



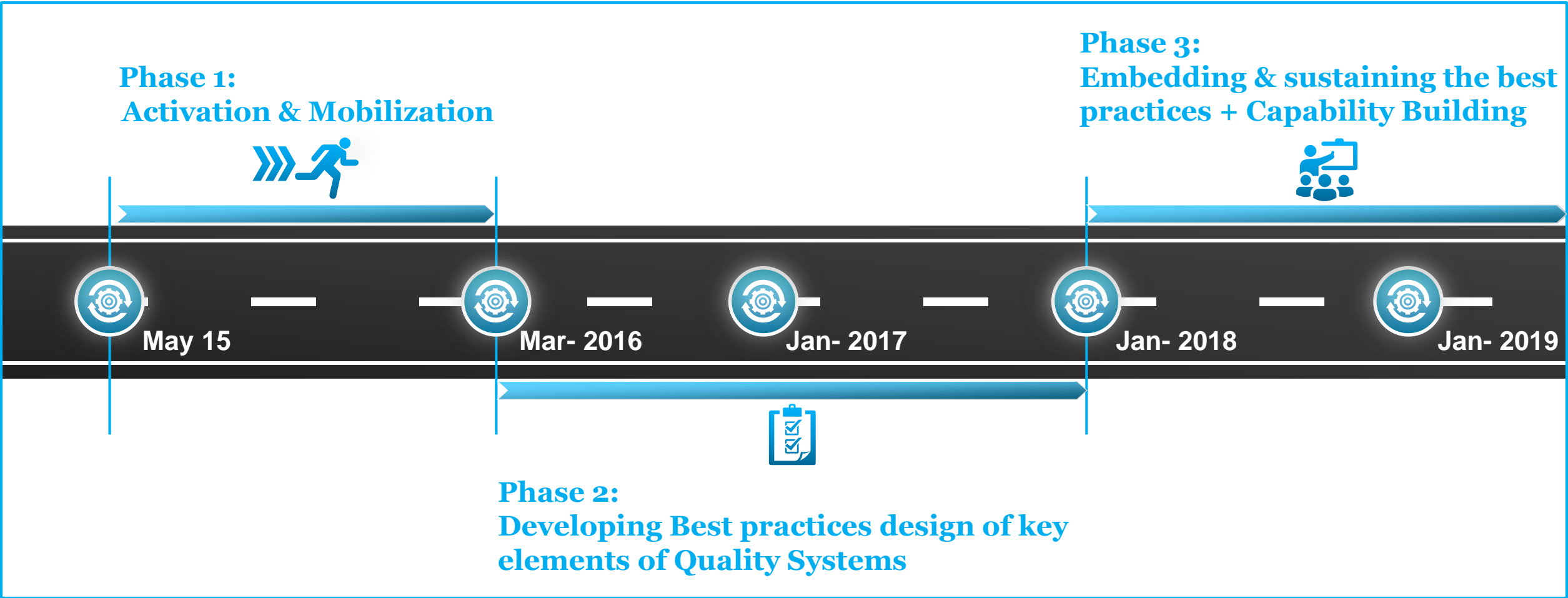
IPA Quality Forum – Reflections on the journey so far

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IPA CONFERENCE | FEBRUARY 2019

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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Performance snapshot on compliance outcomes



