IX ALL-RUSSIA GMP CONFERENCE

MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

Data Integrity. Implentation in Practice, Regulatory Expectations

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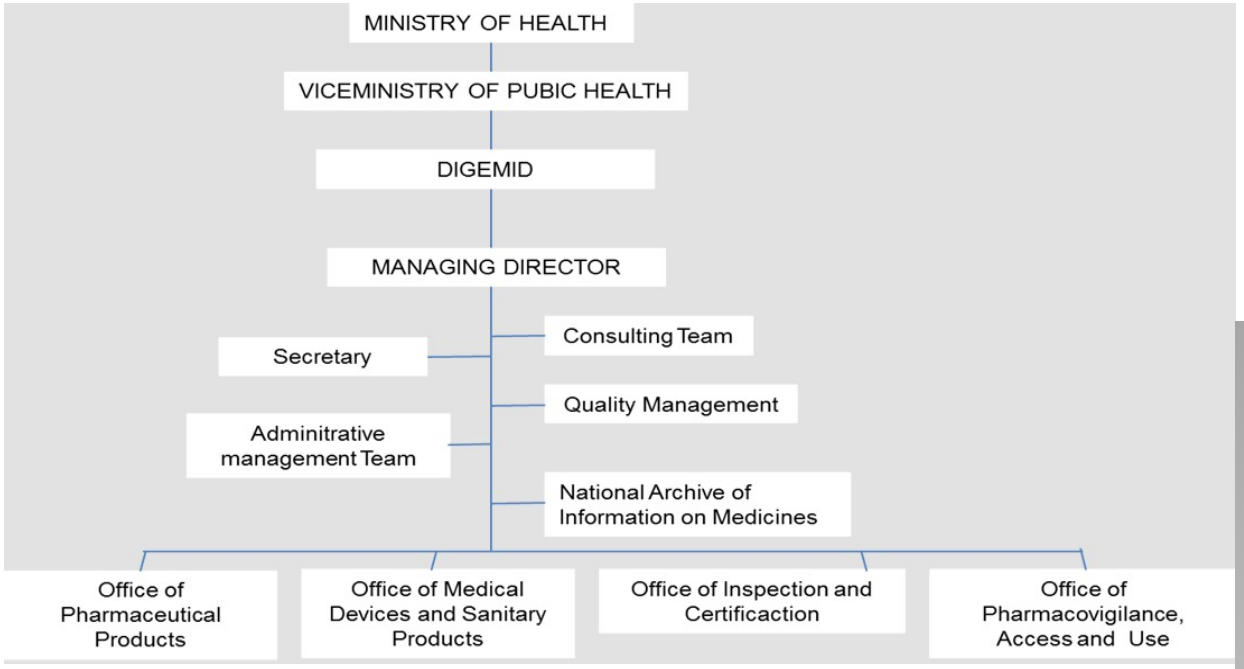
