

Literature-based biomedical waste disposal validation



Table of contents

Abbreviations	3
Abstract	3
Background	3
Biomedical waste disposal methods in EU member states	5
Conventional waste disposal validation process and drawbacks	7
Alternative validation approach	9
Benefits	11
Conclusion	11
References	12
Authors information	13

Abbreviations

ISO	International Organization for Standardization
EU	European Union
IFU	Instructions for Use
GSPR	General Safety and Performance Requirement
WHO	World Health Organization
EC	European Commission
PPE	Personal Protective Equipment
DHF	Design History File
MDR	Medical Device Regulation

Abstract

Regulation (EU) 2017/745 had mandated several requirements for medical device manufacturers aiming to sell and distribute their products across European member states. Among these requirements is the necessity to identify and test the safe disposal method of the device itself and its accessories and consumables, as well as any related waste substances. Additionally, the Instructions for Use (IFU) of the medical device must include the validated disposal procedure. Traditionally, manufacturers have relied upon conducting the actual disposal validation exercises to address this regulatory requirement.

However, this conventional approach presents several challenges such as identifying and outsourcing a suitable vendor, non-utilization of existing resources, need for experts to govern and report the findings, higher execution cost and larger turnaround time. Nonetheless, these shortcomings can be mitigated by adopting an alternate strategy to validating the disposal method. This whitepaper proposes employing a systematic literature search to justify the regulatory requirement on safe disposal for any pre-validated disposal techniques such as the autoclave method.

Background

Regulation (EU) 2017/745 concerning medical devices was adopted by the European Union in April 2017 and took effect on May 26, 2021. The regulation imposes compliance with 23 specific General Safety and Performance Requirements (GSPRs) outlined in Annex I of the New Medical Device Regulation.

To demonstrate compliance with the GSPRs, the manufacturer must provide sufficient evidence of conformity to all relevant requirements.

Chapter II of GSPR delineates the requirements regarding design and manufacture (Clause 10 – 22). Clause 14 specifies the construction of devices and their interaction with their environment. Sub Clause 14.7 emphasizes the manufacturer to identify and validate a suitable method for safe disposal of the device and associated waste substances. Furthermore, the validated disposal procedure should be documented in the IFU.

Based on the outlined requirement, the manufacturer is tasked with developing a comprehensive framework for medical waste management and establishing a validated procedure for environmentally compatible and safe disposal of biomedical waste. The management of waste must be conducted in a manner that safeguards human health and prevents harm to the environment, particularly by:

- Avoiding risks to water, air, soil, flora or fauna resources
- Preventing nuisance through noise or odor
- Avoiding adverse impacts on the countryside or places of special interest

Moreover, waste legislation and waste management policies must adhere to the EU waste hierarchy, prioritizing the most environmentally beneficial option. However, Deviations from this hierarchy may be justified for a specific cycle, taking into account the overall impact of the waste generation and management.

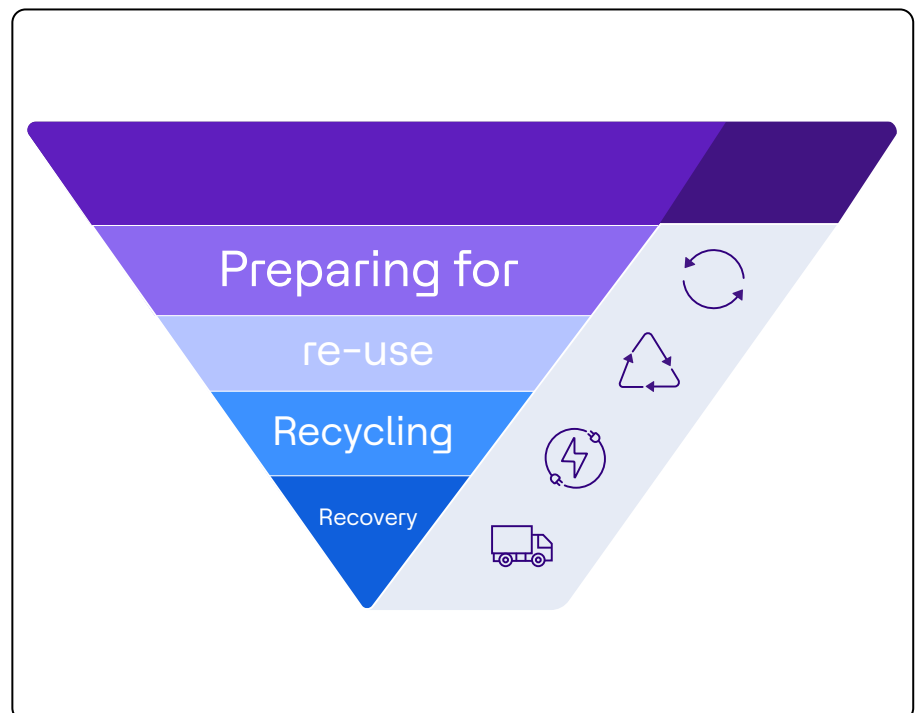


Figure 1: Waste management hierarchy

Biomedical waste disposal methods in EU member states

Healthcare fraternity across European member states employ a wide range of disposal strategies based on the waste type, access to technology and convenience. Below are the most used methods of biomedical waste disposal and management.

