Regulatory inspections

We regularly participate in regulatory inspections to help ensure the highest quality in our operations in development, manufacturing and distribution.

Health authorities, including the European Medicines Agency (EMA), Swissmedic and the US Food and Drug Administration (FDA), carried out the following inspections in the last three years.

Regulatory authorities	2022	2023	2024
Total inspections	106	113	124
Inspections found to be acceptable (%)	100	99.1	100

US FDA

FDA inspections	7	10	9
FDA warning letters	0	0	0
FDA Form 483	5	5	4

Inspections	2022	2023	2024
Inspections related to clinical trial management and pharmacovigilance	n/r	n/r	21
Number of FDA VAI (Voluntary Action Indicated) classifications	0	1	0
Number of FDA OAI (Official Action Indicated) classifications	0	0	0

n/r: not reported

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