

Quality excellence: The next frontier for the Indian pharmaceutical industry



Indian Pharmaceutical Alliance

“

QUALITY

means doing
the right thing
when no one is
looking

”

Henry Ford



Indian pharma is a significant contributor to global public health



60%
of global
vaccine
production

30%+
annual
UNICEF
supply
globally



60%+
of global
supply of
ARV drugs

40-70% of
WHO demand for
DPT & BCG



90%
of WHO demand
for measles
vaccine

Indian pharma has been able to deliver this impact due to its **distinctive capabilities**

1

Manufacturing capabilities

- Highest number of US FDA-registered facilities outside US (379 facilities)
- 1400+ WHO GMP certified plants; 800+ UK MHRA certified sites

2

Product development capabilities

- 37% of total ANDA approvals
- 22% of the approvals in specialty generics

3

Process innovation capabilities

- One of the world leaders in efficient and cost competitive API manufacturing

Quality in pharma has been an increasing concern, **both globally and in India**

1

Between 2008 and 2014, the number of product recalls and warning letters to pharma companies globally tripled

2

At least one pharma facility worldwide has entered into a consent decree every year since 2008 globally

3

30% of quality related warning letters are attributed to India

4

10% of OAI inspections and 4% of drug recalls in last 5 years are from India

Indian companies in other sectors have continuously received recognition for **Quality excellence**

Sector specific accolades

Sample sector	Player	Award	Year
Steel		<ul style="list-style-type: none">▪ Deming Grand prize	2012
Auto components		<ul style="list-style-type: none">▪ Deming Grand Prize	2013
Infra-structure		<ul style="list-style-type: none">▪ #1 airport by size▪ #5 airport by region (Asia Pacific)	2014
Aviation		<ul style="list-style-type: none">▪ A320 best operational excellence	2014

Indian pharma could achieve quality excellence by focusing on six improvement areas

1

Establishing robust and seamless data management and documentation

2

Ensuring effective and robust investigations

3

Aligning management systems with increasing operational complexity

4

Expanding and upskilling talent pool

5

Embedding quality into product development and technology transfer

6

Building a culture of quality across the organization

Pharmaceutical companies need to take a holistic approach by building 'Quality' into three systems



Potential steps for key stakeholders – individual companies

- Evaluate and **upgrade QMS**
- Embed quality across product lifecycle



- Embed a **culture of quality**
- Strengthen the **organization** with specialist roles
- Develop robust **capability building** infrastructure

- Harmonize metrics driving accountability and collaboration
- Adopt **predictive metrics** over and above output metrics
- Scale up **governance** systems

Potential steps for key stakeholders - IPA

1

Create
guidelines



2

Facilitate
creation
of best
practices



3

Evolve
strong pool
of talent

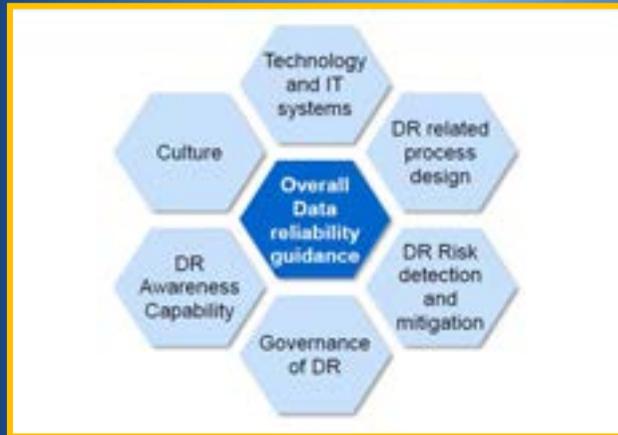


Potential steps for key stakeholders – Government and regulators

- **Guide companies and industry bodies** by providing feedback on guidelines, benchmarks and training modules under development
-
- Continue to **engage in periodic dialogue** to clarify industry's understanding of guidelines, clauses and metrics

The IPA has already **begun the journey** towards quality excellence

1



2

- Select metrics that create transparency on the industry quality performance
- Potentially select validated metrics set
- Metrics should be easily measurable across the organizations and technologies
- Metrics should have clear, exact and aligned definitions and avoid subjectivity as much as possible
- Possibly select a larger set at the start to test feasibility and publish a smaller set later

3



IPA commits to being **conduit of change** in the industry

The start of a long journey ...

