SUN PHARMA

Inspection challenges, efficiencies, and opportunities

October 2025

NSE:SUNPHARMA | BSE:524715 |
Bloomberg:SUNP IN | Reuters:SUN.BO

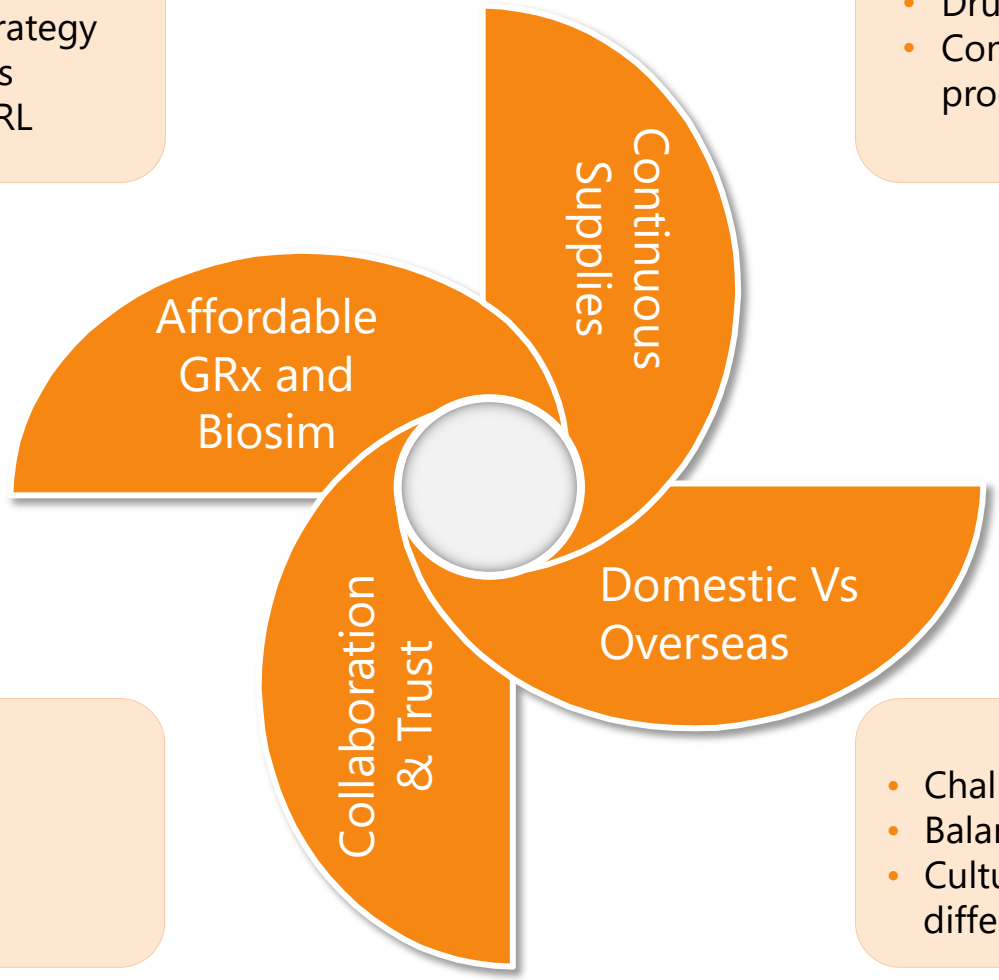
WWW.SUNPHARMA.COM

Disclaimer: *The views and opinions expressed in this presentation are solely those of the presenter and do not necessarily reflect the official policy or position of the company*

Towards Successful Inspections: Challenges & Opportunities

- New Gx approvals
- PAI timelines and strategy
- Late stage facility IRs
- Post classification CRL