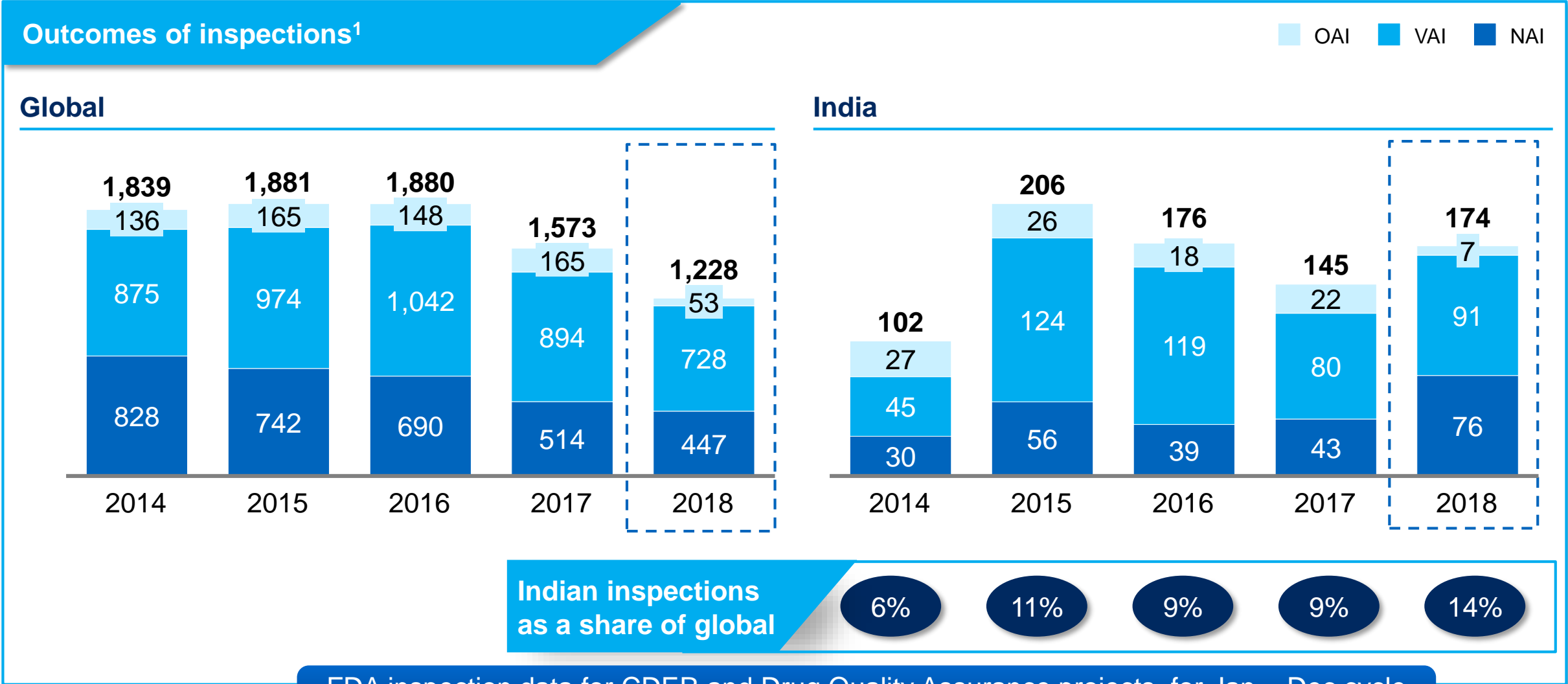
Brief update on initiatives taken by IPA QF in 2018



Priorities going forward



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



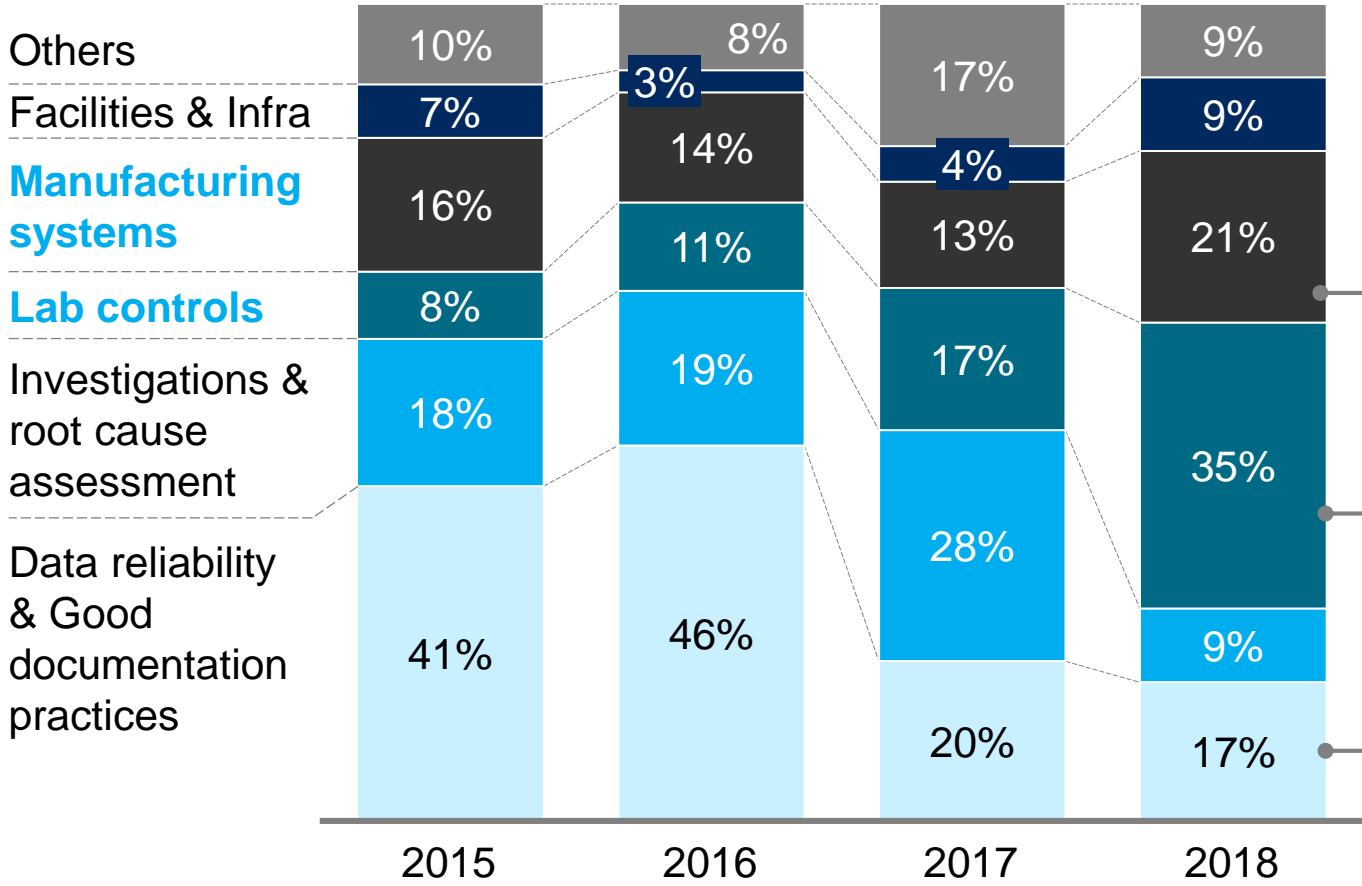
FDA inspection data for CDER and Drug Quality Assurance projects, for Jan – Dec cycle (February 25, 2019)