Over next 5 years IPA will work to:

- Create **targeted guidelines** and best practices
- **Measure and benchmark** Indian pharmaceutical quality with the rest of the world and track progress
- Expand the skill and capability of **quality talent** for Indian pharmaceutical companies

IPA will develop a 5 year plan, with clear intermediate milestones over the next 12 months. IPA will also review progress annually and further refine the plan periodically

Thank You

BACKUP

Management commitment to 'Quality'



Indian pharma industry's contribution to affordable healthcare



90%+
drugs approved by
US FDA for PEPFAR¹



33%+
of all medicines
dispensed in US²



USD254 bn
health system savings in US³
by all generics. Significant
contribution by India

“ *Millions will die if India cannot produce new HIV/AIDS medicines in the future – it is a matter of life and death⁴* ”
– UNAIDS

“ *Generic medicines have saved the US health system USD 1.7 trillion from 2005 to 2014⁵* ”
– CDER, FDA

The Indian pharmaceutical industry has **one of the largest number of manufacturing plants** of international standards

379

US FDA
registered
plants

1400+

WHO GMP
certified sites

800+

UK MHRA
certified sites

250+

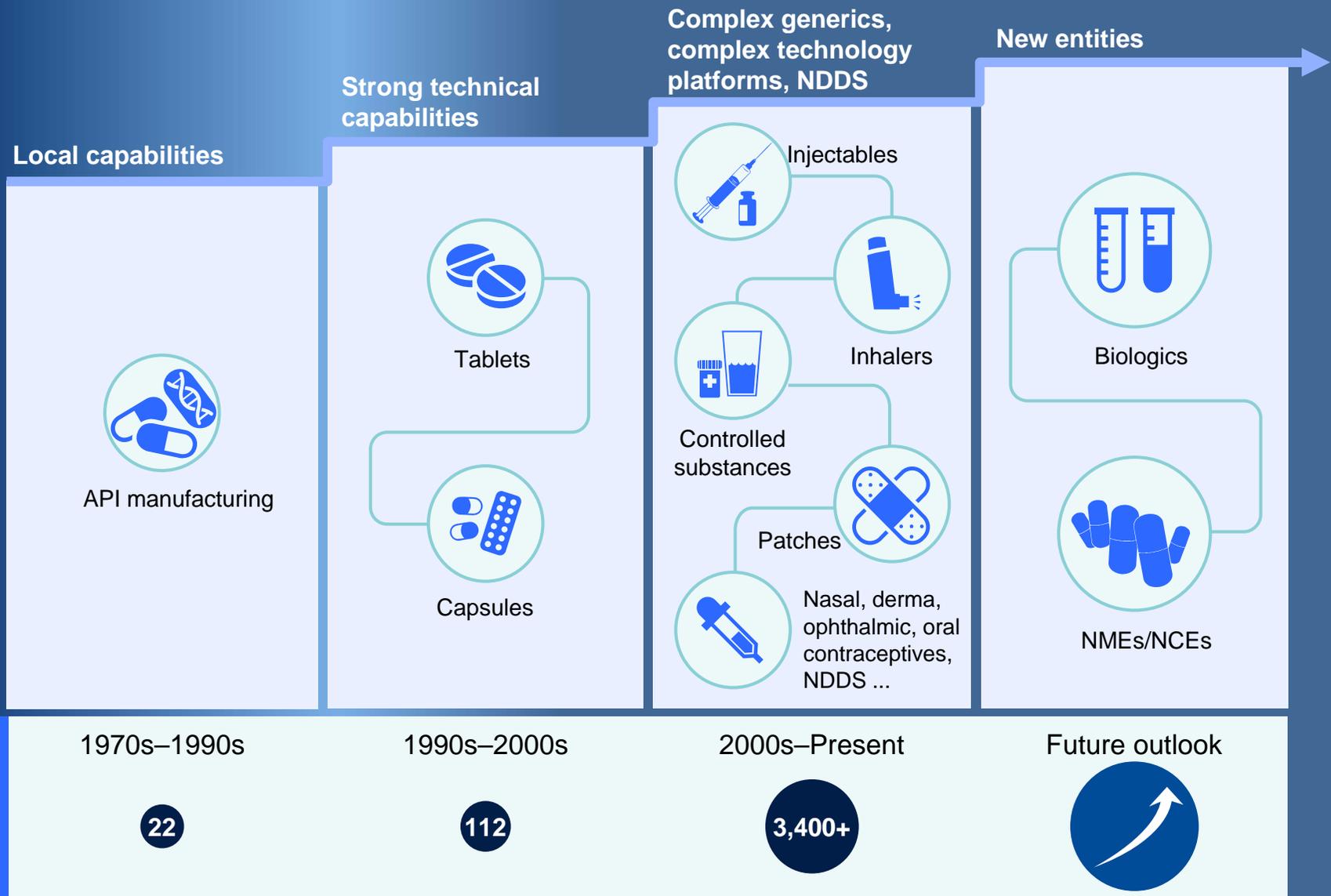
EDQM approved
plants

270+

PMDA (Japan)
accredited
sites



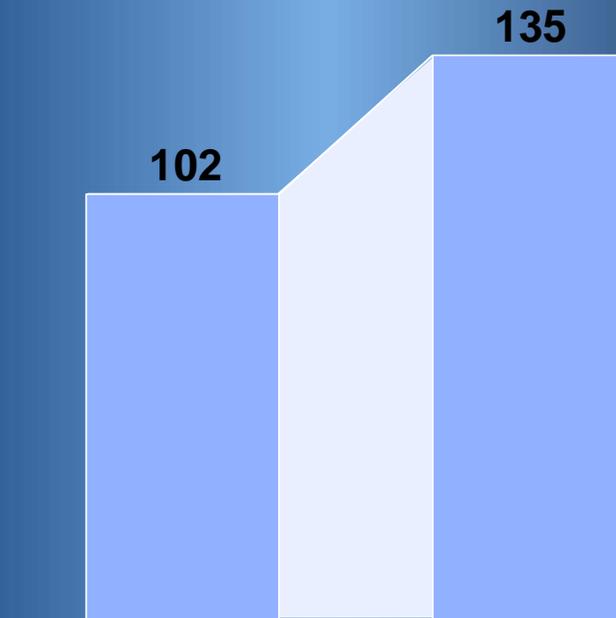
Evolution of the Indian pharmaceutical industry



