

The next step
in the **gamma sterilization**
of pharmaceutical
and biologic products
is here.

*Let us develop a custom plan
to help you benefit from this important,
and cost-saving, advance.*



SteriPro[®]
Consulting

A Division of
Sterigenics International, Inc.

Our solutions. Your success.



Your new product is **cutting edge**. What about your sterilization?

Advanced technology, dosimetry methods and processing capabilities now make it possible to deliver gamma radiation at very low dose rates and Gray level doses. This advance means vaccine nonproliferation, protein conformation integrity, irradiation of active pharmaceutical ingredients (APIs) to reduce bioburden, and enhancement of aseptic manufacturing to better quantify SAL are all achievable when you partner with SteriPro Consulting. For the pharmaceutical and biologic manufacturer it is a breakthrough worth knowing about... and profiting from.

Breakthrough technology... only at Sterigenics.

The company at the forefront of this advanced technology is Sterigenics International. Its high-precision ExCell® irradiator is the only irradiation cell in the world capable of delivering the precise dose tolerances required by AAMI/ANSI/ISO 11137, when using an automated carrier system.

Two ways to enjoy the benefits of irradiation.

While sterilization is a highly beneficial adjunct to aseptic manufacturing, particularly in alleviating the difficulties associated with verification of 10^6 SAL, today's advanced technology produces its greatest ROI when incorporated at the R&D stage as a replacement for aseptic processing.

For nearly a decade, SteriPro Consulting has partnered with cutting-edge gene therapy, biotechnology, biomedical, and pharmaceutical companies in the development of custom irradiation solutions.

Custom planning and process development.

All SteriPro solutions are custom solutions. Each is dependent on the customer's unique needs, products, and current processes and technical resources. Our involvement typically extends from early R&D initiatives through clinical studies, and includes: process development, site setup, requisite dosing determination, validation documentation, and regulatory support.

Pharmaceutical candidates for gamma sterilization.

Irradiation of pharmaceutical materials covers a broad spectrum of potential applications, and an equally broad spectrum of processes.

- Very low bioburden products, for example, many types of pharmaceuticals and container/closure systems, may be terminally sterilized at doses less than 10 kGy, and if previously aseptically packaged, terminal sterilization may be possible at doses as low as 5 kGy.
- Some combination products, such as pre-filled syringes that are not aseptically packaged, may require minimum doses ranging from 15 kGy to 25 kGy for terminal sterilization.
- Devices, containers and closure septa, as well as APIs, may be terminally sterilized using similar doses prior to entry into an aseptic packaging area.

Of special interest to biotech manufacturers.

Radiation processing using the high precision ExCell irradiator brings never-before speed, accuracy and flexibility to biotech product development.

Among the noteworthy breakthroughs now being applied are the following:

- Cancer vaccines that are irradiated for nonproliferation purposes are now being successfully processed.
- The functional properties of proteins are being altered in beneficial ways through radiation-induced changes in the conformation of the protein.
- Some types of hydrogels that have been cross-linked by radiation are now being successfully processed.

- Proteins are being processed without micro-heating, thus avoiding the problem of denaturing.

Knowledgeable regulatory support.

A key component of the SteriPro Consulting program is the team's significant regulatory expertise. From preparation of the initial product application through defense and approval, experienced professionals are available whenever help is needed. In addition, customers may choose a SteriPro retainer to serve as an "insurance policy" covering ongoing assistance with regulatory issues, sterility questions and FDA audit requirements.

Customers most appropriate for SteriPro Consulting services include:

- Manufacturers who desire to benefit from the significant cost- and time-savings made possible by terminal sterilization vs. conventional aseptic manufacturing.
- Those who wish to realize a better quantification of SAL by supplementing their aseptic manufacturing with terminal sterilization.
- Small or start-up manufacturers who lack the staff to perform the sterilization studies required to get a product to clinical trial or to accelerate product to market.
- Those with limited SA/QA personnel, limited technical resources, or those who cannot afford the time needed to support the sterilization process.

To learn more about radiation processing and our innovative custom solutions, please call 877.837.4523.

Our solutions. Your success.

A unique blend of consultative analysis, technical assistance and laboratory services, SteriPro[®] Consulting focuses on the clinical/development stage of a product's life cycle. This early assessment enables medical device, tissue, pharmaceutical and biologic manufacturers to devise and maintain the most cost-effective sterilization processes for their products.

Your entrée to the world-class expertise of Sterigenics International.

As a division of Sterigenics International, the global leader in contract sterilization for the medical device industry, SteriPro Consulting is proud to support its pharmaceutical and biologic clients with cutting-edge experience, know-how and technology. We stand alone in our ability to deliver the unprecedented cost- and time-saving benefits of radiation or EO processing when used as an alternative for, or an adjunct to, conventional aseptic manufacturing.



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