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IPA Quality Forum - Reflections on the journey so far

Conference document | 23rd Feb 2017

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The IPA Quality forum was formed with a vision to help Indian Pharma Manufactures be the global benchmark in quality

Mission

Be the conduit of change through thought leadership, knowledge development and best practice sharing

Measure, benchmark and publicize the achievements of the Indian Pharma Industry in Quality

Expand the skill and capability of Quality talent in India

Deepen and strengthen the industry's relationship with key stakeholders – both within India and globally!

Provide platforms for members and other stakeholders to interact and network

Quality is never an accident.
It is always the result of
intelligent effort

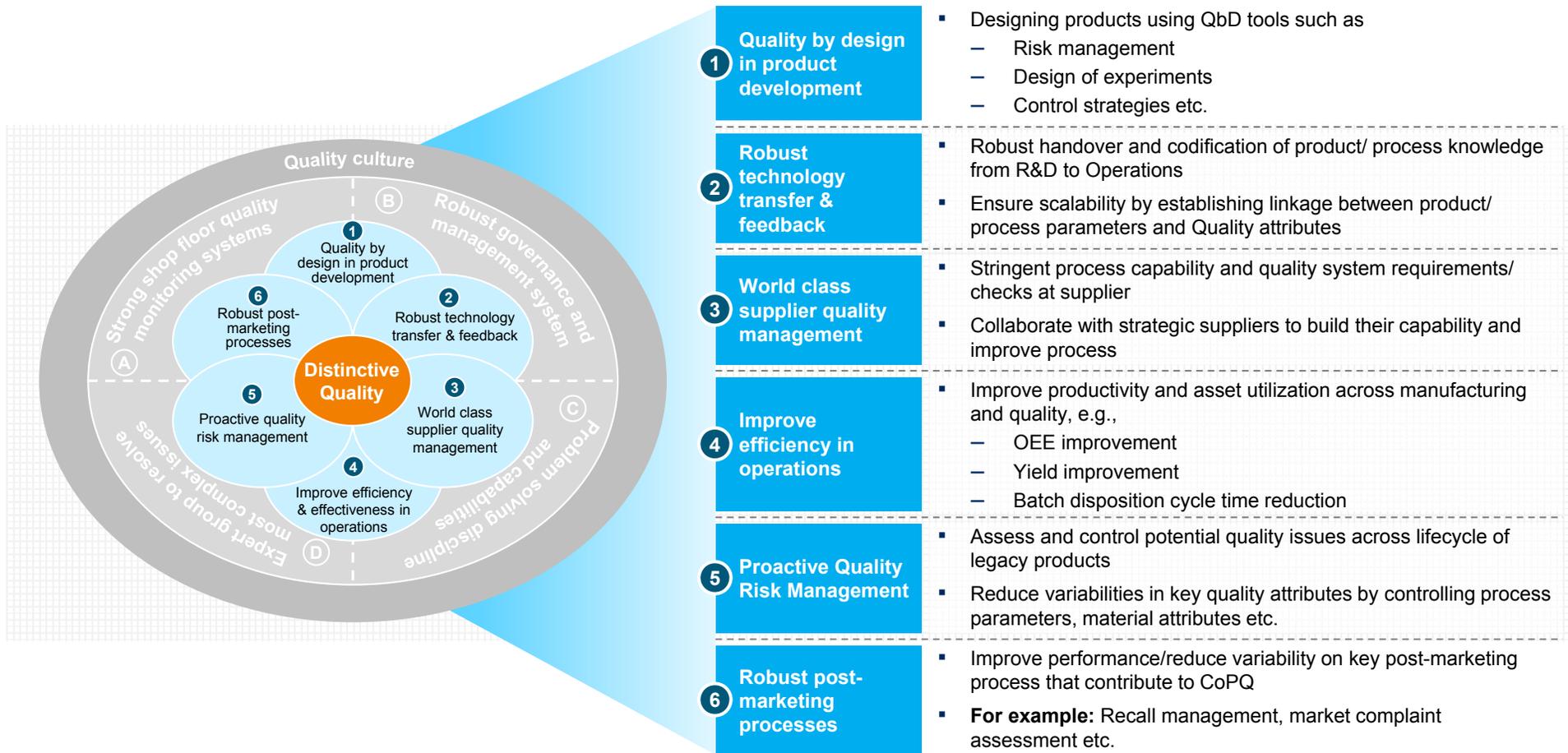
John Ruskin



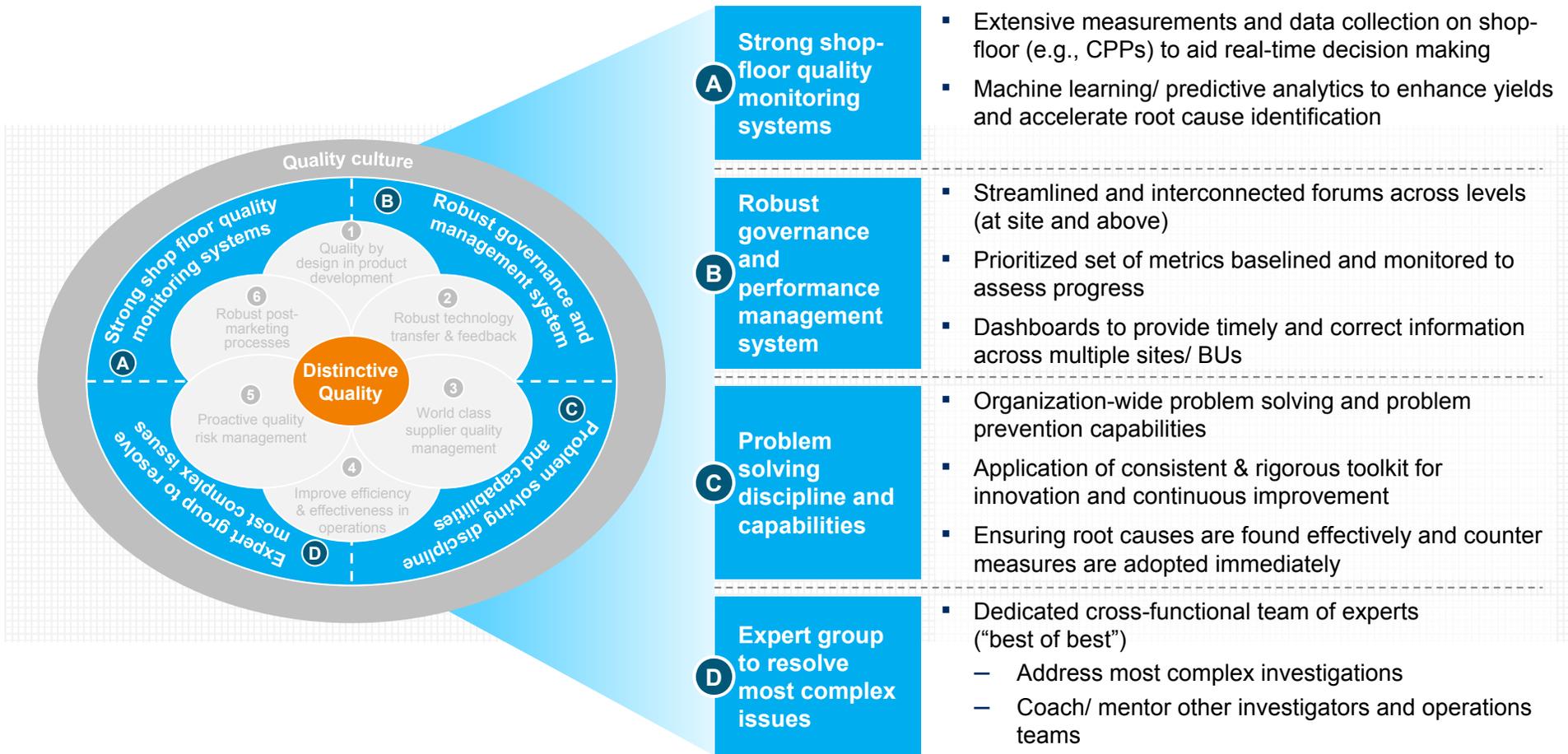
We are adopting a comprehensive approach to design and drive our journey to build an industry leading quality position



