

# Vaccines Inspection Updates

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# Special characteristics of vaccines

## Difficult and sophisticated Mfg. and Control

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



Therefore, need

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

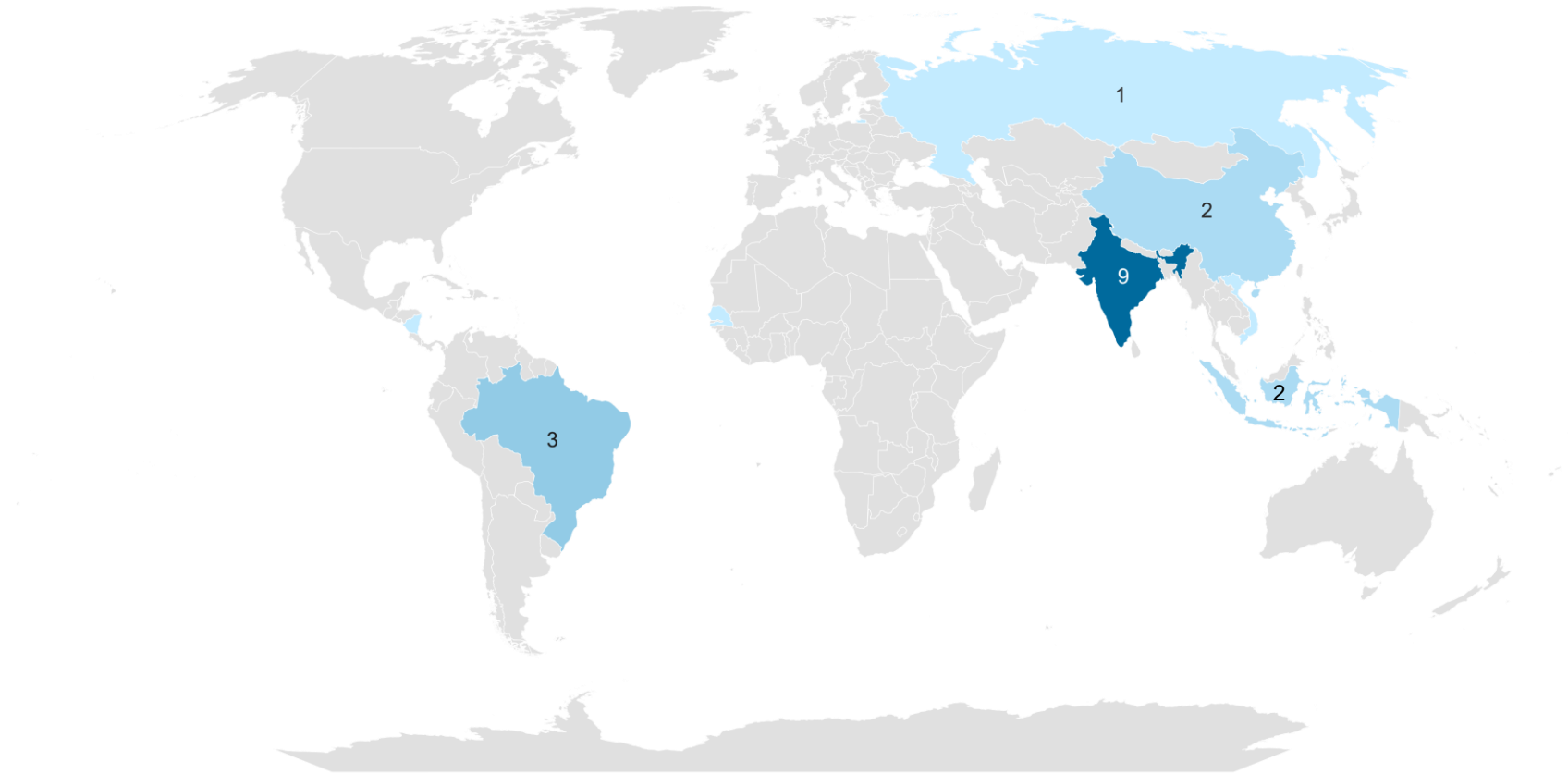
## ❖ Technical Report Series: GMP related

