INFO SHEET

Gamma Irradiation

Benefits:
Gamma sterilization technology is very well understood, safe and easy to validate. It is the protocol of choice for Medical device manufacturers and service providers due to its:

- **Sterility Assurance and Treatment Efficacy** - Consistently meets product and regulatory requirements
- **Safety** - Proven track record in worker and product safety
- **Flexibility and Versatility** - Effectively sterilizes a wide range of products with different variations in dose requirements, densities and packaging/box sizes
- **Reliability** - The reliability and simplicity of the process is unparalleled

Gamma Irradiation

Processing via Gamma irradiation is a sophisticated technique requiring extensive knowledge of the kinetics of microbial inactivation, polymer selection and process controls, with applications ranging from medical device sterilisation, to bioburden reduction of cosmetics and packaging to polymer modification at the molecular level.

The treatment of medical devices by Gamma processing has been one of the principal methods of sterilisation in the healthcare industry since the introduction of the concept of single use, sterile, disposable medical devices in the 1960s.

This simple, proven process is safe, reliable, and highly effective at treating single-use medical devices. With the ability to penetrate products while sealed in their final packaging, Gamma sterilisation economises the manufacturing and distribution process, while still ensuring full sterility of the product.

What is Gamma Irradiation?

The radioisotope cobalt 60 is the energy source for use in Gamma irradiation plants and is manufactured specifically for this purpose. The irradiation process takes place in a specially designed cell, constructed of reinforced concrete often up to two metres thick. Cobalt 60 pellets are sealed inside stainless steel cylinders, referred to as pencils. These pencils are placed into a metal source rack located within the concrete cell. The source rack can only be in one of two positions: the storage position, which is most commonly within a deep pool of water, or in the raised operating position. During operation, the source rack is surrounded by product circulating on a conveyor or carrier system.

A key characteristic of Gamma radiation is the high penetration capability. This enables moderately dense or sealed products to be processed with relative ease and facilitates treatment of palletised product. The unit of absorbed dose is kiloGray, expressed as kGy. The absorbed dose is determined by product density, pack size, dose rate, exposure time and to some degree by plant design. The dose delivered is measured by a dosimetry system. A typical dosimetry system involves the use of Perspex to measure a colorimetric change caused by the dose.

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