



Meteriovigilance is the term used in the context of surveillance of medical devices and its purpose is to improve the protection of health and safety of patients, healthcare professionals, and other users by reducing the likelihood of reoccurrence of incidents related to the use of a medical device.

Presented below in brief is the Post-Marketing regulatory landscape as exist for USFDA and EMA in terms of Medical Device Reporting.

Regulations that Govern Medical Device Reporting

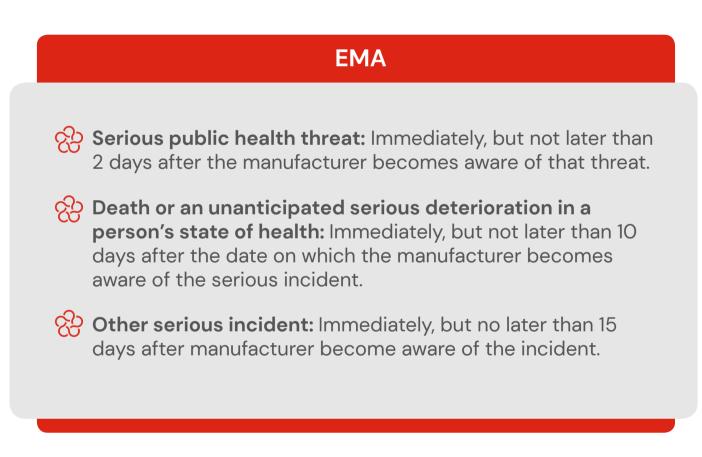
W 21 CFR PART 803 W 21 CFR PART 806



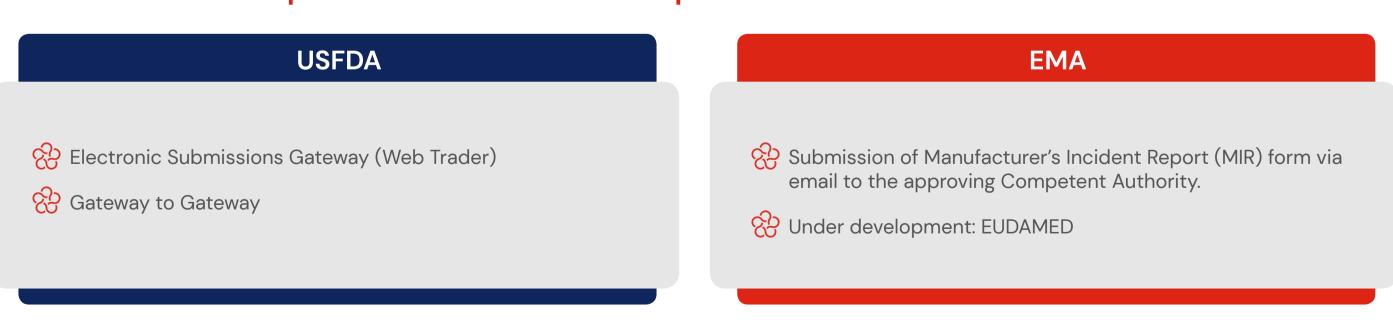
Type of Report and Reporting Timelines

5-day report: No later than 5 workdays after becoming aware of a reportable event that requires Remedial action to prevent an unreasonable risk of substantial harm to the public health. A reportable event for which FDA made a written request. 30-Day report: No later than 30 calendar days after becoming aware of a reportable death, serious injury, or malfunction

USFDA



Method to submit Reportable Medical Device Reports



Requirement for submission of Periodic Report

USFDA	EMA
Not mentioned* *Guidance for Combination product has specific requirements; will be detailed in subsequent posting.	Class IIb and class III devices: Annual PSUR Submission Class IIa devices: PSUR to be submitted at least every two years

Requirement for Trend reporting

USFDA

EMA

Manufacturers shall electronically report any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side effects that could have a significant impact on the benefit-risk analysis, and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits

Watch for the subsequent post for details on USFDA Post-Marketing Medical Devise Reporting requirements......

References:

Not mentioned

- 1. 21 CFR Part 803 -- Medical Device Reporting
- 2. 21 CFR Part 806 -- Medical Devices; Reports of corrections and removals
- 3. https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems (assessed on 17-Oct-2023)
- 4. REGULATION (EU) 2017/745: Medical Devices Regulation https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices (assessed on 17-Oct-2023)

Author



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Disha is a pharmacist with 9+ years of pharmacovigilance experience. She is skilled in processing and review of spontaneous, clinical trial, global literature, E2B, medical device, and cosmetic reports. She has experience in reporting of cases to the US, Canada, EU, UK, and Australia. She has managed various projects and participated in several client audits and regulatory inspections as a lead representative and Subject Matter Expert.

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