MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

GMP

10th PAN-RUSSIAN GMP CONFERENCE

Vietnam GMP status

NGUYEN Thi Lan Huong – Drugs Administration of Vietnam

Viet Nam medicine manufacturers

10th PAN-RUSSIAN GMP CONFERENCE

POLYVAC

Measles

MR, OPV, Rota

VABIOTECH

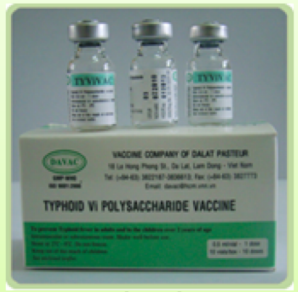
Hepatitis A

Hepatitis

Japanese Encephalitis

Cholera

DAVAC



Typhoid Vi Polysaccharide

IVAC

DPT

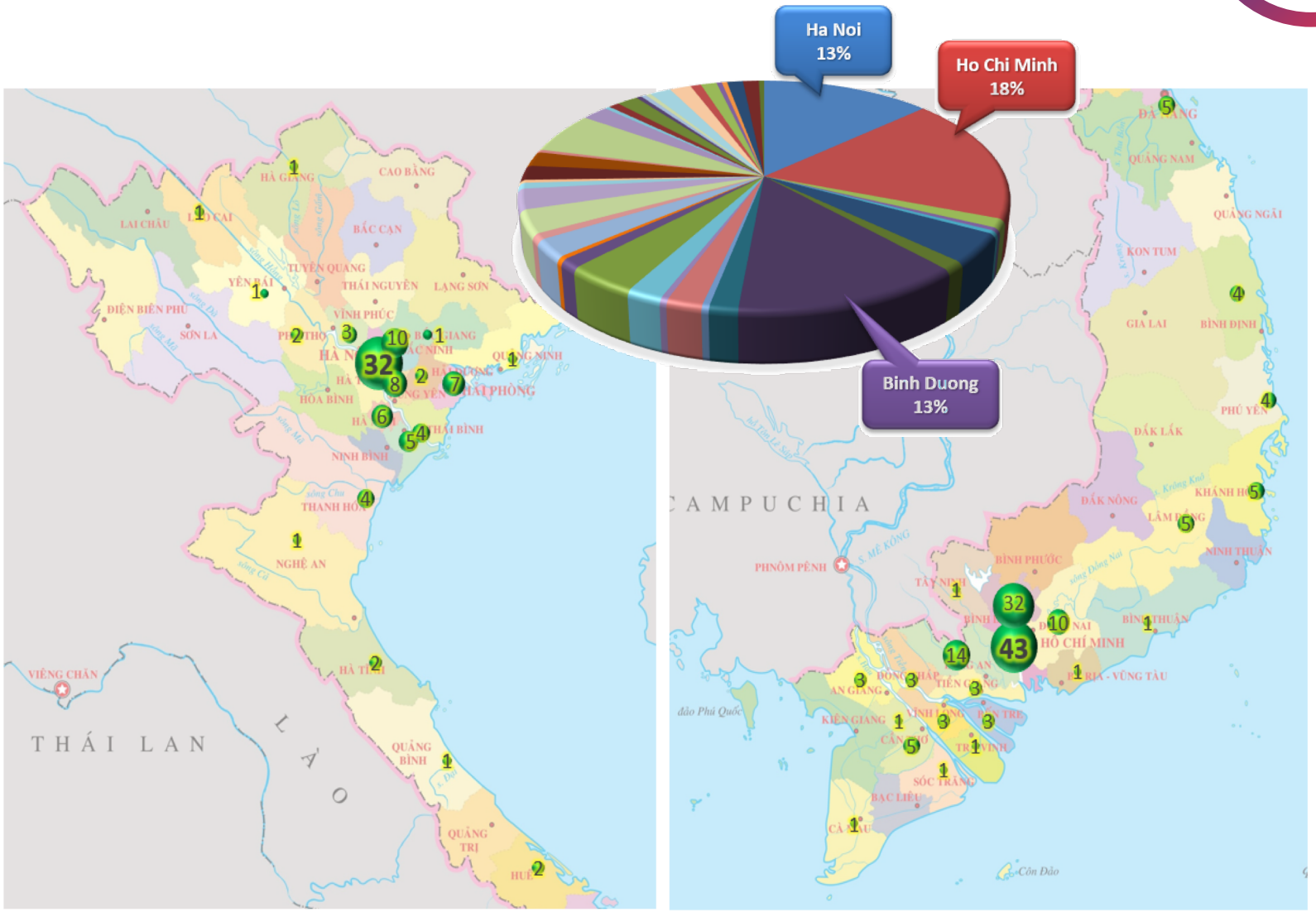
Tetanus

Tetanus-Diptheria

