الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Statistical Report for Medical Devices Manufacturers Inspections 2024

Contents

Introduction:

As part of its oversight on Medical Devices to ensure the safety and effectiveness of medical devices marketed in the Kingdom of Saudi Arabia, the Saudi Food and Drug Authority (SFDA) conducts regulatory inspections/audits on both local and overseas medical device manufacturers.

This report provides a comprehensive statistical analysis of inspections conducted on medical device manufacturers from **January 1, 2024**, to **December 31, 2024**.

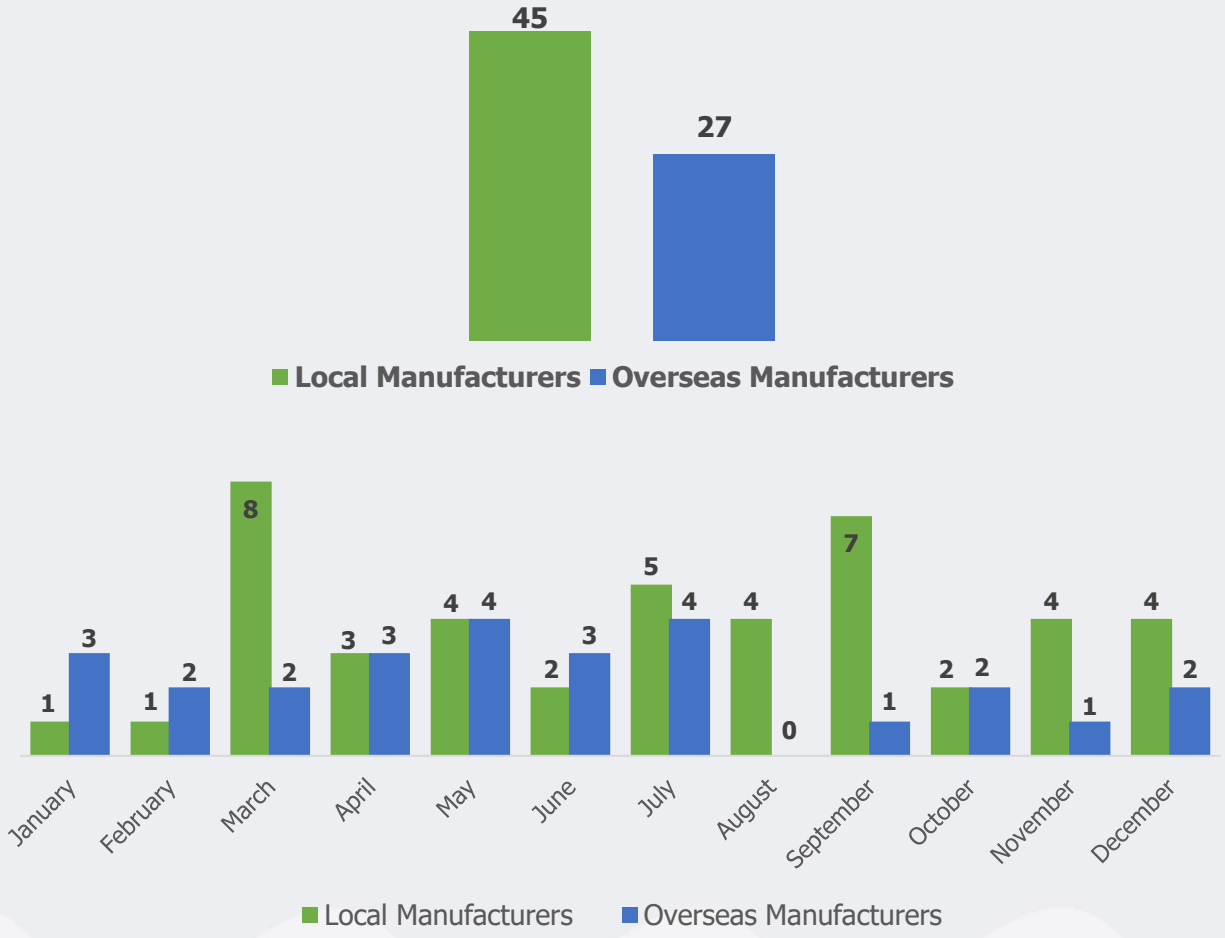
The analysis of inspection data trends aims to promote a culture of continuous improvement and ensure that manufacturers consistently comply with high-quality standards. By identifying the root causes of nonconformities and addressing them proactively, the industry can strengthen its reputation and ensure the sustained availability of safe and effective medical devices.

Executive Summary:

During 2024, SFDA conducted **72** inspections on medical device manufacturers. **41%** of the overseas inspections were conducted on manufacturers who produced high risk medical devices, whereas almost **89%** of local manufacture inspections were conducted on low and moderate/medium risk medical devices. 608 Non-conformities (NCs) were detected (**44%** of them were major NC). Categories of the devices produced by the manufacturer ranged from single use devices to Electro Mechanical Medical Devices. Enforcement actions were taken against a number of local and overseas medical devices manufacture. These actions included **fines for local manufacturers** and **product license suspensions for overseas manufacturers**.

