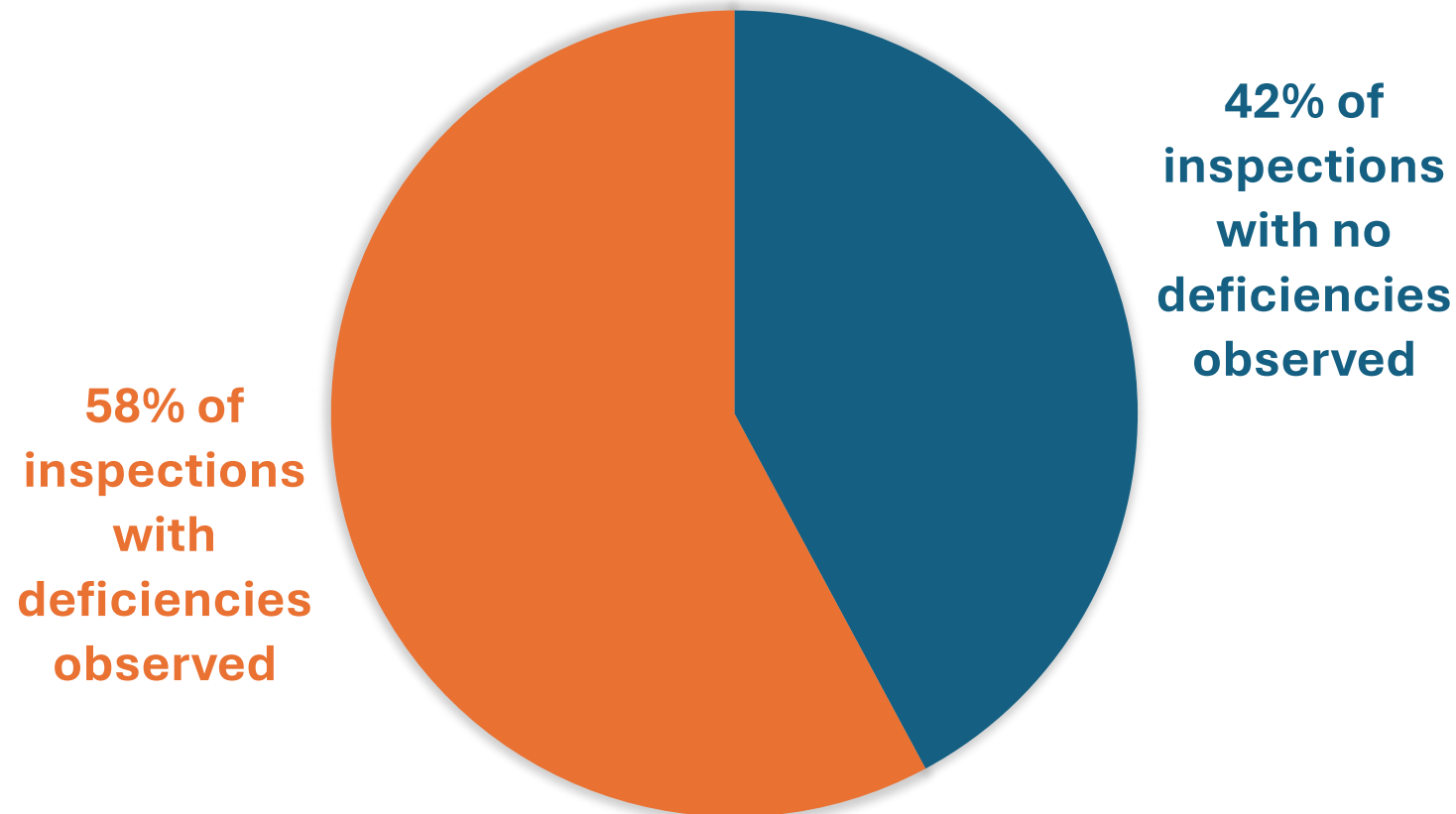


TRENDING OF GOOD DISTRIBUTION PRACTICE (GDP) DEFICIENCIES OF LICENSED DEALERS 2024

Overview of GDP inspections in 2024

- No deficiencies were observed in 42 % of inspections.
- At least one deficiency was observed in 58 % of inspections.



Summary of Key GDP Deficiencies in 2024

5 most-commonly cited GDP deficiencies

#	GDP Chapters	Percentage of Cited Deficiencies
1	Premises & Equipment	29%
2	Documentation	25%
3	Personnel	8%
4	Product Recall	7%
5	Cold Chain	7%

Examples of these 5 areas of deficiencies are provided in Slides 4 and 5 to facilitate understanding of the requirements and improvements by the industry.



Summary of Key GDP Deficiencies in 2024

Example deficiencies from the most-commonly cited GDP Guide Chapters

S/N	GDP Chapters	Example of Deficiencies
1	Premises & Equipment	• Inadequate premises maintenance and cleanliness: Floors were dusty despite cleaning records, storage racks were positioned too close to the floor for effective cleaning, and products were stored directly on the floor, hindering proper sanitation • Insufficient monitoring of ambient storage conditions: Thermo-hygrometers were out of calibration, improperly placed (locations not justified), and lacked alarm systems. Temperature excursions were not addressed, and records were not regularly reviewed. • Poor organization: The warehouse was cluttered with unused items such as old rusty equipment and used cartons, compromising the overall cleanliness and organization of the premises.
2	Documentation	• Inadequate management of Standard Operating Procedures (SOPs): Quality system documents were not reviewed regularly to ensure relevance and accuracy. Some SOPs contained outdated or conflicting information. • Lapses in record-keeping: Some entries showed inadequate documentation practices such as unauthorized alterations, missing information, discrepancies in dates, and improper use of 'ditto' marks. • Poor integrity and traceability of records: Use of erasable writing materials, pre-filling of records, and discrepancies between physical stock and inventory system entries compromised data integrity. Some records lacked essential details for traceability of activities or events.



Summary of Key GDP Deficiencies in 2024

Example deficiencies from the most-commonly cited GDP Guide Chapters

S/N	GDP Chapters	Examples of Deficiencies
3	Personnel	- Insufficient training documentation: Records of initial and ongoing GDP training for personnel were inadequate or unavailable. Training records lacked details on content, dates, and proper approval signatures. - Lack of clarity in personnel responsibilities: Inconsistencies were found in SOPs regarding who was responsible for specific tasks.
4	Product Recall	Absence of a formalized mock recall process: Written procedure on product recall process was unavailable. There was also no system in place to assess the effectiveness of recall procedures.
5	Cold Chain	- Inadequate temperature monitoring and excursion management: Temperature monitoring devices were out of calibration, records were not regularly reviewed, and there was no clear process for addressing temperature excursions. - Insufficient qualification and validation of cold-chain equipment: Insulated cold chain boxes or cooler bags for packing for transport of cold chain products were not qualified or validated.

Comparing Top 5 GDP Deficiencies Observed in 2023 & 2024

Most Common Deficiencies 2023

#	GDP Chapters	Percentage
1	Documentation	43%
2	Premises & Equipment	23%
3	Cold Chain	10%
4	Personnel	6%
5	Self Inspection	6%

Most Common Deficiencies 2024

#	GDP Chapters	Percentage
1	Premises & Equipment	29%
2	Documentation	25%
3	Personnel	8%
4	Product Recall	7%
5	Cold Chain	7%

Premises & Equipment related deficiencies were the most cited type of GDP deficiency in 2024, with documentation coming in second. Compared with 2023, deficiencies related to documentation, premises & equipment, cold chain and personnel remained as the most commonly cited in 2024.