- **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)
- **GMP for excipients**: WHO TRS No. 1052, Annex 2 (2024)



# 2023/2024 Vaccine Inspection Statistics

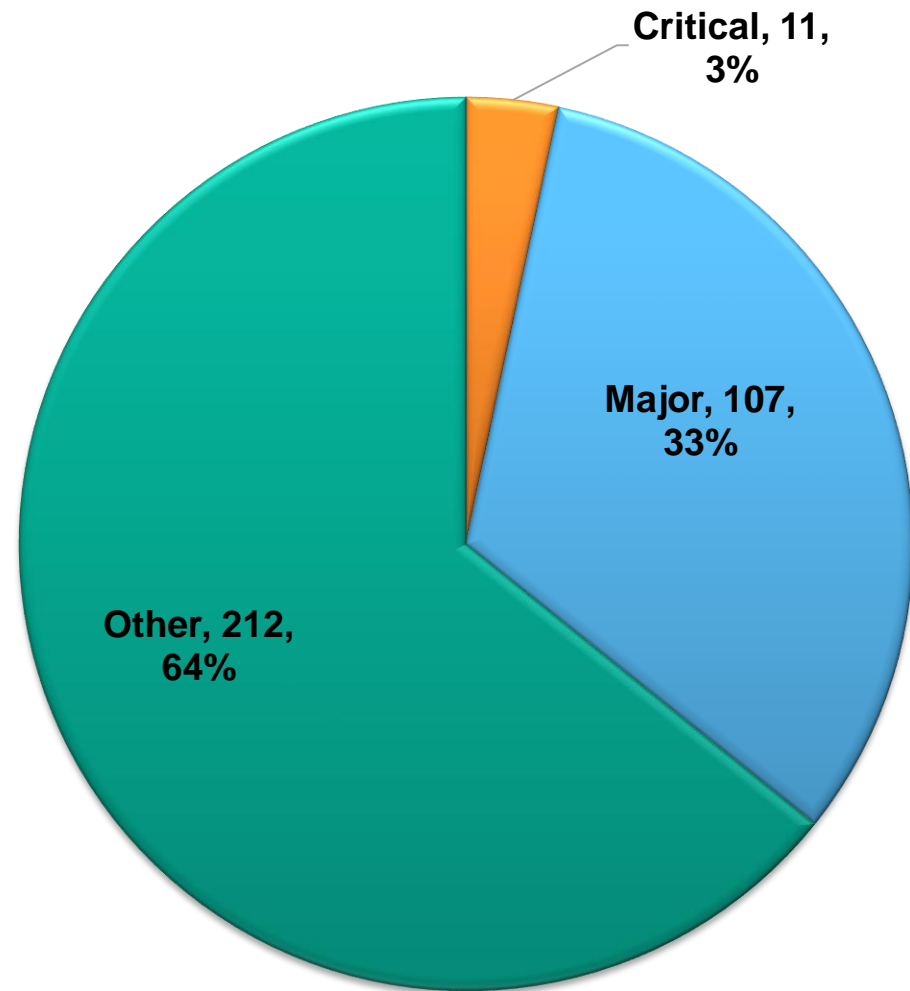
