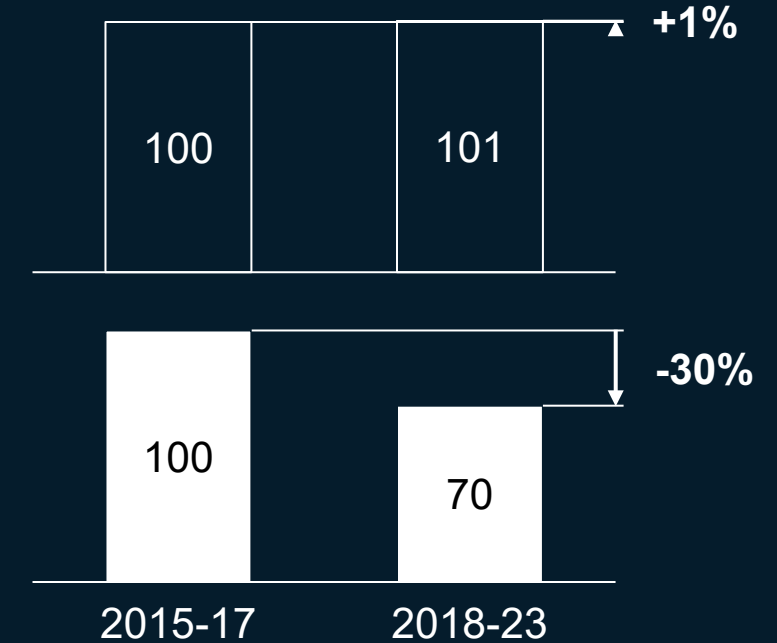
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However, as we look ahead, Pharma companies may need to reimagine their operations

Key challenges



Plateauing performance improvements



Increasing variable costs



Need for different and deeper bench of capabilities



Rising bar on quality & compliance

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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



Continued focus on (cost, delivery and) **quality compliance & excellence**



Reimagine supply chain to build agility and resilience



Where and how to play in **new product technologies/ modalities**



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...

Classic smart lean ways of working...



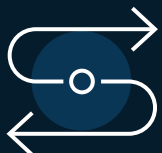
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Visual management



**Digital Performance management
Integrated plant data lake**



MIFA (Material and Information Flow Analysis)



Digital twin (of a plant/process)

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Visual management



**Digital Performance management
Integrated plant data lake**



**Just-in-time,
Single Minute Exchange of Die**



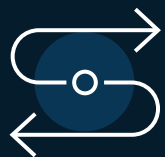
Advanced Analytics based yield optimization and cycle-time reduction



Jidoka and automation



Digital traceability, ML led deviation management, predictive algorithms, proactive alerts and RCA



MIFA (Material and Information Flow Analysis)




Digital twin (of a plant/process)


... and is ushering in the vision of E2E 'Digital Production System'

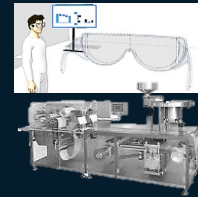
Illustrative/not exhaustive


Manufacturing/production


 AA enabled
Machine settings




 Realtime Digital performance boards




 AR guided
changeovers

 Automatic alerts

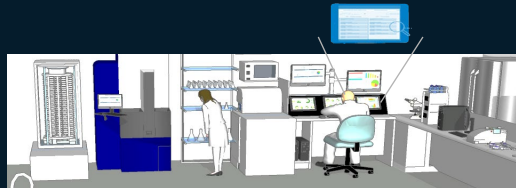
 AA insights to reduce
Micro stoppages


Quality Control Lab

 HPLC equip-
ment 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)

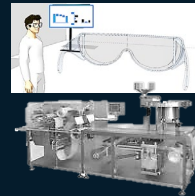
 E2E material traceability





 Material flow dashboards





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 HPLC equipment analytics



 AR guided test instructions




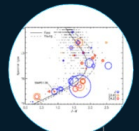
 Live tracking test statuses




Dynamic QC scheduling



 AI powered root-cause analysis



 Predictive maintenance through AA based insights

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Warehouse




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 Material flow dashboards

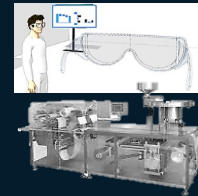



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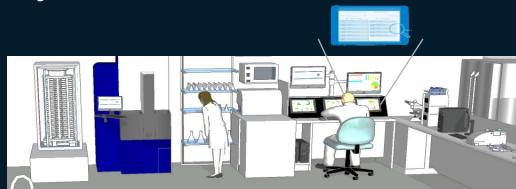
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Dynamic QC scheduling


