الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Statistical Report for Medical Devices Manufacturers Inspections

2023

Introduction:

As part of its oversight on Medical Devices to ensure safe and effective medical devices are marketed in the Kingdom, Saudi Food and Drug Authority conducts regulatory inspections/audits on local and overseas medical device manufacturers.

This report will provide statistical information about inspections that were conducted on medical device manufacturers during the period 1 January 2023 to 31 December 2023.

Article 33 of Medical Device Law :

The SFDA shall inspect the establishments and medical devices to ensure the application of the provisions of the Medical Devices Law, its regulations and the technical regulations.

Introduction:

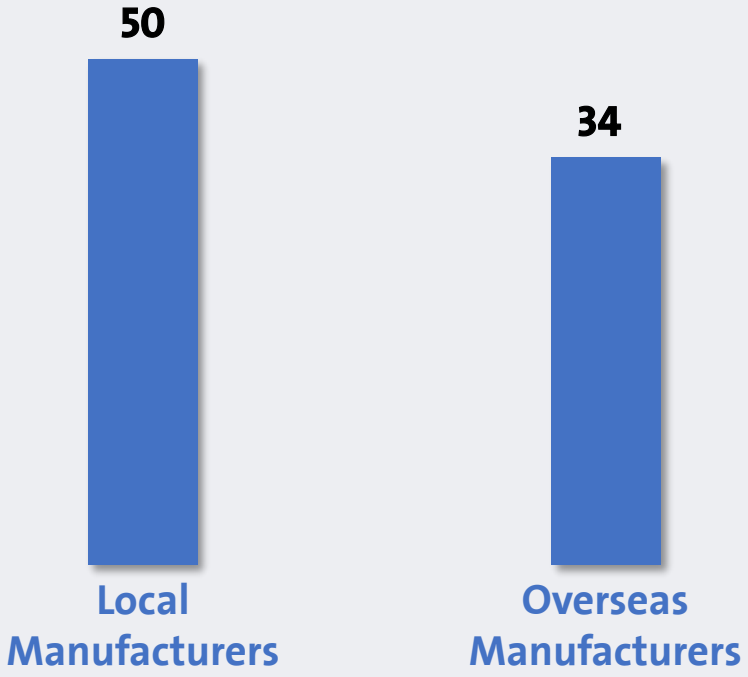
The aim of analyzing medical devices inspection data trends is to promote a culture of continuous improvement and ensure that manufacturing facilities consistently adhere to high-quality standards. By understanding the underlying causes of nonconformities and addressing them proactively, the industry can enhance its reputation, and ensure the availability of safe and effective products.

Executive Summary

During 2023, SFDA conducted 84 inspections on medical devices manufacturers. Those manufacturers were located at different regions (for example: 12 are located in Europe). **50%** of the overseas inspections were conducted on manufacturers who produced high risk medical devices, whereas almost **90%** of local manufacture inspections were conducted on low and medium risk medical devices. Almost **600** Non conformities were detected (**44%** of them are major NC). Manufacturer are producing different product categories such as Anesthesia and Respiratory Devices and Non-active Implantable Devices. Enforcement actions were taken against a number of local and overseas medical devices manufacture which includes production line closure, fines and license suspension.

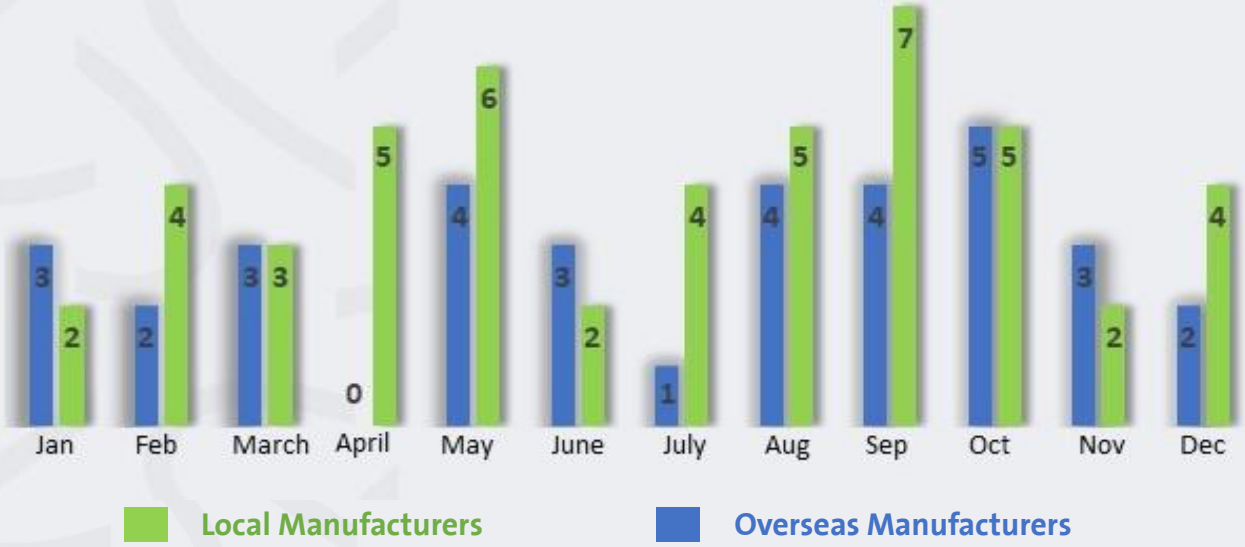
Number of Inspections:

