IJBPAS, August, 2024, 13(8): 4128-4136

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

REGULATORY LANDSCAPE FOR REMANUFACTURED MEDICAL DEVICE: A COMPARATIVE EVALUATION OF FDA AND MHRA APPROACHES

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Received 18th May 2023; Revised 20th Aug. 2023; Accepted 20th Nov. 2023; Available online 1st Aug. 2024

https://doi.org/10.31032/IJBPAS/2024/13.8.8273

ABSTRACT

The purpose of this article is to assess the present situation of medical device remanufacturing while taking into account the differences between the USFDA and the UK MHRA. Medical instruments and equipment are essential in today's health-care institutions. Following up with the invention of new technologies, on the other hand, is impractical for many health institutions, particularly in low-resource settings. As a result, global demand for remanufactured medical equipment is expanding. While new medical equipment is governed by well-established and severe quality and safety regulations, remanufactured medical device rules vary greatly among nations. In this section, we explore the various legislation and practices applicable to remanufactured medical equipment in the United States and the United Kingdom. The need for remanufactured medical devices has skyrocketed during the COVID-19 epidemic. For the purposes of this study, remanufacturing is the process of returning a used product to at least the original manufacturer's performance specifications. The customer's viewpoint and the resulting product are both given a warranty at least comparable to the guarantee of a newly manufactured equivalent. This obviously has significant implications for sustainability, since components that would otherwise be discarded may now be retrieved and of high quality. However, various social, economic, and regulatory issues influence these sustainability benefits. Regulatory rules for the import, sale, labelling, and use of a refurbished medical product are required, and authorities should follow these criteria to guarantee that remanufactured equipment meet high quality and safety standards.

Keywords: Labelling, SUD, Changes, Performance, Process

INTRODUCTION:

The demand for new equipment, there is a rising market for remanufactured medical equipment all around the world. To save capital investments, an increasing number of new hospitals are choosing alternative solutions. Several hospitals favour remanufactured medical gadgets in order to reduce capital investment and provide patients with cheap healthcare services. Furthermore, demand for remanufactured medical equipment is substantially higher in low- and middle-income nations, with one of the key causes being underdeveloped health infrastructure and restricted access to healthcare resources **[1]**. As a result, factors such as affordability and medical devices are an essential component of health-care systems and are used for prevention, diagnosis, treatment, monitoring, rehabilitation, and palliation. Imaging equipment, in vitro diagnostic kits, implants, mobility aids, inhalers, and medical equipment that help practitioners in clinical or surgical operations are examples of such devices. For the purposes of this paper, remanufacturing is defined as the process of returning a used product to at least the original manufacturer's performance specifications from the customer's perspective, and the resulting product is given a warranty that is at least equal to that of a newly manufactured equivalent **[2]**. Along with the growing number of healthcare service providers are expected to fuel market expansion throughout the forecast period. The remanufacturing process is generally divided into six short phases. Inspection, cleaning, disassembly, component remanufacture, assembling, and testing are among them. Each of these categories is crucial to the entire remanufacturing process because it guarantees that a particular product is rebuilt to a high level, with appropriate quality control measures performed at each stage **[3]**.

Remanufactured medical devices in USFDA

Remanufacturing is the act of processing, conditioning, renovating, repackaging, repairing, or performing another act on a completed device that materially modifies its performance or safety criteria, or intended purpose. Such clarification is intended to help provide consistency and better understanding of applicable statutory and regulatory requirements **[4]**.

Guiding Principles:

i. **Assess whether there is a change to the intended use** – Given that the purpose of servicing is to return the device to the safety and performance specifications established by the OEM and to meet its original intended use, any change to the intended use should be evaluated to

determine whether the activity is remanufacturing.

ii. **Determine whether the activities, individually and cumulatively, significantly change the safety or performance specifications of a finished device** – Under 21 CFR 820.3(w), remanufacturing includes activities that significantly change the performance or safety specifications of the finished device. Multiple changes, when considered cumulatively, may significantly change the performance or safety specifications of the legally marketed device and should be evaluated.

iii. **Evaluate whether any changes to a device require a new marketing submission** – Regardless of whether changes made to a legally marketed device are remanufacturing, such changes should be evaluated to determine whether a premarket notification (510(k)) or other marketing submission is required pursuant to the FD&C Act and applicable regulations.

iv. **Assess component/part/material dimensional and performance specifications** – Assessment of changes to dimensional and performance specifications can inform whether the activity performed is remanufacturing.

v. **Employ a risk-based approach** – Entities should employ a risk-based approach, such as one that conforms to or is consistent with ISO 14971: Medical devices – Application of risk management to medical devices when assessing whether an activity they perform is remanufacturing.

vi. **Adequately document decision-making** – When deciding whether an activity is remanufacturing or not, FDA recommends that the rationale for the determination be documented in sufficient detail including reference to supporting verification and validation data **[5]**.

