SteriTek
Expert Sterilization Services

TRIPLE RING
technologies

Simulation of Radiation Sterilization:
Guiding Product Design

In a typical product design process, testing to ensure that the sterilization regulations are met is only performed after the product has been fully designed, built, tested, and readied for mass production. There is an inherent risk to this approach: a great deal of effort and resources have been invested in a product that may or may not make it to production, depending on the outcome of the sterilization tests.

Triple Ring Technologies

Triple Ring Technologies, headquartered in Newark, CA, is an ISO13485 certified innovative R&D company that partners with clients to deliver complex technical solutions. Founded in 2004, Triple Ring's team of scientists and engineers provides leading edge, integrated technical design, engineering, and business services. Clients include entrepreneurs, established companies, and investors in the medical device, life sciences, optics, clean technology, and digital imaging fields.

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Steri-Tek

Steri-Tek, opening in April 2016, will be a high-volume E-beam/X-ray contract sterilizer and R&D innovation center that provides on-demand sterilization, microbiology, crosslinking, and expert consultative services to the medical device, biotech, pharmaceutical and other industries. Particularly with sensitive products, Steri-Tek has developed a proprietary system for radiation-sensitive materials such as combination devices, bioabsorbables, implantables, advanced polymers and other complex products. Steri-Tek will be an ISO13485 and ISO11137 certified facility that will be FDA registered and DEA licensed, bringing over 75 years of combined medical device, biopharma and sterilization expertise to its customers.

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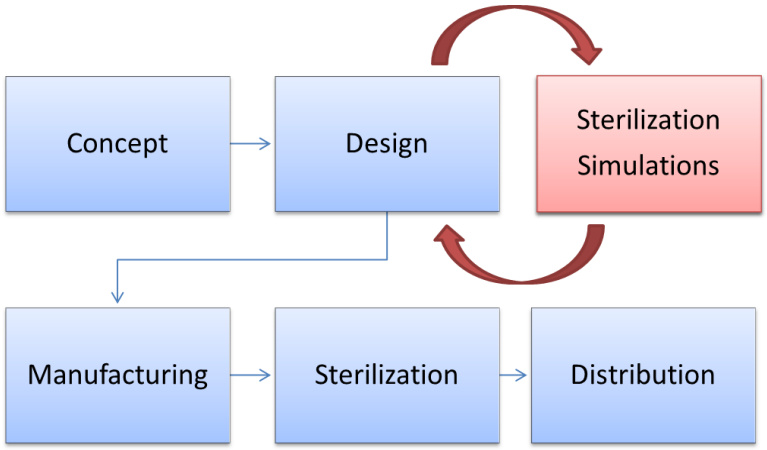
Our solution

To hedge against this risk, computer simulations can be incorporated directly into the product development process as a means to predict the outcome of the sterilization tests. Performing such simulations regularly during product development provides rapid feedback on the influence of any design changes on the dose distribution throughout the device.



For instance, what if the material of a component in the product is changed? How is the resulting dose distribution influenced? Simulations provide direct access to this information by providing a systematic way to test such design choices. In this way, the product's ability to meet the sterilization regulations can be anticipated and actively managed.

How do we do it?

Triple Ring Technologies has developed a powerful software tool capable of realistic simulations of radiation sterilization. The physics in the simulations is powered by the GEANT4 toolbox; developed at CERN, GEANT4 is the most sophisticated and accurate physics library in existence. Our tool can simulate the full three-dimensional dose distribution received by any product from gamma, electron-beam, or x-ray sources.

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