Workforce Management

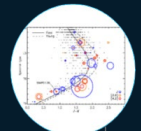
 Dynamic work allocation




 Digital enabled learning/ e-learning on-the-go



 AI powered root-cause analysis



 Predictive maintenance through AA based insights

This has the potential to unlock significant performance

● increase ● decrease

1

Productivity improvement

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



This has the potential to unlock significant performance

● increase ● decrease

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Quality excellence/ improvement

● **30-50%**
Reduction in deviations

● **20-30%**
Reduction in OOS

● **200%+**
Increase in product
robustness



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Conversion Cost optimization

● **20-35%**
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4

Service level optimization

● **15-20%**
Increase in Commit vs.
Actual (OTIF)

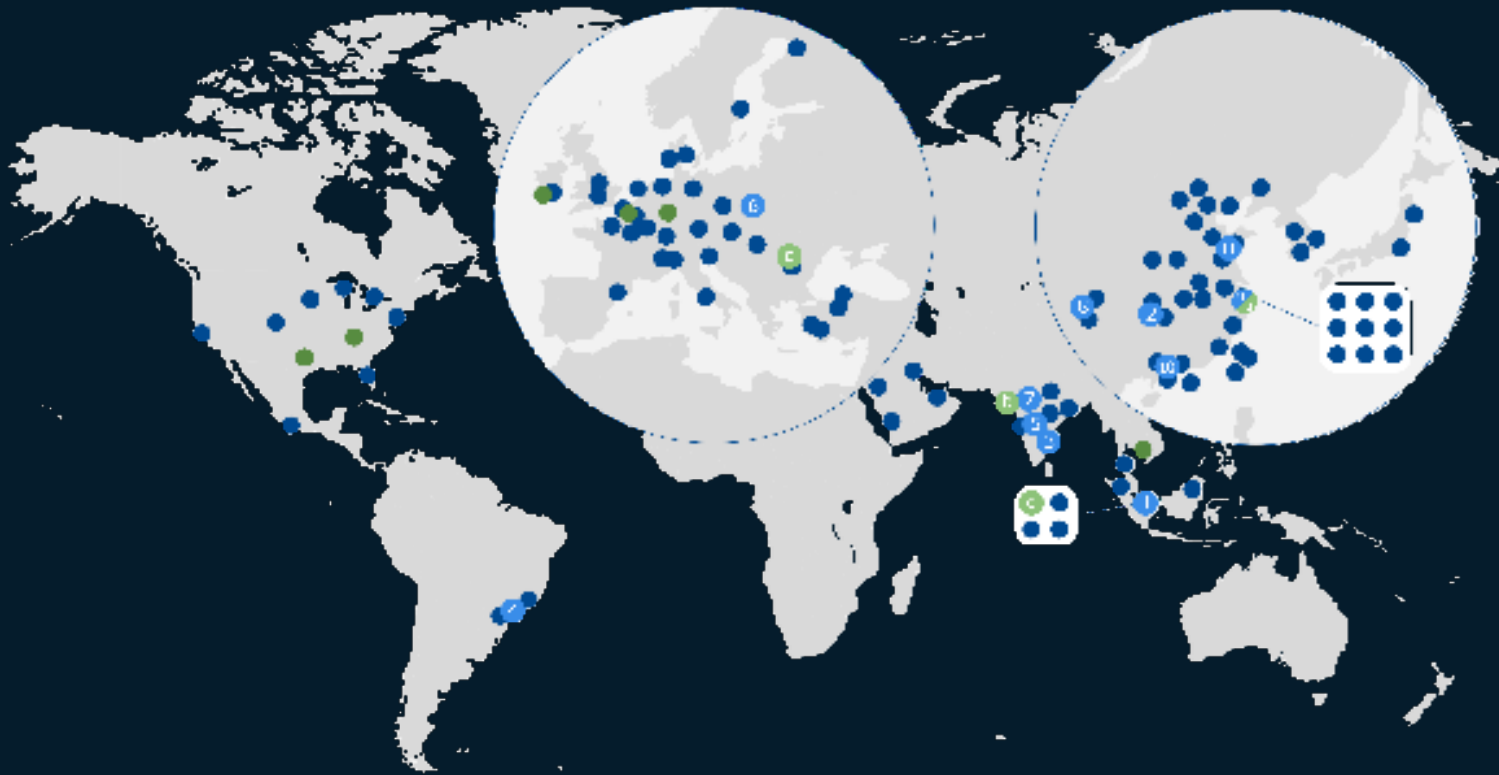
● **15-20%**
Decrease in logistics cost



Digital adoption has accelerated significantly; India exhibits leadership

World Economic Forum accredited lighthouses

● New Lighthouses ● Existing Lighthouses



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



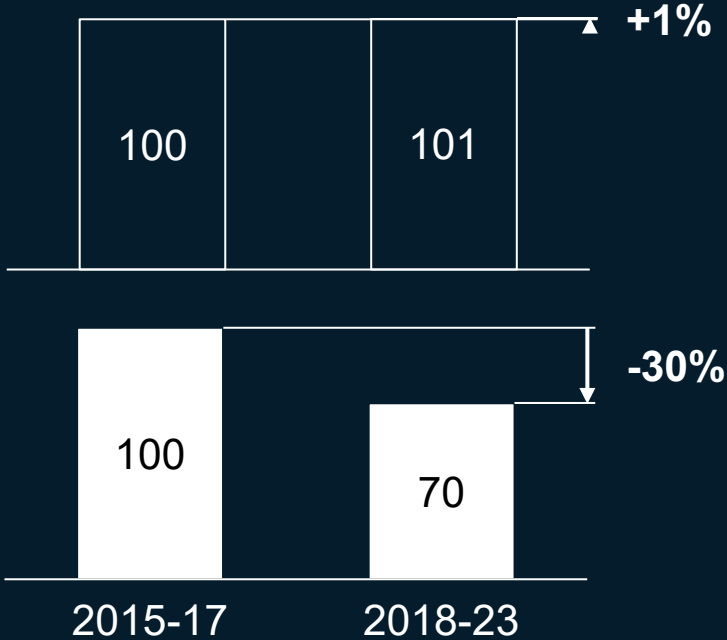
Continued focus
on (cost, delivery
and) **quality
compliance &
excellence**

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's, % (FDA data)

□ Global
■ Asia



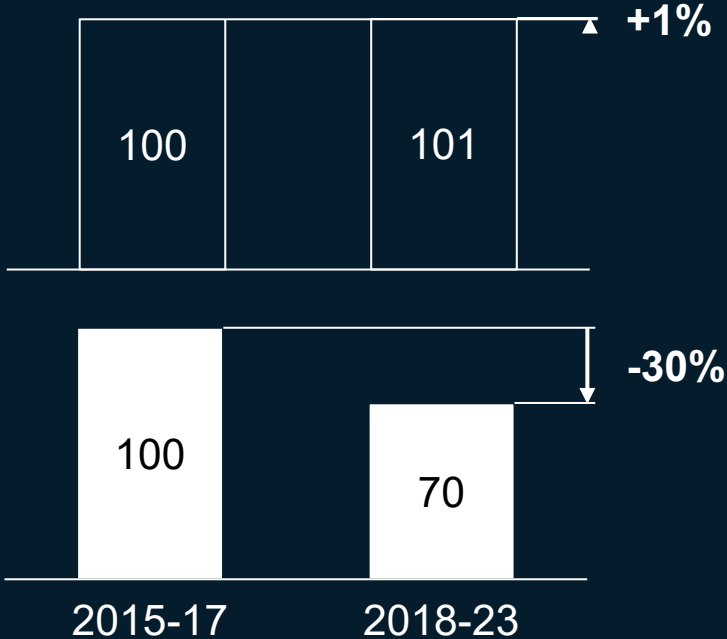
Source: Data sourced from USFDA inspections database for drug-quality inspections. Data from 2021 and 2022 not considered due to paucity of USFDA audits post COVID-19. Based on the inspection of a total of 4425 unique PharmaCos globally and 442 unique Indian PharmaCos in the last 8 years