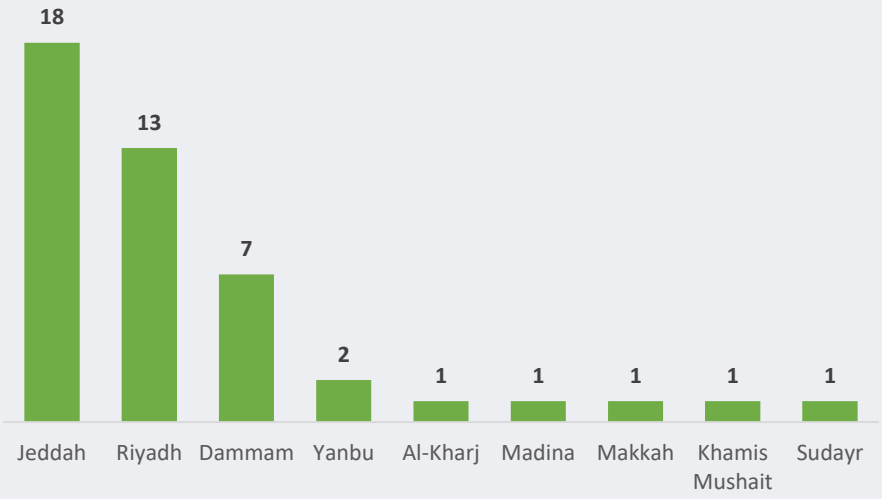
Number of Inspection Visits:

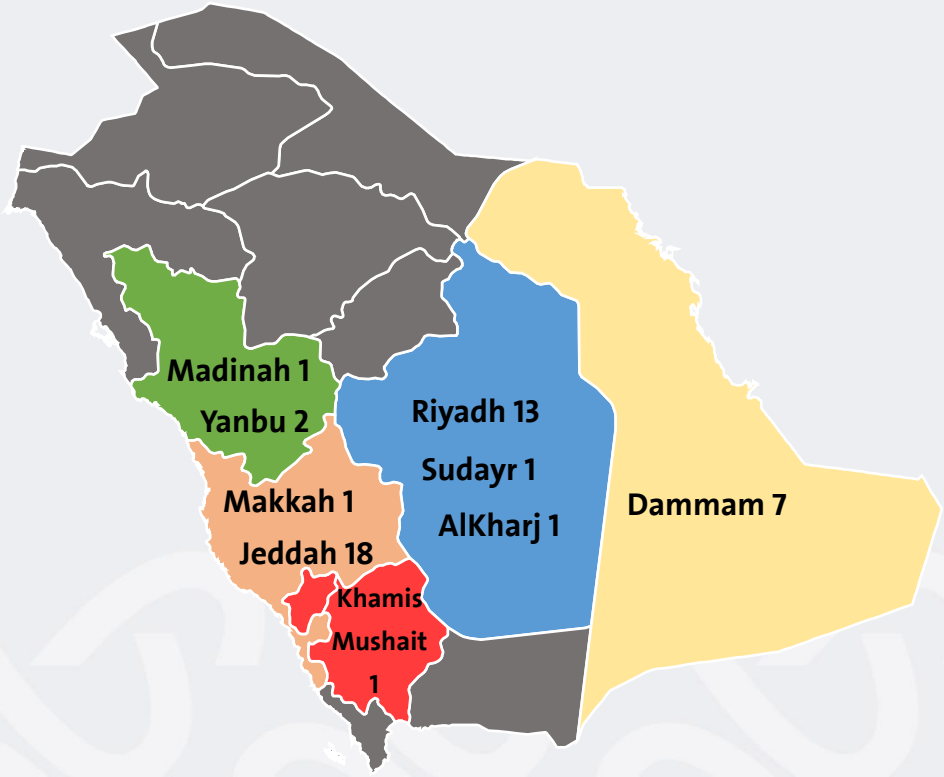
In **2024**, a total of **72** inspections were conducted on local and overseas medical device manufacturers, where almost **38%** of these inspections were conducted on overseas manufacturers. On a monthly basis, the maximum number of inspections conducted for local manufacturers were **8** inspections, whereas the largest number of inspections for overseas manufacturer were **4** inspections. The average of the inspections for both local and overseas manufacturers were about **6** inspections per month.



Location of local Manufacturers:

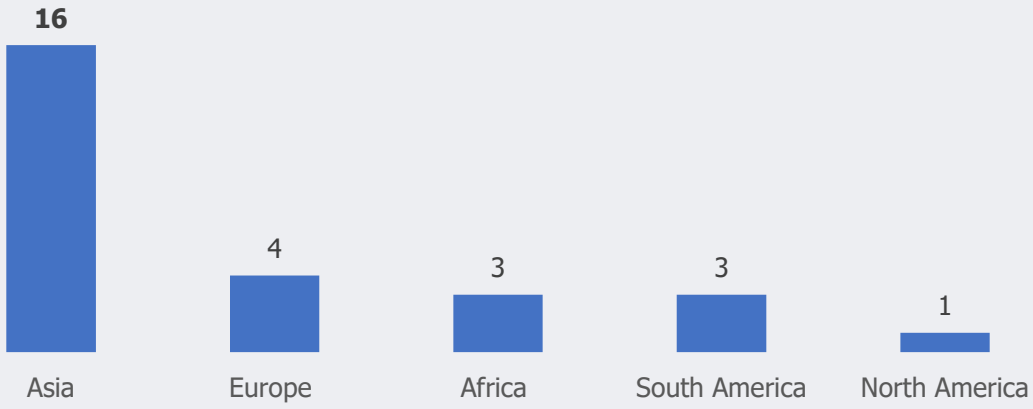
The majority of inspection visits were conducted in **Jeddah** accounting for **40%** of inspections followed by **Riyadh** representing **29%** of inspections. **31%** of the remaining inspections were conducted in different cities in the kingdom.