In 2023, 84 inspections were conducted on local and overseas medical device manufacturers, where almost 40% of these inspections were on overseas manufacturers.



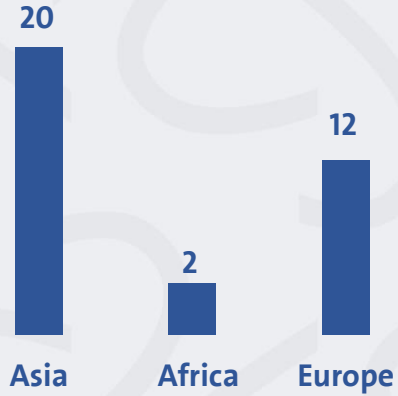
Inspection Date:

On a monthly basis, the maximum number of inspection was conducted for local manufacturer was 7 inspections , where the largest number of inspections for overseas manufacturer was 5 inspections. The average of the inspections for both local and overseas were about 4 per month.



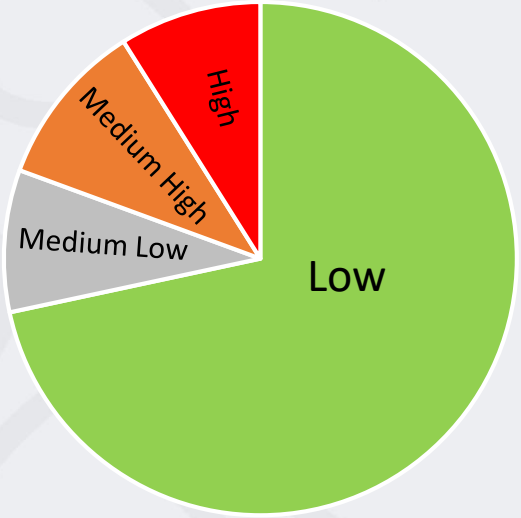
Location of Manufacturers:

For overseas manufacturers, 59% of the inspections were for manufacturers located in Asia while the 35% were for European manufacturers.

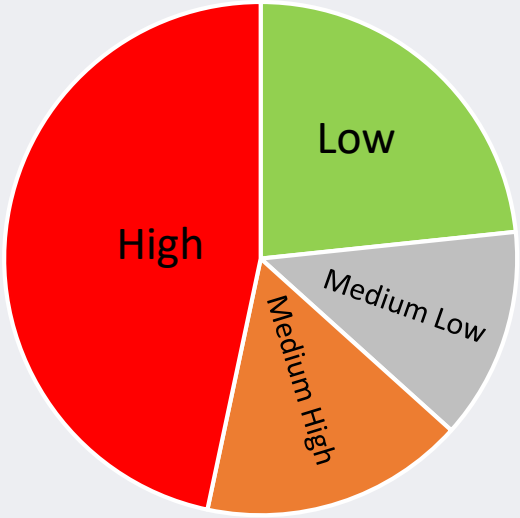


Risk Classification of Medical Devices:

For overseas manufacturers, almost 50% of the inspections were conducted on manufacturers who produced high risk medical devices, whereas almost 90% of local manufacture inspections were on low and medium risk medical devices due to that most local manufacturers are producing low and medium risk medical devices.



