

## Gamma Irradiation

Although the development of serum free and protein free media formulations has increased dramatically, animal sera, specifically Fetal Bovine Serum (FBS), remains one of the most common media supplements used in cell culture today. Trypsin, a pancreatic enzyme derived from porcine pancreas, is the most commonly used cell detachment solution. The continued use of these and other animal-derived materials in cell culture has raised significant concerns regarding adventitious agents they may harbor.

The presence of viruses interferes not only with cellular studies, but also with the production of biologically active products, thereby raising regulatory issues and potential negative impacts to humans and animals. Several approaches to inactivate viruses from such biologicals have been developed, including chemical disinfectants, heat, UV light, and  $\gamma$ -radiation. However, due to the presence of biologically active components, the use of heat and chemicals would negatively impact overall performance of the material.

Gamma irradiation is a well-established process for viral inactivation of human and animal-derived products without affecting functionality. The validated procedure effectively eradicates both animal and human viruses using a Cobalt-60 source, performed at a commercial irradiation facility in accordance with 9CFR 113 Parts 46 and 47. Recognized by both the United States Pharmacopoeia (USP) and the European Pharmacopoeia (EP) as a safe, scaleable, and effective solution, Gamma Irradiation is the most trusted treatment to render biologicals virus-free.

Only gamma-irradiated trypsin is used in the manufacture of Mediatech's trypsin solutions. The process inactivates viruses, including porcine parvovirus.

Please contact your Mediatech Sales Representative for information regarding gamma irradiating serum products.