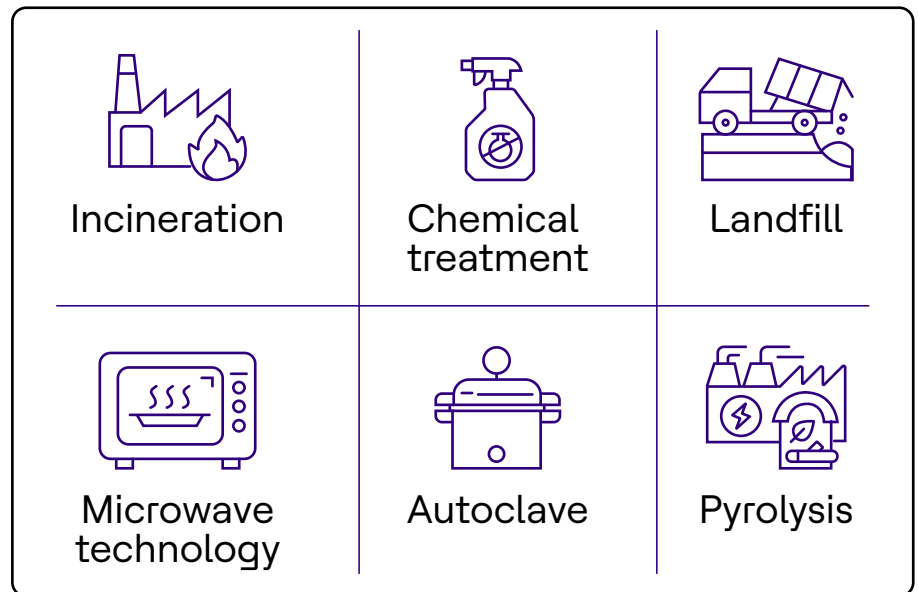


Figure 2: Biomedical waste disposal methods

- **Incineration:** Incineration refers to a high temperature, (85° C to 110° C) dry oxidation process that reduces organic and combustible waste to inorganic, incombustible matter, resulting in a significant reduction in waste volume and weight.
- **Landfill:** A landfill is an engineered site to dispose of medical and non- medical wastes. However, disposing hazardous wastes without prior treatment into a general non-hazardous landfill increases the risks to human health and the environment. Therefore, it is poor practice to dispose of hazardous waste directly into a non-engineered landfill.
- **Steam-based treatment:** Steam-based treatment technologies are used to disinfect or sterilize highly infectious waste by subjecting it to moist heat and steam for a defined period, depending on the size of the load and the content. Below are the two types of steam-based treatment:

- Autoclaving is the most common type of steam treatment that utilizes saturated steam under pressure to decontaminate waste from 121° C to 134° C.
- Microwaving technology heats the water contained in the waste with microwave energy. Waste goes through a shredder and is exposed to steam and heated to 100° C by microwave generators.
- **Chemical treatment:** Chemical treatment methods mostly leverage disinfectants. However, these methods produce toxic effluents and increase the risk of exposure to such toxins among healthcare waste-handling workers. Although, there are two exceptions to this method – ozone treatment and alkaline hydrolysis.
- **Pyrolysis:** Pyrolysis involves decomposing waste materials thermally without oxygen. Here, organic waste materials are converted into smaller molecules, gases and liquids by exposing to extremely high temperatures.

Presently, after Brexit, the EU has 27 member states and each of them has its preferred means of disposing of medical devices. The table below demonstrated the various biomedical waste disposal methods for each member state. Manufacturers can plan their optimized validation strategies based on the target market segment and region of sales.

