Towards Excellence in Quality
IPA Annual Conference
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The success of Indian Pharma

• 10% of world’s drugs (by volume)
• 12-17% annual pharmaceutical growth rate (~$20B in 2015)
• PharmaVision 2020 – “end to end” leader
• “Make in India”
  • incentives for bulk drug manufacture
  • >$200B spend on medical infrastructure
• New pharmaceutical parks
India – “Pharmacy of the World”
2015 ‘High impact’ inspection findings

- Failing PQS
- Risk based investigations and actions
- Personnel knowledge / experience
- Documentation issues
2015 ‘High impact’ inspection findings

- Failing PQS
- Mgmt oversight and resourcing – ICH Q10
- Quality defect investigations and actions
- Operational cross contamination controls

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Common themes; increasing severity
2015 ‘High impact’ inspection findings

- Serious PQS failure
- On-going stability programme
- Quality defects with public health impact
- Data Integrity

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(Attributed, Legible, Contemporaneous, Original, Accurate)

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Common themes; increasing severity
Challenges to be faced:

- No compromise on Quality
- Ongoing austerity
- Global population changes (ageing, co-morbidities, polypharmacy, chronic conditions)
- Transparency and communications
- Opportunities for use of Real World Data
- Internet and illegal supply
Opportunities yet to be realised:

- World leader in biosimilars?
- World leader in drug discovery and development? (currently only ~2% of global trials in India)
- Innovative biologicals (from domestic products)
- Personalised medicines/Genomics
- Companion diagnostics
- Increased automation and efficiency
- Use of Real World Data
Excellence in Quality?

“Individual efforts can bring excellence but only collective efforts can deliver effectively”
THANK YOU FOR YOUR ATTENTION

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