¹ Includes active Type II DMF filings

Inspections of Indian Pharma manufacturing sites by US FDA

Number of inspections went up in 2015



Avg. 2011-14 *

Share of global total

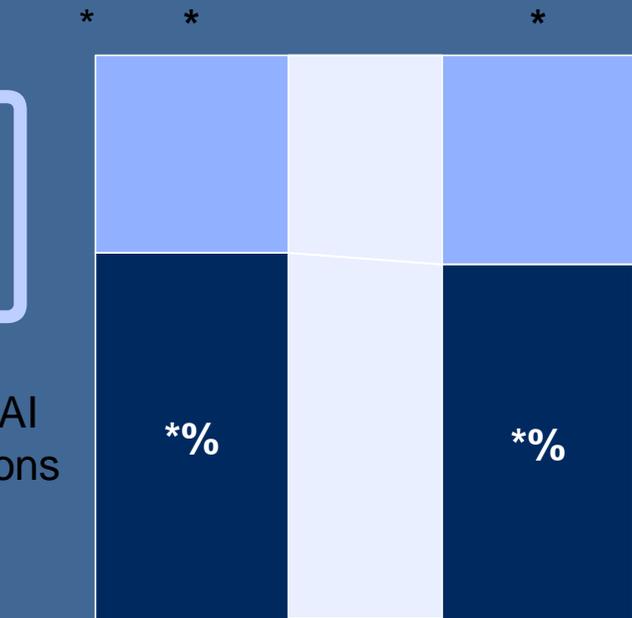
6%

11%