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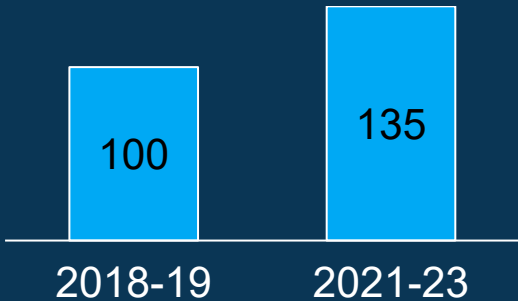
Inspections resulting in OAI's, % (FDA data)

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

■ India



+35%
Increase in OAI's as % of USFDA inspections in India

~70%
of OAI's in 2022 were from top Pharma companies in the country (part of IPA group)

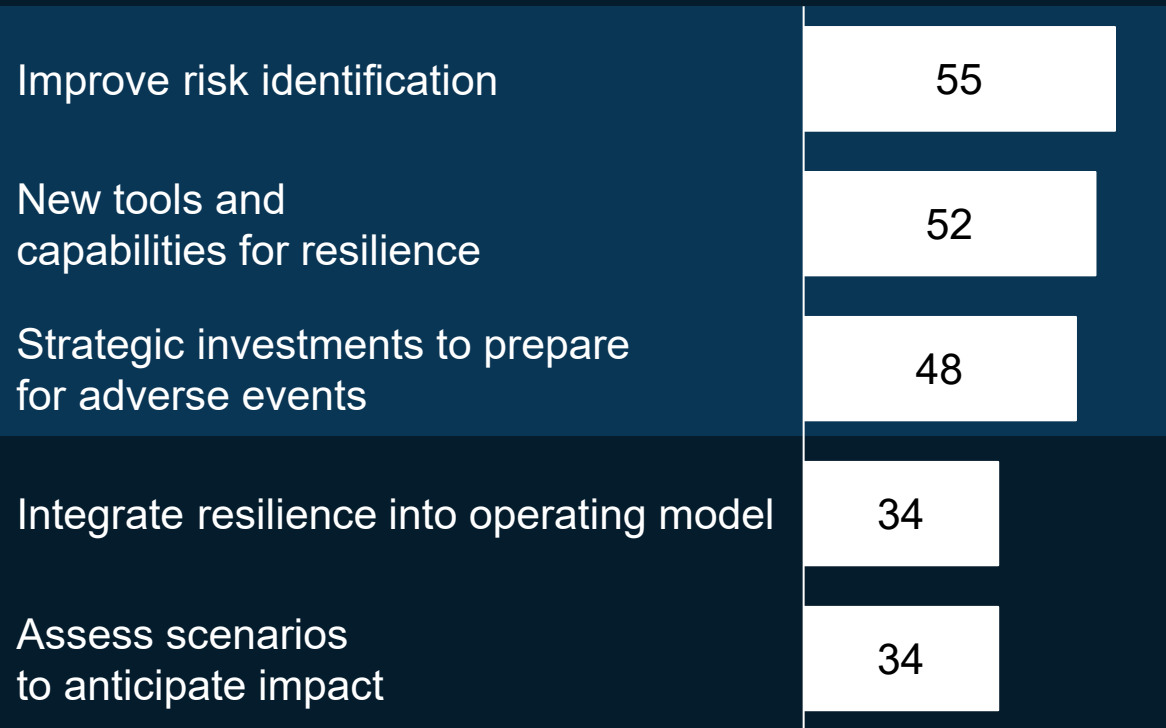
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Leading PharmaCos have already started to think about this

