



IPA Quality Forum – Reflections on the Journey so far

India Pharmaceutical Forum 2018

23rd Feb 2018



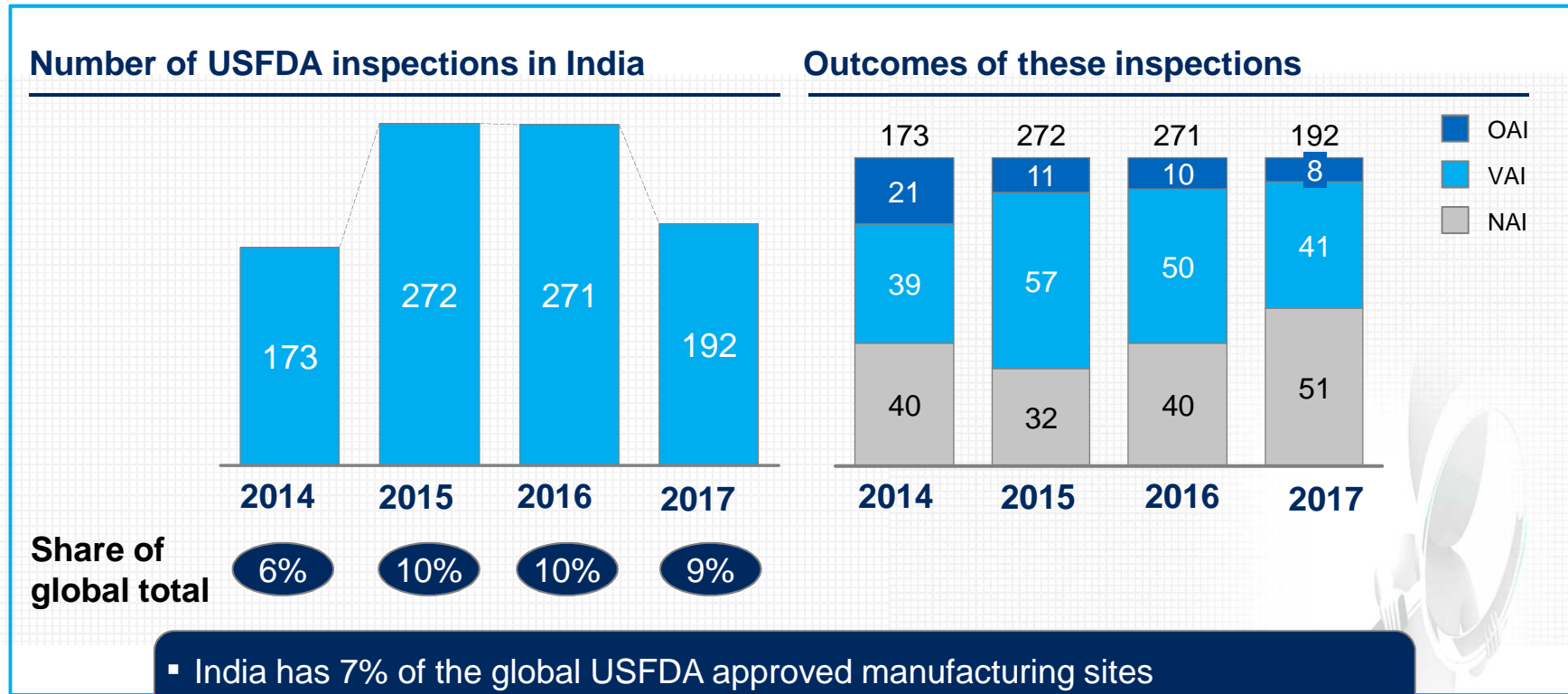
The IPA Quality forum was formed with a vision of helping the Indian pharma industry achieve excellence in quality

RECAP



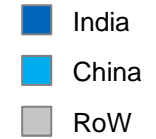
The IPA Quality forum was setup 3 years back, by a group of 6 founding member companies, and supported by McKinsey & Company as their knowledge partner