Building a distinctive Quality system - 6 core elements



Building a distinctive Quality system - 4 key enablers



A Strong shop-floor quality monitoring systems

- Extensive measurements and data collection on shop-floor (e.g., CPPs) to aid real-time decision making
- Machine learning/ predictive analytics to enhance yields and accelerate root cause identification

B Robust governance and performance management system

- Streamlined and interconnected forums across levels (at site and above)
- Prioritized set of metrics baselined and monitored to assess progress
- Dashboards to provide timely and correct information across multiple sites/ BUs

C Problem solving discipline and capabilities

- Organization-wide problem solving and problem prevention capabilities
- Application of consistent & rigorous toolkit for innovation and continuous improvement
- Ensuring root causes are found effectively and counter measures are adopted immediately

D Expert group to resolve most complex issues

- Dedicated cross-functional team of experts (“best of best”)
 - Address most complex investigations
 - Coach/ mentor other investigators and operations teams

Building a distinctive Quality system - 5 dimensions of quality culture



i Right-First-Time performance mindset

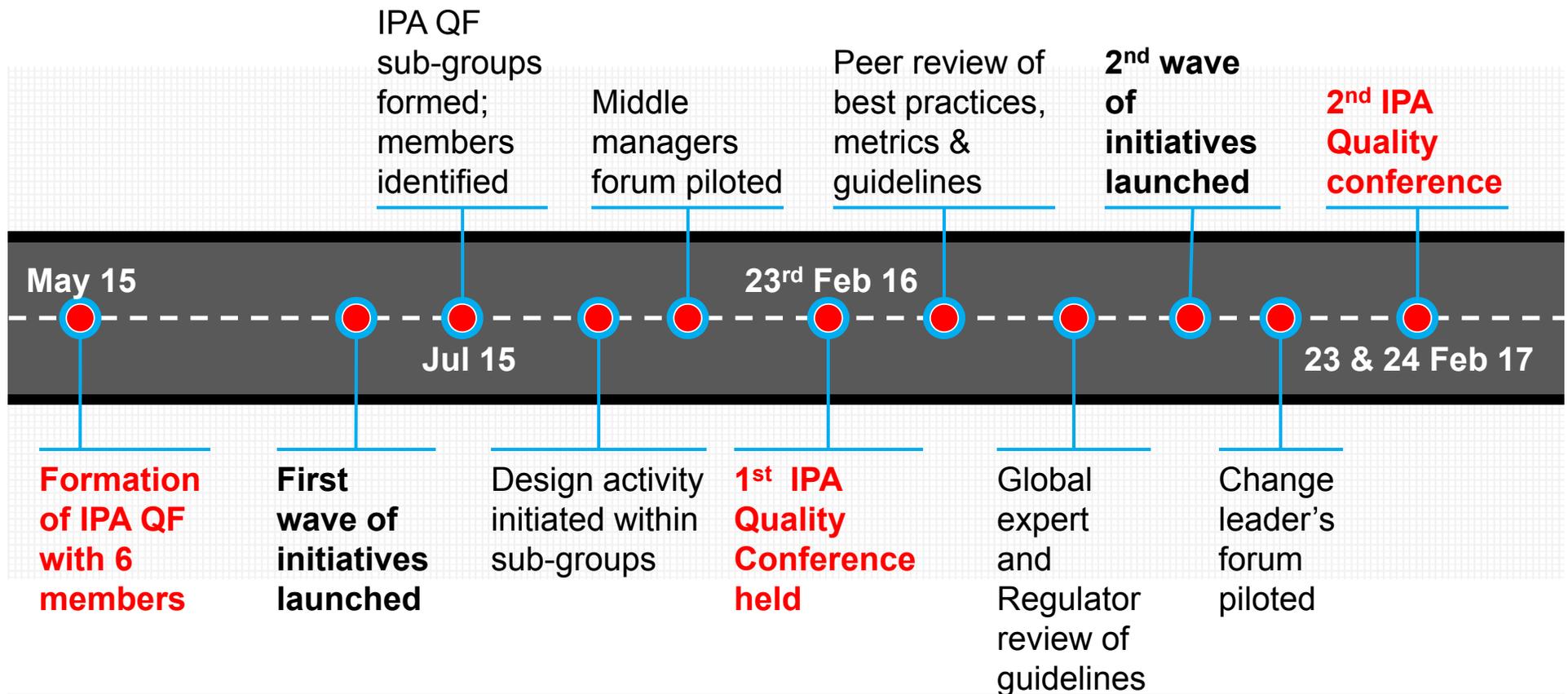
ii Variability reduction

iii Focus on identifying root cause

iv Data driven decision making

v Line ownership of quality, cost & delivery

The IPA Quality Forum is now in the second year of this journey



We have made significant progress on last year's focus themes

1 Data reliability



- Developed a robust **data reliability guideline document**
 - **Incorporates and builds** on existing regulatory guidance from FDA, and other regulators such as MHRA, WHO
 - **Vetted by leading subject matter experts** and each of the member companies

2 Metrics and best practices



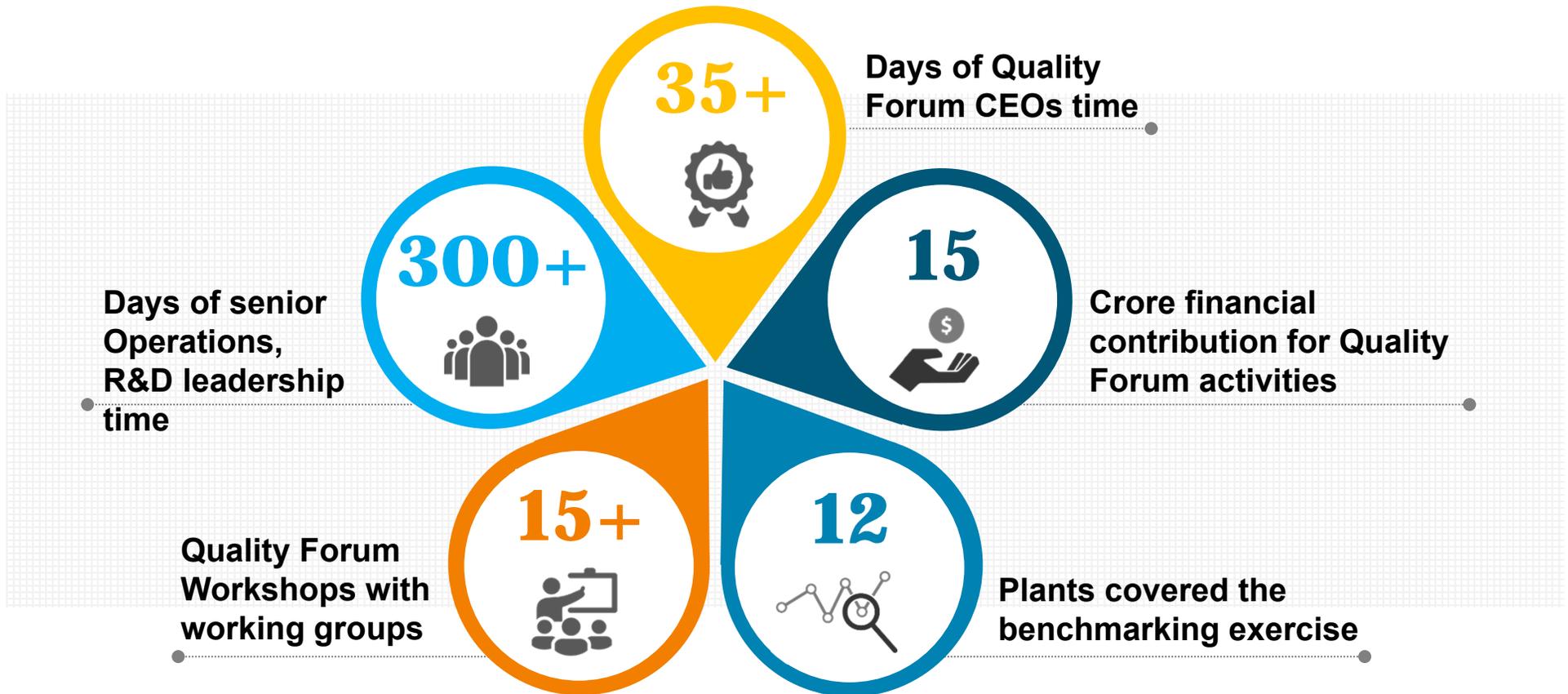
- Aligned on a detailed definition of a **standard set of quality metrics** in-line with FDA draft guidance
- Collected data on these metrics at the pilot sites
- Collated best-practices for **investigations and process validation**