Survey of top 10 PharmaCos globally, 2022

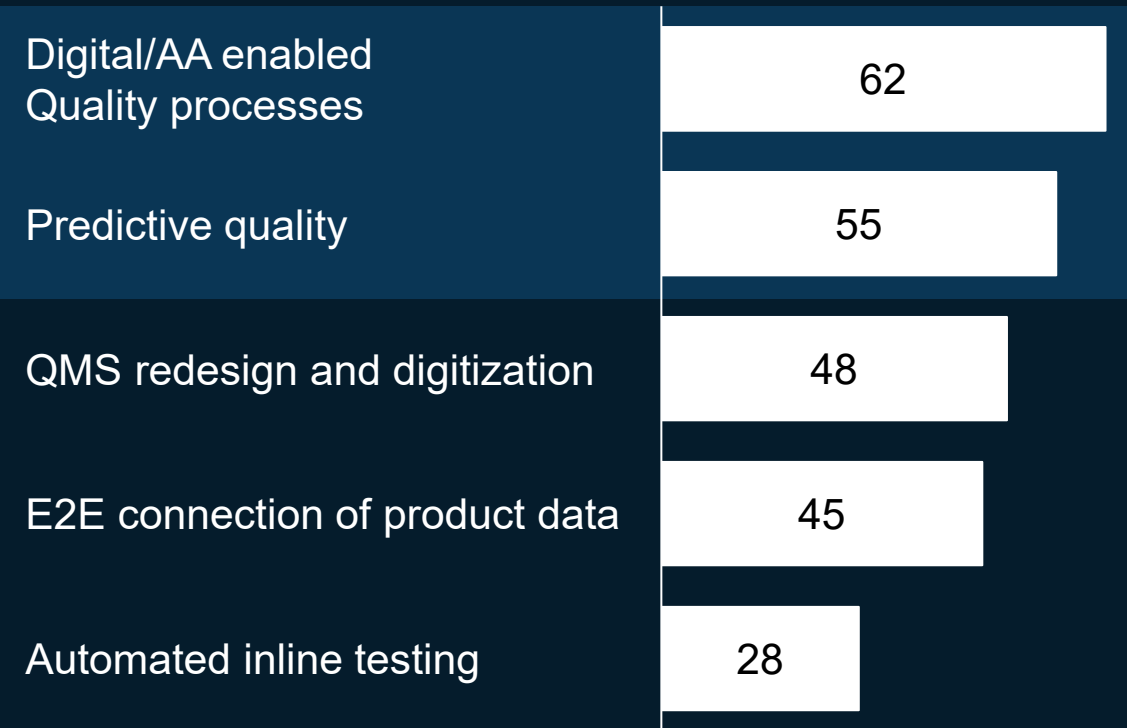
Q: What are your biggest priorities to make your Quality function more resilient?

% of respondents



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

% of respondents



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

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



- Direct sources of value
- Enablers

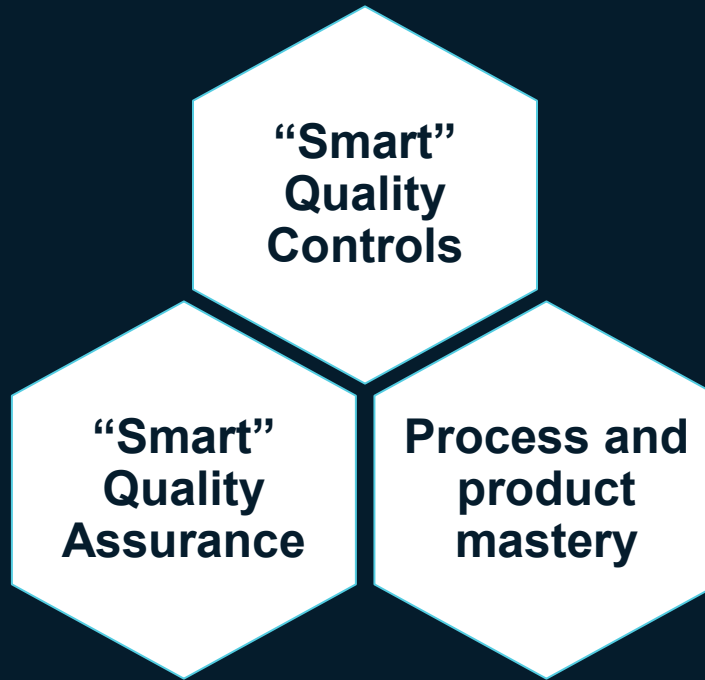
5 pillars of Quality excellence of the future – “Smart Quality”