The Industry has made progress over the last 3 years (1/2)

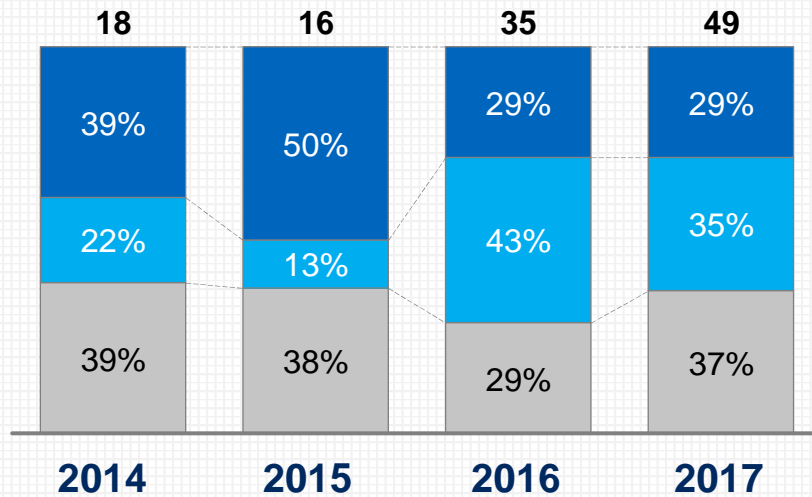


1 FY14 taken as Oct 2013 to Sep 2014. Similarly for FY15,16 &17
SOURCE: CDER

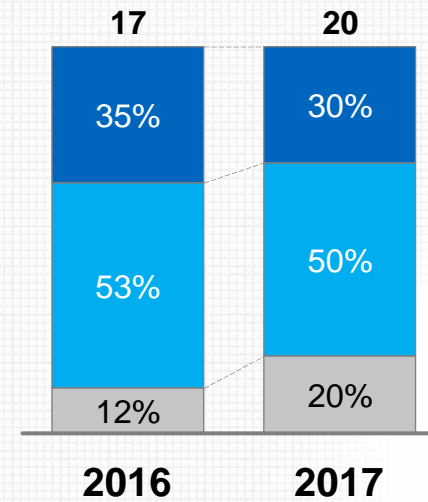
The Industry has made progress over the last 3 years (2/2)