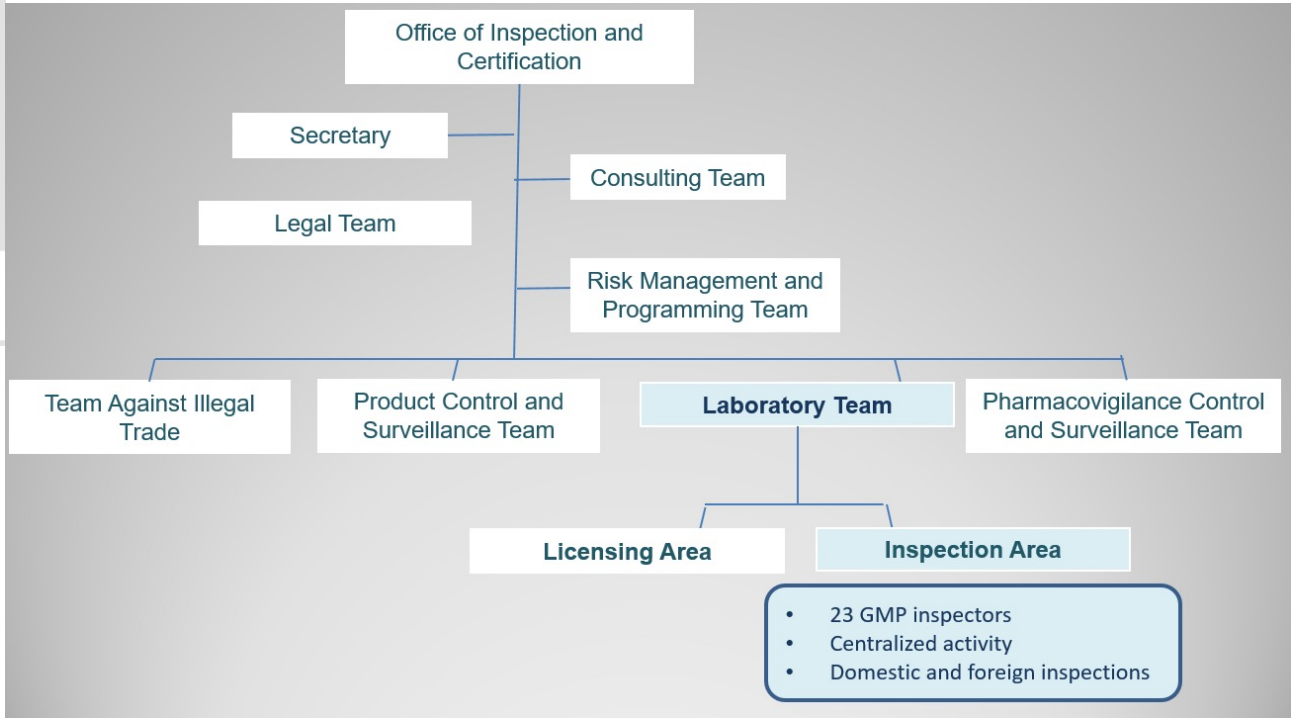
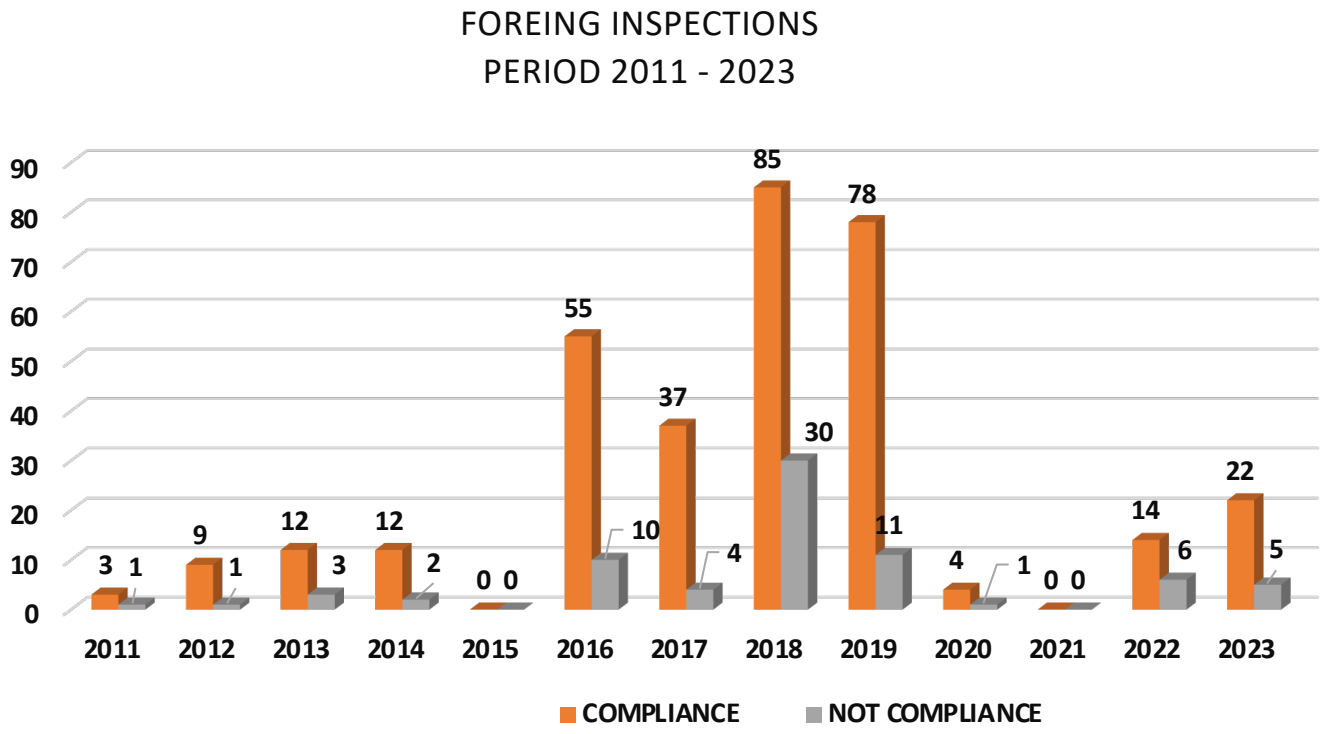
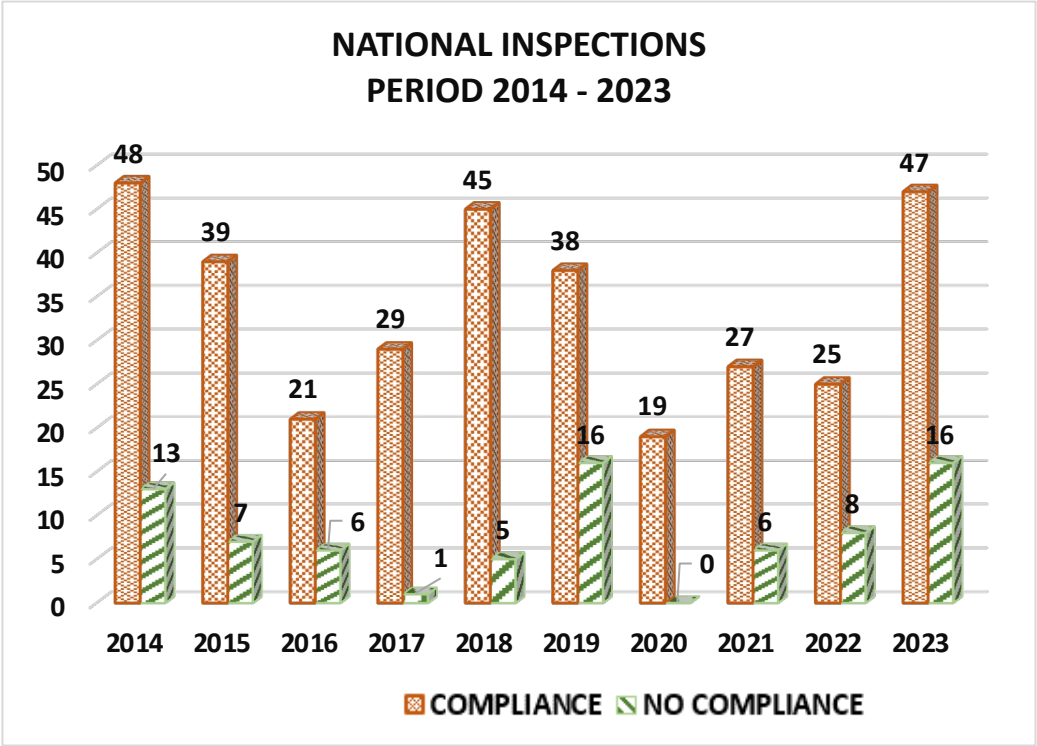
ORGANIZATION





