McKinsey & Company

IPA Quality Forum – Reflections on the journey so far

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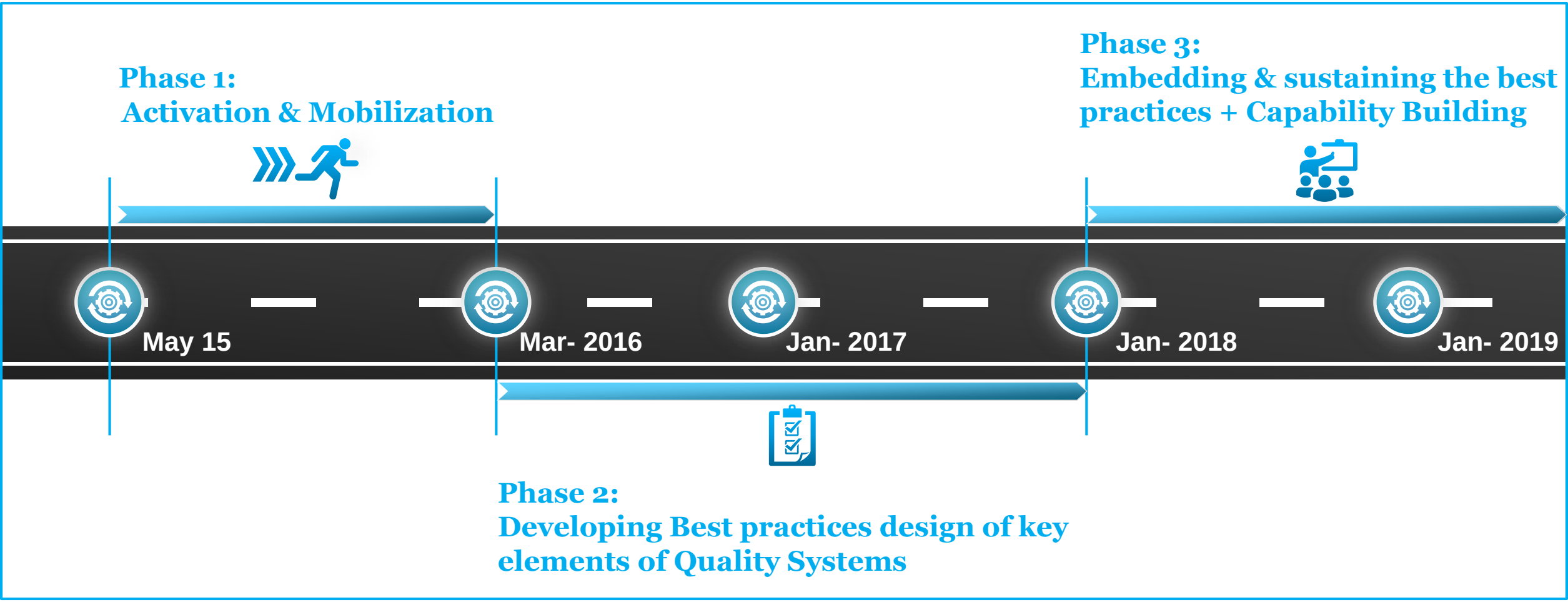
IPA Quality Forum is in the 3rd phase of its journey to help the Indian pharma industry achieve excellence in quality