USFDA Warning letters for Non-US sites¹



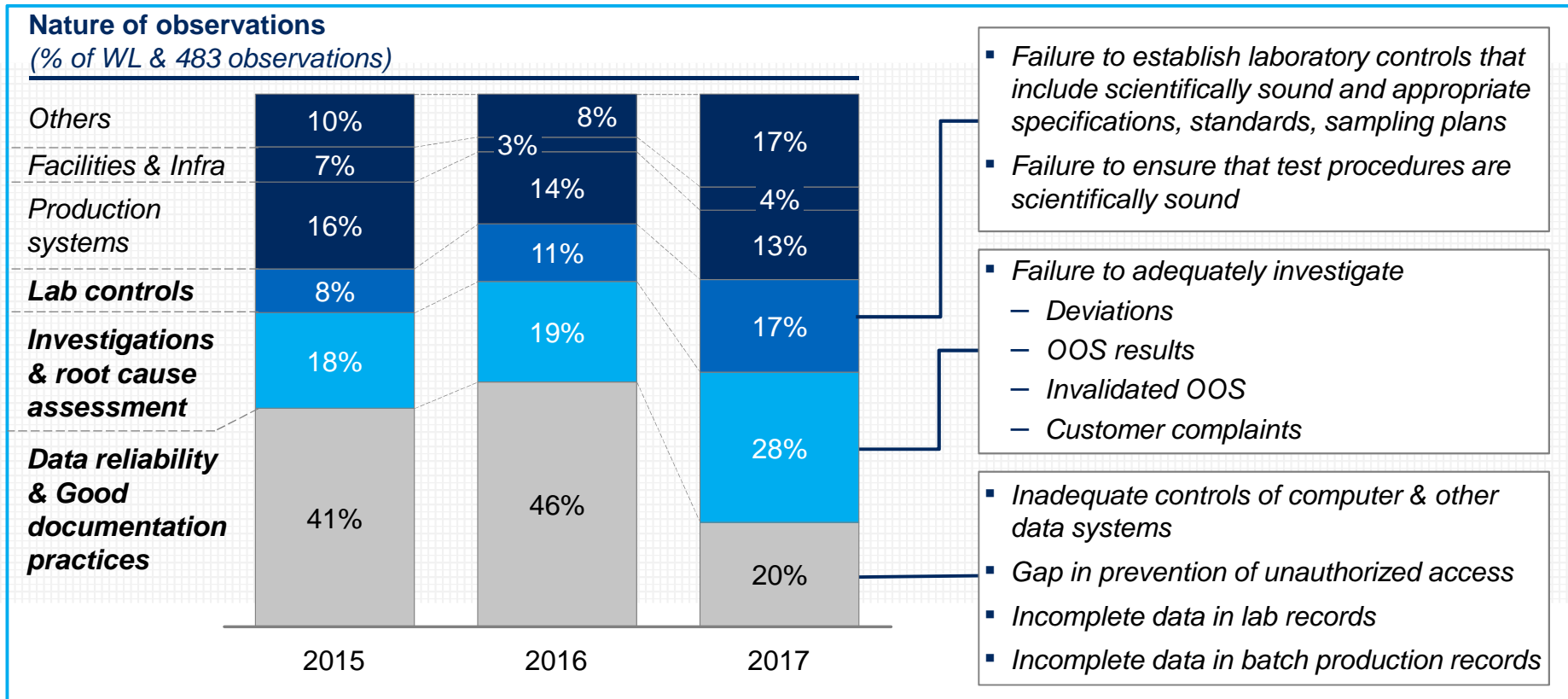
USFDA Import alerts for Non-US sites¹



- Improvement in quality standards and regulatory outcomes over last 2 years
- Significant effort required to achieve sustainable excellence in quality

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

There has been a reduction in data-related errors; Gap in Investigations and root cause assessments is now a leading source of non-compliance