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

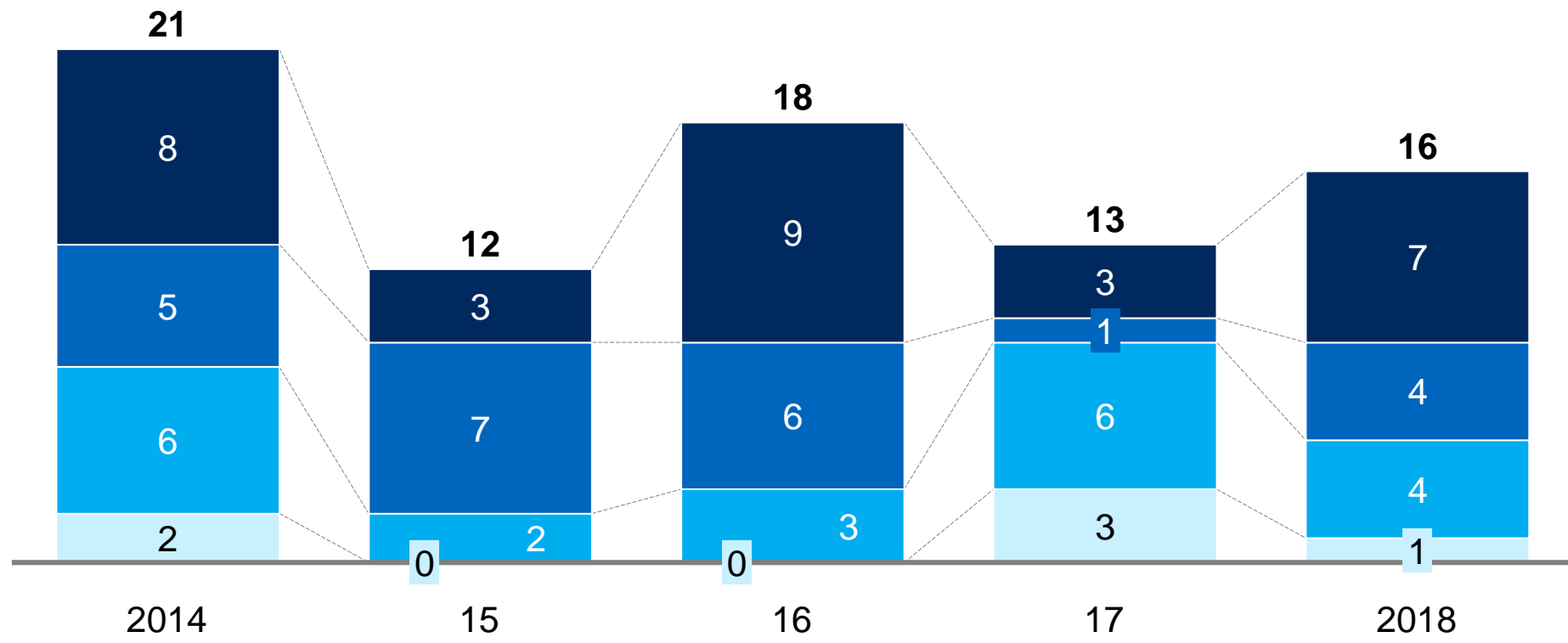
SOURCE: US FDA Warning letters & 483 observations available in public domain