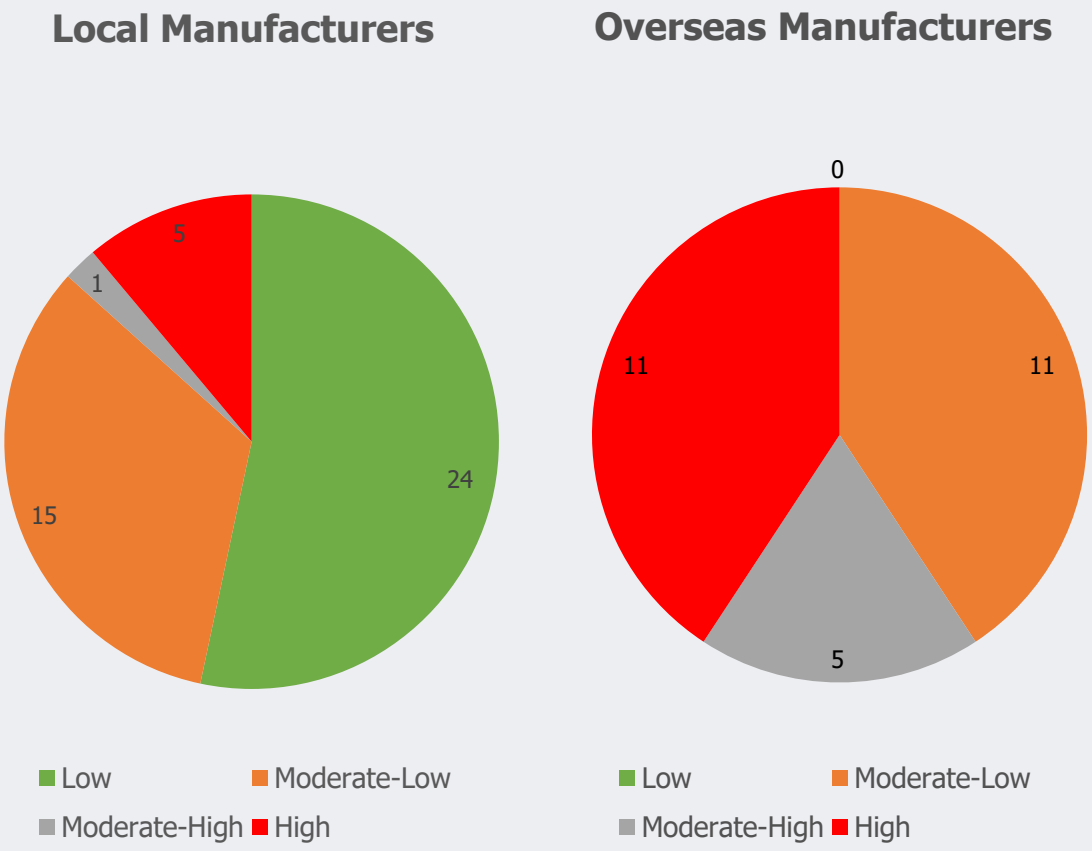
Location of Overseas Manufacturers:

The majority of inspection visits were conducted in **Asia**, accounting for **16** inspections. Moreover, **4** inspections were conducted in **Europe**, **3** in **Africa**, **3** in **South America** and **1** in **North America**. Asia was the primary location for inspected medical device manufacturers representing **approximately 59%** of the total inspection visits.



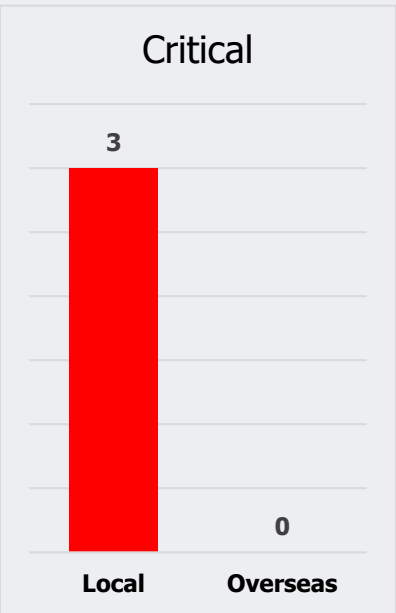
Risk Classification of Medical Devices:

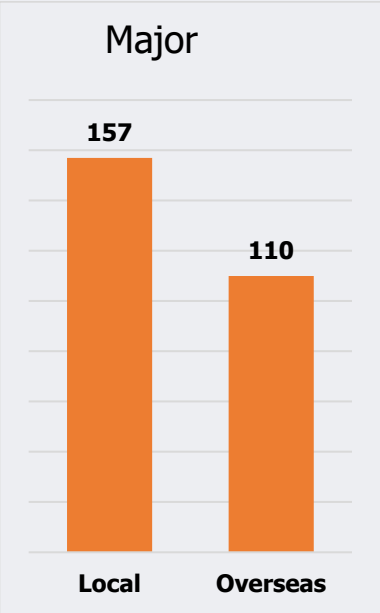
For overseas manufacturers, almost **41%** of the inspections were conducted on manufacturers who produced **high risk** medical devices, whereas **89%** of local manufacture inspections were on **low and moderate/medium risk** medical devices as most local manufacturers are producing low and medium risk medical devices.