Building Excellence in Quality is a 3-step journey

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**

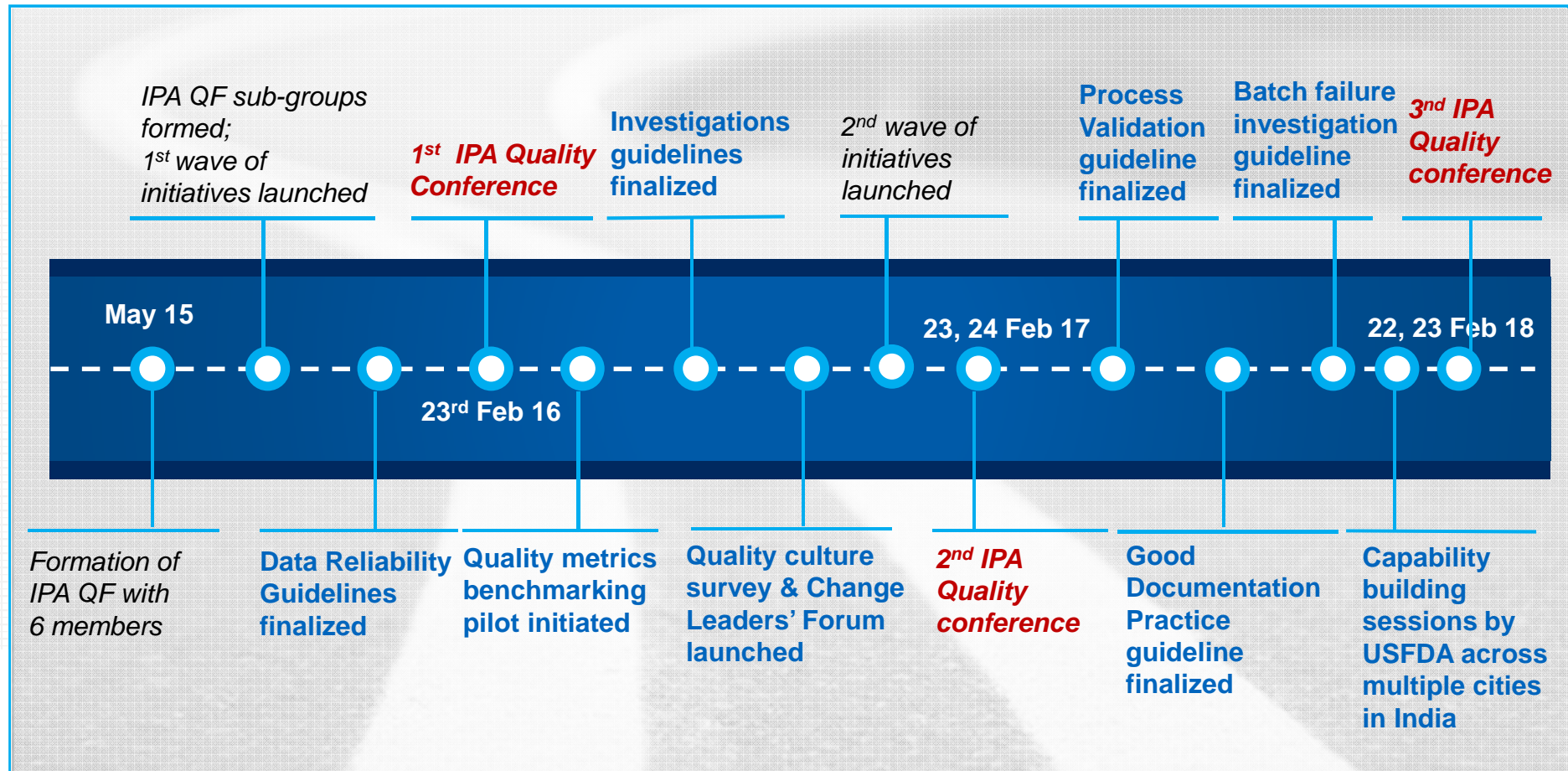
Indian pharma focus over the last 2-3 years