- 20 inspections



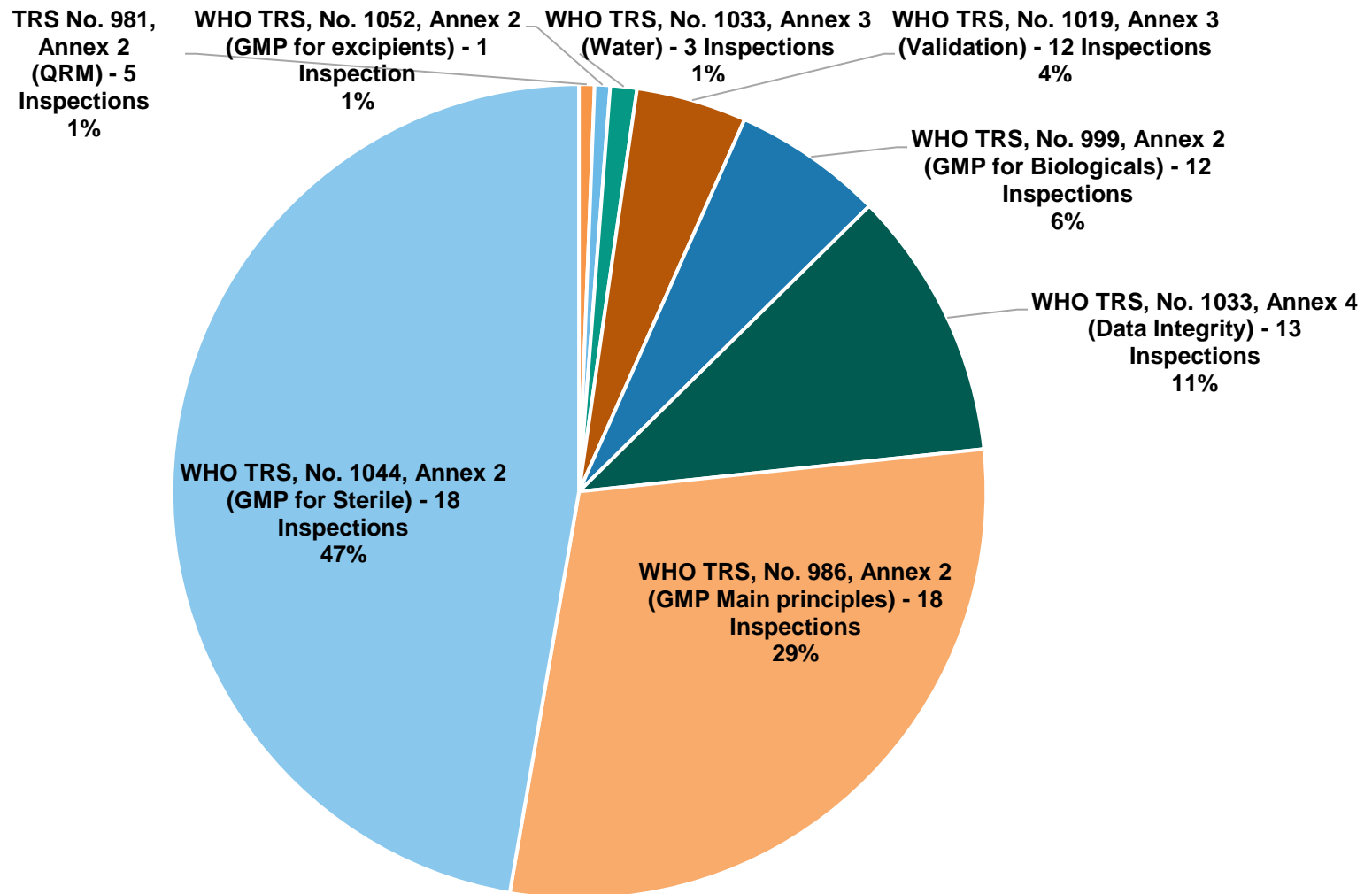
# 2023/2024 Vaccine Inspection Statistics

- 20 inspections\*
- 330 deficiencies
  - Critical – 6 inspections
  - Major - Average 5.35
  - Other - Average 10.6

