Trends – Vector Control Product Inspections

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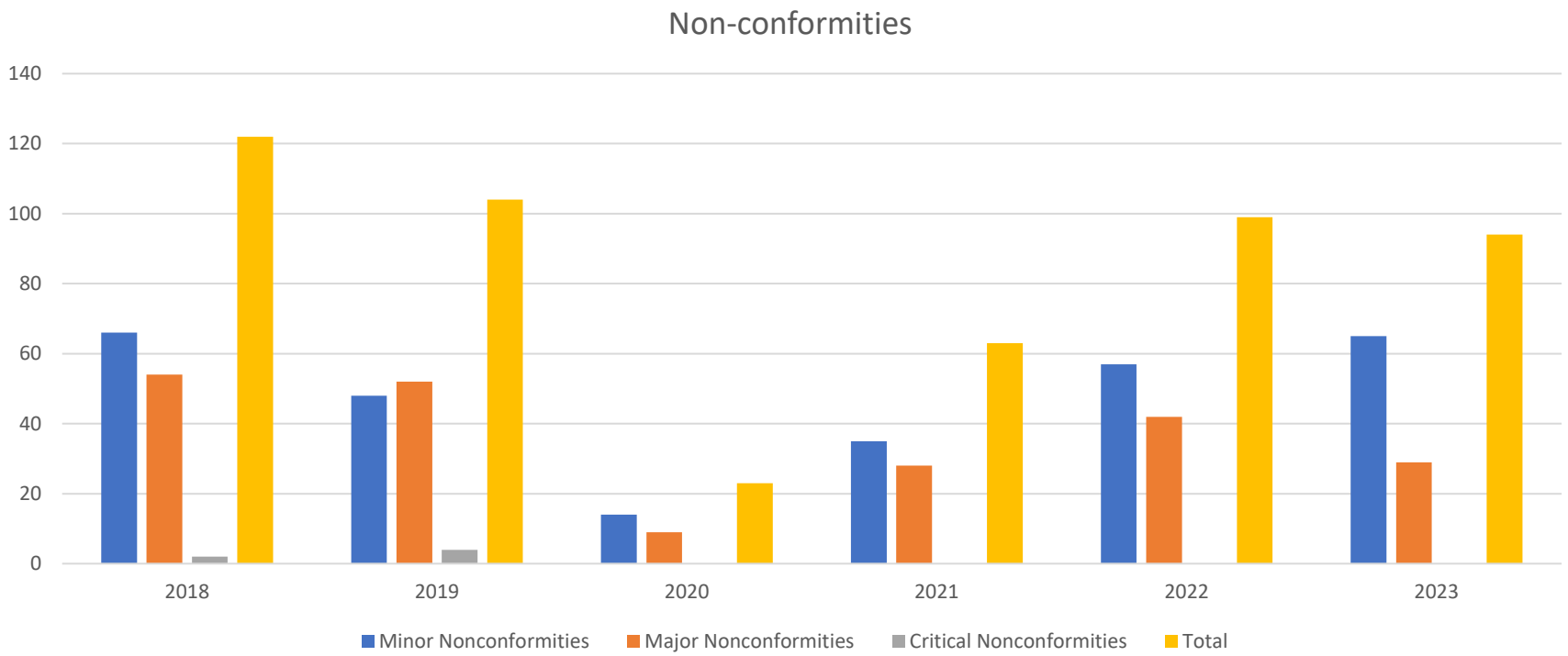
Outline

- Trends
- Examples of Common nonconformities
- Upcoming developments
- Conclusion