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

GMP Non-compliance issued by EMA¹

Number of sites

- India
- China
- EU
- RoW



Share of global total



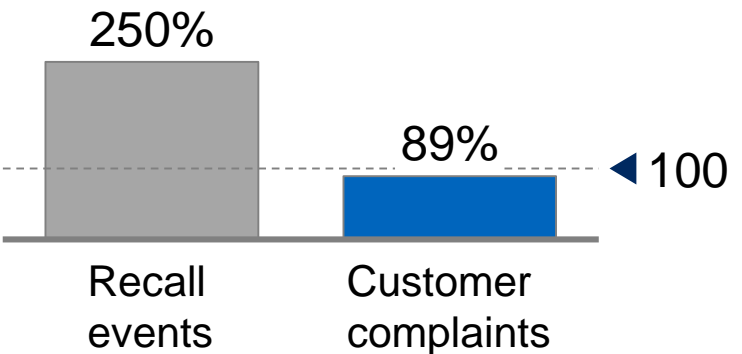
¹ Numbers shown for FY - FY14 taken as Oct 2013 to Sep 2014; Similarly for FY15,16 &17

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

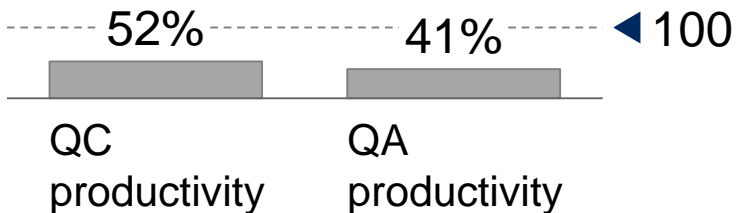
■ India outperforming global peers
■ India underperforming global peers