Labelling Considerations:

- A summary of the important performance and safety requirements;
- The maintenance actions and timetable that are suggested;
- Routine testing and acceptance criteria are recommended to ensure that the device 536 remains within its performance and safety parameters.
- A description of the device's fault codes, warnings, and alarm functions;

- Precautions and warnings regarding device servicing;
- The software's version number and release date.
- Important technical or functional parameters,

such as:

1. Physical dimensions

2.Electrical properties, such as battery chemistry, amperage, voltage, and rechargeability, internal fuses, and power supply voltage, amperage, and frequency; and

3. Device-specific performance criteria, such as flow rate accuracy or range, humidity, temperature, and wavelength **[6]**.

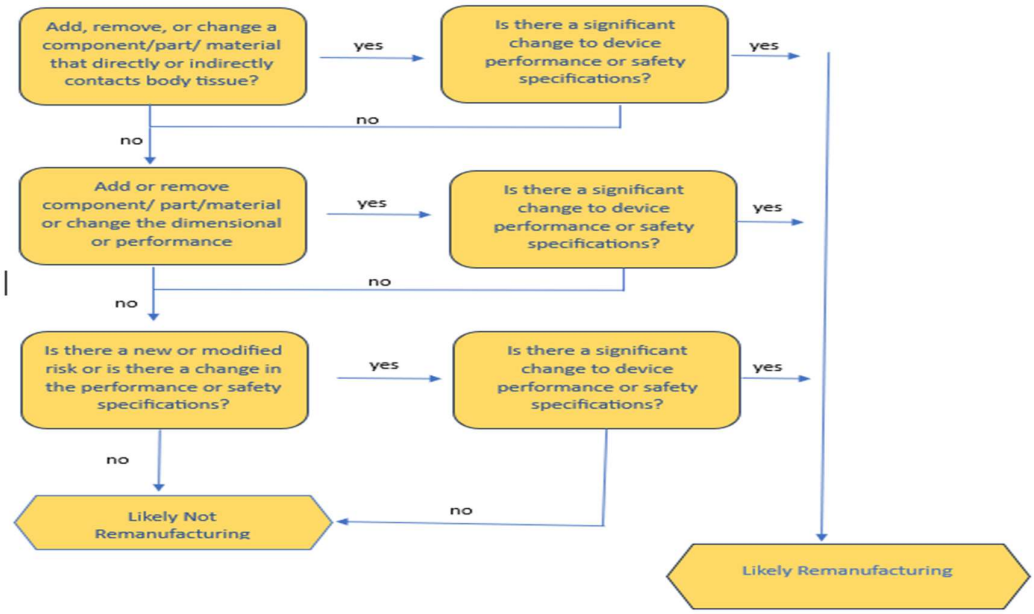


Figure 1: Flowchart to determine whether activities performed are likely remanufacturing

Case study on Remanufacturing Assessment

Product: Pump ABC, Serial# 246-586

Date of activities performed: 21/11/2023

Date assessment performed: 21/10/2023

Description of device: Syringe pump

Description of activities performed: Replaced broken door with part #xxx

Determination of whether the activity is remanufacturing: While a change to a body 1085 contacting component, the door used was OEM-provided and is identical to the broken door. 1086 Because it is a replacement of an identical part, there are no changes to performance or safety 1087 specifications. This activity is not remanufacturing.

Reference to related documents supporting the decision-making process: N/A
Technician performing service: xxxx
Reviewed by: xxxx
Signature(s): xxx **[7]**

Remanufactured medical devices in UK MHRA

Re-manufacturing is the process through which a firm acquires a CE mark for re-manufacturing single-use items. A re-manufactured SUD may not have had all of its components altered throughout the remanufacturing process. However, before the device is placed on the market or put into operation, it will be cleaned, disinfected, and sanitized, and it will be tested against the re-manufacturer's requirements to ensure the SUD continues to perform safely and as intended **[8]**. According to this guideline, re-manufacturing SUDs entails a re-manufacturer proving the conformance of the re-manufactured SUD with the applicable medical devices regulation and attaching a CE mark on their product. This should be done before releasing the product to the public or putting it into use. It is the obligation of the remanufacturer to keep track of how many times the gadget is remanufactured and reused **[9]**.

Technical documentation:

The remanufactured product must fulfil the applicable directive's safety and performance standards. Full technical documentation, including clinical proof, should be prepared and maintained by the re-manufacturer. Clinical proof may be supplied in the form of the results of the re-manufacturer's clinical trial or extensive information on equivalence to the OEM's device.

Copies of technical documentation must be kept for at least 5 years by the manufacturer or the EU authorized agent. The maker of implanted devices must preserve the paperwork for at least 15 years after the last product is placed on the market **[10]**.