Step 3: Achieve sustained excellence in Quality

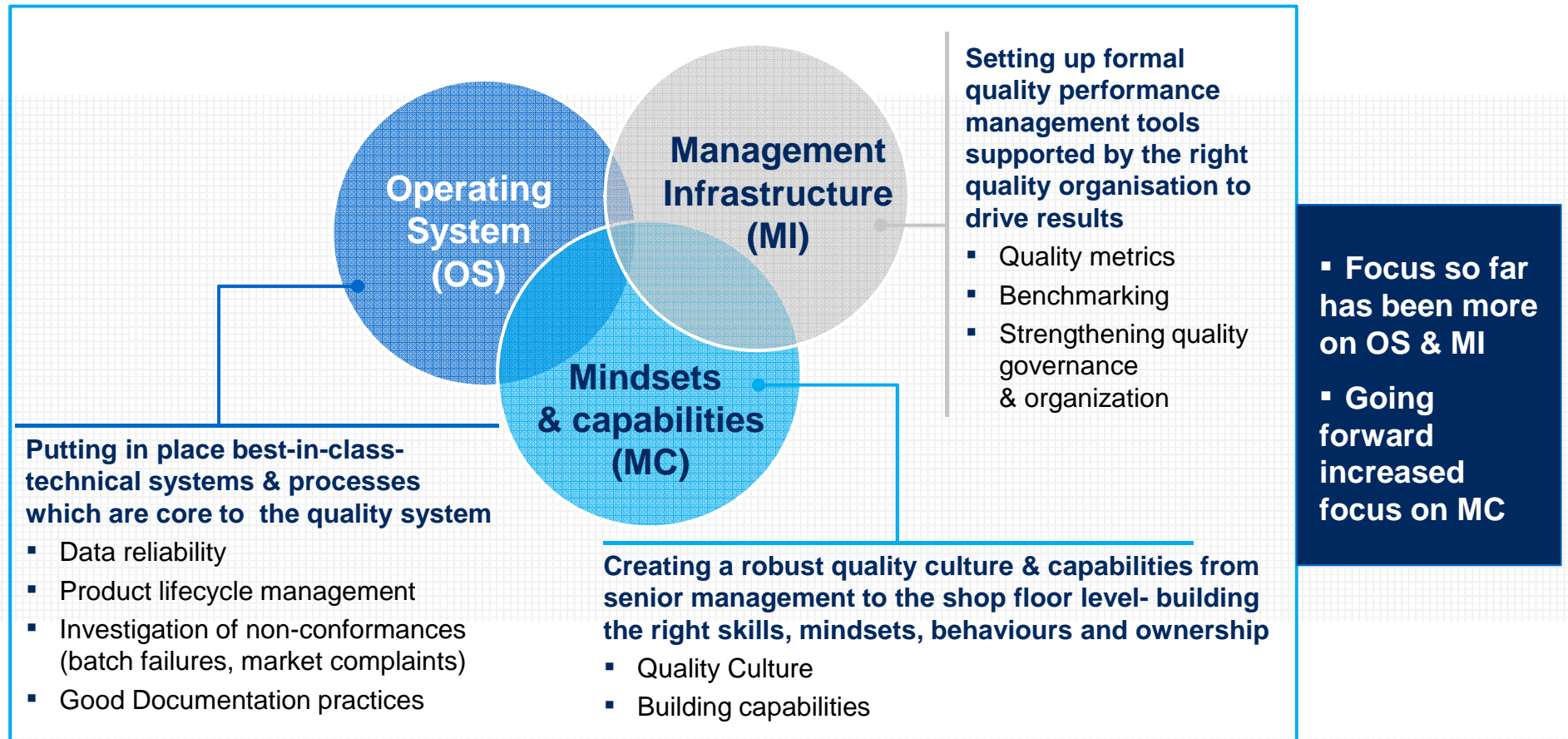
- ① Build a robust **Quality culture** across the network from top to bottom
- ② **Drive quality & productivity** in an integrated manner
- ③ **Develop capabilities** to sustain quality excellence across all levels
- ④ **Adopt next generation (Ops 4.0) tools** to leverage Digital & Advanced Analytics