Proportion of OAI + VAI decisions has remained the same



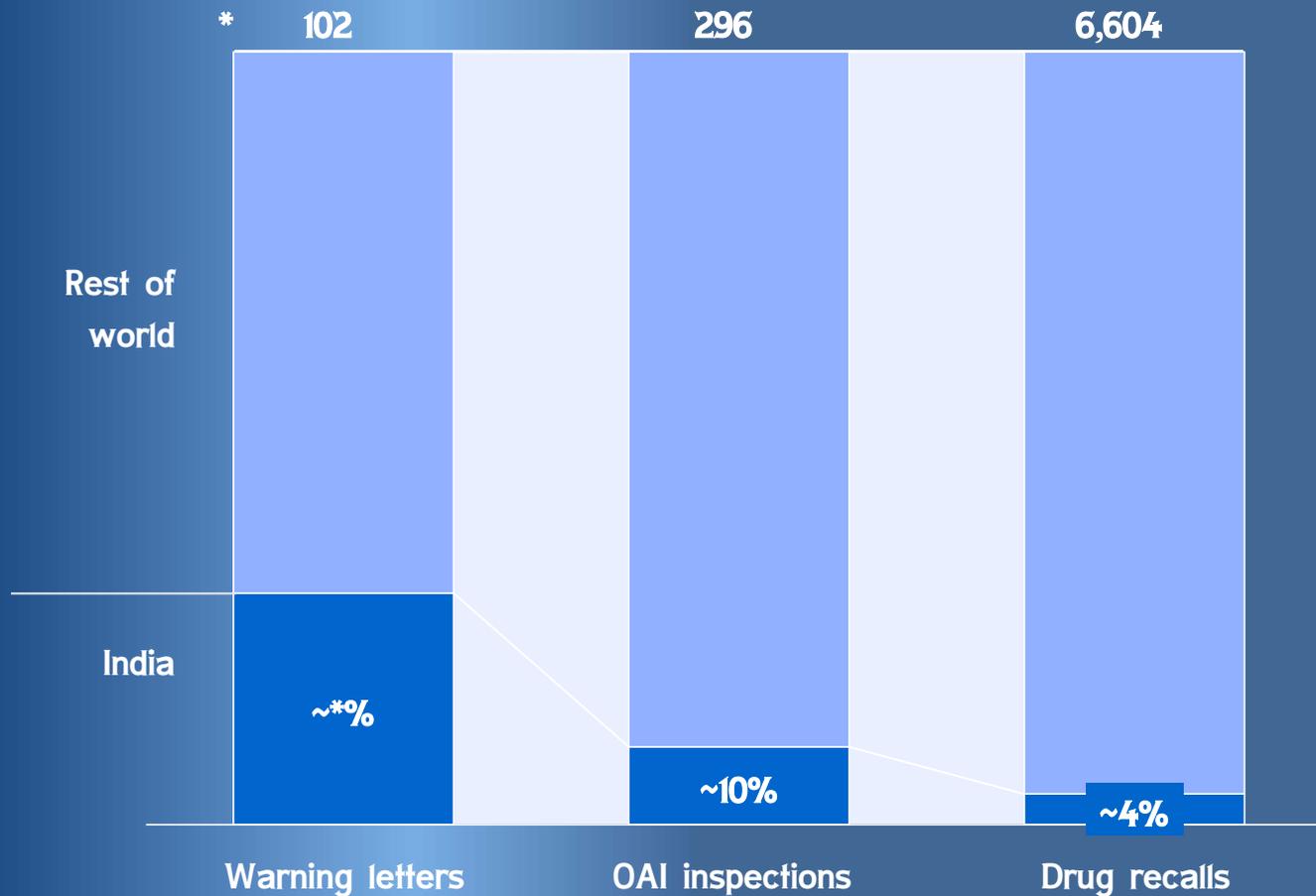
OAI + VAI inspections



Avg. 2011-14

*

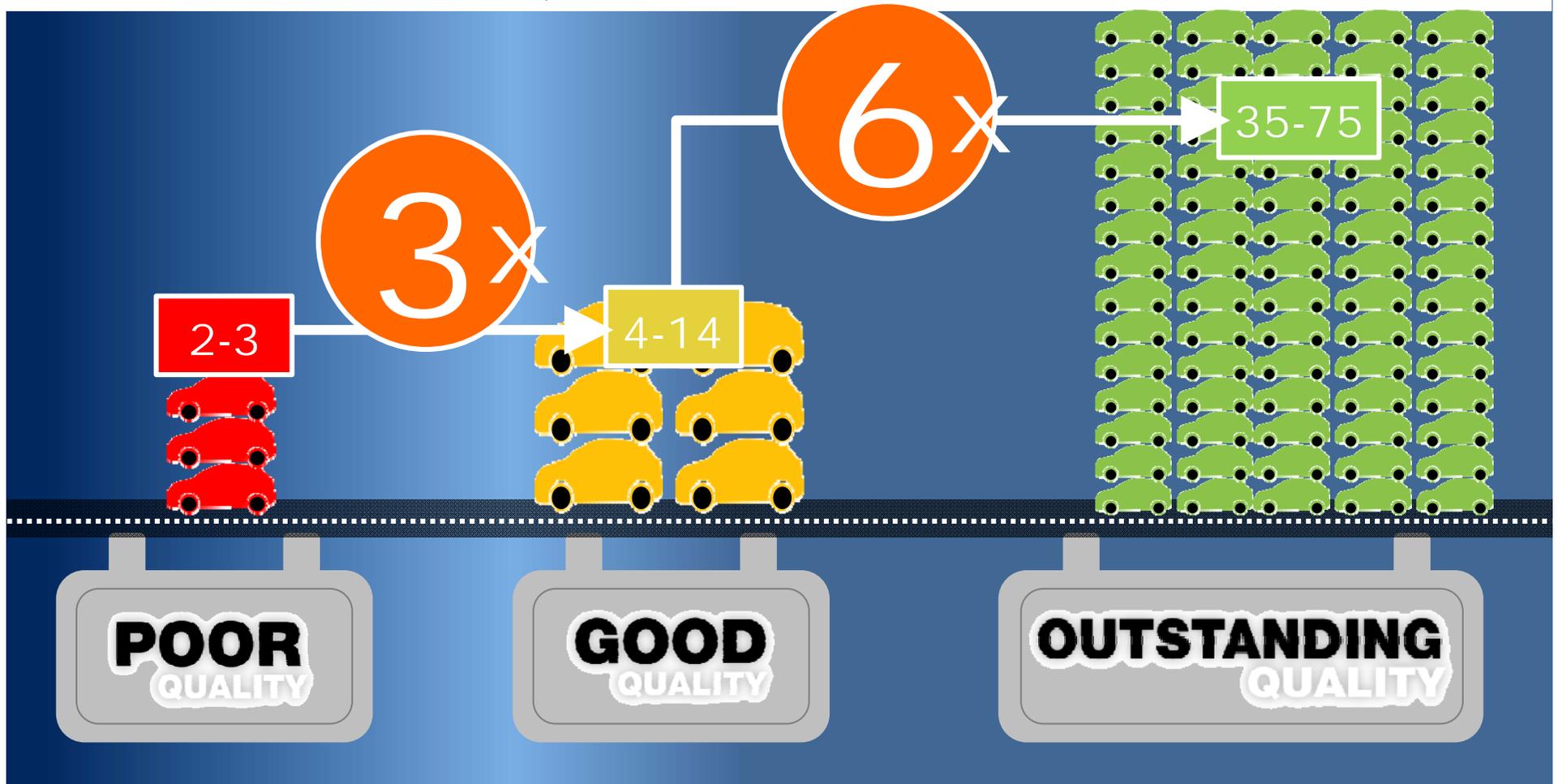
Regulatory actions on Indian pharma manufacturing sites by US FDA



