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Radiation Sterilization of Devices and Scaffolds for Tissue Engineering

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A sterile medical device is one that is free of viable microorganisms. This can be achieved through: a terminal sterilization process, sterilization of some components, a combination of chemical/physical sterilization and aseptic processing. The choice of a sterilization process and the Sterility Assurance Level (SAL) should be addressed early in the development of the product and process design requirements in conformance with an integrated quality and risk assessment management system. For radiation sterilization, many standards are proposed to validate the process, and the substantiation of this sterile claim over time is through the dose audit process.
For the sterilization of all medical devices the most rigorous SAL (10-6SAL) should be selected and used based upon the ability of the product to function after it undergoes the sterilization process. But, many of the proposed scaffold materials do not withstand high doses to reach a 10-6SAL; so a lower SAL should be investigated on a risk based assessment, that involved the following criteria according the pretended use: Products intended to come into contact with breached skin or compromised tissue; Invasive products that enter normally sterile tissue; Products with claims of sterile fluid pathways; Surgically implanted devices; Products not intended to come into contact with breached skin or compromised tissue; Topical products that contact intact skin or mucous membranes; among others.
Sterilization by irradiation has shown a strong applicability for a wide range of products, such as single-use medical devices, tissue-based devices, combination devices, implantable devices and pharmaceuticals. Most of them are sensitive products, but, due to the new standards approaches, radiation sterilization has proven itself to be an effective and flexible method as indicated by its acceptance in the different pharmacopeias and sanitary authorities.

Country/Organization invited to participate

Argentina

Primary author: Ms HORAK, Celina (Comisión Nacional de Energía Atómica, Argentina)

Presenter: Ms HORAK, Celina (Comisión Nacional de Energía Atómica, Argentina)

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