S. No.	EU Member State	Incineration	Landfill	Steam Sterilization (Autoclave)	Other methods (chemical treatment, microwave, pyrolysis)
1	Austria	Yes	No	Yes	No
2	Bulgaria	Yes	No	No	Yes
3	Croatia	Yes	Yes	No	No
4	Cyprus	Yes	No	No	Yes
5	Czech Republic	Yes	No	Yes	No
6	Estonia	Yes	Yes	No	No
7	Finland	Yes	Yes	Yes	No
8	France	Yes	No	No	Yes
9	Germany	Yes	No	Yes	No
10	Greece	Yes	Yes	No	No
11	Hungary	Yes	No	Yes	No

12	Ireland				
13	Italy				
14	Latvia				
15	Lithuania				
16	Malta				
17	Netherlands				
18	Poland				
19	Portugal				
20	Romania				
21	Slovakia				
22	Slovenia				
23	Spain				
24	Belgium				
25	Denmark	For these member states, there are no guidelines or references available for medical waste disposal. Hence classification, segregation and disposal of medical waste as per the World Health Organization (WHO) standards can be followed.			
26	Luxembourg				
27	Sweden				



-  Represents the commonly adopted disposal methods in respective member states.
-  Represents the disposal methods not adopted in respective member states.

Table 1: Waste disposal in EU member states

Conventional waste disposal validation process and drawbacks

The conventional waste disposal validation process is resource-intensive, lasting from several hours to days, depending on the chosen method and adherence to the applicable regulation, directive or best practices in general. For instance, incineration must comply with the operational conditions, technical requirements and EU emission limit values specified in the EU Waste Incineration Directive 2000/76/EC.

The success of the disposal method depends on compliance with defined parameters such as temperature, time, pressure, concentration and more, particularly crucial while dealing with infectious waste materials – e.g., soiled disposables, contaminated PPE, etc. Regulatory requirements dictate that the chosen method ensure safe disposal for manufacturer and other intended parties like the user, patient or others.

Let us take a specific case of the autoclave method (steam sterilization- based treatment) for hazardous waste treatment.

The validation test involves distinctive steps to validate the efficiency and efficacy of the process:

- The validation test requires the use of four biological indicator strips, with one serving as a control left at room temperature and remaining three placed in the center of three containers holding the waste. Personal protective equipment must be worn while handling the containers and placing the biological indicators.
- At least one of the containers with a biological indicator should be positioned in the most challenging location for steam penetration, generally the bottom center of the waste pile.
- The occupier or operator shall conduct this test three consecutive times to define the minimum operating conditions.
- Once the temperature, pressure and residence time are determined, the occupier or operator of biological indicator vials or strips for three consecutive tests show complete inactivation of the spores, the minimum operating conditions for the autoclave will be defined.
- After determining the minimum temperature, pressure and residence time, the occupier or operator of a common biomedical waste treatment facility shall conduct this test once in three months and records in this regard shall be maintained.

Similarly, each waste disposal method described in Table 1 has its validation steps and process, but shares the following disadvantages in common:

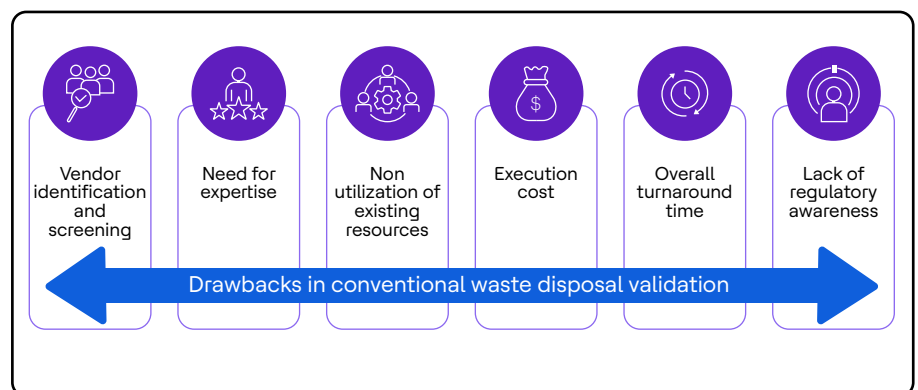


Figure 3: Drawbacks in conventional waste disposal validation

- **Vendor identification and screening:** Many disposal strategies, such as autoclave, pyrolysis and more, necessitate significant capital in equipment and machinery. Consequently, manufacturers must expend additional efforts to establish the requisite processes and procedures for identifying and screening vendors to outsource validation activities.
- **Non-utilization of existing resources:** Numerous validation articles and literature already exist for similar or identical medical products. Instead of capitalizing on this existing information, manufacturers often duplicate the entire validation process (like reinventing the wheel).
- **Need for expertise:** Dedicated subject matter experts must be assigned to oversee the entire validation process and finalize the process parameters.
- **Lack of regulatory awareness:** Many vendors within waste collection and decommissioning chains, particularly operating within underdeveloped and developing countries, are not completely aware of regulatory requirements regarding medical waste disposal in their respective geography. This lack of knowledge leads to the disposal of biomedical waste in an unregulated, haphazard manner.
- **Execution cost:** Validating a disposal method through conventional processes requires a significant investment, often as part of DHF remediation activities for MDR compliance.
- **Overall turnaround time:** The overall validation entails vendor selection and screening, creation of a waste sampling plan, waste segregation, packaging, labeling, shipping, validation testing, measurement of emission and contamination limits and generating the process parameters. Each of these processes consumes a substantial time to complete.

