

A close-up photograph of a hand wearing a blue nitrile glove. The hand is holding a clear glass vial with a syringe attached to its bottom. The vial contains a clear, colorless liquid. The background is a blurred blue and white, suggesting a clinical or laboratory setting.

# Trends in the inspection of Vaccine manufacturing sites

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# Special characteristics of vaccines

## More difficult and sophisticated Mfg. and Control

- Biological origin- *inherent variability*
- Sterile – *overall injectable*
- Vaccine mostly given to babies and children or healthy subjects
- Risk of contamination (microbial, viral, BSE/TSE)
- Thermolabile



Therefore, need

- Strong ***Pharmaceutical quality system*** and ***Quality Risk Management***

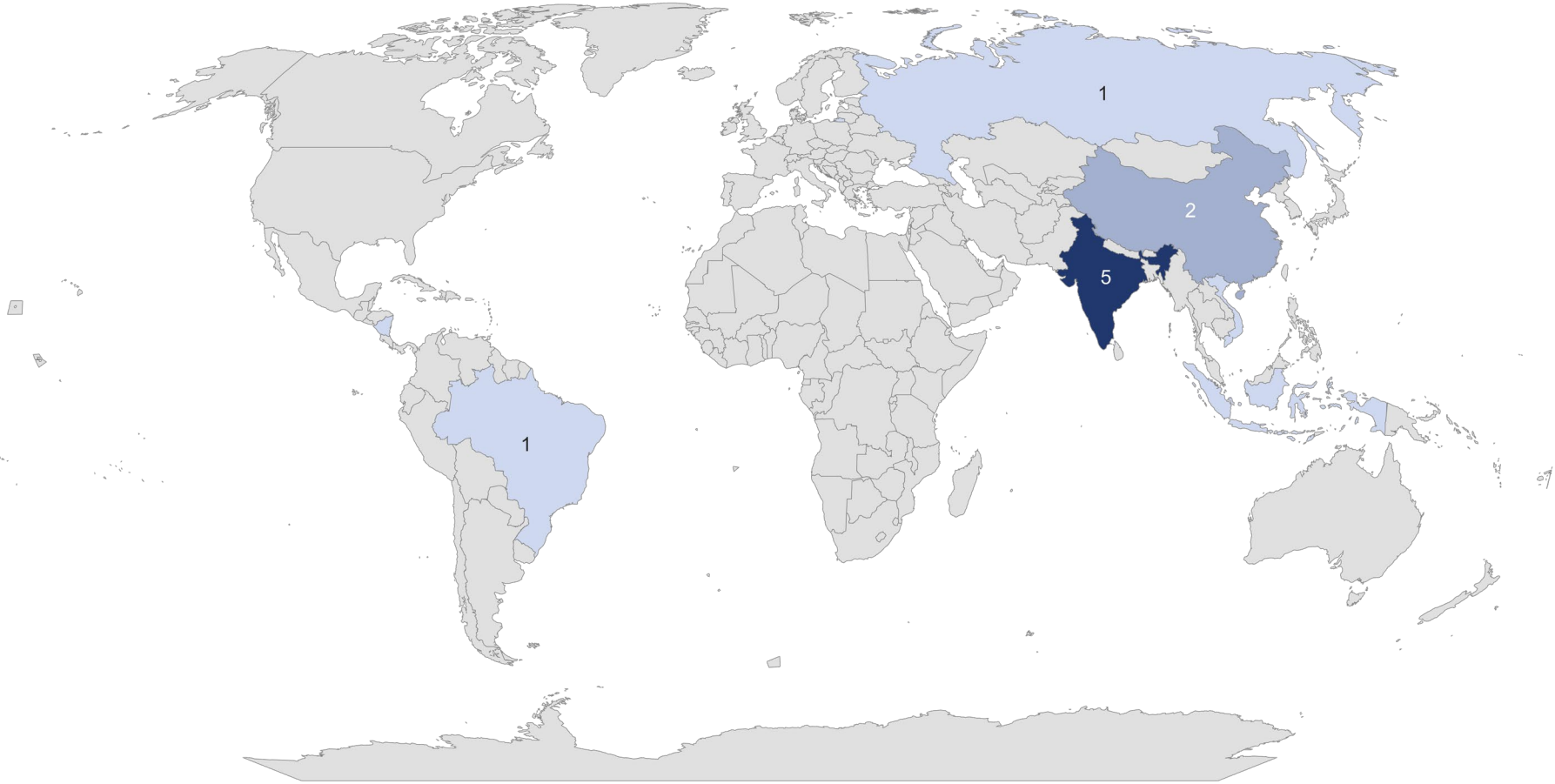
## ❖ Technical Report Series: GMP related