👍 Global performance is indexed at 100%

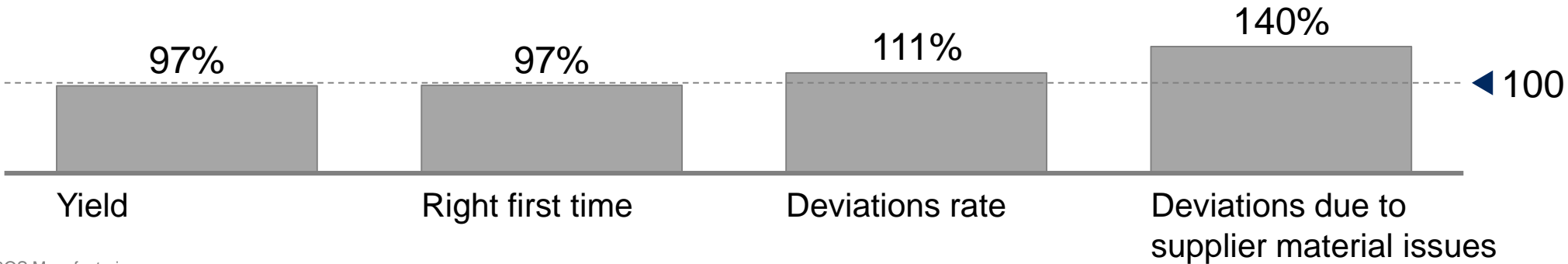
Quality outcomes



Productivity



Operational and Quality maturity



SOURCE: POBOS Quality, POBOS Manufacturing

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Priorities going forward



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

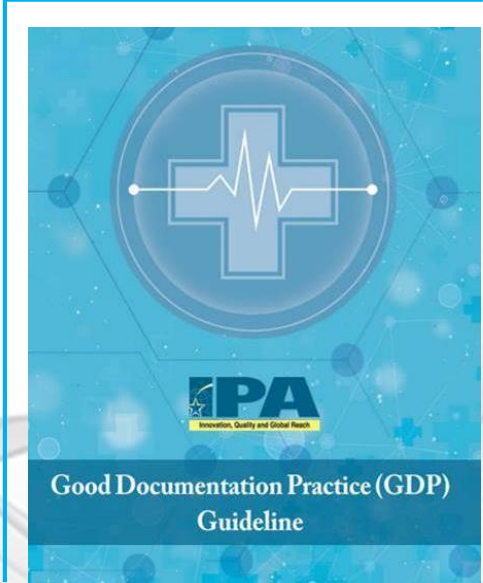
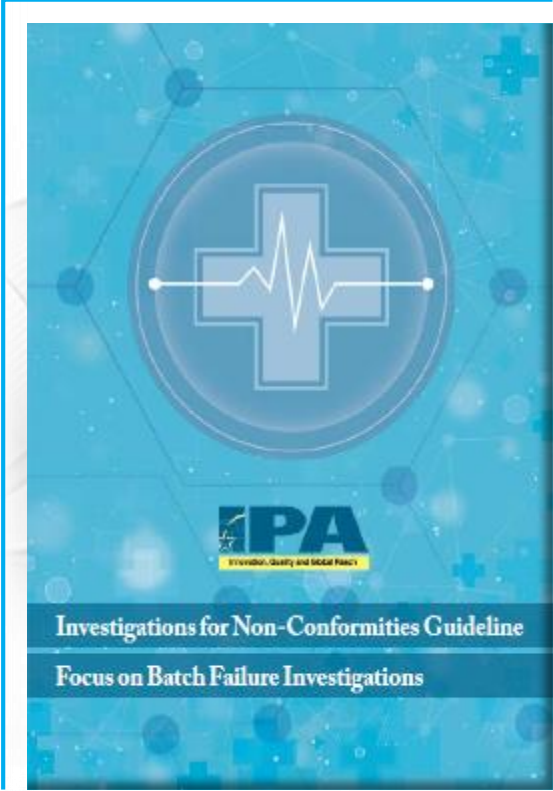
Skills to be developed	Delivery channel / methodologies
Leading sustainable quality transformations: <ul style="list-style-type: none"> ▪ Leading self: Understanding the right mindsets and behaviors related to quality at the individual and group level ▪ Leading others: Understanding of how to influence change ▪ Effective governance: Learning how to drive effective performance dialogs using metrics ▪ Role modeling & building a quality culture: Learning to role-model quality & build a robust quality culture 	<ul style="list-style-type: none"> ▪ Change Leaders Forum: 2-3 day site leadership offsite / workshop aimed at: <ul style="list-style-type: none"> – Identifying key mindsets and behaviors limiting culture of quality at organizational and individual level – Understanding how to lead change at scale and influence key internal and external stakeholders – Action planning to shift limiting behaviors & embed a world-class quality culture ▪ Individual 1-1 coaching sessions: Personalized development based on key shift behavioral shifts required in individuals ▪ Go & See: Visiting one of the best-in-class sites globally to showcase best practices in operations & quality ▪ Gemba: Expert facilitated Gemba walks to coach on "learning to see", building shopfloor connecting & role modeling quality

Skills to be developed	Delivery channel / methodologies
<ul style="list-style-type: none"> ▪ Setting up strong quality systems <ul style="list-style-type: none"> – Fundamental understanding of unit operations – Investigations & root case assessment – Good documentation practices – Process Validation (lifecycle management of product) ▪ Driving performance on the shop floor <ul style="list-style-type: none"> – Quality metrics – Effective shop floor dialogs – Advanced managerial skills (e.g., decision making, influencing) ▪ Building a robust quality culture <ul style="list-style-type: none"> – Developing trust & transparency – Rewards & Recognition – Cross-functional collaboration 	<ul style="list-style-type: none"> ▪ Case-study-based classroom sessions: <ul style="list-style-type: none"> – Conducted by multi-disciplinary experts from the industry & McKinsey Leadership Institute. – Cases based on real-time issues / non-conformities / non-compliances from the industry ▪ Digital & E-learning modules: Web & smartphone based applications to provide refreshers during downtime e.g., travel time. ▪ Mock reviews & performance dialogs: Role-playing & coaching by industry experts on conducting best-in-class review sessions

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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Priorities going forward



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 (incl. 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 approach 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% reoccurent)
Deviation handling/ closure time	-90% reduction of deviation closure time by AA based deviation advisor tool



THANK YOU