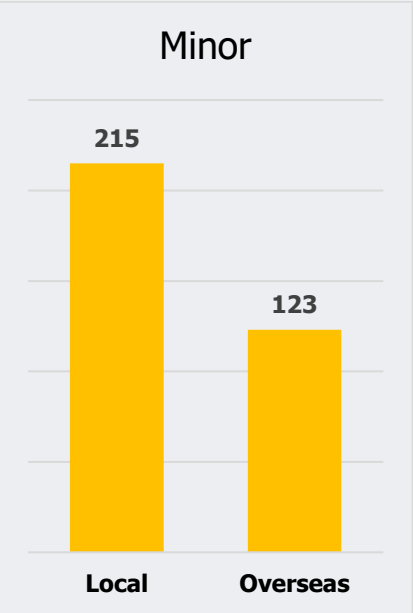


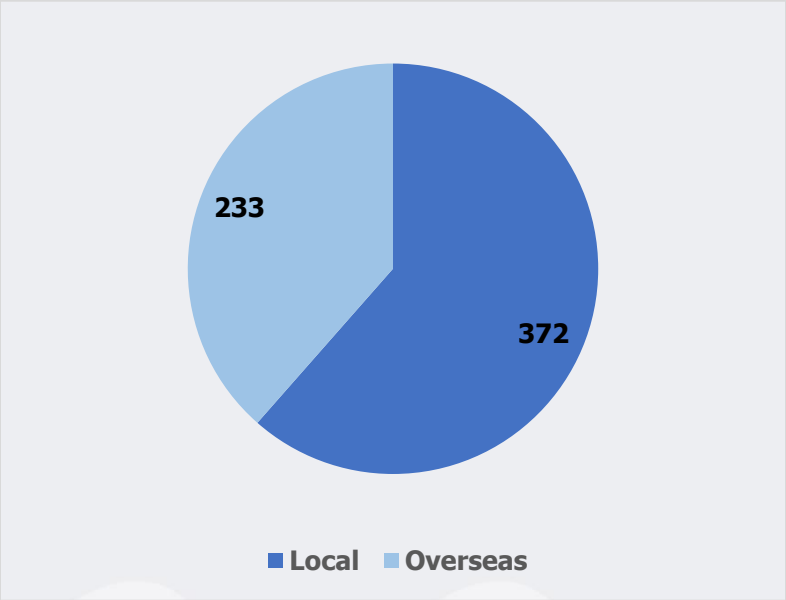
Number of Nonconformities (NCs):

A total of **608 nonconformities** were detected during inspection visits in **2024**. **Major nonconformities** accounted for **44%** of the total NCs.