Outstanding 'Quality' creates disproportionate upside

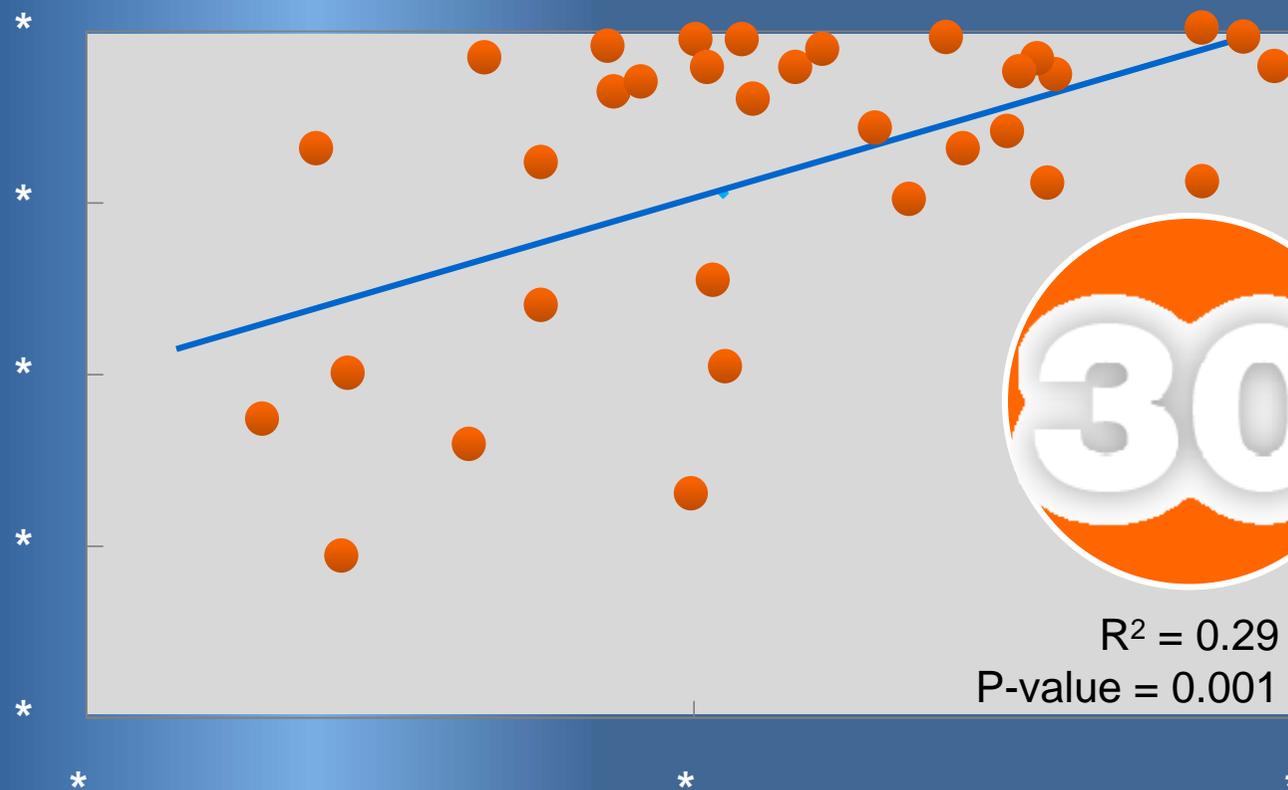
Intent to purchase

~1 million responses in surveys



Industry studies suggest, culture drives 30% of 'Quality' outcomes

Quality outcomes,
Percentage of quality lots



Quality culture, index

Indian players have been able to build a **culture of quality** and discipline

#1 ranked airport worldwide: **Delhi International Airport**; in the top 3 for **4 years in a row**

Mumbai and Delhi airports are among the **Top 5** airports in Asia-Pacific in terms of **Airport Service Quality (ASQ)**

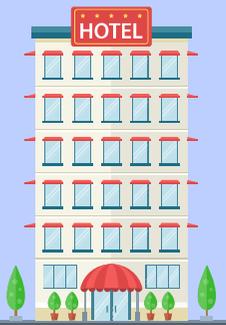


10th best in cumulative air accidents record; ahead of US, UK, and France

Top 3 in Asia with a **customer satisfaction score of 8/10**



Indigo Airline WON the Best Operational Excellence Award among 311 airlines; **Top 10** in on-time performance in Asia-Pacific