Alternate validation approach

Most disposal methods are already validated for the minimal optimal parameters for achieving the required amount of disinfection and disposal without affecting the environment and humans. Safe waste disposal method validation can be alternatively achieved by a technically sound and systematic literature search, utilizing established data worldwide using scientifically legit databases and journals. This method ensures compliance with regulatory requirements, such as GSPR 14.7 for medical device waste disposal.

The literature search aims to specify the identify potential data to justify chosen disposal methods. The objectives of the literature search are as follows:

- Acquire data pertinent to the target disposal methods
- Obtain information appropriate to the applicable regulation and guidance
- Procure relevant data pertinent to the disposal methods' specific functional parameters and operating conditions

A prospective literature search strategy is established to identify, screen, select, collate and review all available data systematically complying with the operational parameters of the disposal method. Multiple iterations of literature search is performed with the help of an appropriate search engine modifying the search strategy to optimize the relevant article outcome. Scientifically accepted and valid search engines can be used for systematic search, which provides access to a range of databases, e-journals and e-books. Appropriate keywords are fed into the search engine as strings or any suitable input format and search results (articles) are screened based on their suitability.

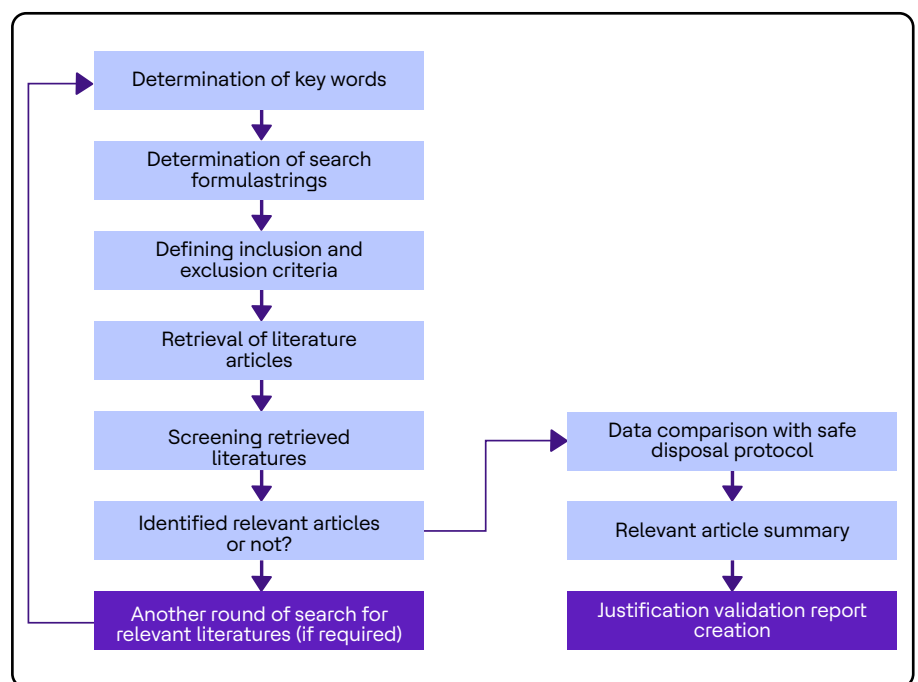


Figure 4: Literature search process flowchart

Considering an example of autoclave method validation. The literature search strategy in this case must focus on the parameters such as temperature, time, pressure and biological indicators used. By adopting the process flow described in Figure 4, the following key parameter data was obtained after a thorough screening of over 500 relevant scientific articles using a valid search engine:

- Sterilization temperature in the range of 123° C – 134° C.
- Sterilization time of 15-180 minutes.
- Pre-charge pressure of 1-20 PSI/15-34 PSI for a pre-vacuum or high-vacuum autoclave.
- Biological indicators used to test the autoclave's performance by spore testing are rapid biological indicator (3M Attest 1292) and Standard Biological indicator (3M Attest 1262). Both consist of a *Geobacillus stearothermophilus* spore strip.

