

GMP Inspection Results Summary



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GMP

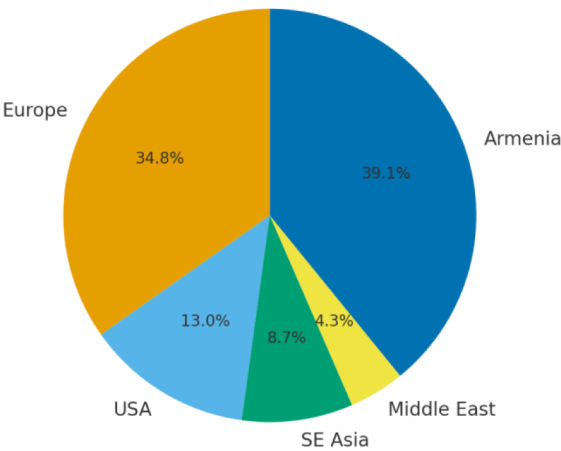
**10th PAN-RUSSIAN
GMP CONFERENCE**

Number of conducted inspections

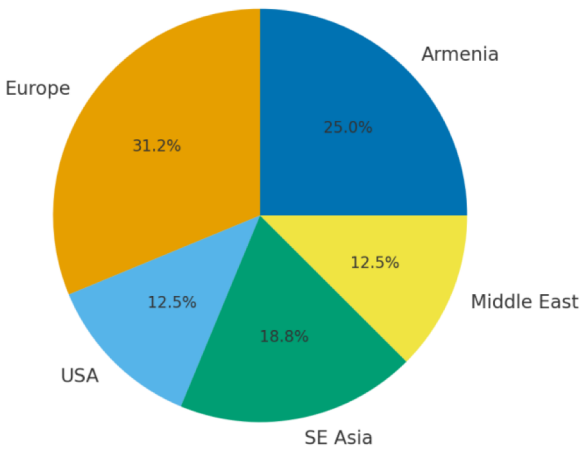


	2023	2024	2025 (I-II quarter)
Foreign manufacturing	23	23	17
Local manufacturing	9	7	3
Acceptable GMP inspection results	23	23	20
Unacceptable GMP inspection results	0	0	0

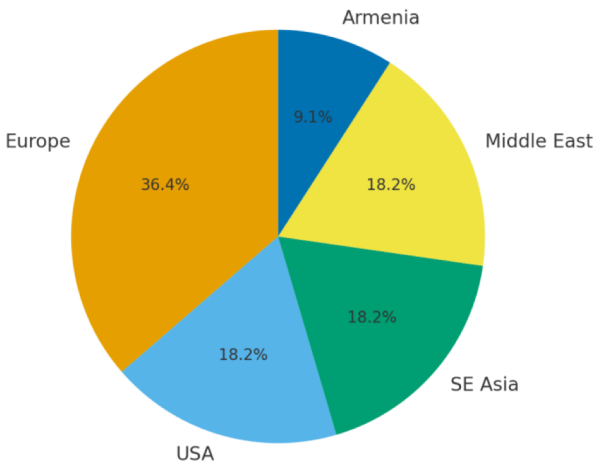
Inspections by Region in 2023



Inspections by Region in 2024



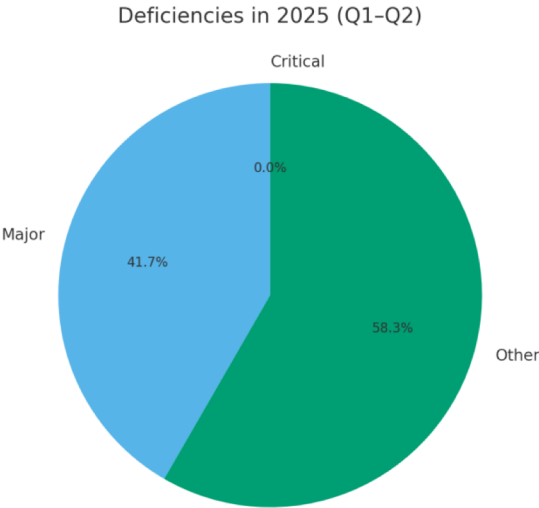
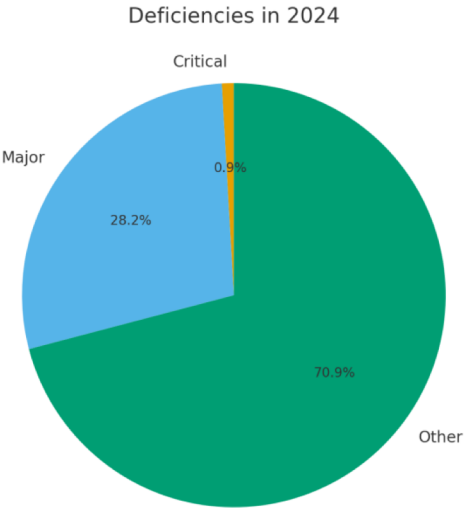
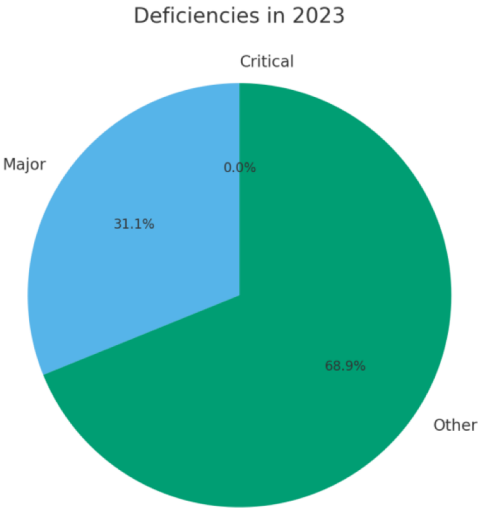
Inspections by Region in 2025 (Q1-Q2)



