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Emphasis on Medical Device Complaint Handling Can Lead to Improved Product Performance

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Recently, the Food and Drug Administration (FDA) has taken steps to increase transparency and public access to adverse event reporting for medical devices.[1,2] Most notably, FDA formally ended the Alternative Summary Reporting (ASR) Program in June 2019.[3] This program was one way in which reports regarding well-known categories of adverse events could be brought to the attention of the FDA as required under the Medical Device Reporting (MDR) regulation.[4]

The FDA requires a manufacturer, device user, importer, health care professional, patient, caregiver, or consumer to report certain medical device issues once they become aware.[5] Depending on the specific instance, reporting may be either voluntary or mandatory. The latter occurs when a party has become aware that a product has caused or contributed to a death or serious injury, for example. Under the ASR Program, instead of providing quarterly summary reports of these events with FDA concurrence, manufacturers could request an exemption from the MDR requirement of filing individual medical device reports for certain events that were considered well-known and resulted from well-established risks.[6] Typical records of MDR reports can be found in the Manufacturer and User Facility Device Experience (MAUDE) database or the Device Experience Network (DEN) reports. The public release of ASR data has come under scrutiny as various media sources have referred to the ASR Program as a "hidden device database" and "a loophole that allowed millions of [adverse event report] files to remain hidden."[7,8,9]

Complaint reporting and the subsequent investigations of the complaints are proceduralized under a company's quality system. In many cases, the complaint involves a returned product that can be evaluated to determine the cause of any issue and plan the appropriate path forward. If a rigorous retrieval or return program is not in place to handle the investigations and documentation processes, critical adverse event data may be lost. This data not only informs the investigation but can provide valuable insight regarding the performance and risk profile of the marketed product, thereby aiding in a rigorous determination of the event's root cause.

Importance of Robust and Reliable Retrieval Programs

The FDA and other regulatory bodies have suggested establishing retrieval programs as early as investigational device exemption (IDE) studies (e.g., Preparation and Review of Investigational Device Exemption Application (IDEs) for Total Artificial Discs[10]). Creating a program

[1] https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-increase-access-adverse-event-report-data-medical-products-used-animals
[2] https://www.fda.gov/news-events/press-announcements/statement-agencys-efforts-increase-transparency-medical-device-reporting
[3] https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/mdr-data-files
[4] 21 CFR Part 803, Food and Drugs Chapter I – Food and Drug Administration Department of Health and Human Services Subchapter H - Medical Devices – Medical Device Reporting
[5] https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems
[6] https://www.fda.gov/news-events/press-announcements/statement-agencys-efforts-increase-transparency-medical-device-reporting
[7] https://www.fiercebiotech.com/medtech/five-things-found-fda-s-hidden-device-database
[8] http://www.startribune.com/fda-releases-millions-of-records-of-incidents-involving-medical-devices/511631502/?refresh=true
[9] https://www.massdevice.com/report-fda-hiding-millions-of-adverse-event-reports-from-docs-public/
[10] Guidance for Industry and FDA Staff: Preparation and Review of Investigational Device Exemption Applications (IDEs) for Total Artificial Discs, issued April 11, 2008.

early in the product development life cycle guarantees a source of data that can support regulatory submissions, evaluations of potential failure modes, and assessments of product performance by correlating with longer-term trending of post-market surveillance information. Data from early retrievals can also help to evaluate the robustness of preclinical testing and serve as a helpful comparison in correlating in-vitro and in-vivo data.

Establishing a robust and reliable retrieval program involves careful thought regarding the logistics of device return, chain of custody, and the selection of the ideal evaluation techniques to ensure scientific rigor. Procedures such as those outlined in ASTM F561-19, *Standard Practice for Retrieval Analysis of Medical Devices, and Associated Tissues and Fluids*,[11] and ISO 12891-2, *Retrieval and Analysis of Surgical Implants*,[12] are helpful in that they provide a staged approach to the analysis. This staged approach allows the company to choose the appropriate technique based on clinical considerations (i.e., implantation time, reason for revision/removal) and device factors (i.e., wear patterns, unexpected appearance of materials).

It should be noted that retrieving and analyzing medical devices after revision or removal are critical components in the product life cycle. Retrieval programs help to inform product development, augment regulatory submissions, implement continuous improvement, evaluate and mitigate risks, develop new designs or product enhancements, and implement continuous improvements.[13]

Exponent's Expertise

Exponent's multi-disciplinary team of biomedical engineers, scientists, and regulatory experts can help manufacturers evaluate medical devices throughout the entire product life cycle. We provide expertise in the areas of preclinical testing, program development for product return and evaluation, quality system establishment and review, regulatory pathway advice, clinical study development, and post market surveillance including complaint investigations.

[11] ASTM F561-19, Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids, ASTM International, West Conshohocken, PA, 2019, www.astm.org.
[12] International Organization for Standardization, ISO 1289-1:2, Retrieval and Analysis of Surgical Implants, ISO, Geneva, Switzerland, 2015.
[13] J.A. Ochoa, R.L. Siskey, C.M. Kuehn, and L. Ciccarelli, "Medical Device Regulation and Retrieval Analysis," in Beyond the Implant: Retrieval Analysis Methods for Implant Surveillance, ed. W. Mihalko, J. Lemons, A. Greenwald, and S. Kurtz (West Conshohocken, PA: ASTM International, 2018), 23–38. https://doi.org/10.1520/STP160620170131.

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