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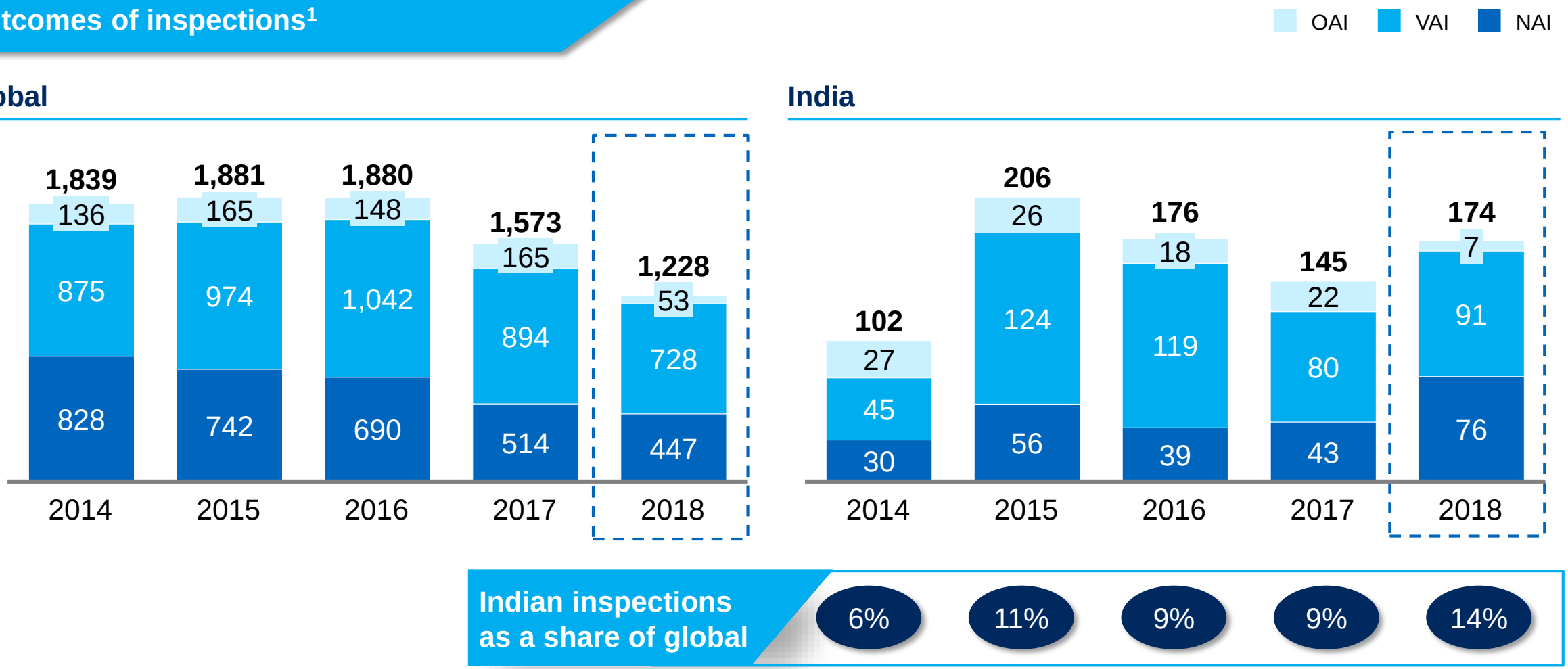
The Industry has continued to show progress- Inspection outcomes in India have improved and are now more in line with global outcomes

Outcomes of inspections[1]



Indian inspections as a share of global	2014	2015	2016	2017	2018
	6%	11%	9%	9%	14%

