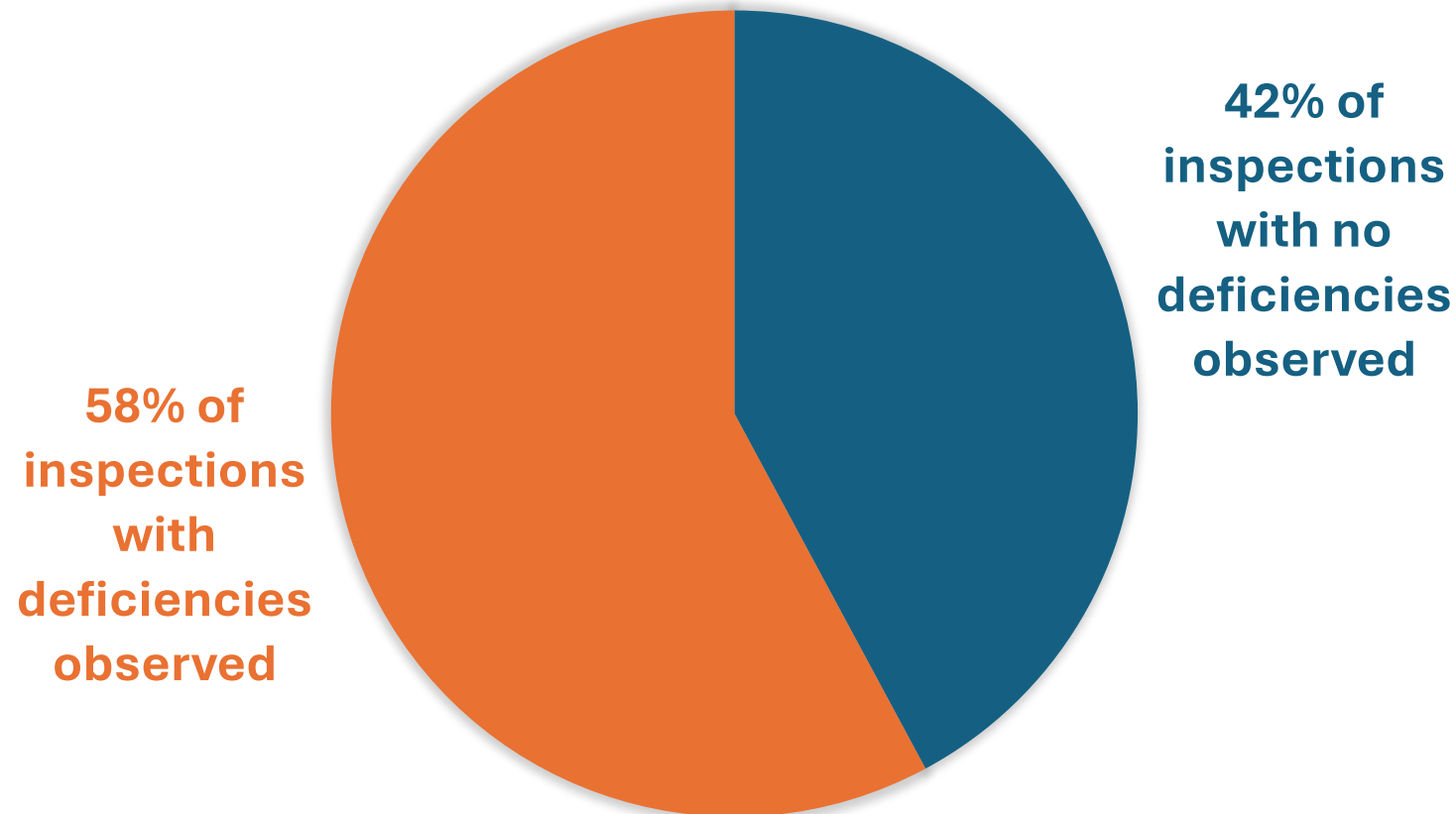


# **TRENDING OF GOOD DISTRIBUTION PRACTICE (GDP) DEFICIENCIES OF LICENSED DEALERS 2024**

# 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	<ul style="list-style-type: none"><li>• 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</li><li>• 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.</li><li>• 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.</li></ul>
2	Documentation	<ul style="list-style-type: none"><li>• 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 Some SOPs contained outdated or conflicting information.</li><li>• 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.</li><li>• 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.</li></ul>



# 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	<ul style="list-style-type: none"> <li>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.</li> <li>Lack of clarity in personnel responsibilities: Inconsistencies were found in SOPs regarding who was responsible for specific tasks.</li> </ul>
4	Product Recall	<ul style="list-style-type: none"> <li>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.</li> </ul>
5	Cold Chain	<ul style="list-style-type: none"> <li>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.</li> <li>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.</li> </ul>

# 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.