3 Culture and capability



- Priority **technical training modules** developed as part of Quality Forum initiative (e.g., data reliability, investigations)
- **Quality Culture assessment done across** pilot sites
- Quality Change leadership forum implementation launched to **drive behavioral change**

Extensive time and resource investment has gone into the effort so far



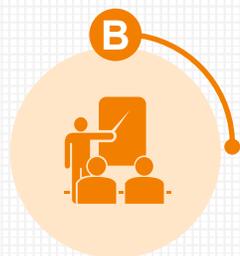
A good start is half the race



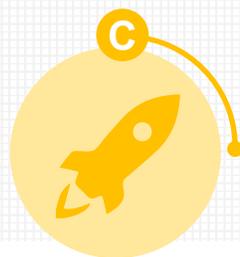
Focus areas for the IPA Quality forum going forward



Sharing learnings and expanding the quality forum work to other IPA members



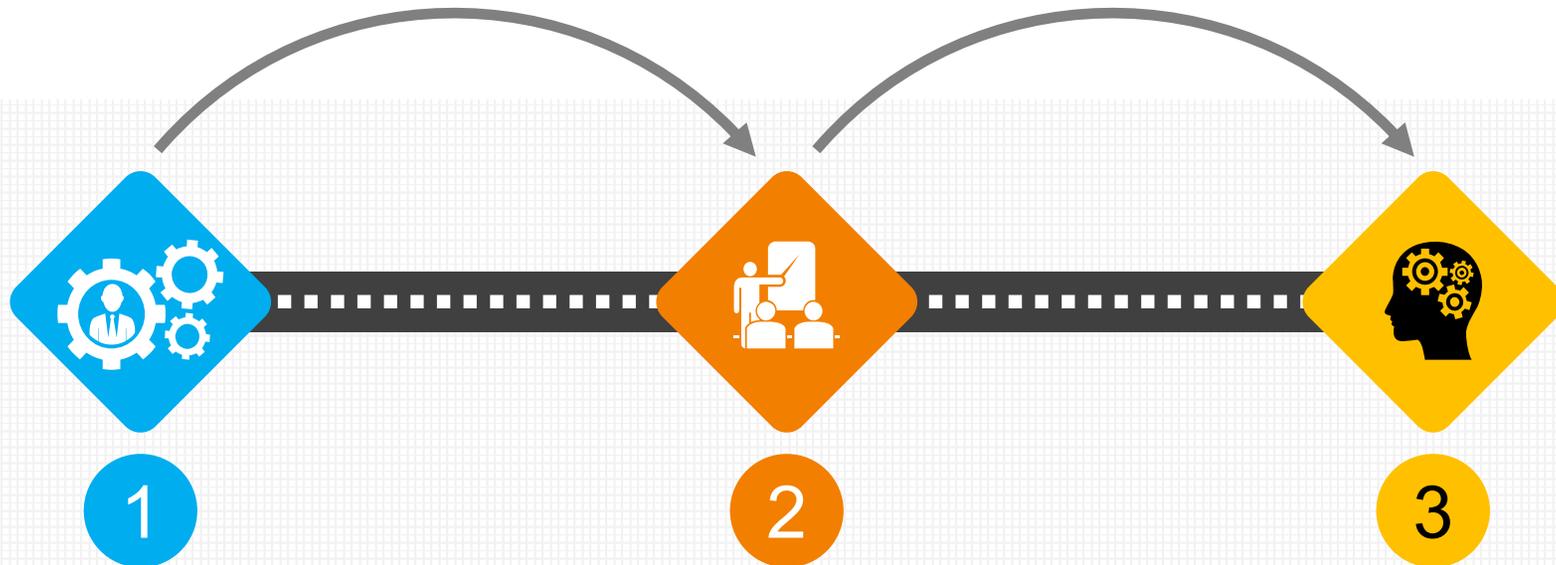
Enabling capability building and training at scale



