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Reprocessing & Cleaning Validation - Medistri

🚀 Reprocessing & Cleaning Validation

👉 What is Reprocessing & Cleaning Validation?

Reprocessing refers to a process carried out on a used medical device in order to allow its safe reuse. It includes cleaning, disinfection, sterilization, and related procedures, as well as testing and restoring the technical and functional safety of the used device, while cleaning validation is the process of ensuring that a cleaning procedure effectively removes any residue from the manufacturing process of a medical device and has as objective establishing evidence that cleaning processes for manufacturing equipment prevents product contamination.

Reprocessing and cleaning validation are essential processes in the medical device industry - it's critical to ensure the safety and effectiveness of medical devices. These processes help to prevent the transmission of infections and ensure that devices function as intended. Both reprocessing and cleaning validation are subject to strict regulations to ensure that they are carried out correctly and effectively.

👉 Why is the Reprocessing & Cleaning Validation important:

Reprocessing and cleaning validation are important to ensure that medical devices are safe for the intended use and reuse.
Manufacturers must ensure that their products are clean and sterile before it becomes available in a healthcare setting. On the other hand, cleaning validations specify how blood, tissues, and feces are removed from reusable medical devices during reprocessing. Cleaning validations are used to simulate "worst-case" contaminant conditions and verify that certain cleanliness levels can be met consistently following a set cleaning protocol. Ineffective cleaning processes not only lead to more downtime and batch failures, but it also results in FDA rejection and costly fines due to drug adulteration.

In Europe, reprocessing standards are governed by Regulation (EU) 2017/745 (MDR) on medical devices. In the USA, the U.S. Food and Drug Administration (FDA) became the first regulatory authority in the world to create a pathway for commercial single- use device (SUD) reprocessing in 2000. The regulation explicitly uses the term "reprocessing" when establishing requirements for the reprocessing and further reuse of single-use devices. Cleaning validation should be properly documented to demonstrate Current Good Manufacturing Practice (CGMP) for finished pharmaceuticals. It is required because Active Pharmaceutical Ingredients (APIs) cross-contaminated with chemical residues and microbes can compromise patient safety. For medical devices, AAMI ST98 is a standard for cleaning validations that provides more details on considerations for cleaning validation, including, but not limited to, validation of extraction methods, extraction efficiency requirements, TOC acceptance criteria, and justification of sample size. These standards are important to ensure that the device is safe for patient use and that there is no cross-contamination between patients.

👉 How are Reprocessing & Cleaning Validation processes done:

Reprocessing refers to a process carried out on a used device in order to allow its safe reuse. It includes cleaning, disinfection, sterilization, and related procedures, as well as testing and restoring the technical and functional safety of the used device. Medical devices intended for multiple use or single-use that are not supplied in sterile condition must be reprocessed before use in accordance with the current state of technology and science, taking account of the manufacturer's instructions and the requirements of good hygiene.

The efficacy of reprocessing methods must have been demonstrated and be transparently and reproducible guaranteed within the framework of an appropriate quality management system.
Cleaning validation is a scientific technique within the medical device sector that ensures several aspects such as the previous product traces have been removed to predetermined levels, development of a contamination-free product, safe batch-to- batch transitions, and many others.
According to AAMI ST98, some of the requirements for cleaning validation of medical devices include:

- Defining the cleaning process(es) and product(s) in the cleaning validation documentation.
- Selecting and applying test soil based on the medical device's intended use(s) and clinical condition.
- Validating the extraction methods used in the cleaning process with an extraction efficiency greater than 70 percent.
- Establishing product families based on different criteria to reduce the number of validations required by validating the master product(s) of the family.

By understanding the importance of reprocessing and cleaning validation, we can better appreciate the efforts that go into ensuring the safety and effectiveness of medical devices. Reprocessing and cleaning validation are complex processes that require a high level of expertise and attention to detail. There are many challenges involved in these processes, including the need to ensure that all residue is effectively removed from medical devices and that the cleaning and sterilization processes are carried out correctly. Despite these challenges, Medistri is continuing to invest in these processes and adhering to strict regulations so we can help ensuring that medical devices remain safe and effective for patients.

🎯 To learn more about Medistri's Reprocessing & Cleaning Validation, visit on our website at www.medistri.swiss or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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