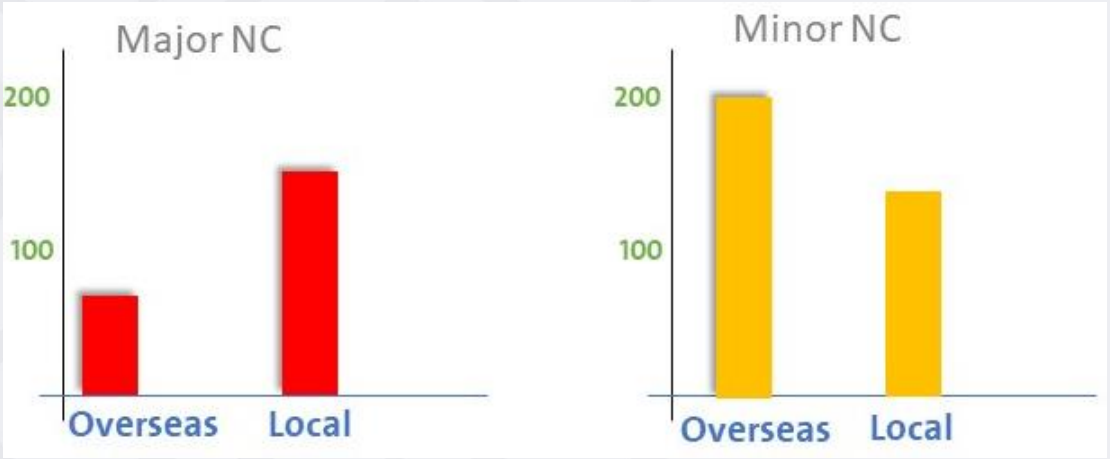
Local Manufacturers

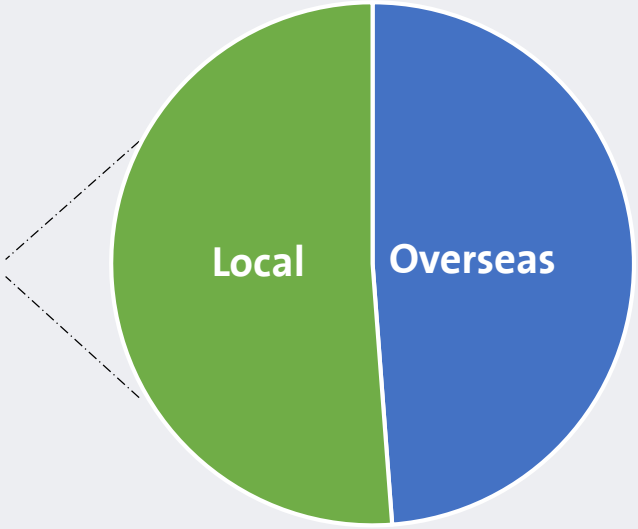


Overseas Manufacturers

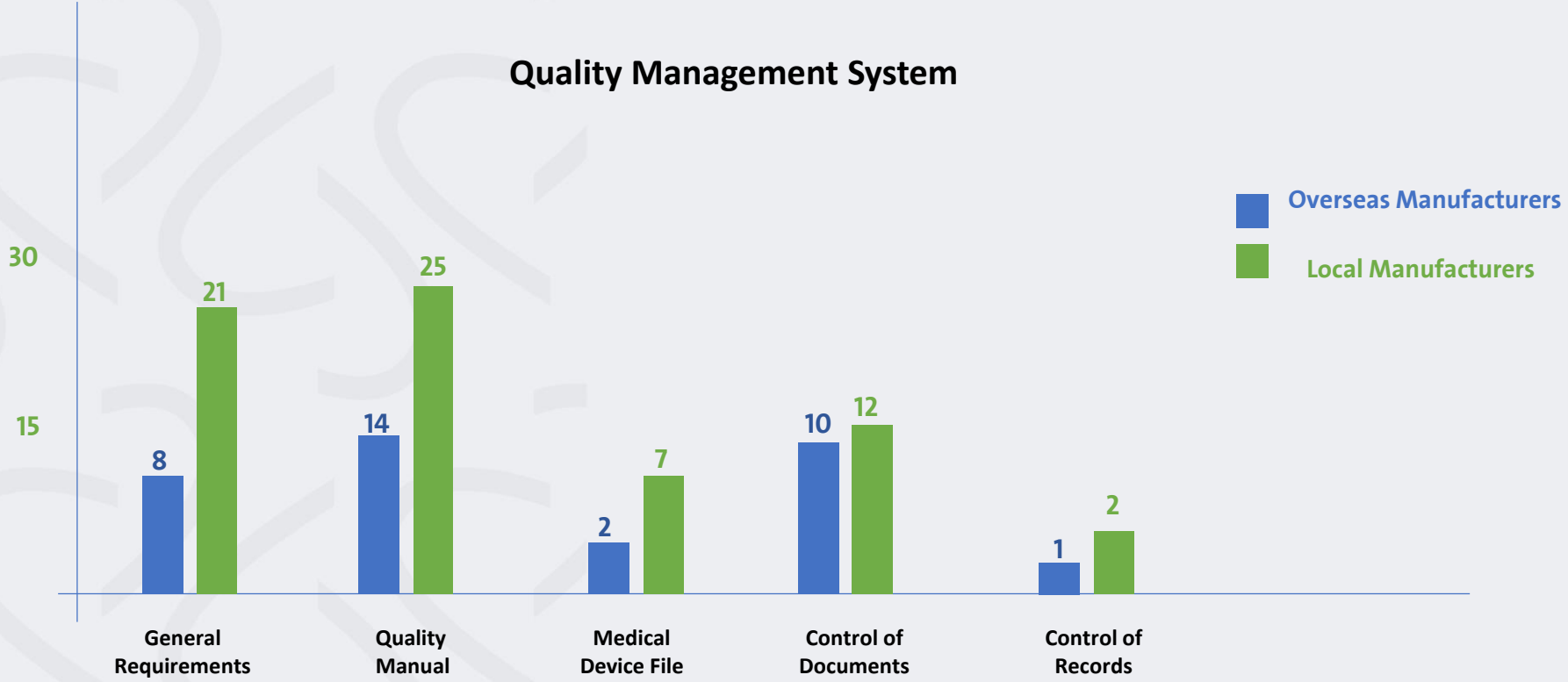
Number of Nonconformities:

In total, Almost **600** Non conformities were detected during the inspections during the year 2023. the major NC is 44% of the total NC.