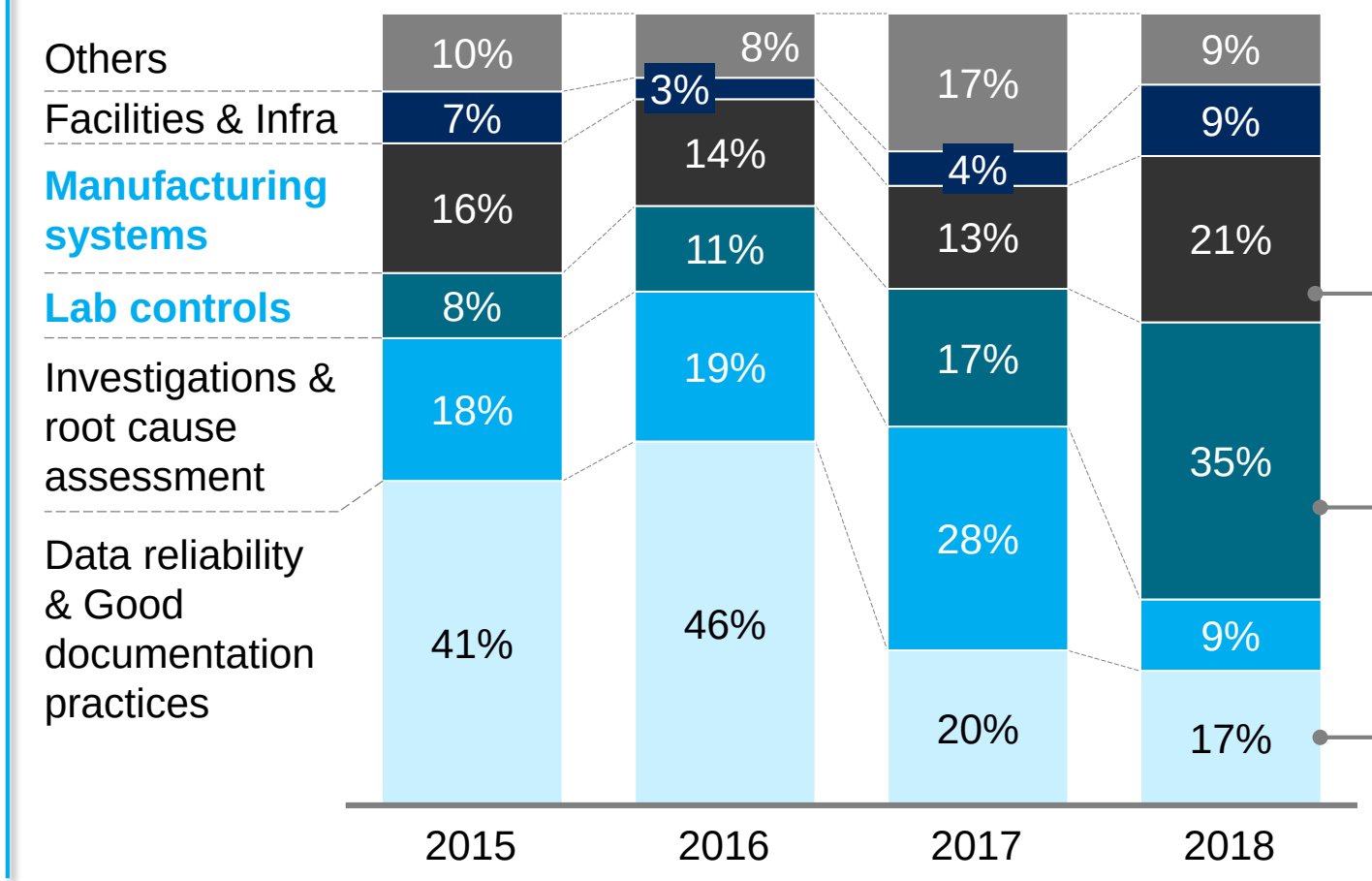
FDA inspection data for CDER and Drug Quality Assurance projects, for Jan – Dec cycle (February 25, 2019)

1 Data from Jan – Dec cycle

SOURCE: FDA inspection data for CDER (Drug Quality Assurance), data pull on Feb 25, 2019

There has been a reduction in data reliability, and investigation & root cause assessment related errors; Gap in manufacturing systems and lab controls are now a leading source of non-compliance

Nature of observations (% of WL & 483 observations)



- Gaps in adherence to good shopfloor practices or SOPs
- Gaps in manufacturing / packaging / process equipment reliability