Bioburden, decontamination, cleansing, and sterilizing:

The re-manufacturer should have proven SUD decontamination, cleaning, and sterility methods as part of the bioburden evaluation. Testing for cytotoxicity, sensitization, endotoxins, prion/TSE, irritant, toxic and leachable compounds should be included in validation. Testing should be carried out in accordance with current requirements. The re-manufacturer should also have measures in place to guarantee that devices from various healthcare facilities or re-manufacturing lines do not cross-contaminate **[11]**.

Labelling

The packaging and usage instructions should make it apparent that the SUD is a re-manufactured replica of the original. The re-manufacturer's identifiers should be prominently displayed to ensure device

users know who re-manufactured the SUD and who to report device concerns to.

• the re-manufacturer's name, complete address, and serial number or unique identifier on the label and packing

• on the device: when applicable, the re-manufacturer's own unique identifiers

To maintain traceability of the original manufacturer's device and as part of risk mitigation, the re-manufacturer should consider including the original manufacturer's identifiers, specifically the company name, full address, and serial number or unique identifier, on the device label and packaging **[12]**.

All legal responsibilities imposed by the applicable directive must be met. Because the device is intended for single use, it shall bear the following sign when it has been re-manufactured:

Figure 2: Labelling requirement of remanufactured medical device in UK

Risk management

As part of establishing high quality systems, the re-manufacturing firm should show compliance with EN ISO 14971. Medical devices: risk management applied to medical equipment. The notified authority should examine conformity with the harmonised risk management standard. This standard outlines the criteria for medical device risk management systems, defining best practices throughout the life cycle of the re-manufactured single-use device, including a risk analysis identifying all potential hazards and related mitigation techniques **[13]**.

Post-market surveillance

SUD re-manufacturers are responsible for reporting adverse events under EU standards on a Medical Devices Vigilance System. The re-manufacturer should have a constant monitoring mechanism to identify any problems related with the re-manufactured devices and modifications the OEM makes to components, materials, or specifications within the context of quality control and as part of post-market surveillance operations. There are several options for accomplishing this:

• continual market observations or safety information (for example, Field Safety Notices) issued by the OEM

• public FDA marketing approval or safety information

• safety information from competent authorities

• information from end users

• Electrical, material, performance, and safety evaluations are performed on all devices throughout re-manufacturing.

• Manufacturing and departing goods inspections are performed on all devices.

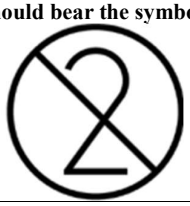
Under post-market surveillance, the re-manufacturer is responsible for managing

product safety issues associated with their re-manufactured product and any product safety notification or recall that the OEM has implemented and which has an impact on a remanufactured device.

The re-manufacturer is also expected to have post-market surveillance in place to:

- trace the re-manufactured device to the batch or serial number of the original device
- maintain a record of who was supplied with re-manufactured devices. This is to ensure any regulatory actions can be carried out quickly and effectively **[14]**.

Table 1: Comparison of remanufacturing of medical devices regulations in USFDA and MHRA

	USFDA	MHRA
Definition of remanufacturing	**Remanufacturing is the processing, conditioning, renovating, repackaging, restoring, or another act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.**	**Re-manufacturing is where a company obtains a CE mark for the re-manufacturing of single use devices.**
Technical documents	**When deciding whether an activity is remanufacturing or not, FDA recommends that the rationale for the determination be documented in sufficient detail including reference to supporting verification and validation data.**	**The re-manufacturer should prepare and maintain full technical documentation including clinical evidence.**
Labelling	**Information to facilitate routine device maintenance and repair**	**should bear the symbol** 
Risk management	**employ a risk-based approach consistent with ISO 14971: Medical devices – Application of risk management to medical devices when assessing whether an activity they perform is remanufacturing.**	**manufacturing company should demonstrate that they comply with the standard EN ISO 14971 Medical devices: application of risk management to medical devices.**
Post market surveillance	**Remanufacturer must follow requirements such as tracking systems, reporting of device malfunctions, serious injuries or deaths related to marketing remanufactured medical devices**	**Within the framework of quality management and as part of post-market surveillance activities, the re-manufacturer should have a continuous monitoring process to identify any problems associated with the re-manufactured devices**

CONCLUSION:

This article examined the different differences between adopting medical device remanufacturing in the UK and the US. Although remanufactured medical equipment save materials and resources, the remanufactured device industry must be regulated to assure the quality and safety of these goods. As a result, a regulatory framework or acceptable standards for remanufacturing medical equipment, as well as rules for their import, sale, labelling, and usage, are required. The FDA and MHRA guidelines, which were created and implemented, can reduce the possibility of damage to patients or users as a result of remanufactured device malfunction. This article is helpful to the remanufacturers who

wants to market remanufactured medical devices in US and UK to understand the guidelines required for remanufacturing medical devices.

ACKNOWLEDGMENT

All the authors are appreciated for their contribution and synthesis of the manuscript.

CONFLICT OF INTEREST

Authors declare no conflict of interest amongst themselves.

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