

National Academies Meeting on Food and Drug Regulatory Systems Abroad

**by
D G Shah
Secretary General
Indian Pharmaceutical Alliance**

**Washington DC
9 January 2019**

* Focus so far
has been more
on QS & MI

* Going forward
increased focus
on MCL

IPA Quality Forum

A Private Sector Initiative for Capability Building

Key Elements

- ❑ Focused on Total Quality, Not Mere Compliance.
- ❑ Capability Building Has Lasting Value and Could Help Reduce Burden of Snapshot Inspections.
* Focus so far has been more on QS & MI
- ❑ Custom-made Capability Building Programmes Provide Better Outcomes than General Training Programmes.
* Forward increased focus on MCI
- ❑ Need On-going Support of FDA to Effectively Run the Initiative.
- ❑ Institutionalize the Effort To Achieve Better Outcomes.

Fulfills FDA Mission of Ensuring Safe, Effective and Quality Medicines

IPA Quality Forum

A Private Sector Initiative for Capability Building

After Attending IPA's 2nd Annual Conference 2017

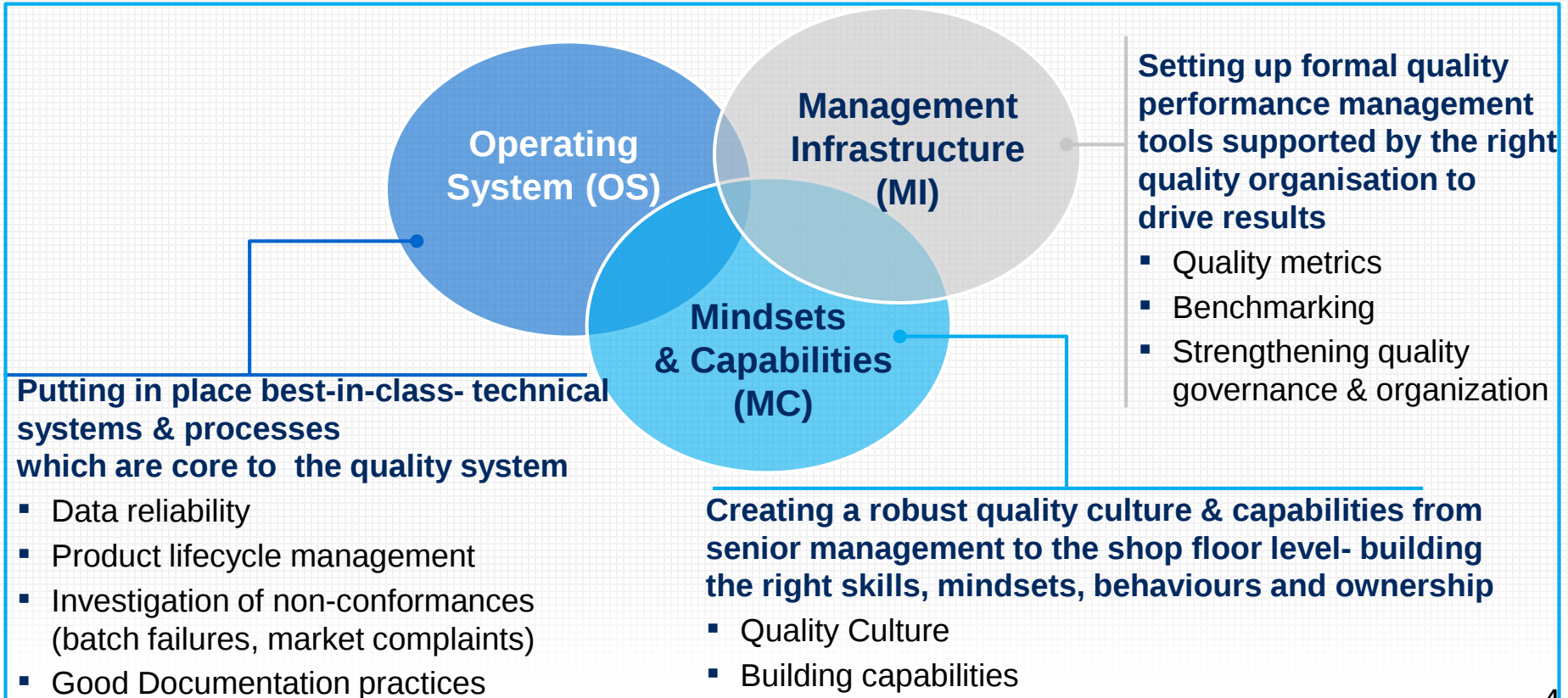
- ❑ “It was a pleasure to listen to IPA's current initiatives to improve drug safety for pharmaceutical products exported to the United States.”
- ❑ “I am hopeful that the IPA will continue to share the outcomes of these encouraging initiatives with the FDA.”
- ❑ “We look forward to your continued leadership and support within India to raise the appreciation and awareness of the criticality of pharmaceutical quality throughout the life-cycle and the importance of improving the safety, quality and efficacy of medicines to the pharmaceutical industry in India.”