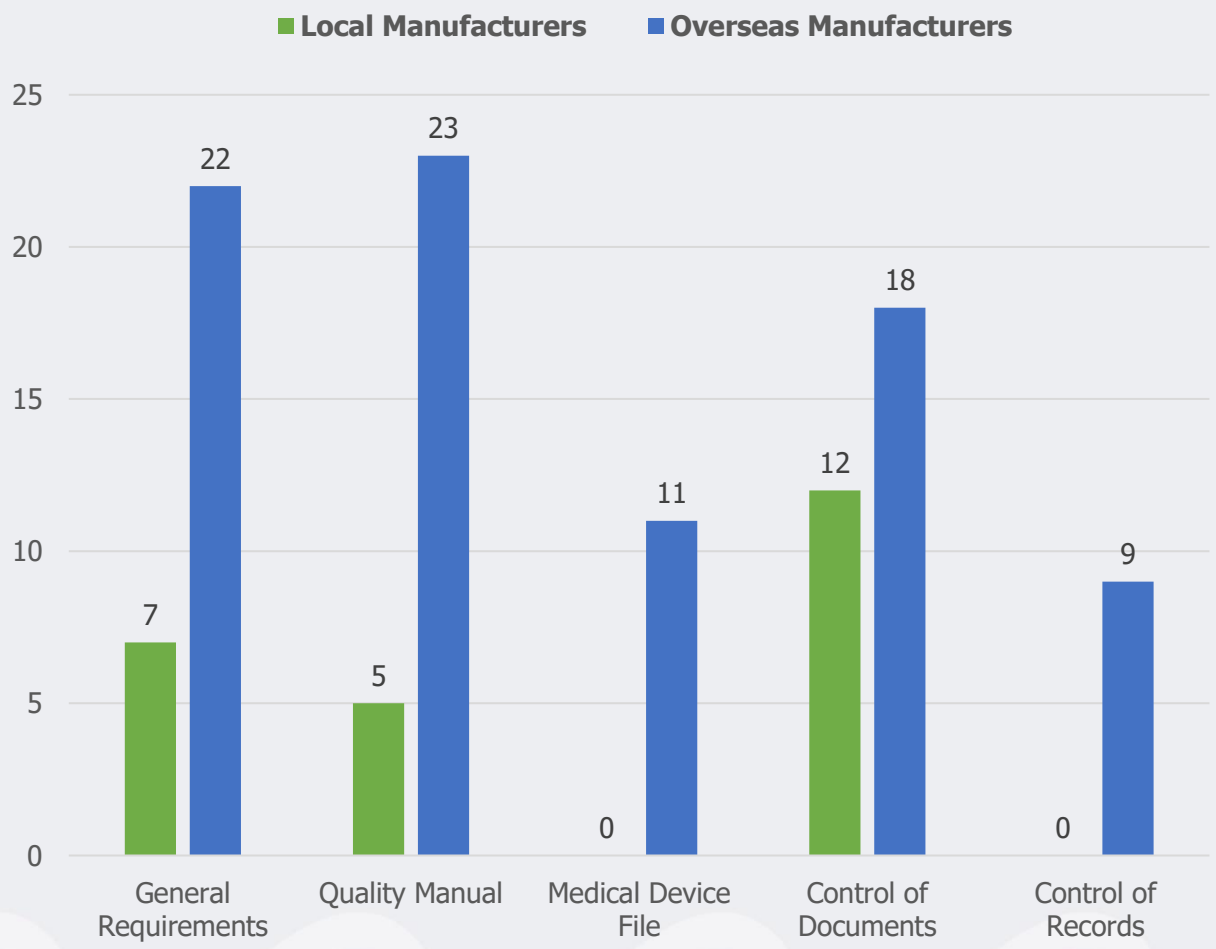




Nonconformities (NCs) Based on Process:

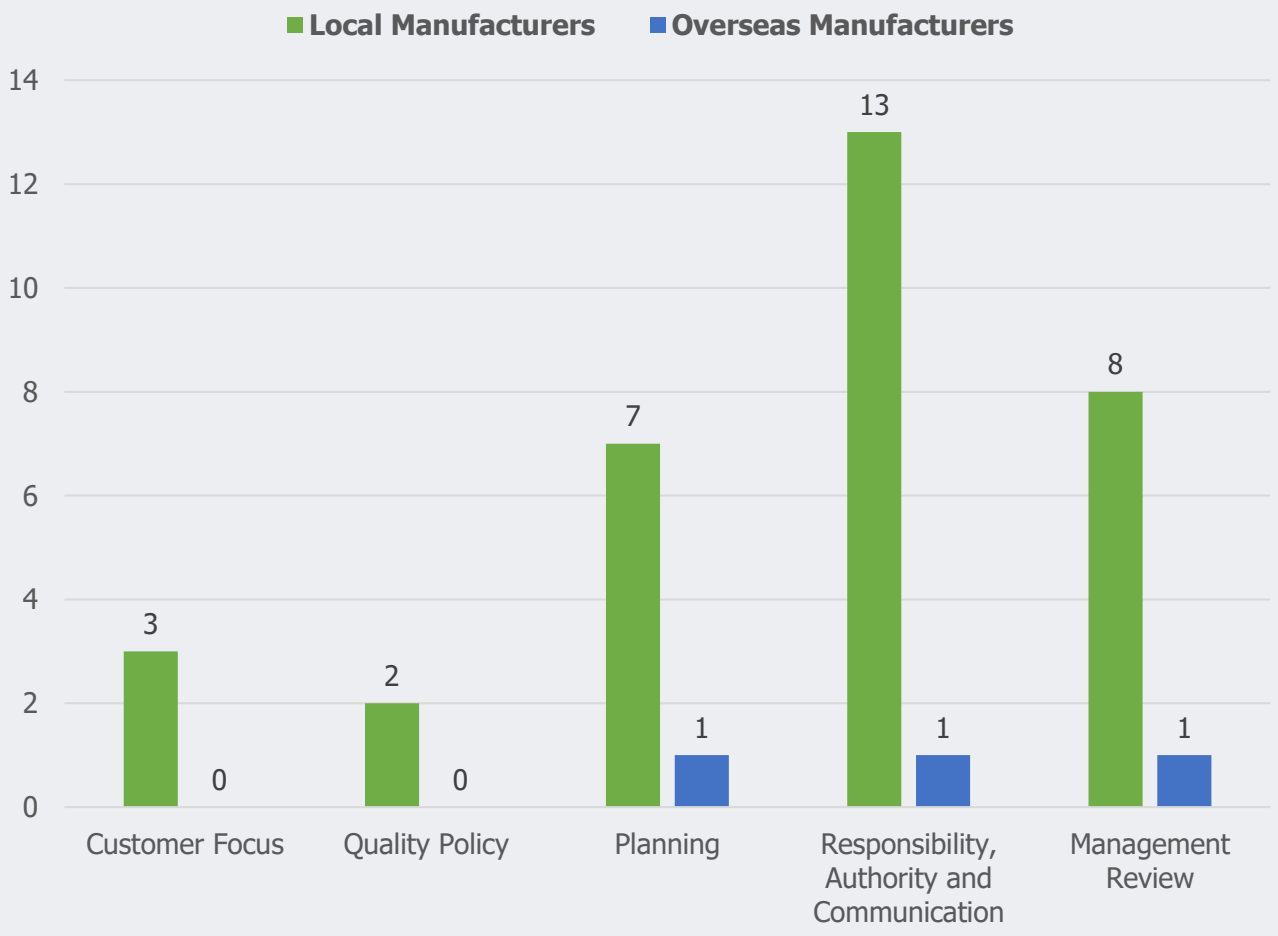
Quality Management System:

The majority of nonconformities on quality management system were detected in relation to control of documents representing **(28%)**, while **27%** were linked to general requirements, **26%** to quality manual, **10%** to medical device file, and **8%** to control of records.