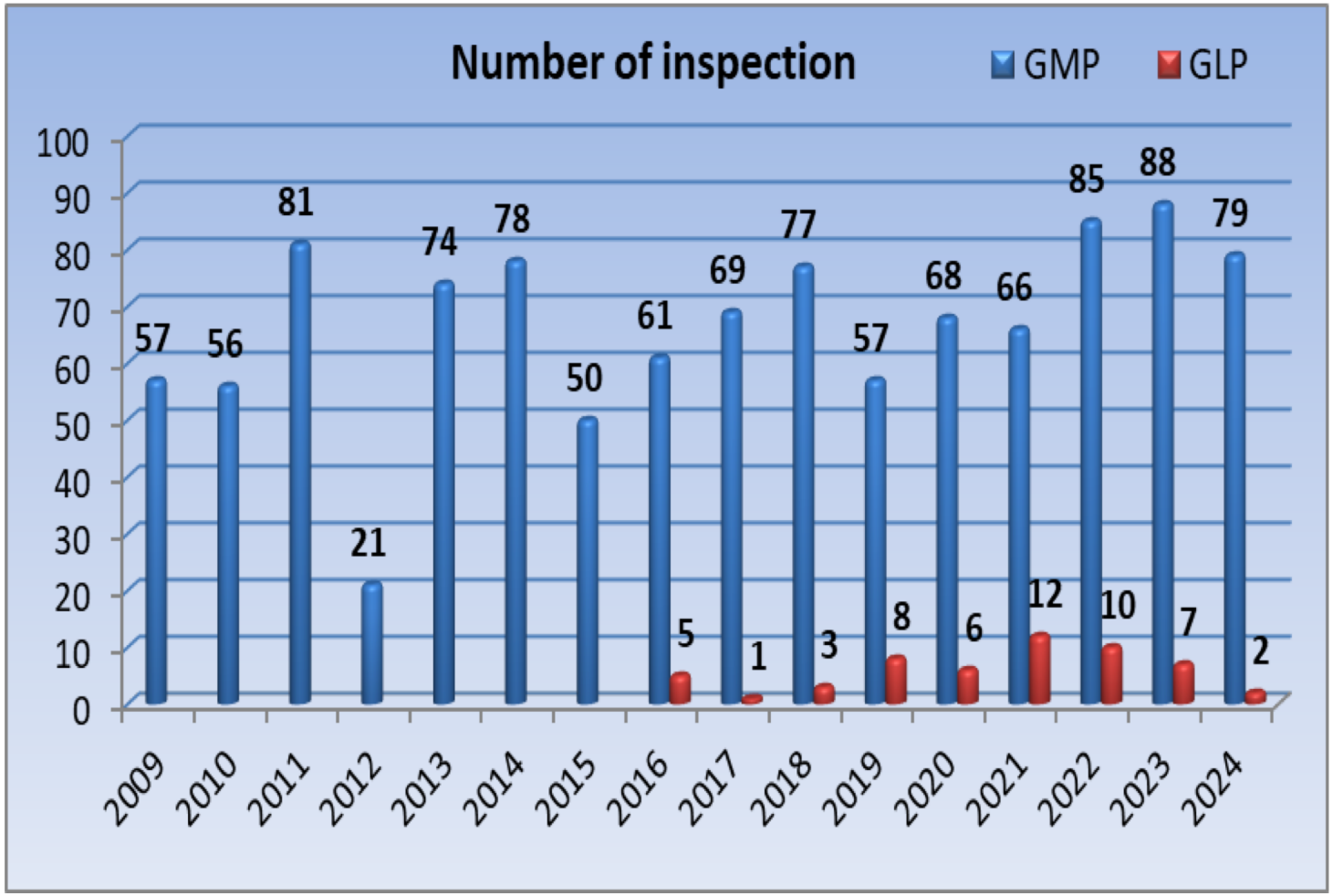
BCG

PRODUCTION LINES	247
Powder for injection	16
Liquid for injection	35
Large volume infusion	15
Lyophilize	11
Oral solid dosage form	178
Suppositories	10
Soft capsules	47
Liquid for internal use (including herbal)	127
Liquid for external use (including herbal)	91
Semi solid	83
Sexual hormones	4
Cytotoxic (sterile/ non sterile)	4
Herbal ingredients	
* Herbal extract * Processed herbal	58 26
Chemical ingredients	3
Biological ingredients	3
Vaccines	4 (12 vaccines)

