



Medicines & Healthcare products  
Regulatory Agency



# Towards Excellence in Quality

## IPA Annual Conference

23<sup>rd</sup> February 2016

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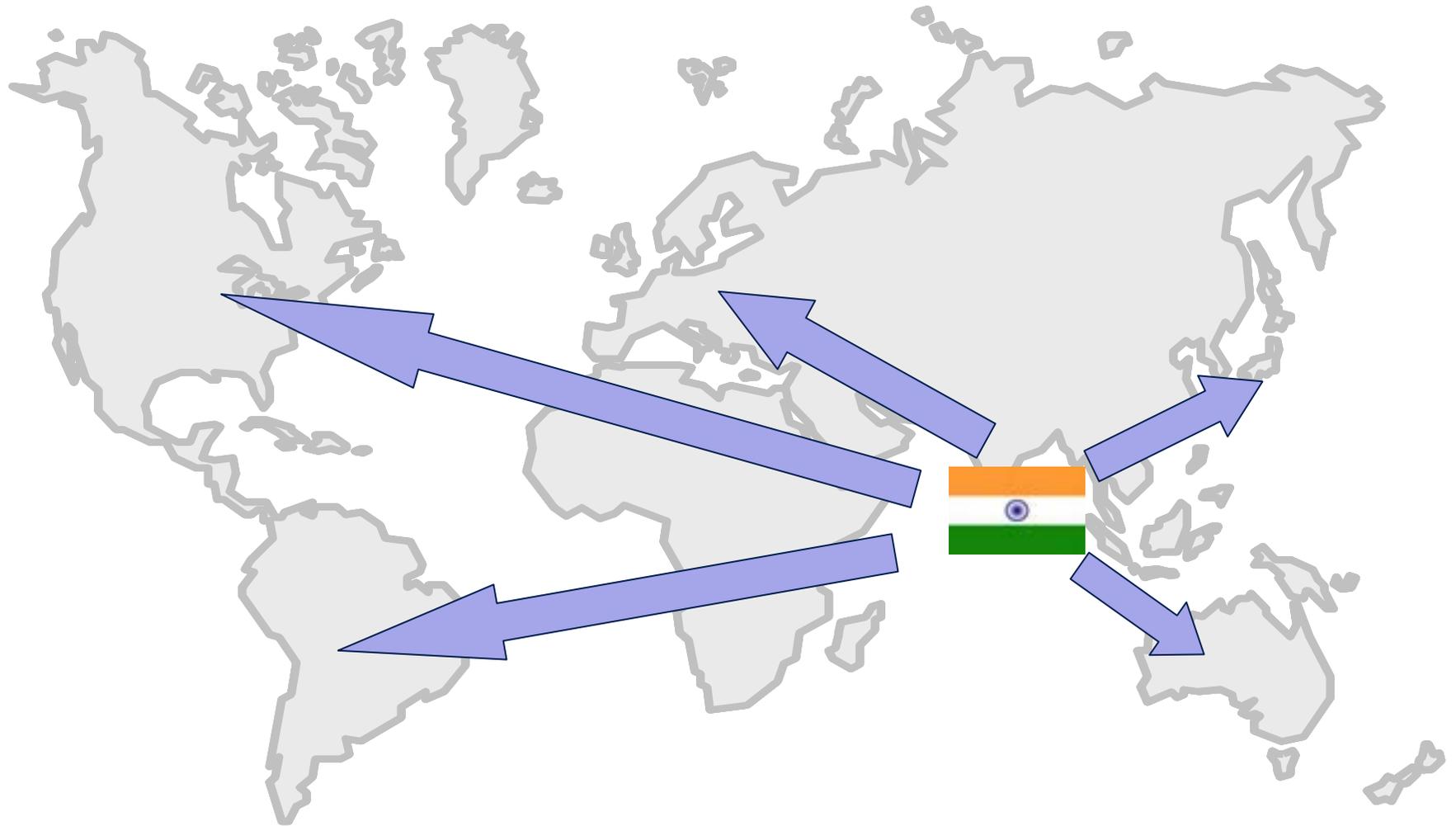