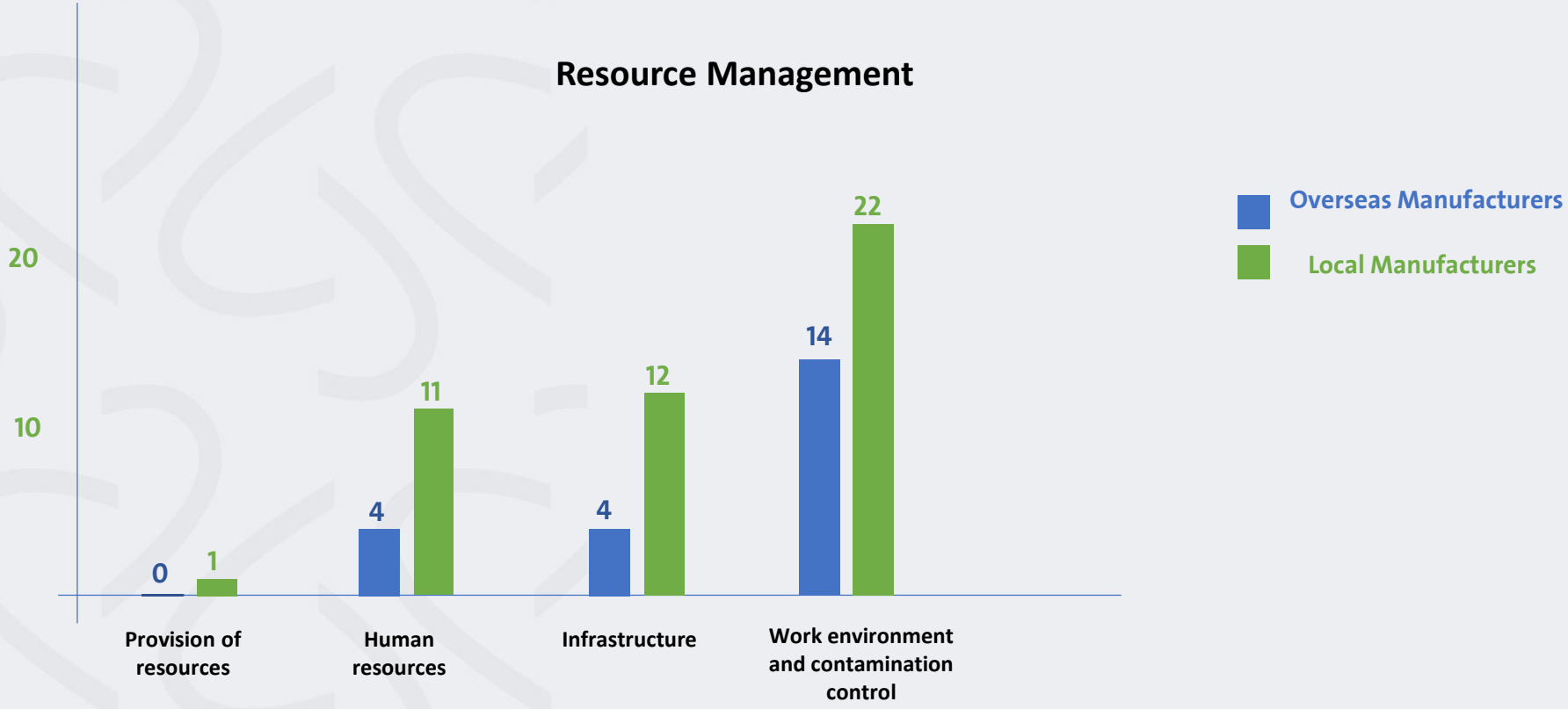


Nonconformities types based on the process:

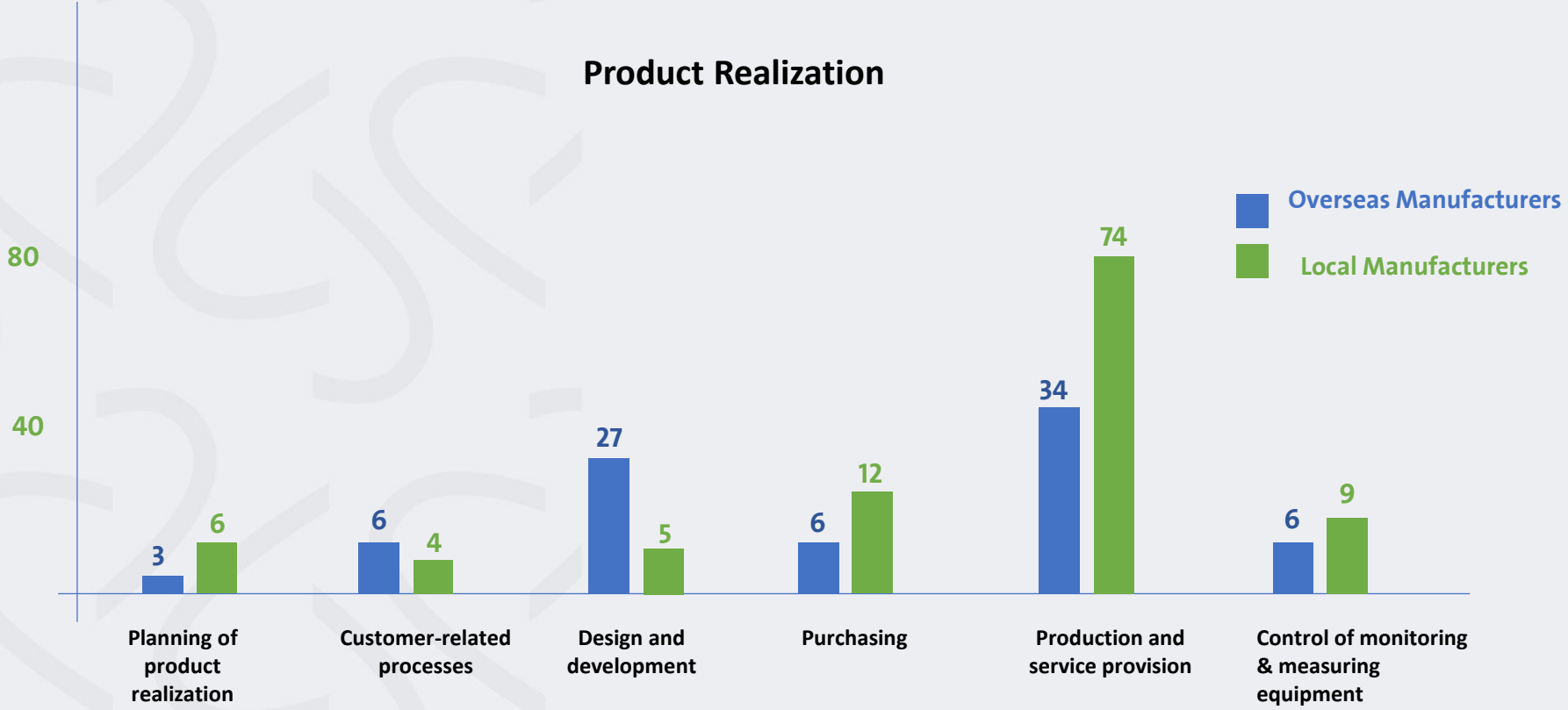


Nonconformities types based on the process:

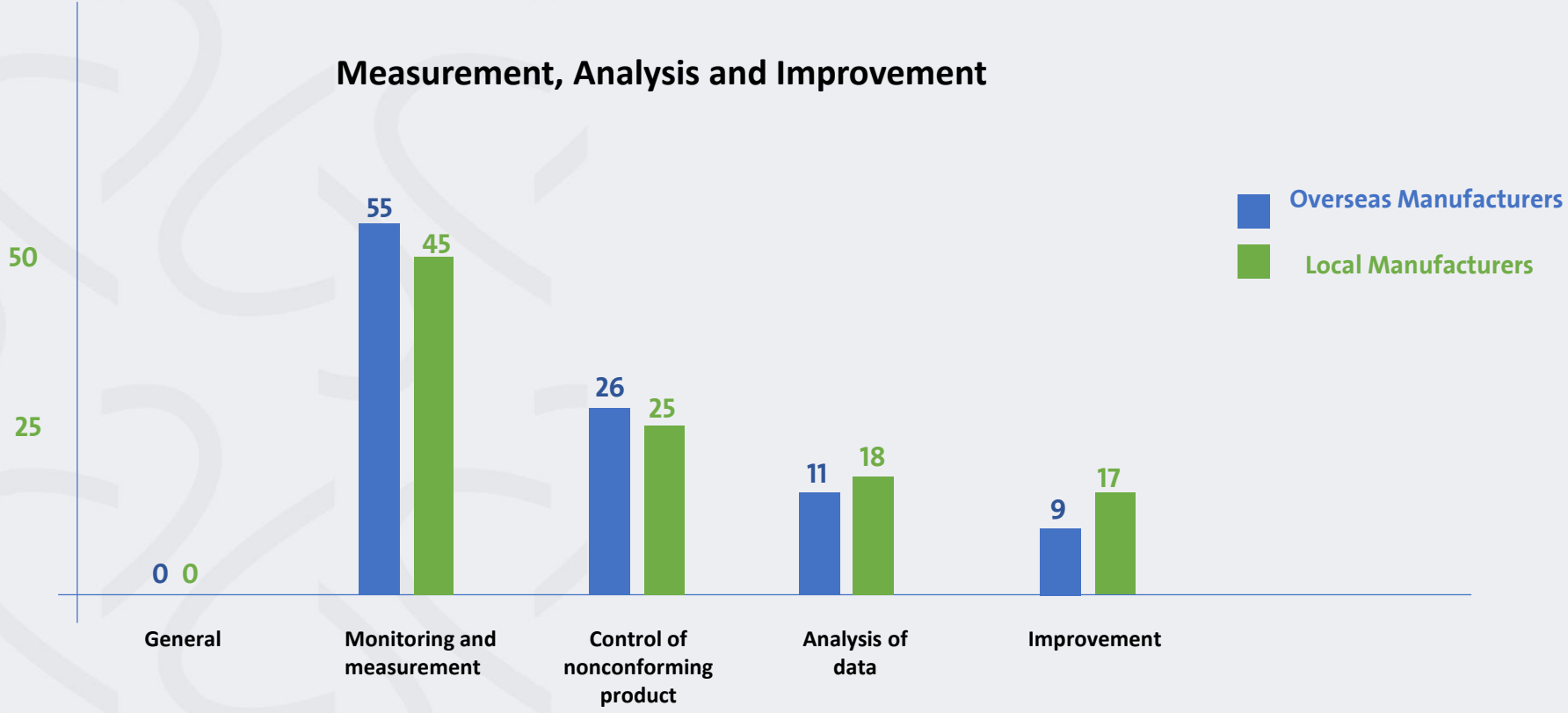
Nonconformities types based on the process:



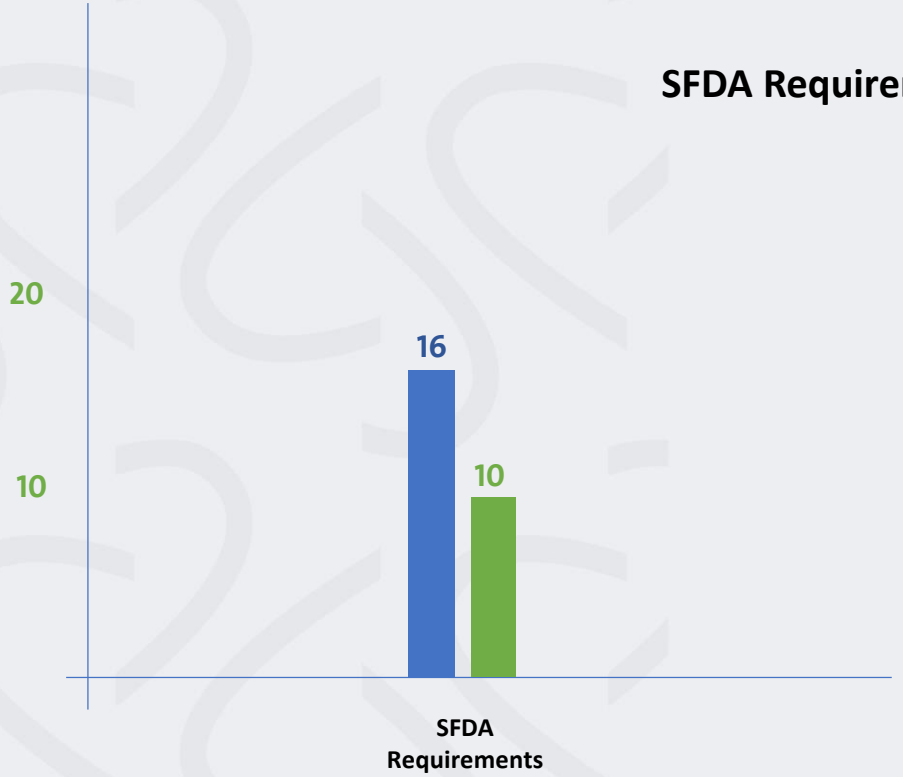
Nonconformities types based on the process:



Nonconformities types based on the process:



Nonconformities types based on the process:



Product categories:

	Local	Overseas
Single Use Device	16	16
In Vitro Diagnostic Devices	5	8
Electro Mechanical Medical Devices	4	2
Reusable Devices	1	0
Non-active Implantable Devices	9	1
Dental Devices	1	3
Biologically Derived Devices	2	0
Ophthalmic and optical devices	2	1
Diagnostic and Therapeutic Radiation Devices	1	1
Complementary Therapy Devices	1	0
Anesthesia and Respiratory Devices	0	3
Assistive Products for Persons with Disability	0	2
Healthcare Facility Products and Adaptations	0	1
Other Categories	0	26

Enforcement actions:

Enforcement actions were taken against a number of local and overseas medical devices manufacture. Almost **10%** of the inspected oversees manufactures were transferred to enforcement due to the severity od the nonconformities detected. On the other hand , enforcement actions were taken against **18 %** of the inspected local manufacturer. Moreover , during the inspection, more than 2 million non conforming products were seized.

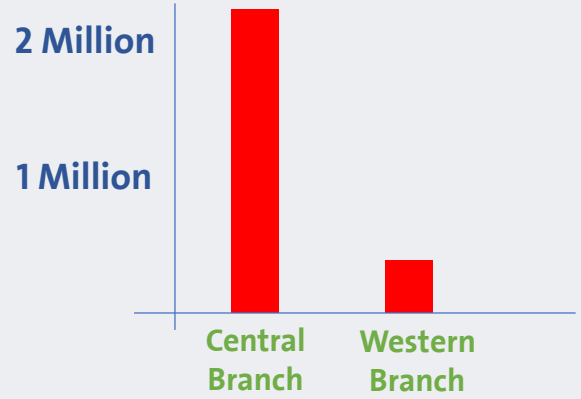
Local Manufacturers

Production line closure	1
Fines	8
Warning	3

Overseas Manufacturers

License Suspension	3

Enforcement Actions



Seized Products

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Thank You