Vietnam Medicine manufacturers

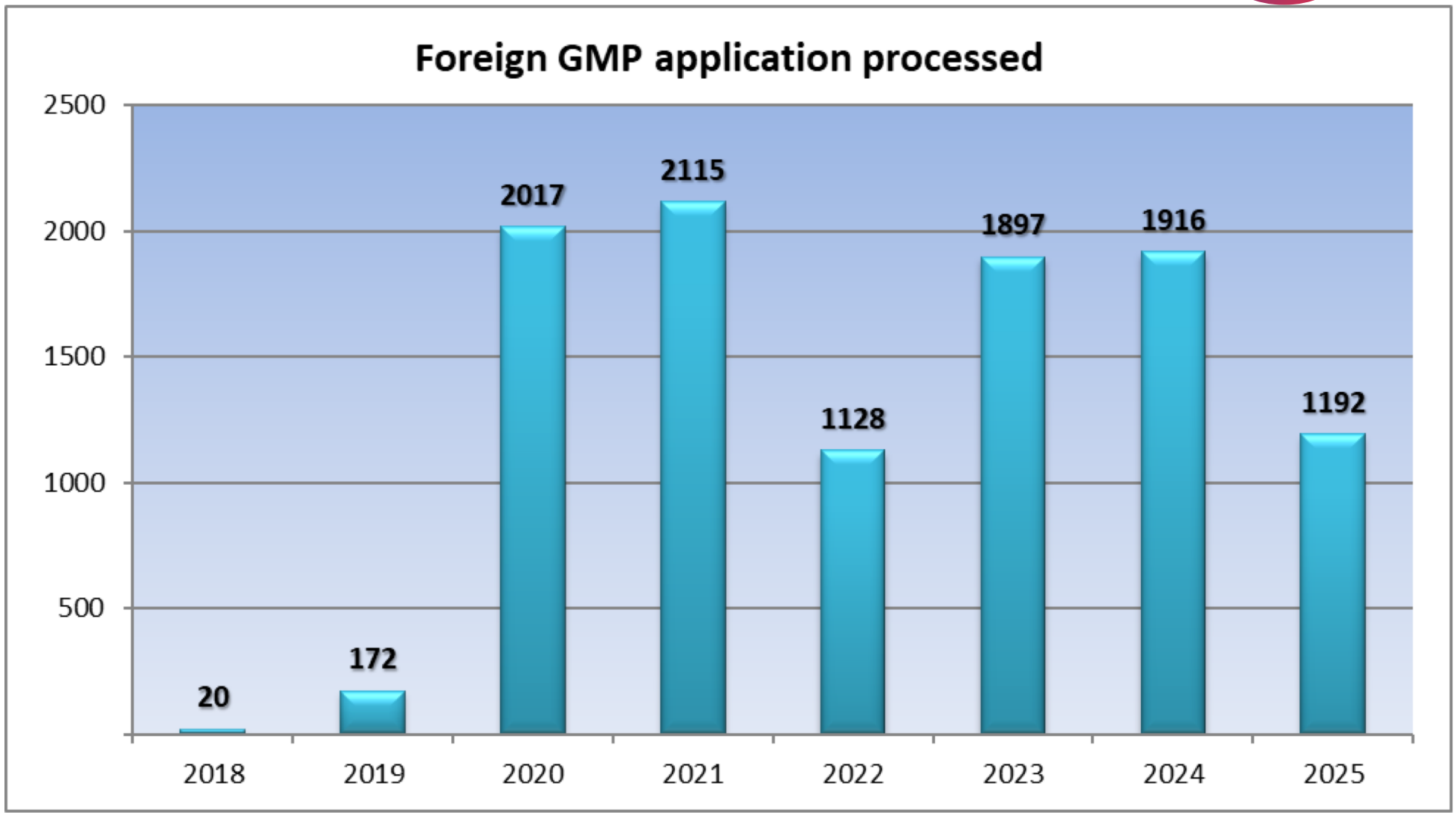


Number of conducted inspections



Functions	Leader	GMP Inspector	Experts (Out-source)
GMP, GLP	4	8	NIDQC: 23 HCM-IDQC: 36 NICVB: 19

Desktop GMP assessments



** Data of first half of 2025*

Examples of critical (or major) deficiencies

No	Paragraph or Chapter of GMP guidance	Example of critical (or major) deficiencies (no more than 10 examples)
1	WHO TRS 986 Annex 2 GMP Main Principles 1.10 (Product Quality Review)	Defects in evaluating changes • There were no records of who decided the importance of changes and how it was decided, changes and how it was decided. • The quality unit only checked the contents of the plan when approving an implemented change; it did not assess the influence on quality and various assessment results influence on quality and various assessment results. • There were no written procedures for the quality unit to check the appropriateness of the change results.
2	WHO TRS 1033 Annex 2 Water for pharmaceuticals 8.6 System sanitization and bioburden control	Defects in management of water for production (in management to prevent microbial contamination): The purified water pipework was unidirectional; purified water was stagnating in the pipework except when it was used and do not rinse before use. It was not sterilized periodically;
3	WHO TRS 986 Annex 2 GMP Main Principles 4.1 Validation	Defect in validation: • Inlet air quality for the fluid bed dryer was not assessed. • Cleaning validation for vials and bottles has not been performed for all volume sizes
4	WHO TRS 961 Annex 6 GMP for Sterile pharmaceuticals products 3.3 4.25 7.7 4.24	Sterile Manufacturing deficiencies: Sanitation and Disinfection Program: The sanitation and disinfection program was inadequate. For example: Sporicidal disinfectants were not included in the class A & B cleanrooms. Sterile disinfectants used in class A & B cleanrooms were not properly sterilized. Integrity Testing for Gases: Integrity testing for gases used in aseptic production (e.g., nitrogen for powder for injection) was not implemented. Media Fill Process: After filling, the company did not incubate all the vials being filled. Some vials were removed to perform the volume uniformity test.


Thank you
for your
attention