Potential focus going forward

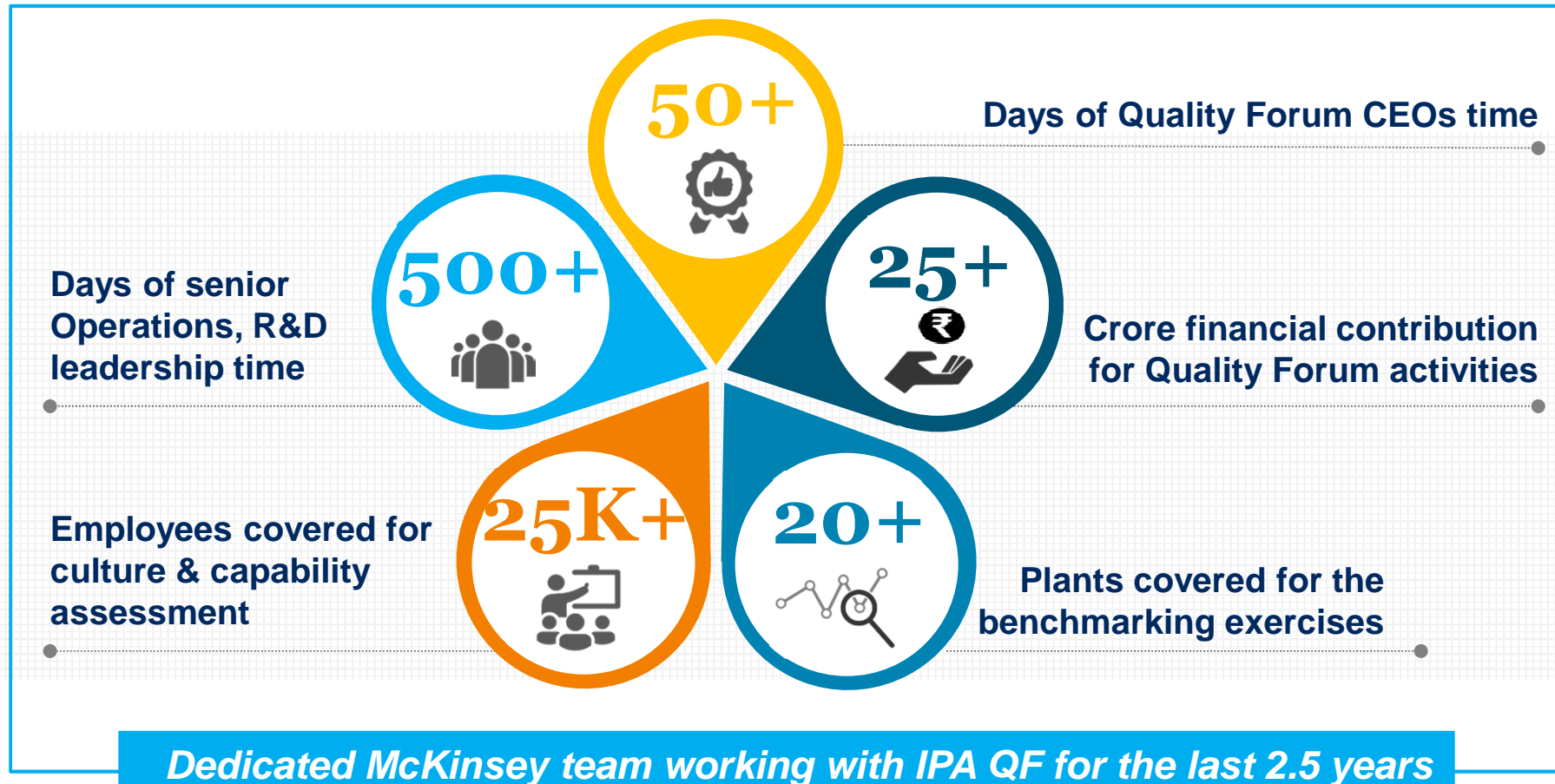
IPA Quality Forum is now in its third year



IPA Quality Forum has approached Quality Excellence through 3 lenses



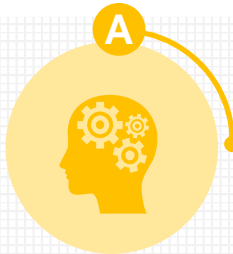
Extensive time and resources have been invested in this effort so far



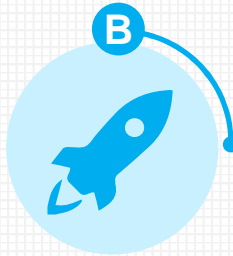
3 focus areas were outlined for IPA Quality forum last year

● Limited progress
● Very strong progress

Progress this year



Continue to develop best practice guidelines for Indian pharmaceutical companies



Expand reach of Quality Forum activities within IPA QF members, and other IPA members



Driving capability building, and training at scale



Best-practices being deployed to further improve quality standards



1

Design and deploy a comprehensive Production System to enable a consistent set of practices, standards & tools across the network

2

Digital performance management by real-time tracking of process parameters & leading metrics

3

Advanced analytics to improve product & process robustness by reducing deviations/ OOS, improving yield etc.