\*2 reports are not yet finalized



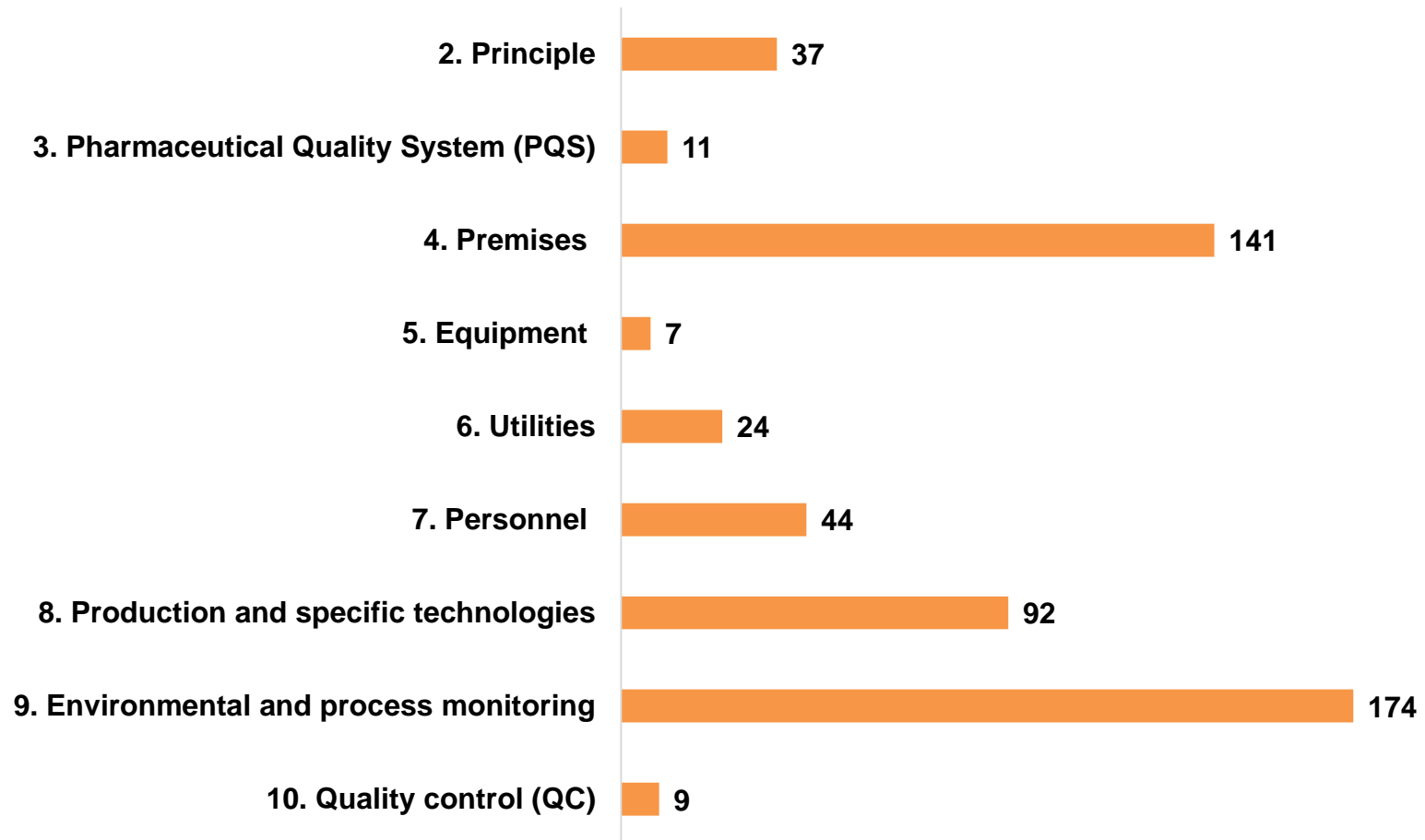
# 2023/2024 Critical and Major deficiencies:\*



\*Based on 18 inspections, 2 reports are not yet finalized



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



\*Based on 18 inspections, 2 reports are not yet finalized

# WHO TRS 1044 Annex 2 – Most Referred Paragraphs

## 12 Inspections:

- 9.4 Environmental Monitoring Programme
- 9.36 Aseptic Process Simulation (APS)

## 11 Inspections:

- 4.11 Transfer of materials, equipment and components into the grade A or B areas
- 4.21 RABS and Isolator Gloves integrity, sterilization/biodecontamination
- 4.32 Requalification of cleanrooms and clean air equipment
- 7.18 Personnel - Aseptic Practices



# In Summary

**India, the most inspected country, plays a significant role in the global vaccine supply**

**Around 50% of critical and major deficiencies were related to GMP for sterile products – WHO TRS 1044 Annex 2 (new EU-PIC/S Annex 1)**

**Deficiencies related to sterile manufacturing were mainly related to the current requirements for premises, production, RABS and isolators, EMP, and APS**

**Vaccine Manufacturers are encouraged to check and implement the current GMP requirements.**



Thank You

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