Certification inspections carried out until 2023 (Foreign and National)





405 Inspections worldwide

35 Countries inspected

The same requirements apply to all. The certifications are valid for 5 years, but the national ones also have unexpected inspections and inspections for each authorization of additional areas.

Manual Of Good Manufacturing Practices and ALCOA++

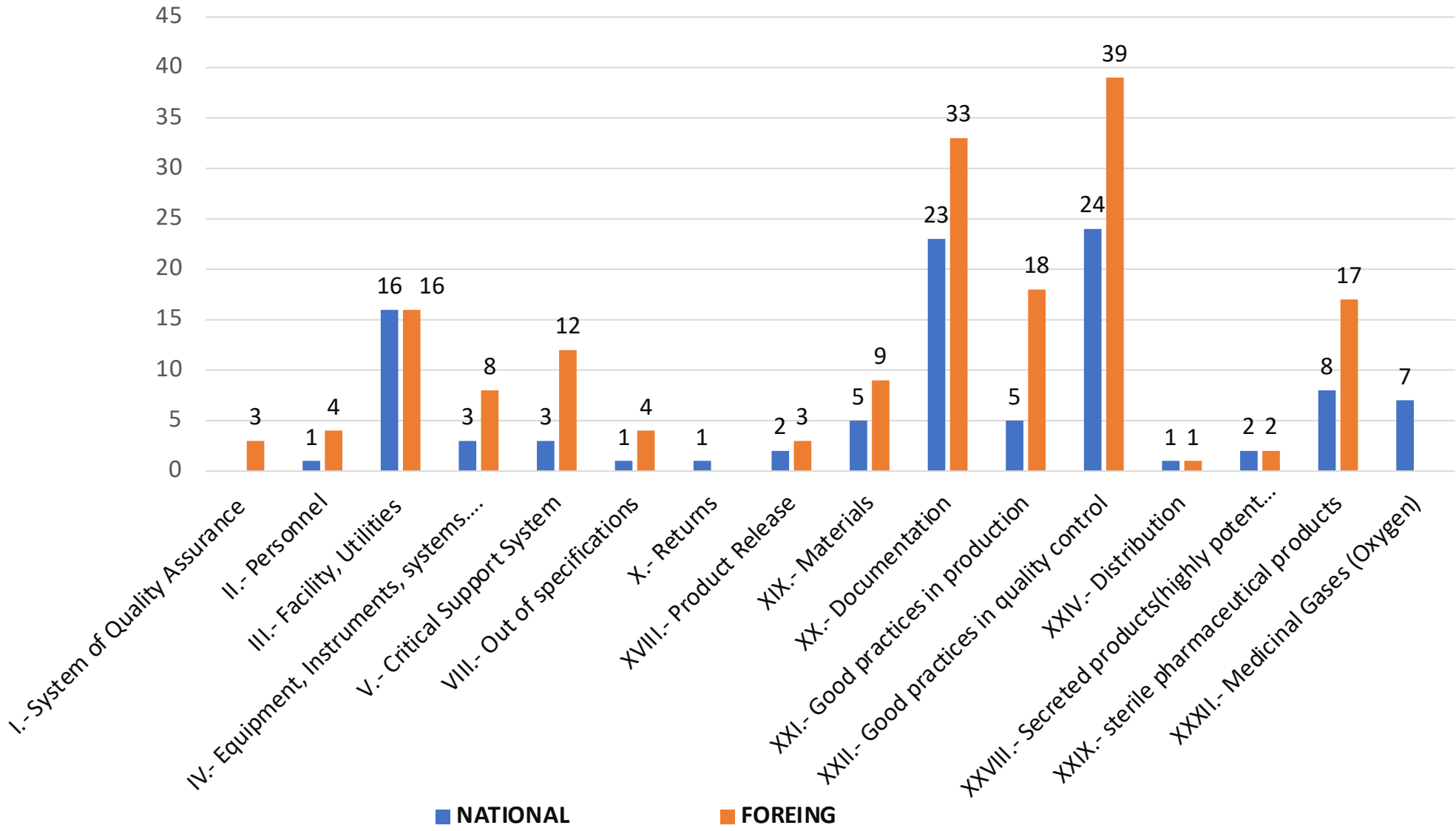
Manual Of Good Manufacturing Practices in Perú, It has 34 sections, within them it contains some items related to ALCOA ++ compliance in manual or computerized systems, most of them are found in **Section XX Documentation**, but others are found in other numerals such as:

Section IV Equipment, Instruments, Systems, subnumeral **4.33; Section V, Critical support system, subnumeral 5.70** and **5.72** on data integrity, that is, to ensure the accuracy of the data managed in computerized systems, a protection system must be implemented to prevent modification by unauthorized personnel.