4

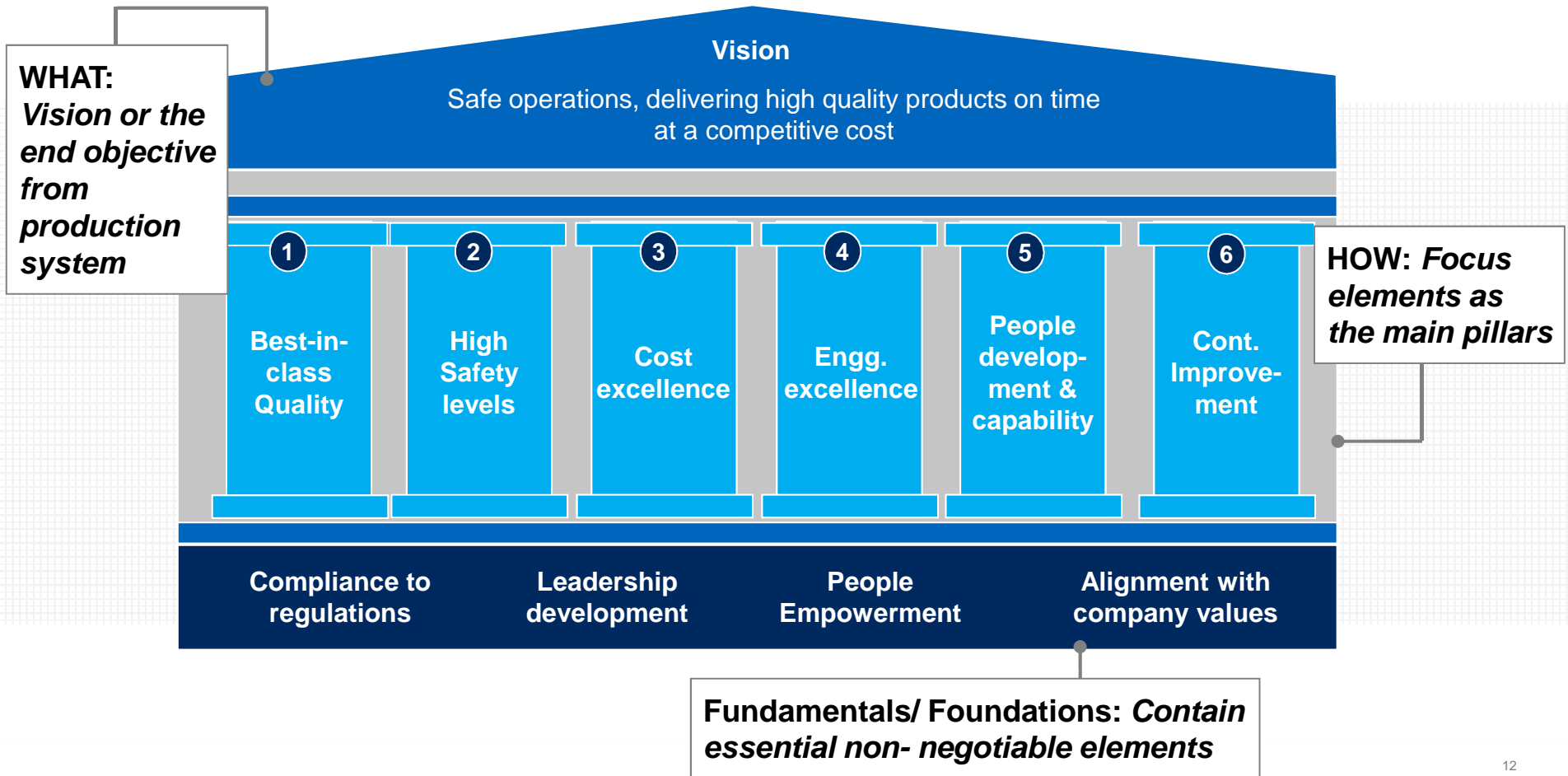
Lean tools to drive efficiencies in Lab operations e.g., enhancing QC lab throughput, improving QA/ QC productivity

5

Building next-gen quality capabilities & culture across the organization through experiential learning & use of digital channels

Most production systems have 3 elements

EXAMPLE



Focus areas for IPA Quality Forum next year

A



Publishing remaining best practice guidelines- Batch failure investigations and Market complaints handling

B



Launching middle management capability building pilot, followed by at scale implementation

C



Scaling up IPA QF interventions to other IPA members