Quality Management Systems and processes reimagined with design thinking approach, enhanced with automation



- Direct sources of value
- Enablers

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

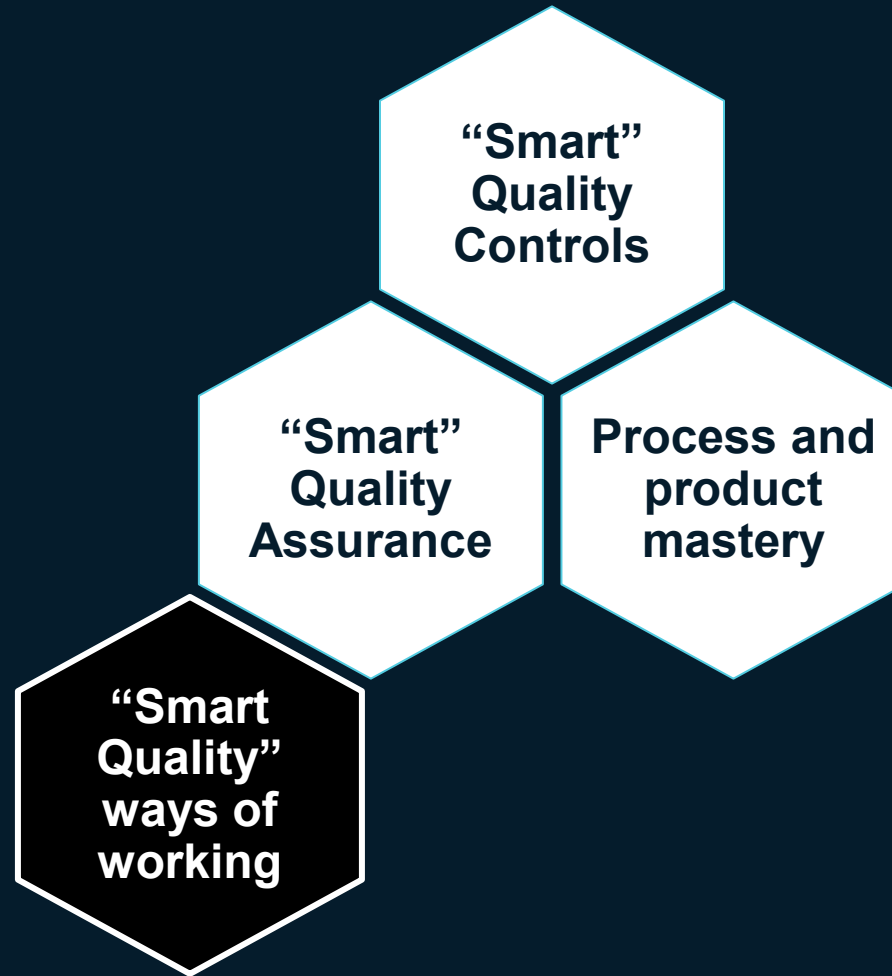


- Direct sources of value
- Enablers

Advanced analytics and risk based decision making to predict and prevent quality issues