# The success of Indian Pharma



- 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”





**Innovation, Quality and Global Reach**

# 2015 'High impact' inspection findings



Compliance  
Management

Failing PQS

Risk based investigations and actions

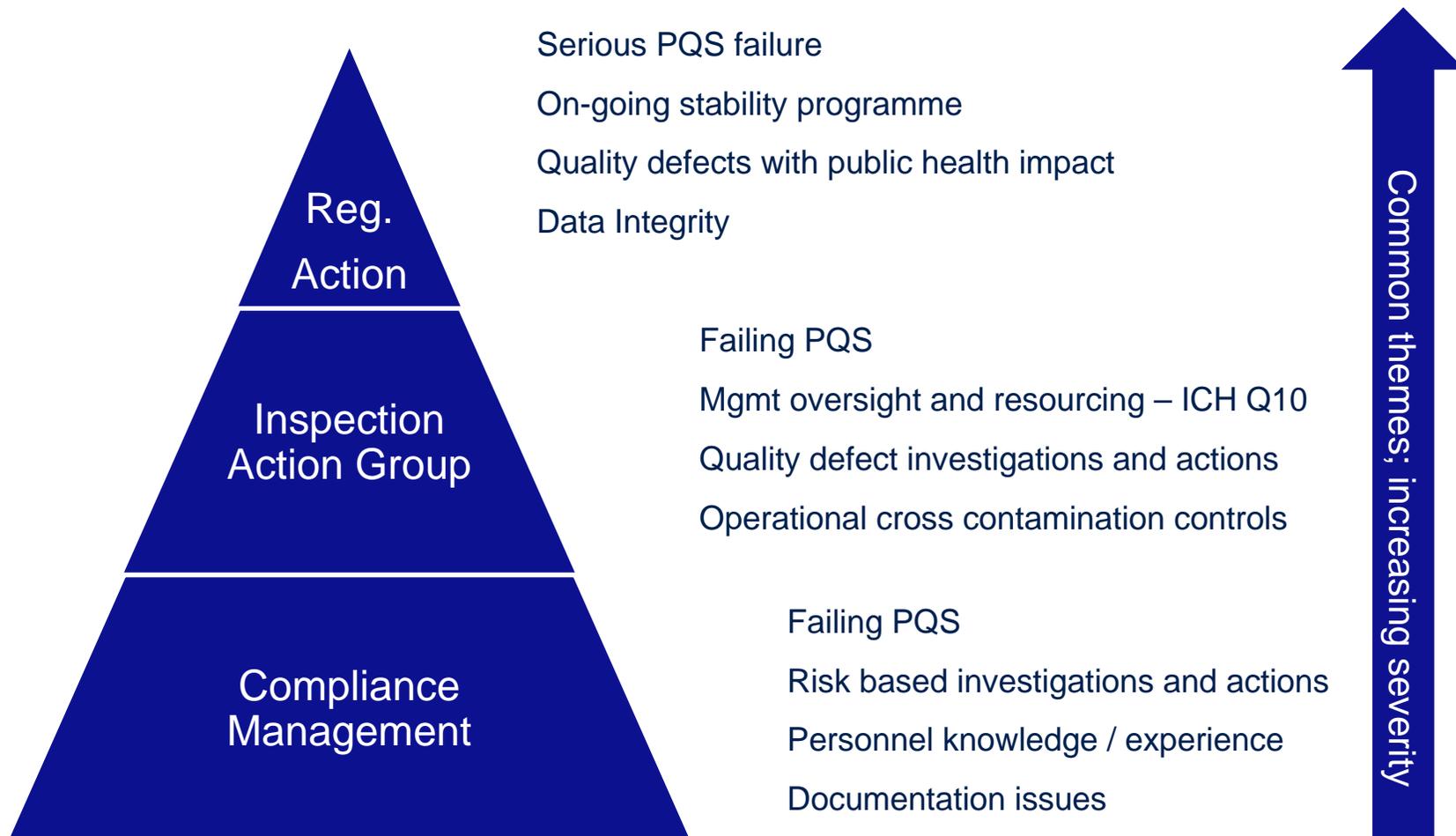
Personnel knowledge / experience