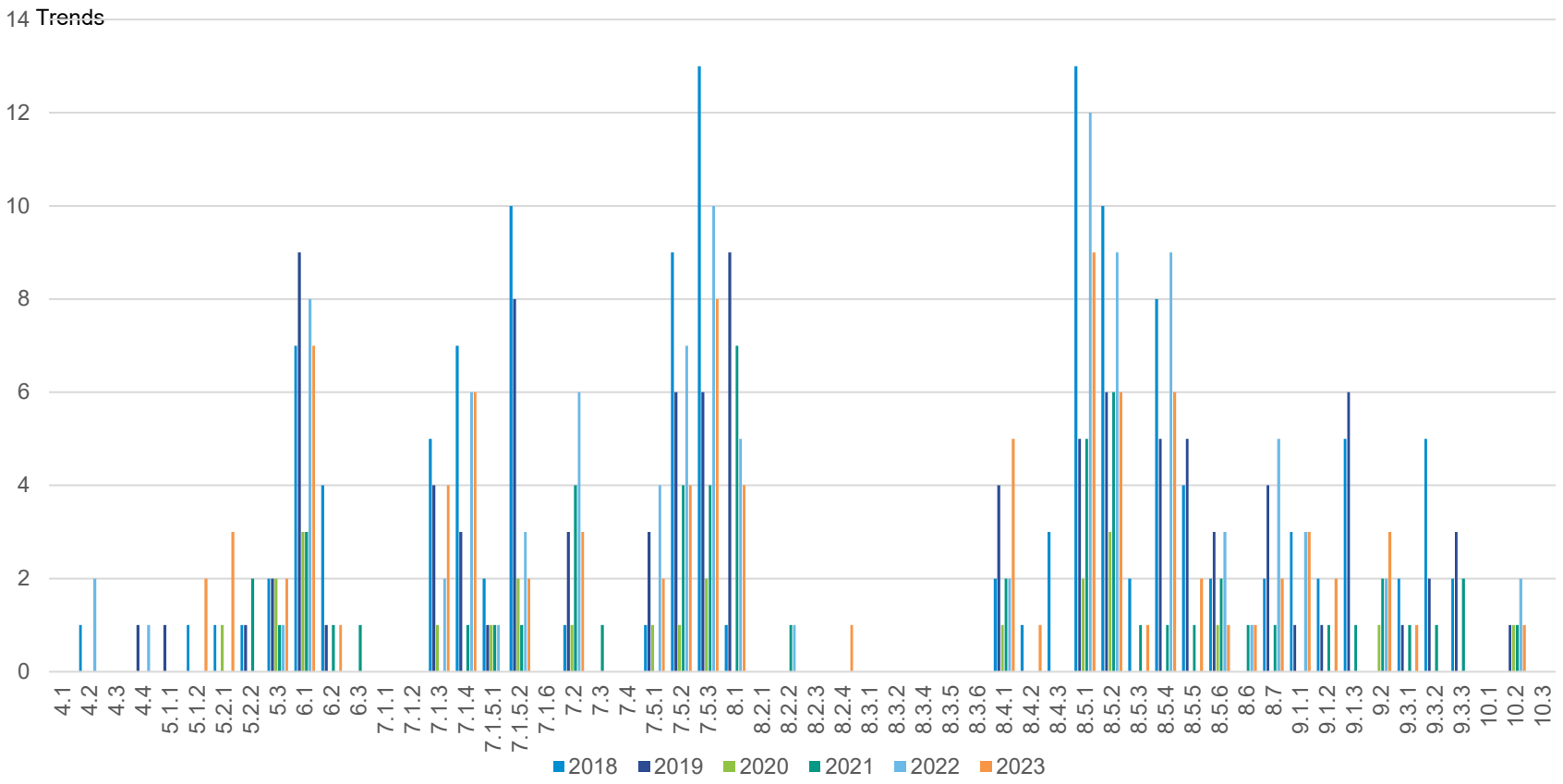
Trends – Vector control products

	2018	2019	2020	2021	2022	2023
Initial Inspections	18	13	4	7	13	8
Re-inspections					3	3
Follow-up inspections		2				
Special Inspections		1				1
Desk assessments				3	7	7
Total	18	16	4	10	23	19

Trends – Vector Control Products



Trends


Trends
14
12
10
8
6
4
2
0
4.1
4.2
4.3
4.4
5.1.1
5.1.2
5.2.1
5.2.2
5.3
6.1
6.2
6.3
7.1.1
7.1.2
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7.1.5.2
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8.3.6
8.4.1
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9.1.3
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9.3.3
10.1
10.2
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2018
2019
2020
2021
2022
2023

Non-conformities-Clause 8.5.1 – Control of production and service provision

- There was no evidence of cleaning of the shared packaging line. Additionally, no procedure for cleaning of the packaging line was in place.
- Though process validation had been performed the batch manufacturing formula used to produce the WHO prequalified product was different from that submitted to WHO PQ.
- There was a potential for mix-ups as different product labels found on the label printing lines. The printing lines were not segregated from each other. Additionally, in the label storage area, Labels belonging to different products were found stacked together in piles without any segregation.
- On review of the available raw data and chromatographs, the results obtained did not match those indicated in the production report

Nonconformities - Clause 7.5.3 – Control of documented information

- A superseded procedure for nonconforming products was found in use.
- The control of documents was the responsibility of the QA department; however, it was common practice for production to photocopy batch production records and use different copies of the batch production records during production. One copy of the batch production records was found in production area, and another was in the laboratory.
- Recently filled and completed batch production records were found discarded in the bin.

Nonconformities-Clause 7.1.4 – Environment for the operation of processes

- Birds (pigeons) were seen in the production areas.
- Rodents were seen in the raw material warehouse and production area.
- The monitoring of room temperature and humidity in the QC laboratory had not been recorded as required by the company procedure

New developments – ISO 9001:2015 standards

- Proposals to revise the definitions of risk and process
- Revisions to documented information and handling of planned changes.
- Confirmation on these decisions awaited from the International Organization for Standardization committee.

Conclusion

- Compliance with ISO 9001 will result in improved productivity and efficiency of the QMS.
- With conformance to ISO 9001 standard requirements there is increased confidence that your processes are able to consistently produce products that meet WHO product specifications and meet requirements of UN procurement agencies and other customers
- Reduction in the number of critical non-conformities
- WHO is flexible and allows for improvement of industry's QMS and compliance with ISO 9001:2015 standard

END

Thank you

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