Leaders in hospitality globally: **Oberoi Group** and **Taj Hotels**

Have properties ranked in **Top 10** by **Travel and Leisure** magazine

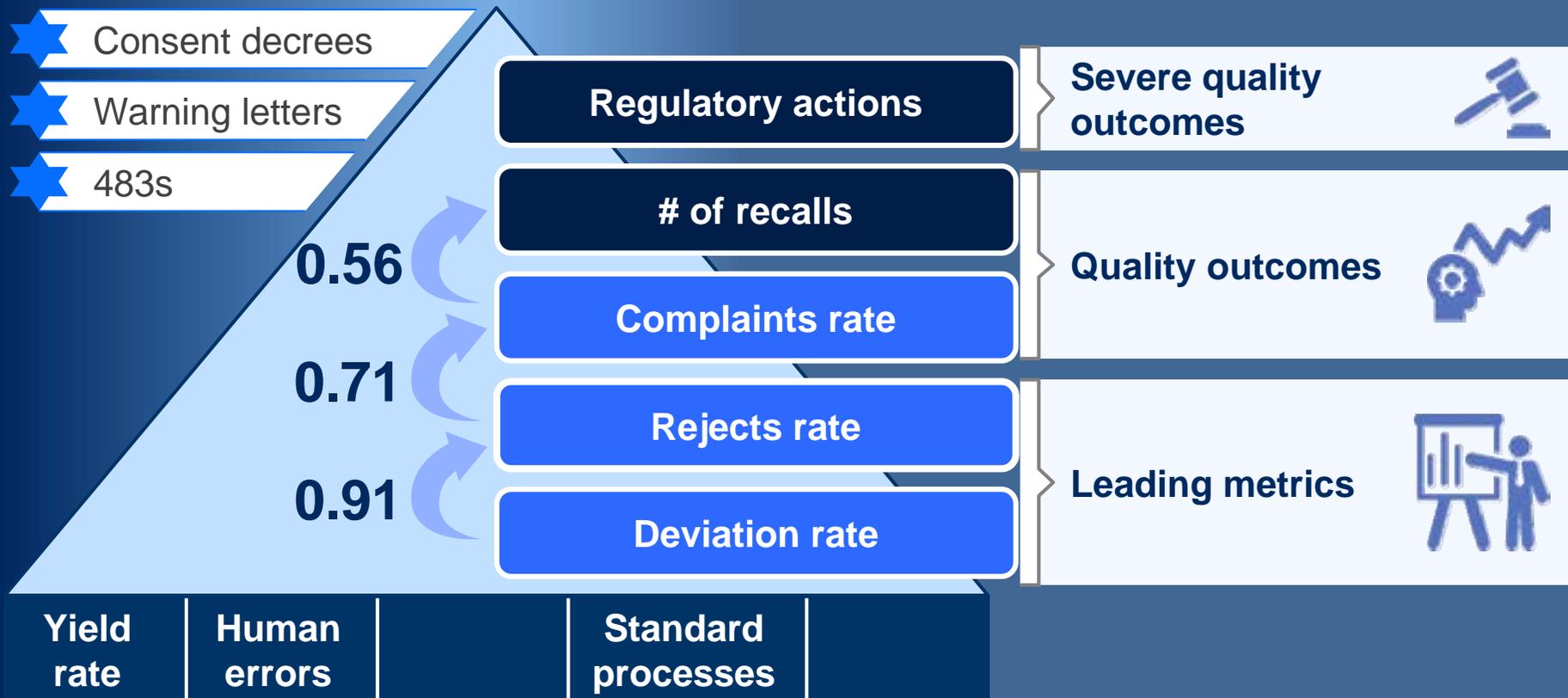


Management system — Build right leading metrics to **predict and correct** future quality challenges