Deficiencies



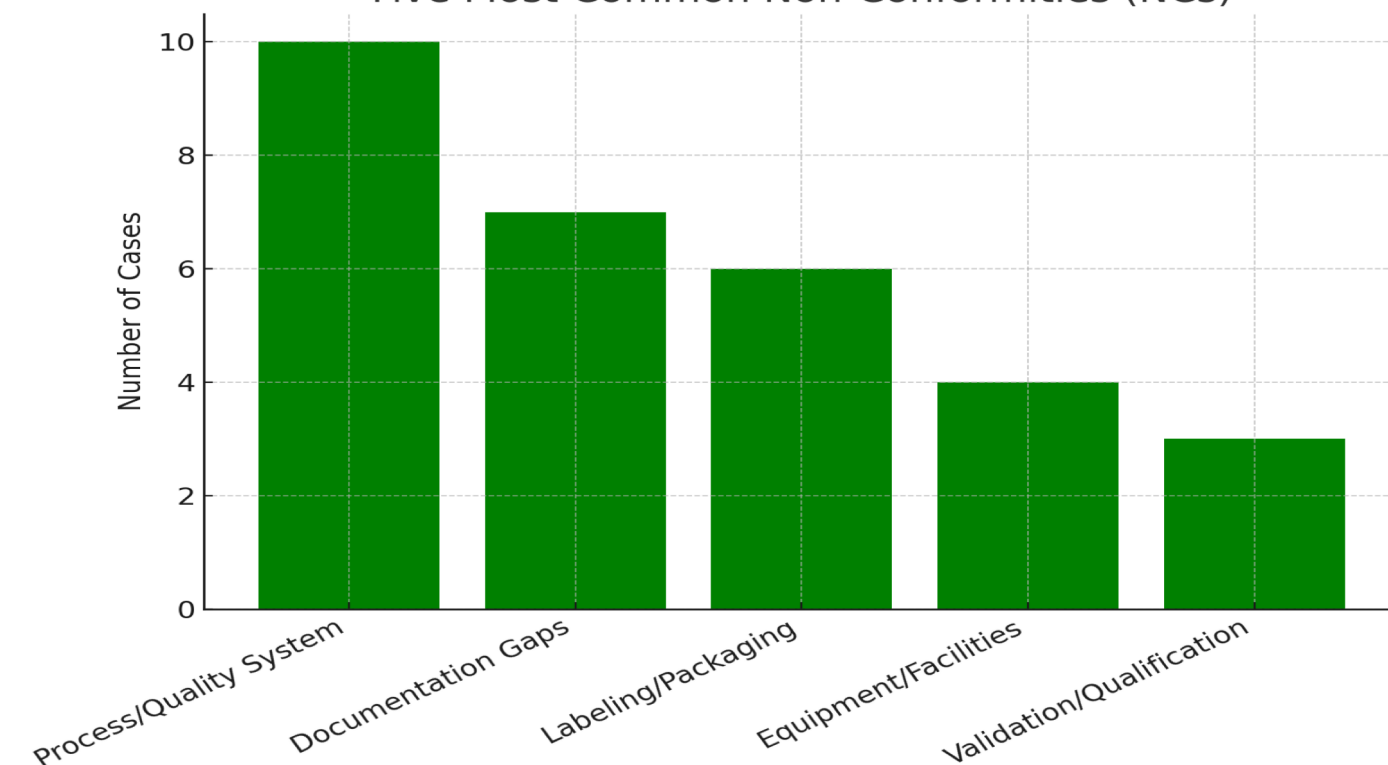
	2023	2024	2025
Critical	0	1	0
Other	146	78	15
Major	66	31	21



The most common NCs



Five Most Common Non-Conformities (NCs)



1. **Process control and quality system weaknesses** – inadequate procedures, insufficient justifications, or incomplete systems.
2. **Documentation gaps** – missing details in batch manufacturing records and incomplete procedural justifications.
3. **Labeling and packaging deficiencies** – procedures not considering labeling requirements, issues with storage of packaging materials.
4. **Equipment and facility compliance issues** – non-compliant tanks, pipelines, and valves.
5. **Validation and qualification gaps** – insufficient or missing validation steps, lack of justification in qualification processes.

THANK YOU FOR ATTENTION