- Drug shortages
- Concerns for exempt products



- Alternate tools
- Mutual recognition

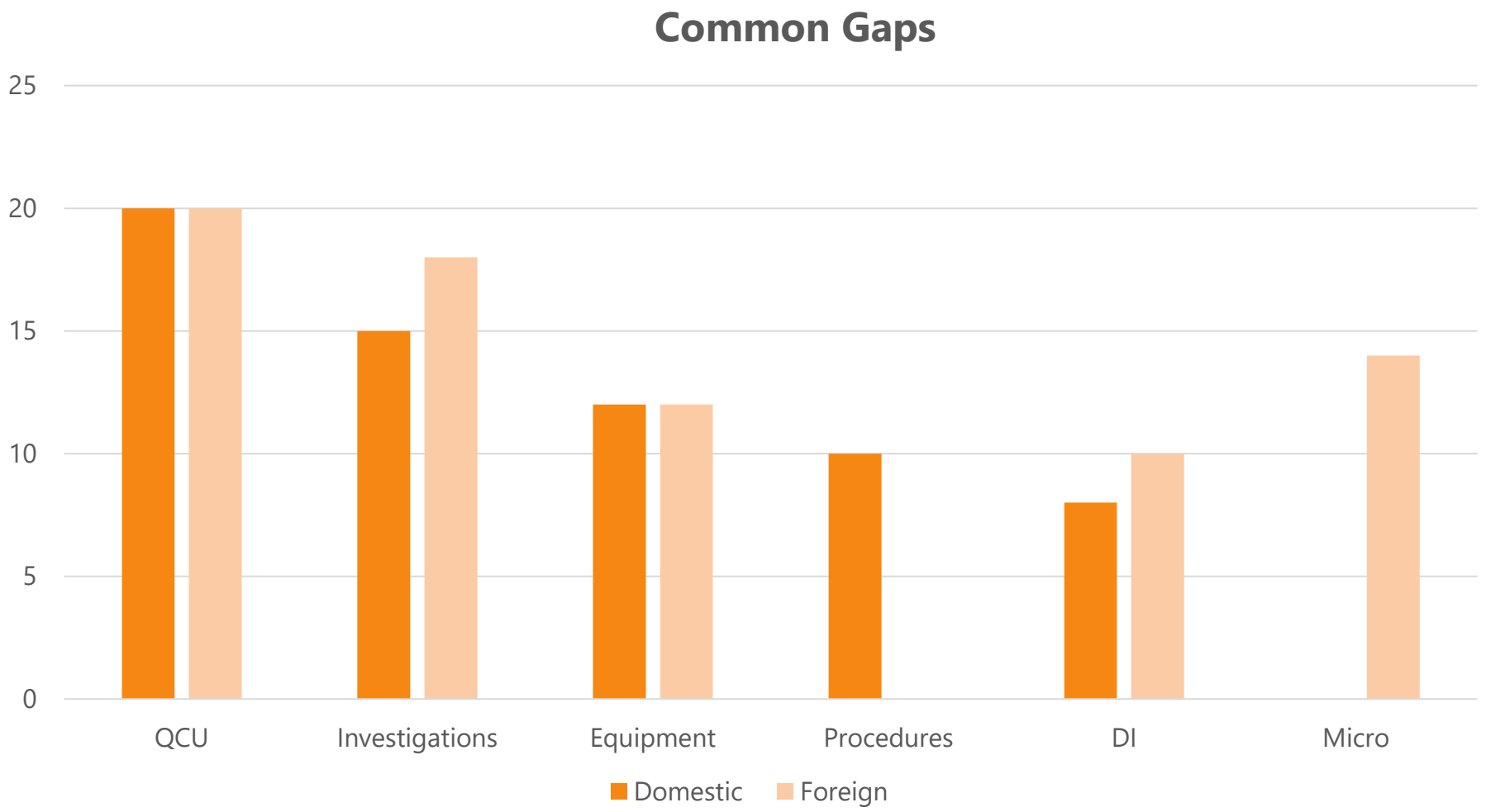
- Challenges & outcomes
- Balancing supply chains
- Cultural and procedural differences

Towards Successful Inspections: Domestic Vs Foreign

SUN PHARMA
GRx+Biosims

Aspect	Domestic	Foreign	Remarks
Frequency	~50% Proximity & lower cost	~50% 60% Gx facilities	Foreign - recovering post COVID
Pre/Unannounced	~80% pre- Unannounced increasing post May 25 policy shift	~90% pre- Travel/visa	Pre announced may compromise findings?
OAI classification	~8%	~45%	US sites benefit from stronger oversight
Late-cycle inspection	~15% tied to facility	~25% CRLs	Foreign sites face higher CRL risk due to complex supply chain
FDA challenges	Workforce High demand	Travel barriers, Visa, Language, Jurisdictional limits	Foreign need more planning, increased backlog
Industry Challenges	Fewer DI issues	Cultural/language barriers; higher scrutiny	Foreign firms face delays due to clx remediation & IA

Towards Successful Inspections: Domestic Vs Foreign



Assessment

- Sterile manufacturing sites
  - Evolving technologies
  - Globalized supply chains
  - Differing interpretation of regulatory expectations
  - Older facilities
  - Aseptic practices ex close loop transfers
- Prohibitions
- Limitations – timing & frequency
- Cultural

Collaboration

- Policy/guidance on PAI
  - Products/site coverage
  - Time frame
  - Action till classification
  - Application major CRL time – post compliance
- Education Vs enforcement
- Leveraging mutual recognition/participation in such inspections: remote?
- Alternative tools
  - Section 704(a)(4) records request
  - Remote Interactive Evaluations (RIES)
  - Remote Subject matter experts (SME)
- Transparency in submissions
- Appropriate PV involvement – well evaluated HHE ….
- Comprehensive view of improvements Vs Vicious cycle
- Trust

References

1. FY 2023 Annual Report on Inspections of Establishments (and related dashboards), Source: U.S. Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA). Published in 2024. https://www.fda.gov/media/180100/download

2. https://www.gmp-compliance.org/gmp-news/frequency-and-quality-of-foreign-fda-inspections#:~:text=During%20the%20COVID%2D19%20pandemic,in%20a%20backlog%20of%20inspections; https://apnews.com/article/fda-inspections-drug-manufacturing-india-china-7b3a7e9b45bcc3aea86ce5bf781271f3

3. FDA Inspection Observation Data, 2022-2024; Source: U.S. Food and Drug Administration (FDA), Inspections Compliance Enforcement and Criminal Investigations. Updated weekly as of 2024–2025. Inspection Classification Database and Inspectional Observations Page FDA Dashboards – Inspections

4. Inspection Observations: Trends and Analysis for Drug Manufacturing Facilities (FY 2022–2024), U.S. Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), and Center for Drug Evaluation and Research (CDER). Published: 2024, with updates through 2025. (compilation from various excel files present at FDA database)

5. Late-cycle inspection: Multiple reports at FDA site, FDA warning letters to companies available in public domain

6. Bar Graph for common gaps: data extracted from excel files in FDA's 483 database for FY 22, 23, 24

Thank you