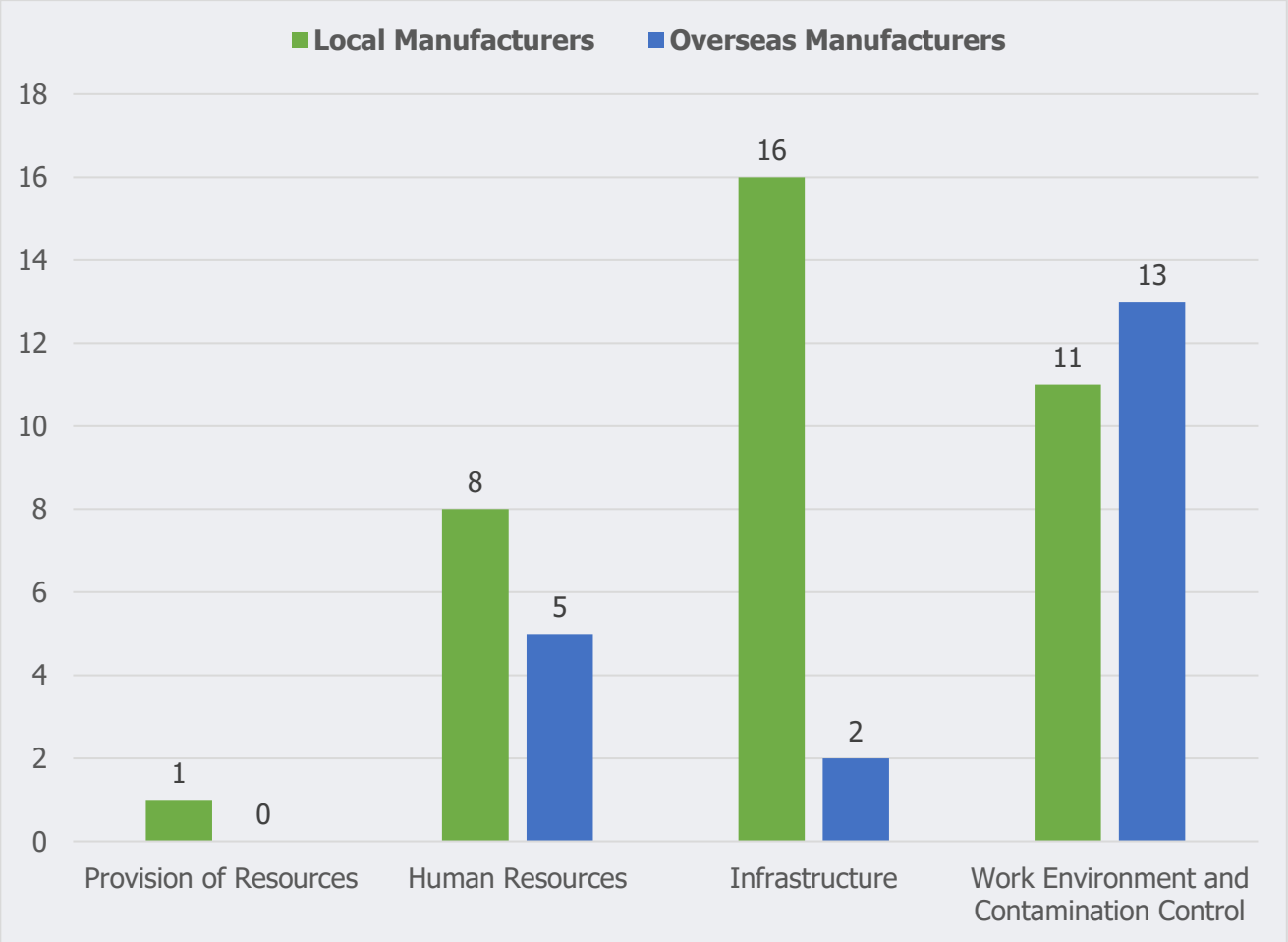
Management Responsibility:

The majority of nonconformities on management responsibility were detected in relation to responsibility authority and communication representing **(36%)**, while **8%** were linked to customer focus, **5%** to quality policy, and **22%** to planning.