- **GMP Main Principles**: TRS 986 annex 2 (2014)
- **Biological products**: TRS 999 annex 2 (2016)
- **Sterile products**: TRS 1044 annex 2 (2022)
- **QRM**: TRS 981 annex 2
- **Guidelines on validation**: TRS 1019 annex 3 (2019)
- **Water for pharmaceutical use**: WHO TRS No. 1033, Annex-3 (2021)
- **Guideline on data integrity**: WHO TRS No. 1033, Annex-4 (2021)
- ...



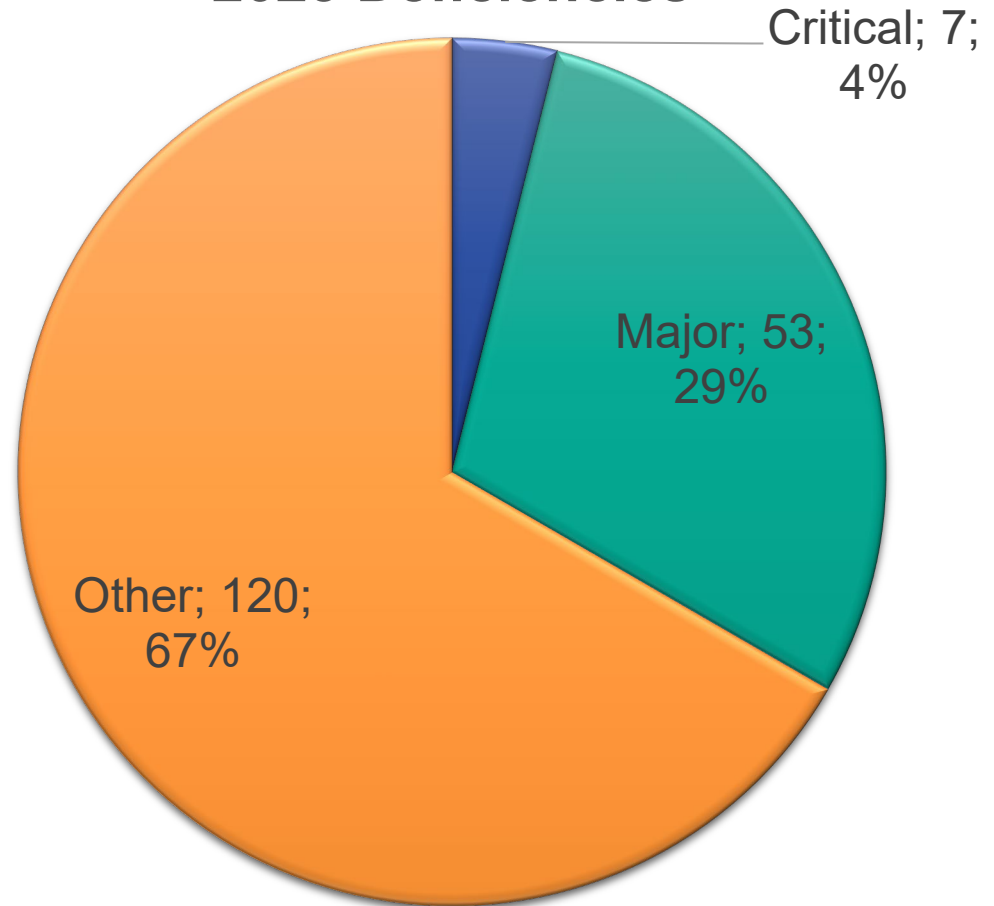
# 2023 Vaccine Inspection Statistics

- 12 inspections



# 2023 Vaccine Inspection Statistics

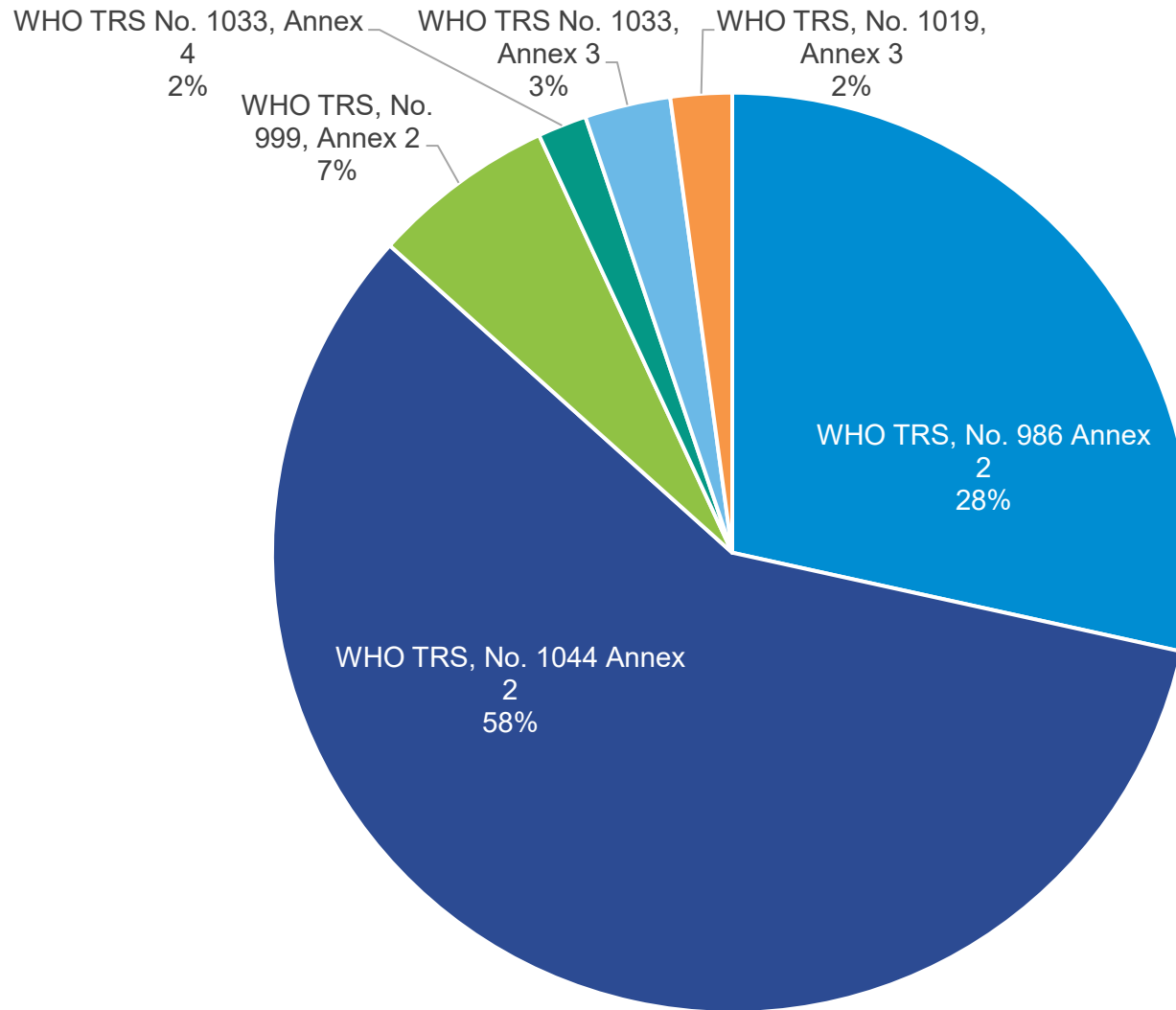
## 2023 Deficiencies



- 12 inspections\*
- 166 deficiencies
  - Critical - 4 inspections
  - Major - Mean 4.41
  - Other - Mean 10