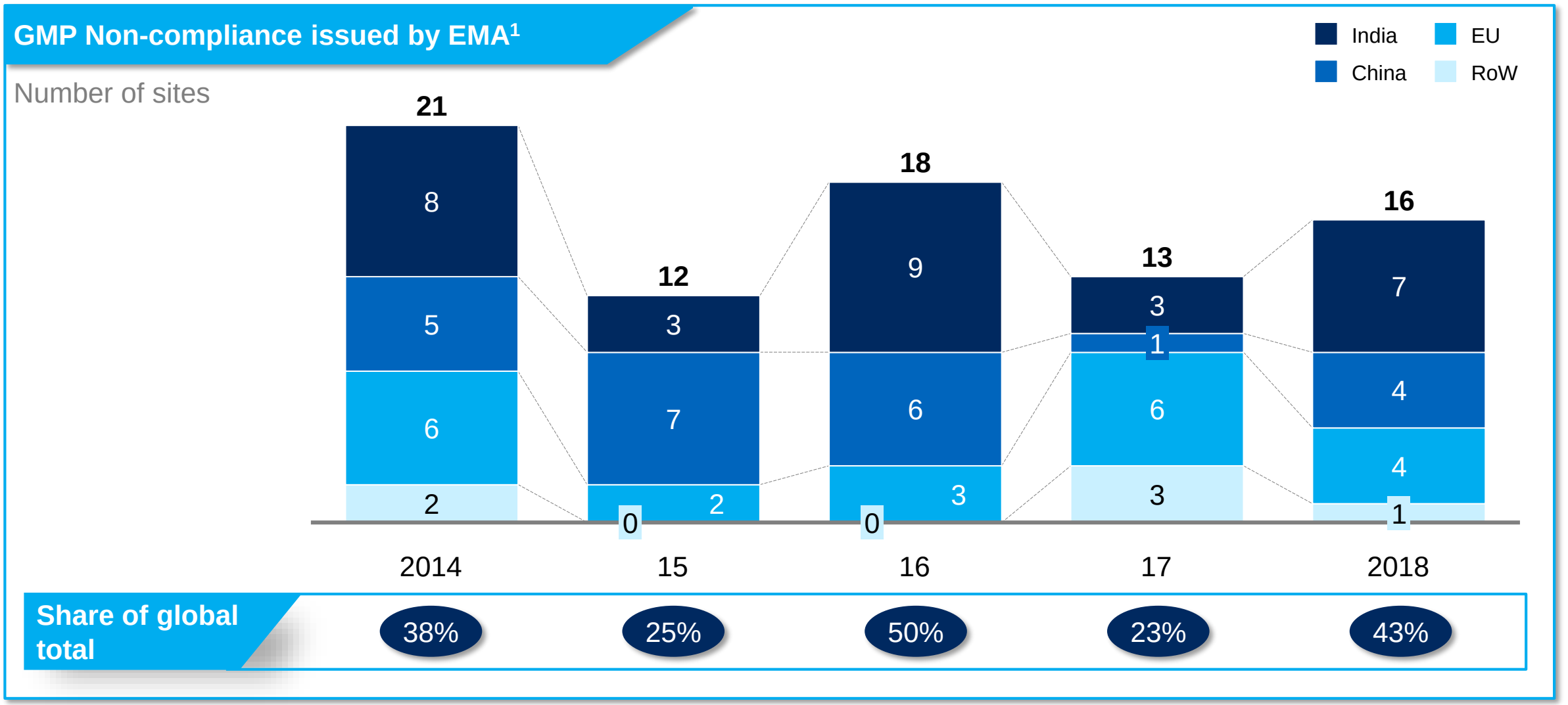
- Failure to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans
- Failure to ensure that test procedures are scientifically sound

- Inadequate controls of computer & other data systems
- Gap in prevention of unauthorized access
- Incomplete data in lab records
- Incomplete data in batch production records

SOURCE: US FDA Warning letters & 483 observations available in public domain

India’s GMP compliance for EMA sites continues to be a concern

GMP Non-compliance issued by EMA[1]