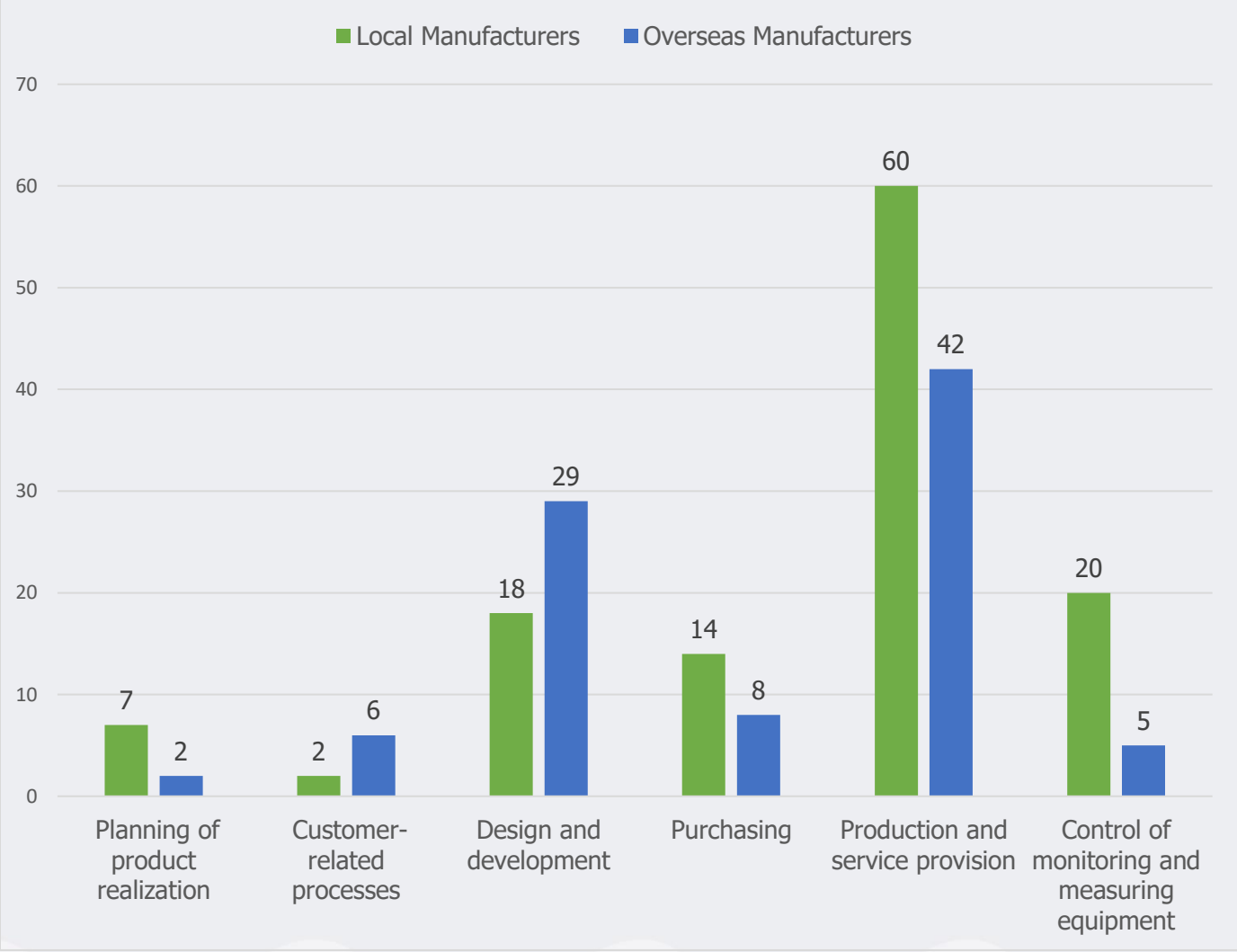
Resource Management:

The majority of nonconformities on resource management **(42%)** were detected in relation to work environment and contamination control representing **(42%)**, while **2%** were linked to provision of resources, **23%** to human resources, and **32%** to infrastructure.



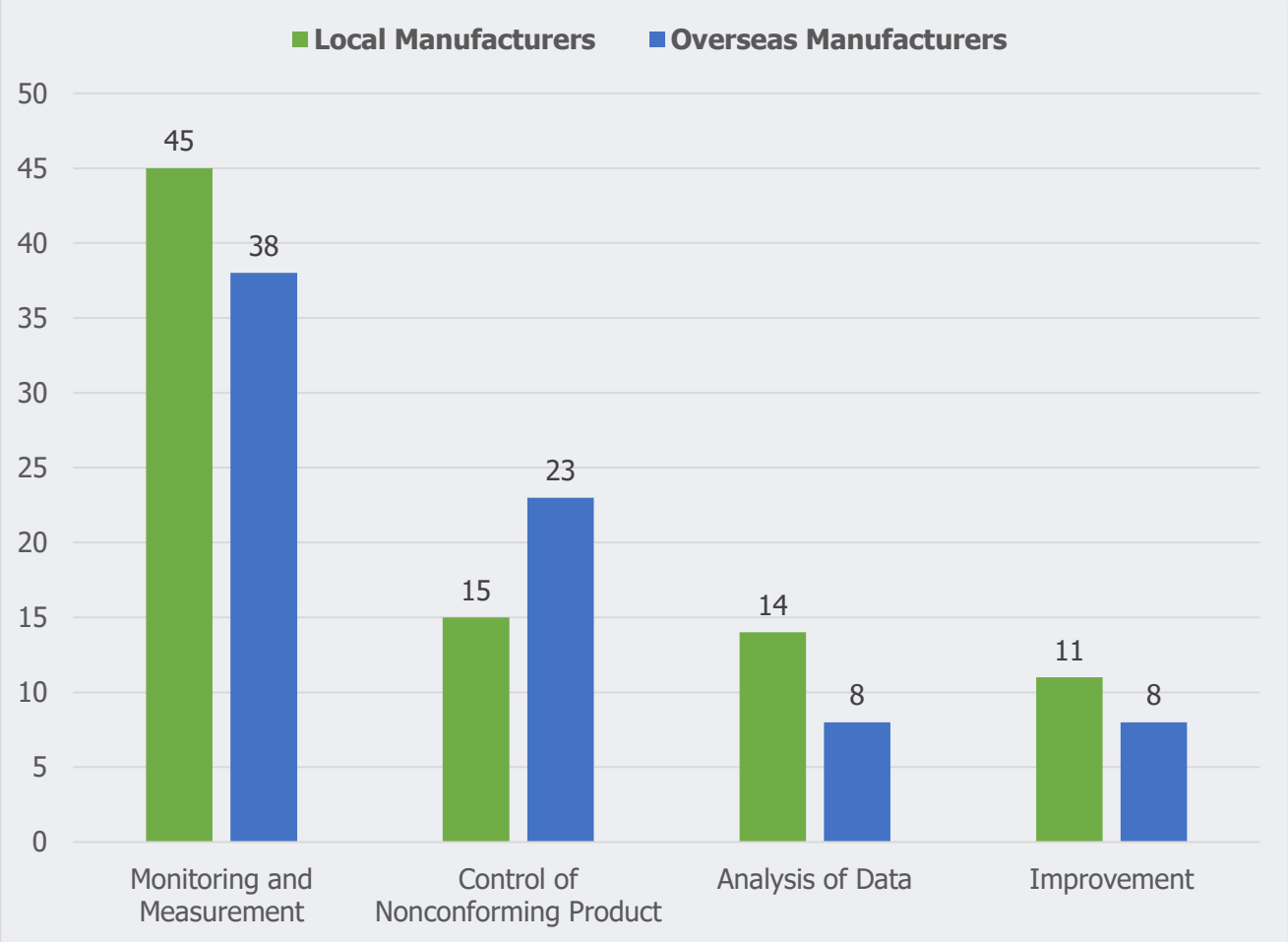
Product realization:

The majority of nonconformities on product realization **(47%)** were detected in relation to production and services provision representing **(47%)**, while **3%** were linked to customer related processes, **22%** to design and development, and **11%** to Control of monitoring and measuring equipment.



Measurement, Analysis and Improvement:

The majority of nonconformities on measurement, analysis and improvement were detected in relation to monitoring and measurement representing **(51%)**, while **23%** were linked to control of nonconforming product, **14%** to analysis of data, and **12%** to improvement.



SFDA Requirements:

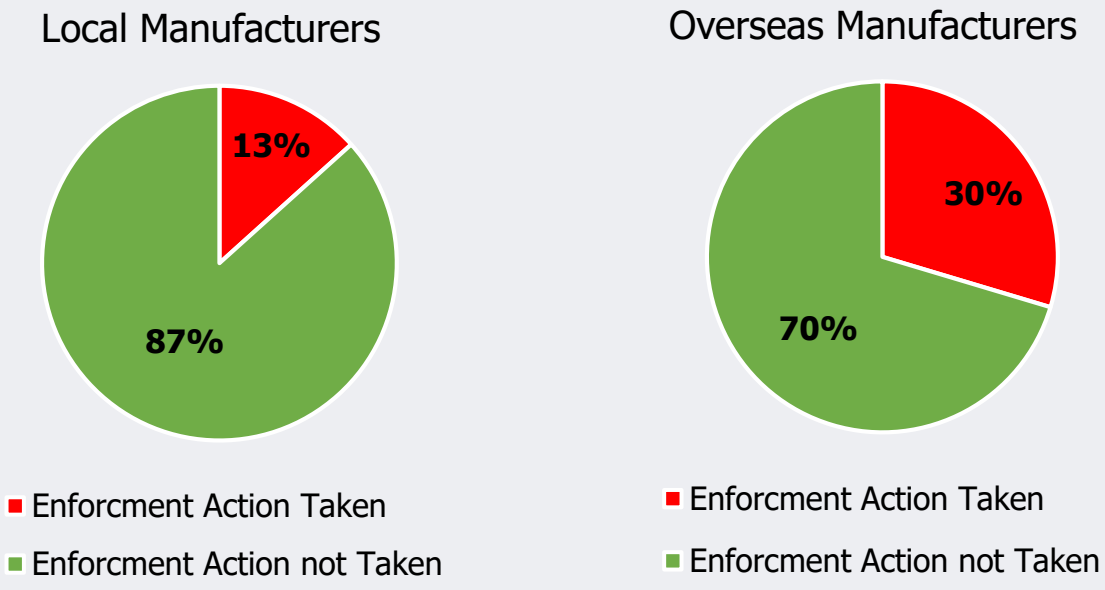
60% nonconformities related to SFDA requirements were detected during the inspection of local medical devices manufacturers, whereas **40%** were identified during the inspection of overseas medical devices manufacturers.

Product Categories:

	Local Manufacturers	Overseas manufacturers
Single Use Device	29	16
Electro Mechanical Medical Devices	2	1
In Vitro Diagnostic Devices	7	3
Non-active Implantable Devices	3	7
Ophthalmic and optical devices	3	0
Reusable Devices	1	0

Enforcement Actions:

Enforcement actions were taken against **8 Overseas manufacturers** resulting in **product license suspension** which represents **(30%)** of inspected manufacturers. Whereas **6 Local manufacturers** were **fined** as a result of major nonconformities detected representing **(13%)** of inspected manufacturers. Moreover, the total number of seized products during local manufacturers inspections were 258,872.



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