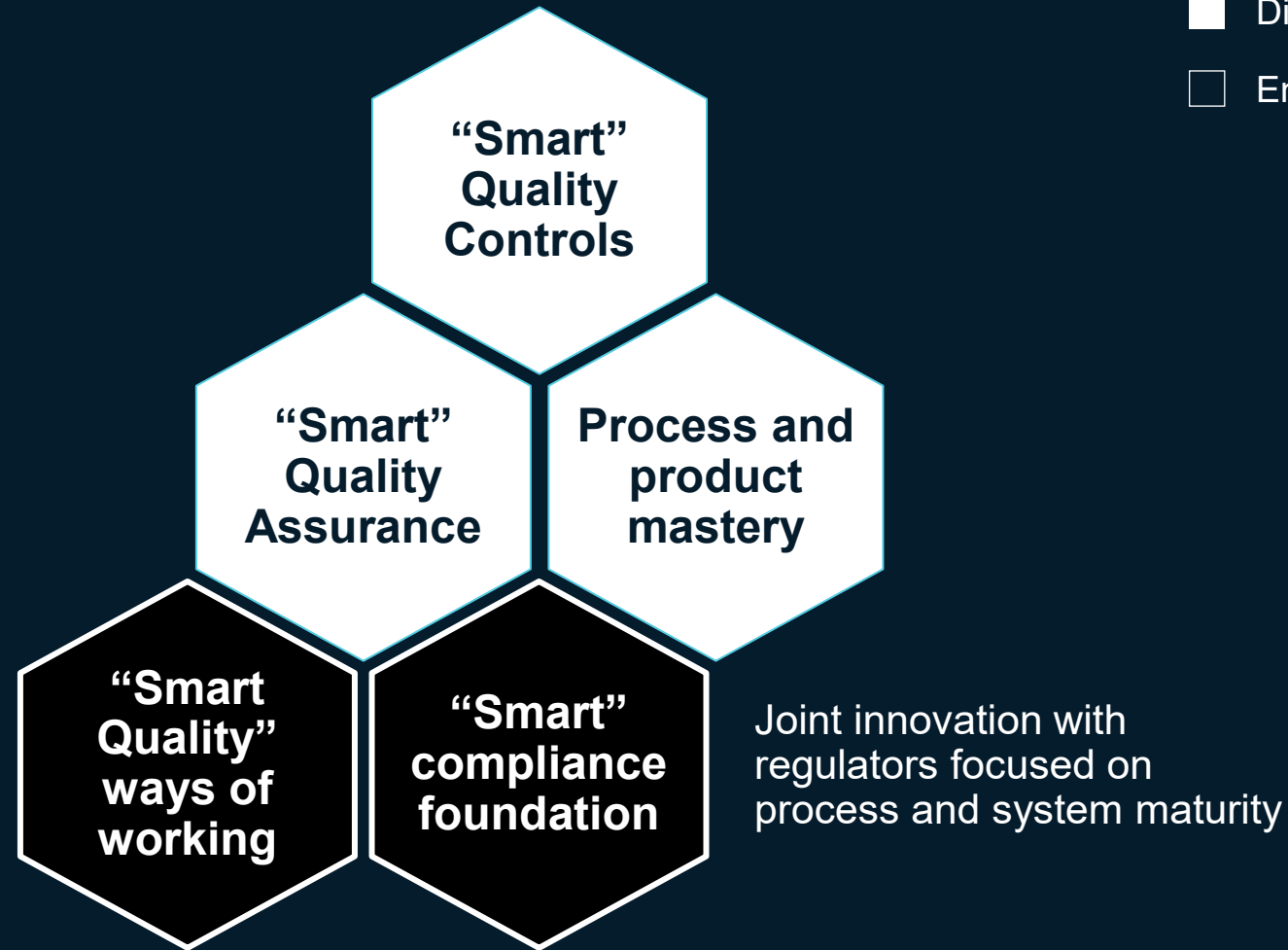
5 pillars of Quality excellence of the future – “Smart Quality”

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Pan-Enterprise collaboration and quality capability building built into day-to-day work

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

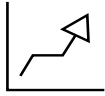


Six areas PharmaCos can reimagine operations



Focus on ESG in the
medium term

ESG is becoming important for doing business today; even more important in future



**Strong investor
appetite**

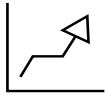
\$17T

**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 products³

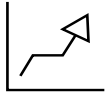
50%

of CPG growth came
from sustainability-
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Talent attracted to sustainable firms