Benefits

The EU MDR has been developed to emphasize device safety and efficacy right from design to disposal. Compliance to Clause 14.7 is a new requirement in the MDR, which can be demonstrated through any method. Leveraging pre-clinical and literature data instead of extensive clinical trials is a common strategy adopted in clinical evaluation. Similarly, instead of actual testing and validating a suitable disposal method, a literature-based strategy can be utilized to demonstrate the safe disposal of devices. Among other benefits, it is economical and saves a lot of time for manufacturers involved in DHF remediation activities.

Conclusion

The literature-based approach for validating waste disposal methods serves as an alternative strategy for substantiating the actual autoclave or incineration process. Through a formulated literature search procedure, potential data necessary to justify chosen disposal methods as per the operational parameters of the validation method.

Literature screening for autoclave-based disposal justification reveals alignment between functional or operational parameters like sterilization temperature, pressure and time for autoclaves identical to the parameters mentioned in the disposal directives, ISO standards and WHO guidelines.

The autoclave procedure described in the literature ensures environmentally compatible and safe disposal of infectious medical waste. Hence, the justification report drafted in accordance with scientific literature demonstrate regulatory requirements such as EU MDR 2017/745, Annex I, Clause 14.7 for safe disposal validation.

References

- Regulation (EU) 2017/745
- Safe management of wastes from health-care activities, Second edition– WHO guideline
- Guidelines for Management of Healthcare Waste as per Biomedical Waste Management Rules, 2016 (Directorate General of Health Services Ministry of Health and Family Welfare and Central Pollution Control Board Ministry of Environment, Forest and Climate Change)
- EU Waste Incineration Directive 2000/76/EC.
- <https://corpbiz.io/bio-medical-waste-recycling-plant>
- [The Waste \(England and Wales\) Regulations 2011 No. 988 \(legislation.gov.uk\)](https://www.legislation.gov.uk/uk/2011/988)

Author information



Himanshu Khandelwal

Himanshu holds a master's degree in biotechnology from Bangalore University, Bengaluru. He is a certified internal auditor for ISO 9001, ISO 13485, ISO 14001 and FSSC 22000. He has eleven years of experience in medical device sterilization with ethylene oxide, gamma radiation, electron beam, steam sterilization and cleaning and disinfection of reusable medical devices. He is currently handling medical device directive gap assessment, remediation and technical query response to medical device regulation on sterility assurance and providing technical support to various medical device sterilization and allied services.



Gayathri Devi S

Gayathri holds a bachelor's degree in biomedical engineering from Sri Sivasubramaniya Nadar College of Engineering (affiliated with Anna University). She has five-and-a-half years of experience in the Medical Device Regulatory Domain. She has worked in achieving regulatory and standards compliance for different target markets across various geos. She has performed compliance assessments and Technical File Compilation for a wide range of products (Blood bags, cardiovascular catheters, dialysis machines, blood glucose controllers, Embolization coil, Tumor localization RFID Marker, Endoscopes, ophthalmic devices, Infant Incubators and implants) for the EU, US, Chinese and ASEAN markets.



Vinega P

Vinega has a bachelor's degree in metallurgical engineering from the Government College of Engineering, Salem (affiliated with Anna University). She has four-and-a-half years of working experience in OEM (Original Equipment Manufacturing) R&D in the Automobile industry. She has expertise in failure analysis, chemical composition analysis, material compliance, new product development and manufacturing operations. In addition, she has three years of experience in the product stewardship, in material assessment for hazardous nature and evaluation of the impact on the material properties during the manufacturing process, d biocompatibility standard gap assessment and remediation as per US FDA and EU MDR requirements under the medical domain. She also supported for PFAS assessment of implantable medical devices.



Nandhini Pooja M

Nandhini has a Bachelor's degree in Biomedical Engineering from the College of Engineering, Guindy, Anna University, Chennai. She has nearly three-and-a-half years of experience in the New product development and Product stewardship in Medical Device R & D domain, especially in material assessment for hazardous nature and evaluation of the impact on the material properties during the manufacturing process, alternative material selection, biocompatibility standard gap assessment. In addition, She has handled medical device material and biological evaluation per the US FDA, EU MDR, Japan MHLW, as well as quality assurance of preclinical testing at HCLTech, Chennai. She is currently working on Eco-design of Medical device and performing Life Cycle Assessment for medical products to comply the sustainability goals.

HCLTech | Supercharging Progress™

HCLTech is a global technology company, home to 222,000+ people across 60 countries, delivering industry-leading capabilities centered around Digital, Engineering and Cloud powered by a broad portfolio of technology services and software. The company generated consolidated revenues of \$12.3 billion over the 12 months ended December 2022. To learn how we can supercharge progress for you, visit hcltech.com.

hcltech.com