Section XXII Good practices in quality control, subnumeral **22.5**

We have a study “Analysis of compliance with Good Manufacturing Practices of National and Foreign Laboratories Inspected by the National Medicines Authority in Peru” from 2022, where it is observed that the majority of non-conformities are found in section XX Documentation and in XXII Quality Control, both in national and foreign inspections.

Comparison of subnumerals not met by each section (Nationals and Foreigners 2022)



Comparison of subnumerals not met by each section (National and Foreign 2022)

SECTION	MAIN NON-CONFORMITIES National laboratories	Numeral	Non Conformity
XX	DOCUMENTATION: referring to the existence of procedures, records, instructions among other documents that demonstrate compliance with Good Manufacturing Practices.	20.2	Major
XX	DOCUMENTATION: Data records must be clear, legible and indelible and must be entered immediately after executing the activity.	20.19	Major
XX	DOCUMENTATION: Records of production and control activities must be maintained to demonstrate traceability	20.24	Major
XX	DOCUMENTATION: Establishes the requirements that the information that must be recorded during the production and packaging processes must contain.	20.54	Critical
XX	DOCUMENTATION: Identification that must be placed on containers, equipment or facilities are clear, unambiguous, so that their condition can be known, for example if it is dirty or clean, approved or rejected, etc.	20.32	Major

SECTION	MAIN NON-CONFORMITIES Foreing laboratories	Numeral	Non Conformity
XX	DOCUMENTATION:in relation to the existence of documentation that evidences the traceability of research linked to the manufacture of medicines and its availability when required, such as, for example, in the event that deviations occur.	20.5	Critical
XX	DOCUMENTATION: referring to documented evidence of compliance with the requirements established in the GMP	20.1	Critical
XX	DOCUMENTATION: related to the identification that inputs and products must maintain at all stages of the process with respect to their name, batch number, expiration, special storage conditions and name of the manufacturer	20.33	Critical

Subnumerals 20.2 (major), 20.32 (major) and 20.54 (critical) were cited with the same frequency and correspond to the same subnumerals that were most unfulfilled in the case of national pharmaceutical laboratories.

Examples of recentes non-conformities

- The usage record for Equipment TOC-002 was not available. It was requested to verify the data saved on the equipment, the analysis carried out at Point M5 on 01-06-202, which could not be traceable, because it does not keep the records. (5.70; 20.5)

- The 3 HPLC equipment that has the Openlab EzChrome software and the gas chromatograph equipment that has the Compass CDS software do not have an audit trail and the folder where the files are saved is freely accessible. Likewise, it is possible to edit the date and time of the PC of the equipment, which do not ensure data integrity. (5.70)

- In relation to HPLC equipment:

a) It was requested to modify the Dilution Factor in the HPLC-020 Equipment in the analysis of Belladona batch xx, however, in the printout of the report it is not evident that there was a modification of the data, which does not ensure the integrity of the data. (5.72; 5.74)
b) It was observed that on the HPLC-026 and HPLC-021 equipment, the date and time can be modified. (5.72)
c) Usernames and passwords are recorded on the equipment.(5.66; 5.72)

- It was observed that the equipment to determine the melting point does not have a printer to record the results obtained and a double verification has not been implemented to ensure the reported results. (22.5 d)

- Analysis reports for the following raw materials were not found:

-Sorbic Acid Analysis No. T-MP-004-23, Glycerin Analysis No. T-MP-005-23, Ethyl Alcohol Analysis No. T-MP-007-23, which were used in the finished product XY 1% skin solution lot 123456.
-Povidone Iodine analysis No. MP-017-24, which was used in the finished product YYY 7.5% topical solution lot 654321.
-Citric acid Analysis No. MP-037-24
It is not possible to verify that the raw materials meet the specifications. (22.5)

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Question
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ORGANIZERS

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