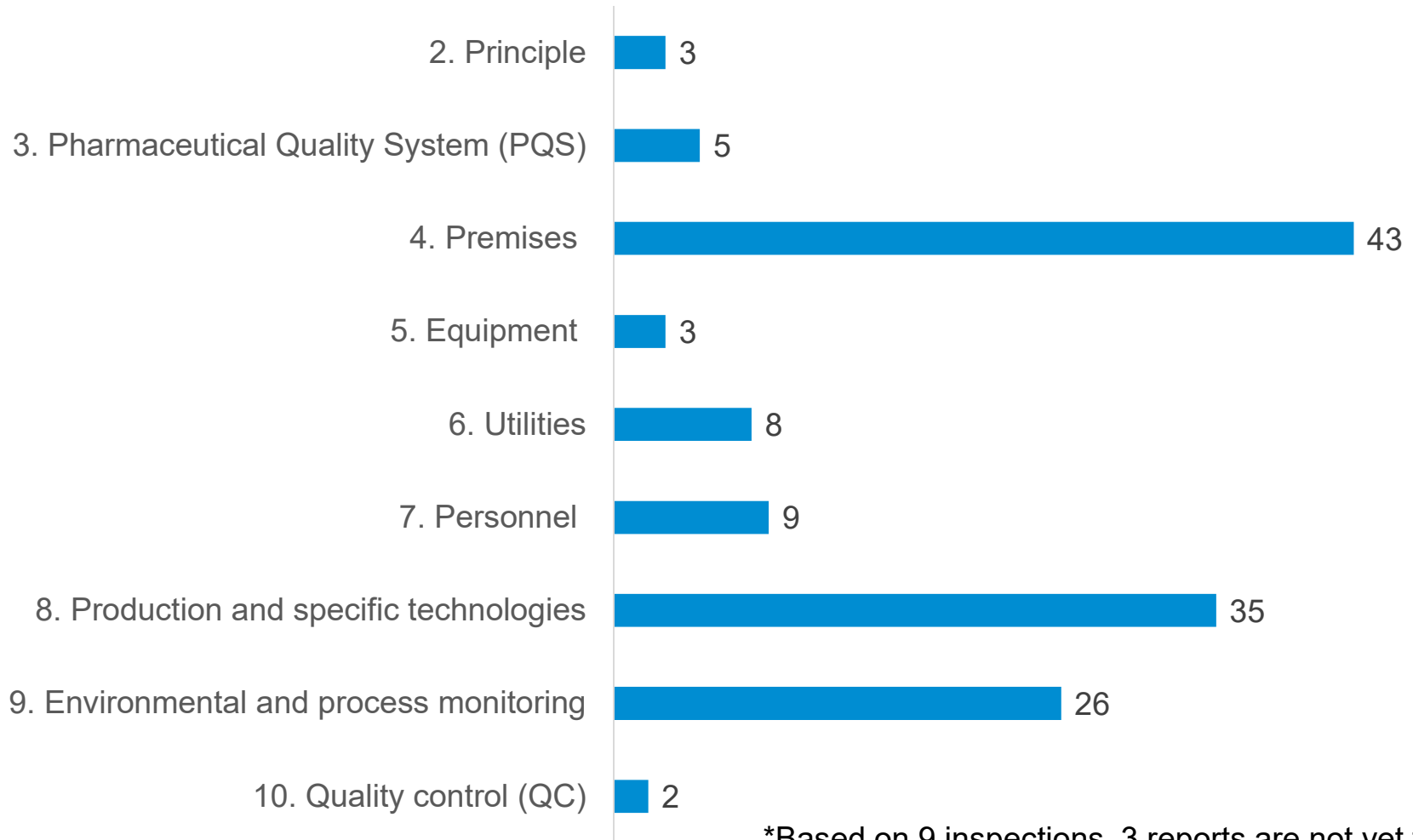
\*3 reports are not yet finalized

# Critical and Major deficiencies:\*



\*Based on 9 inspections, 3 reports are not yet finalized

# Deficiencies related to WHO TRS 1044 Annex 2 (EU, PIC/S Annex 1)\*



\*Based on 9 inspections, 3 reports are not yet finalized



# Summary



- India was the most inspected country
- More than 50% of critical and major deficiencies were related to GMP for sterile products – WHO TRS 1044 Annex 2 (new EU-PIC/S Annex 1)
- Regarding the WHO GMP for sterile products the top 3 areas of deficiencies were the sections 4 (Premises), 8 (Production) and 9 (EM and APS).



# Thank you!



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