Documentation issues

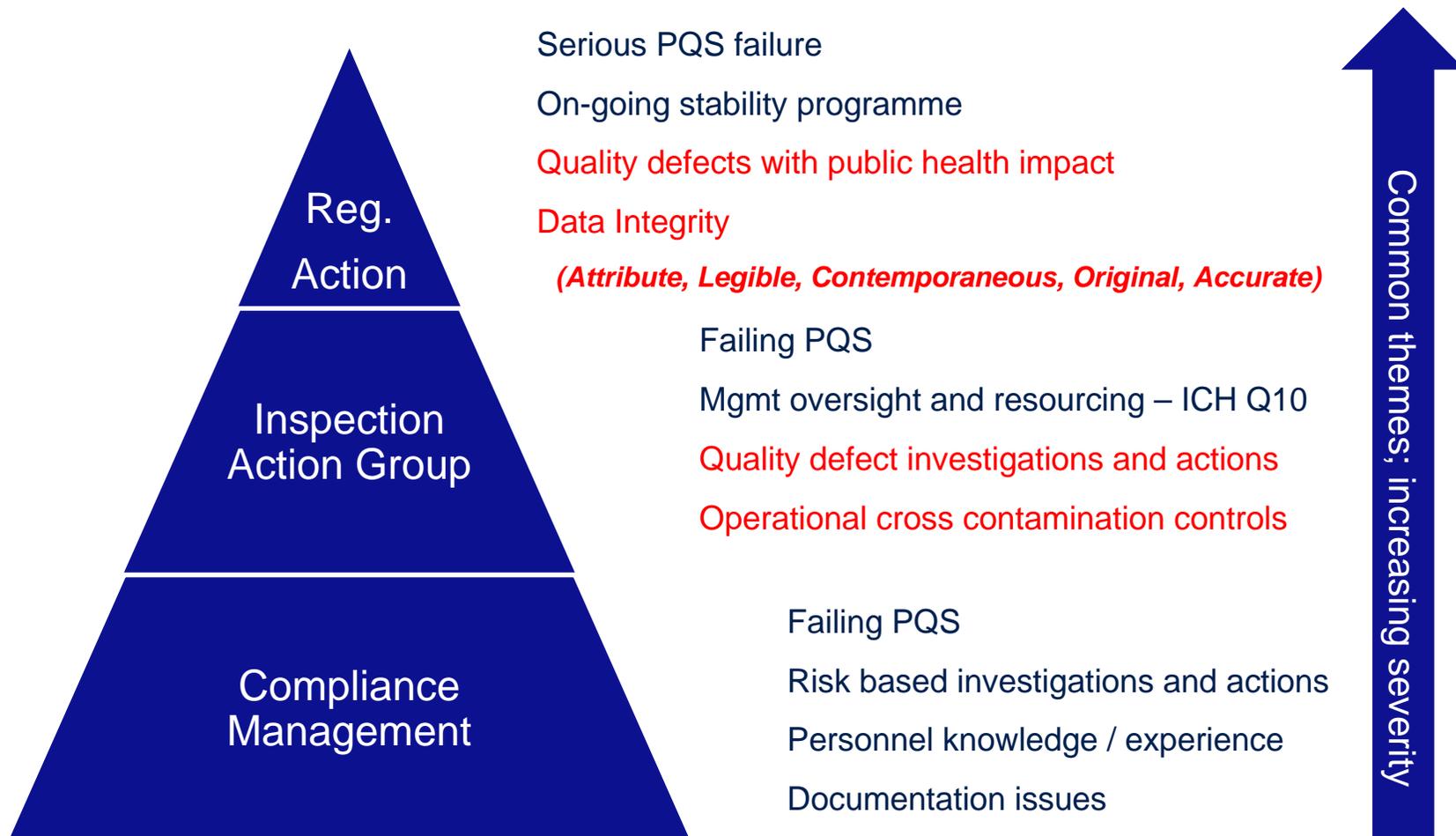
# 2015 'High impact' inspection findings



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# 2015 'High impact' inspection findings



# 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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