Pyramid of leading quality indicators

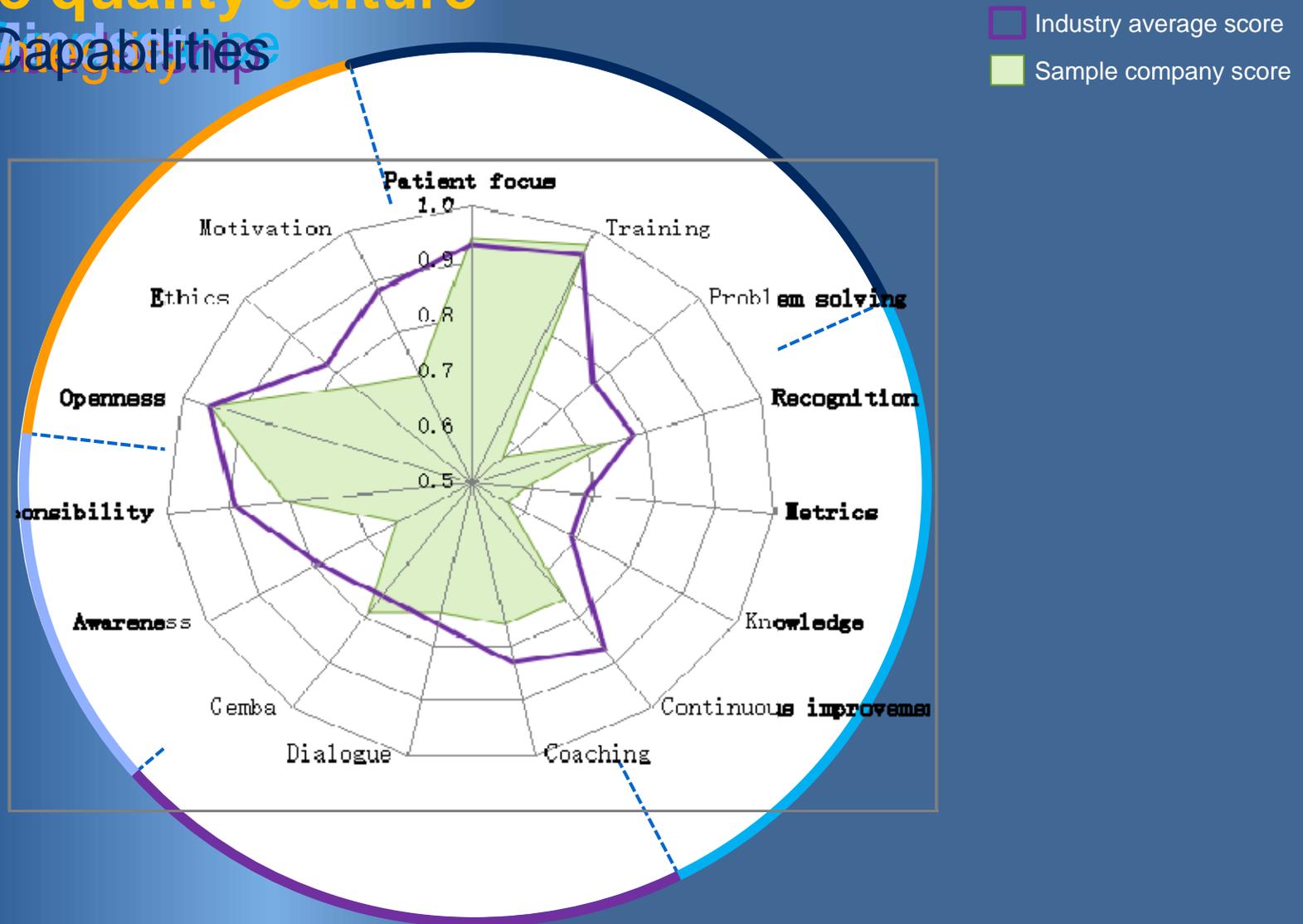
Correlation coefficients between quality metrics

(Perfect correlation = 1.00)



Contrary to popular perception, it is possible to measure quality culture

Capabilities



Certain imperatives arise for all key stakeholders individual companies, IPA and regulatory bodies..

1

Pharma
companies

- Diagnose and identify challenges
- Prioritize based on risk
- Design and implement solutions, both corrective and preventive

2

Indian
Pharmaceuti
cal alliance

- Facilitate industry-wide collaboration, like creation of best practices and guidelines
- Develop training content and industry-wide mechanisms

3

Government
and
regulators

- Support the industry by providing inputs and feedback on initiatives by industry to ensure quality
- Create platform for dialogue with pharmaceutical companies on regulations