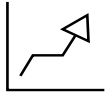
76%

of millennials
attracted towards
sustainable companies²

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Aspirational target setting

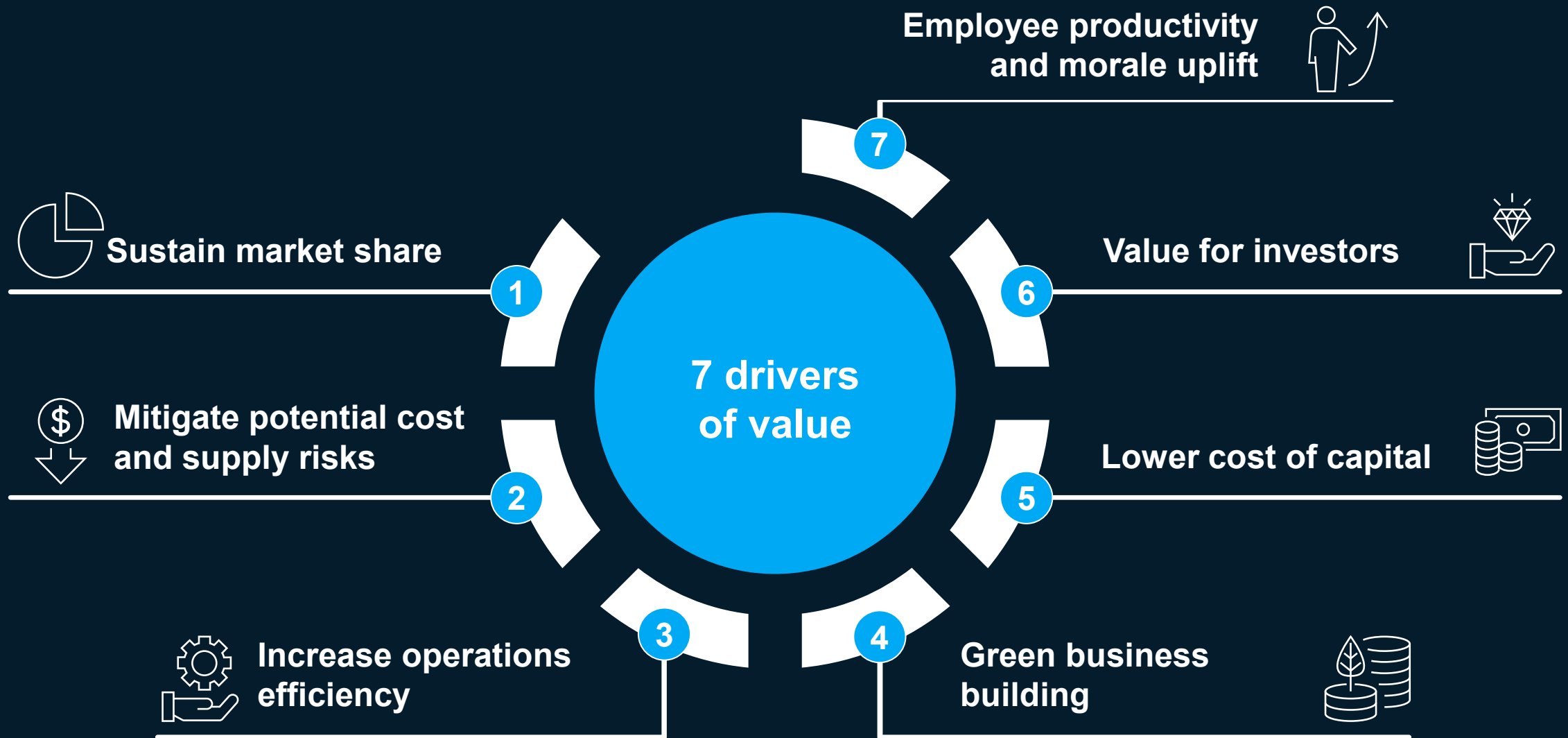
>20%

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



The ESG near-term potential and vision in Pharmaceuticals

Environment



2030

50% reduction

reduction of total carbon footprint¹;
Carbon **neutral** for scope 1 & 2

Vision

NET ZERO with

- Decarbonization along the value chain
- Waste elimination

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 in low & middle income countries. Type III diseases are currently researched 8 times less than type I diseases burdening mostly high Income countries

Source: Yegros, et al, 2019 Exploring Why Global Health Needs Are Unmet by Research Efforts, <http://dx.doi.org/10.2139/ssrn.3459230>

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100% availability

priority treatments in portfolio
accessible and affordable to all
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Reduce global disease burden

- Maximize access & equity
- Invest and innovate to address true unmet needs

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accessible and affordable to all
patients worldwide

100% reporting of self

sustainability reporting for **own**
operations certified by independent
3rd party

Vision

NET ZERO with

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- Waste elimination

Reduce global disease burden

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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?