Share of global total	38%	25%	50%	23%	43%

1 Numbers shown for FY - FY14 taken as Oct 2013 to Sep 2014;.Similarly for FY15,16 &17

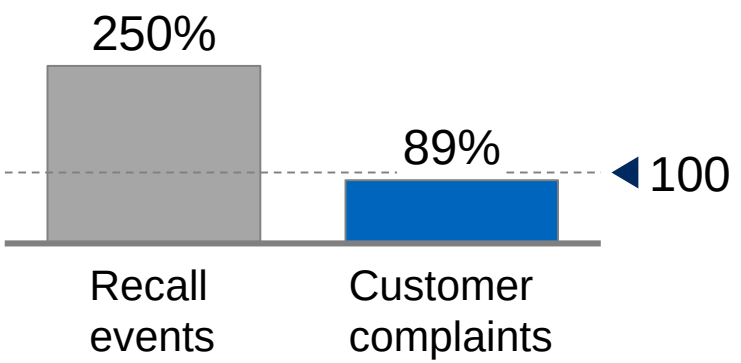
SOURCE: EudraGMP (as of 21st Feb 2019)

Indian Pharmacos continue to lag behind global peers on several indicators of quality- OSD Example

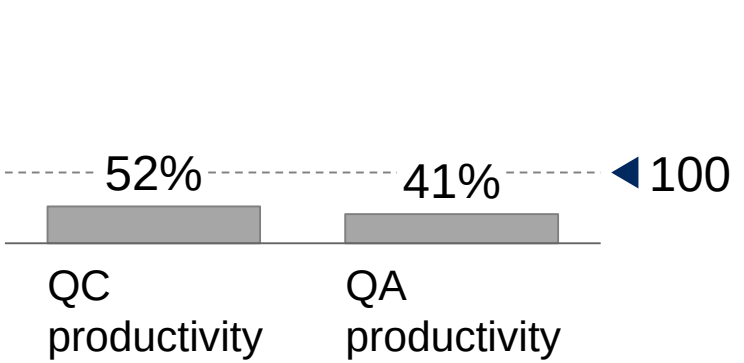
India outperforming global peers
India underperforming global peers

Global performance is indexed at 100%

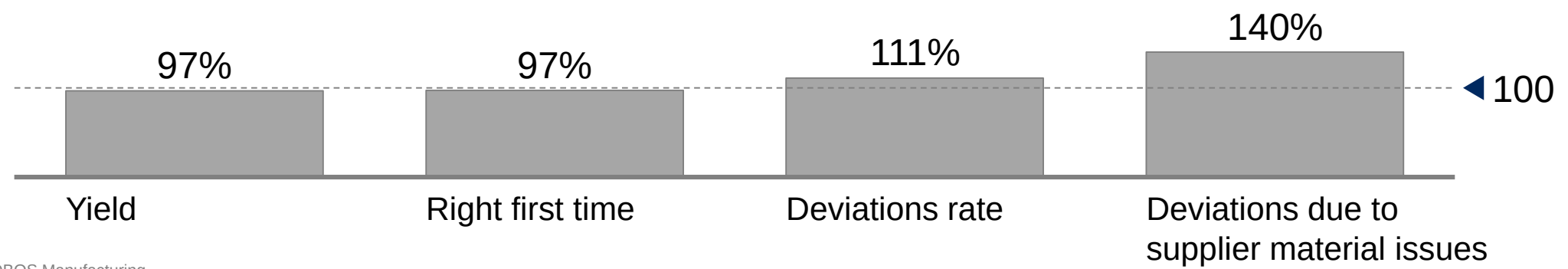
Quality outcomes



Productivity



Operational and Quality maturity



SOURCE: POBOS Quality, POBOS Manufacturing

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IPA Quality Forum undertook various activities in 2018 to build capability across the industry while continuing to drive best practice design and wider industry outreach (1/2)

1 Capability building

Capability building sessions on Day 1 of IPA conference 2018

Topics covered

- Batch Failure Investigation
- Complaints – Investigation and review
- Data Integrity
- Good documentation practices

