Steri-Tek™
Expert Sterilization Services

Why Use Us

1. Fastest standard turnaround in the industry for all R&D, batch, and routine production: 48-hours for E-beam; our standard turnaround beats the industry average of up to one week. We also offer several expedite options.

2. Prices that are among the lowest in the industry, even with premium services included. Our 100% customer-driven culture and operationally efficient business model allows us to offer this level of exceptional value to our customers.

3. Use of our R&D Innovation Center – utilize our E-beam in Silicon Valley to design, test, and innovate to help ensure your products give you a competitive advantage.

4. Ability to schedule our sterilization experts to help with R&D, compliance, design, test, packaging, protocols, validation, and production.

5. Ability to utilize any of Steri-Tek's proprietary optimization methods specifically for your products to reduce costly product re-designs, save money, and get your product to market faster.

6. Protection and elimination of sterility risks for your entire product life cycle from concept through production; receive turnkey sterilization and validation to ensure you meet – or exceed – all ISO 11137 and SAL protocol requirements… guaranteed.

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Steri-Tek
Expert E-Beam and X-ray Sterilization Services

Steri-Tek is a high volume E-beam/X-ray contract sterilizer and R&D innovation center that provides on-demand sterilization, microbiology, cross-linking, and expert consultative services to the medical device, biotech, pharmaceutical and other industries.

The facility boasts two state-of-the-art 10 MeV, 20 KW linear accelerators, using simultaneous beam processing that allows for high volume production, providing uniform dose to the product without having to rotate the customer's boxes. This DualBeam™ configuration significantly increases efficiencies, expands product options and serves as an effective back-up for the accelerators.

This operational format offers medical device, biotech and pharmaceutical companies with:

- Scalable lot sizes (same service at any lot size or frequency of shipment)
- Fastest standard turnaround in the industry (Routine 48 hours, RUSH 24 hours and 4 hours)
- Highest up time in the industry

Steri-Tek is an ISO 11137 and ISO 13485 certified, FDA registered, DEA registered, as well as State of California Medical Device and Drug Manufacturing licensed facility.

E-beam Advantages

The relationship between the flexibility of E-Beam and the sterilization requirements for sensitive materials/complex devices is rapidly evolving to become a key advantage to manufacturers of combination products, drugs/biologics, bioabsorbables, implantables and other complex products.

These advantages include:

- Processing conditions for E-beam are easily specialized and allow for greater control
- E-beam offers more flexibility in processing of sensitive materials and drugs/biologics
- Environmentally friendly – no hazardous or radioactive materials
- Fast turnaround / high throughput time
- High reliability – high level of consistency in achieving sterilization
- E-beam delivers dose rapidly, which protects a product's function
- Low material degradation when compared to gamma
- Compatible with most types of materials (especially plastics and its packaging)
- Penetrates all types of product packaging including foils
- Allows control of temperature during irradiation
- Ease of validation

X-ray Advantages

With its advantages over almost all other current sterilization techniques, X-ray sterilization is the up and coming sterilization technique and warrants consideration both for new products and for transition of current products over gamma. Already included in ANSI/AAMI/ISO 11137 and FDA guidelines, the usage of X-ray sterilization is already approved by international regulatory bodies.

X-ray sterilization offers better penetration characteristics than either gamma or E-beam. The X-rays deeper penetration allows for this technique to be used on many products and packaging configurations that E-beam cannot. X-rays are able be used on products made of all types of materials including metals, liquids and high-density and multicomponent products. In addition, the deeper penetration allows for larger packaging configurations and pallets to be sterilized as well.

Services

Steri-Tek understands that irradiation is only part of a sterilization process. Both the product geometry in the shipper box and the shipper box count are just as important for a validated sterilization process. At Steri-Tek all production boxes are weighed, measured and labeled as a check of conformance to the original dose map and to ensure lot traceability. Boxes off-weight, or suspect in any way, are followed up by a call to the responsible party at the customer's site for disposition prior to processing.

Scalable Lot Sizes

From one box to a truckload. Process validations are applied to single shipped boxes and then are irradiated sequentially.

Validated Processing

Your finished products guarantees compliance to ISO 13485 and ISO 11137. Steri-Tek is able to sterilize medical shipper box configurations up to 76 inches long, 15 inches wide and stacked up to 48 inches tall at the highest service level.

Processing of Drugs/Controlled Substances

Steri-Tek is DEA registered and approved for the processing of controlled substances (Schedule III and higher) with restricted access and continuously monitored secured storage cages for pre- and post-processed product.

Turnkey Sterilization Validation

Steri-Tek provides turnkey Sterilization Validation packages (per ISO 11137 VDmax) for companies that wish to outsource their sterilization validation work.

Managed Validation services provide all irradiation services routinely performed for production validation, generation of original validation protocols for your approval, handling and management of needed microbiological laboratory services, completion of the validation protocol, and a final comprehensive report appropriate for the level of regulatory review associated with your product.

Validated Temperature-Controlled Rooms

Validated Cold (2C to 8C) and Freezer (-16C to -26C) temperature-controlled rooms with separate doors and areas for pre- and post-processing. Both are validated to pharmaceutical standards and maintained with remote sensors/alarms.