Launching the next set of initiatives of IPA QF

- Batch failure investigations
- Market complaint investigation
- Good documentation practices

B Make a step jump in capability



**Mapping skills
to capabilities
across levels**

**Connect class-
room training to
day-to-day
workplace**

**Innovative delivery
that goes beyond
compliance**

C Next set of initiatives for the IPA QF going forward

4 Batch failure investigation



- Draft a detailed checklist for investigating batch failures
- Develop best practice SOPs
- Create a comprehensive guideline document for batch failure investigations

5 Complaints – Investigation & Review



- Compile best practices on complaints investigation and review
- Develop best practice SOPs
- Outline standardized approaches to situations outside SOP

6 Good documentation practices

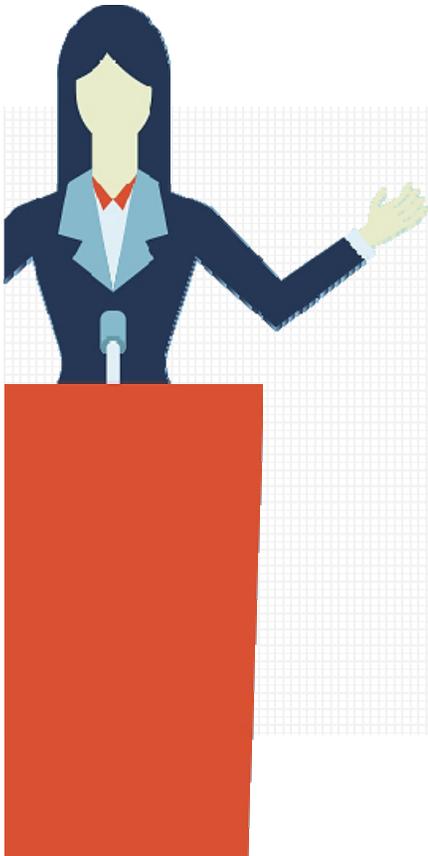


- Document management across lifecycle (QC reports, batch records)
- Simplification – eliminate duplication and rationalize SOPs
- Minimizing human intervention in data capture through IT coverage, Automation etc.

BACKUPS



Key takeaways from last year's conference



- 1 Increasingly reward good performers and challenge poor performers
- 2 Greater differentiation between poor & great quality systems through enhanced surveillance and risk-based inspection approaches
- 3 Indian regulators should play a key role in improving industry-wide quality
- 4 Metrics and data-based analysis will be used to separate good and bad performers
- 5 Quality Culture and role modeling by the senior management to get “Quality outcome”