Advanced GMP workshops for middle-management capability building

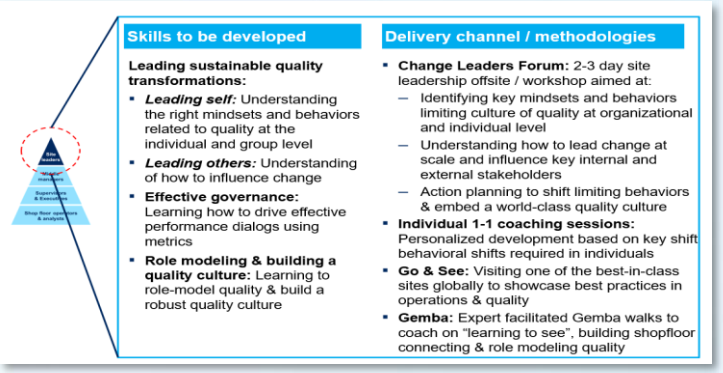
Letitia Robinson, USFDA

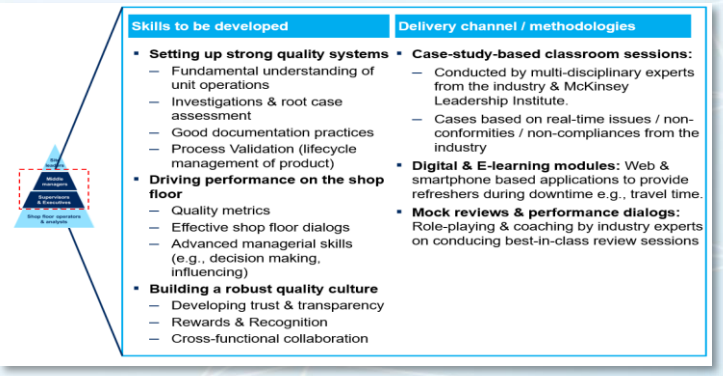
Vimal Sachdeva, WHO

Ewan Norton, MHRA

Thomas Arista

Blue print for capability building of middle managers finalised

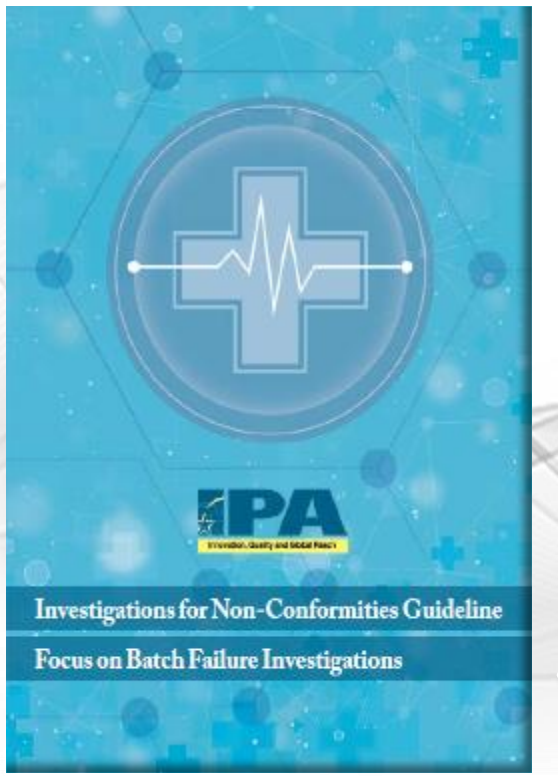


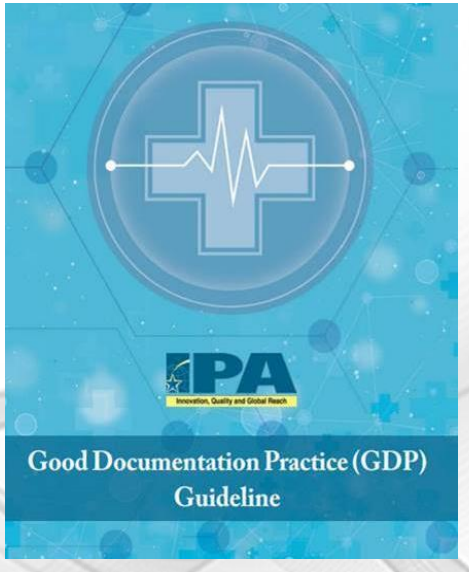


IPA Quality Forum undertook various activities in 2018 to build capability across the industry while continuing to drive best practice design and wider industry outreach (2/2)

