Raising the Bar

How OEMs Meet the Highest Standards for Servicing Medical Devices

AdvaMed
Advanced Medical Technology Association

Proper servicing of complex, life-saving and life-sustaining medical devices is vital to their safe and effective functioning. Original equipment manufacturers (OEMs) and their authorized servicers must follow comprehensive FDA quality system requirements to ensure their devices are properly serviced and maintained and continue to meet safety and effectiveness standards set by the agency. However, tens of thousands of unregulated third-party servicers do not follow the same FDA requirements, putting patients and device users at risk.

FDA REQUIREMENTS	ORIGINAL EQUIPMENT MANUFACTURERS (OEMS)	THIRD-PARTY SERVICERS
Quality System Regulation (OSR) (21 CFR 820) QSRs are documented and approved policies and procedures covering all aspects of a company's operations, including purchasing of replacement parts and components; personnel training; equipment and facilities maintenance; supplier evaluation; record-keeping; complaint files; corrective actions; and more. ***Ensures that all servicing operations are carefully controlled and executed.***	✓	✗
Registration (21 CFR 807) Companies are required to register the location of their facilities with FDA to enable the agency to inspect their facilities. ***Ensures that FDA knows who is repairing medical devices.***	✓	✗
Medical Device Reporting (MDR) (21 CFR 803) MDRs are mandatory reporting to FDA of any deaths, serious injuries or malfunctions involving a medical device. ***Ensures that FDA and OEMs know about potentially serious device problems.***	✓	✗
Voluntary Recalls (21 CFR 7) Recall actions can range from a simple labeling change, to an in-field correction or a partial/full removal of the product from the market. This requirement establishes comprehensive procedures to protect the public health from products that present a risk of injury, gross deception or are otherwise defective. ***Ensures that potential device problems are addressed quickly and efficiently.***	✓	✗
Corrections and Removals (21 CFR 806) Requires companies to report any action in the field to address any risk to health posed by a medical device. ***Ensures that potential device problems are addressed quickly and efficiently.***	✓	✗