Mary Lou Valdez, M.S.M.
Associate Commissioner for International Programs
U.S. Food & Drug Administration

IPA Quality Forum

A Private Sector Initiative for Capability Building

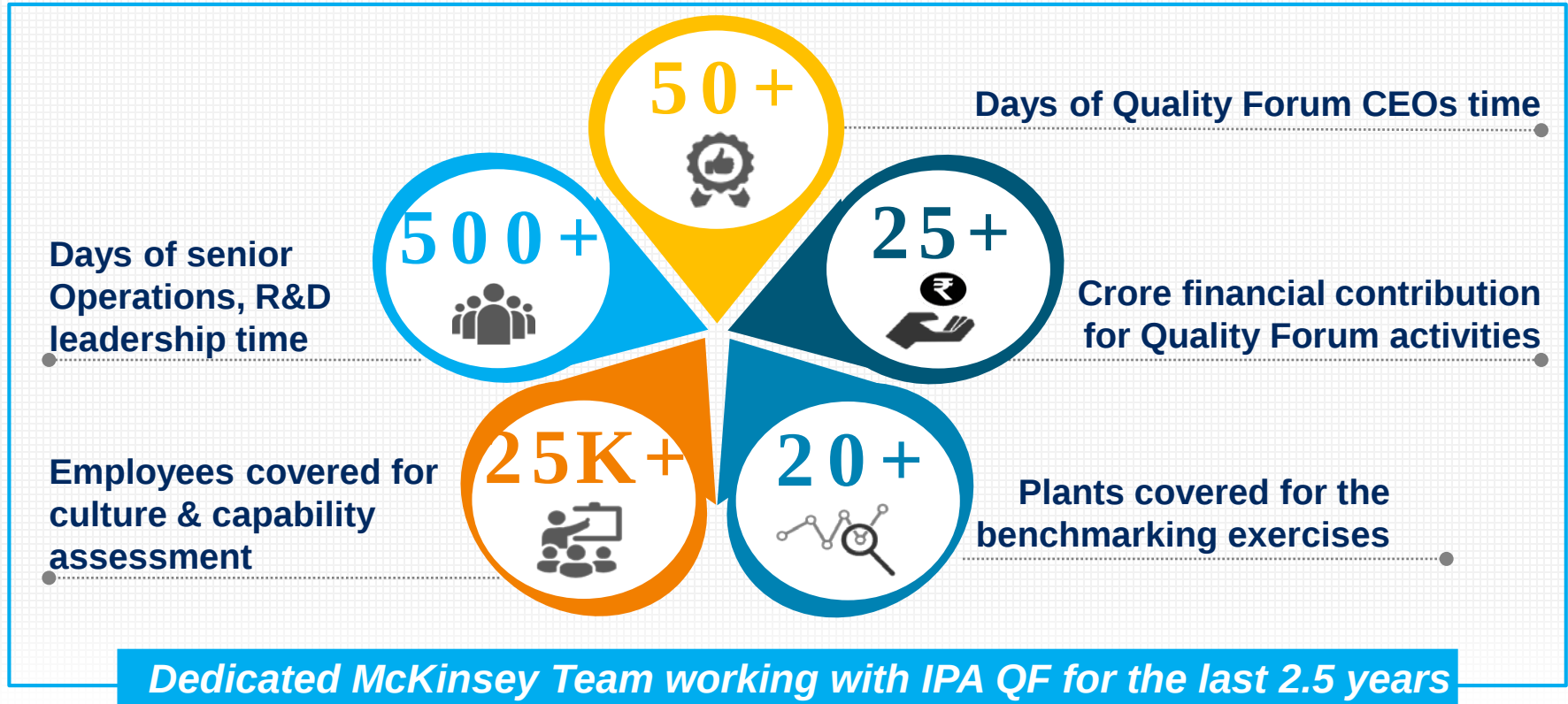
Excellence Through 3 Lenses



IPA Quality Forum

A Private Sector Initiative for Capability Building

Extensive Time and Resources Invested



THANK YOU

dgshah@vision-india.com