2 Best practice design

Guidelines on key quality topics





'Market complaints handling'
(to be published)

3 Broader industry outreach

IPA conference 2018

- Bringing **manufacturers and regulators together** to facilitate discussions resulting in **meaningful and actionable outcomes**
  - **Focus on quality** – the most vital element of the pharmaceutical industry

Going forward, IPA aims to further drive the capability building agenda and drive quality best practices in R&D – Phase 5

3 focus areas for IPA Quality Forum in 2019-20

A 

Capability building with continued focus on dissemination and adoption within individual companies

B 

Integrating quality to R&D with focus on

- Analytical method development
- Product robustness

C 

Continued engagement with regulatory agencies & industry *(IPA conference, Advanced GMP workshop etc.)*

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While Indian pharmacos are at different stages in their Quality journey, many are now striving to achieve sustained excellence in Quality

Characteristics

STEP 1
Achieve 100% compliance across key sites

- Ensure key sites **achieve full compliance** vis-à-vis regulatory guidelines / expectations
- Complete **ongoing remediation efforts** in timely and effective manner
- Achieving **24X7 Audit Readiness**

STEP 2
Put in place a robust Quality systems

- Set-up **the right quality system & processes**
- Introduce **quality metrics & benchmark** with best-in-class
- Designing the **right quality organization** & governance model

STEP 3
Achieve sustained excellence in Quality

- Scale up **single-site quality improvement initiatives to the full network**
- **Building quality culture & capabilities across levels** within the organization (incld. middle managers, supervisors & shop floor operators)
- **Drive quality, delivery & productivity** in an integrated manner
- **Adopt next-generation (Ops 4.0) technologies** to drive continuous improvement in operations

We believe there are 5 key priorities for Indian pharmacos

Proactive Approach to Quality vs. Reactive: Put in place risk-based approached to improve product & process quality, and achieve 24x7 compliance

Drive Quality, Delivery & Productivity in an integrated manner: Deploying Production Systems to drive integrated operations excellence across the networks

Leverage Digital & Advanced Analytics (Industry 4.0) tools to drive next-gen operations excellence: Deploying several use cases across Manufacturing, Quality, Supply Chain & Cost excellence to drive significant performance improvement

At scale capability building across the organization: Leveraging experts, interactive breakout exercises on real life case examples and gamified learning to build capability

Holistic site transformation: Setting up a digital plant of the future through interventions across functions and processes, leveraging IoT, augmented reality and advanced and predictive analytics

Digital lighthouse transformation at Bayer

Situation

Volume increase of 30% requiring a 24/7 production cycle

Increased portfolio complexity – leading to an increase in c/o

50% additional workforce with limited previous experience

What did we do

- **Driving impact through selected Digital & Advanced Analytics applications**
- Extracting data from different sources (SAP, LIMS, ERP, Data warehouse, PLC, Excel)
- Creating a standardized "Plant Data Lake"

Impact

QC lab productivity	+50% increase of lab productivity by applying advanced schedule optimization
Changeover	-30% reduction in time on tablet press using smart glasses
OEE	+40-50% OEE increase on packaging line supported by AA insights and Digital performance management
Deviations	-80% reduction in deviations since applying advanced analytics (0% reoccurrent)
Deviation handling/ closure time	-90% reduction of deviation closure time by AA based deviation advisor tool

SOURCE: McKinsey Analysis


THANK YOU