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## **Optimization of Supercritical Carbon Dioxide Based Virus Inactivation, Characterized by Protein Damage and Maintenance of Epitope Integrity in Vaccine Sterilization.**

NovaSterilis Inc., an industry leader in developing applications for supercritical carbon dioxide (SCCO<sub>2</sub>), has been awarded a Phase II SBIR grant from the NIH National Institute of Allergy and Infectious Diseases. Virus inactivation is often overlooked in sterilization, and gamma radiations fail to effectively inactivate most tested viruses at doses commonly used. The first objective of this effort will be to measure viral inactivation kinetics, study the mechanism of viral inactivation, and understand how the NovaKill™ SCCO<sub>2</sub> sterilization process can be optimized. During any sterilization process, proteins can be exposed to damage. The second objective of this project will be to study the effect of the NovaKill™ SCCO<sub>2</sub> sterilization process on model proteins, by studying structural, biochemical and functional changes in sterilized proteins, and identify sterilization conditions that reduce damage.

For this project, Dr. Julien Fey NovaSterilis Director of Research and Development is collaborating with Dr. Bryce Chackerian (University of New Mexico), Dr. Stephen Eyles and Dr. Igor Kaltashov (U. Mass, Amherst). Dr. Chackerian is a leading scientist in the development of innovative vaccines based on Virus-like Particles against chronic and infectious diseases. VLP vaccines produced in the Chackerian lab will be used as one of the model proteins for sterilization. Dr. Eyles and Dr. Kaltashov will provide key expertise in mass spectrometry, helping to determine how the supercritical process affects the structure and integrity of model proteins.

### **Current scCO<sub>2</sub> applications**

The NovaKill™ / scCO<sub>2</sub> technology is being utilized by US and International Tissue Banks to produce sterile allograft tissue in final packaging ready for transplantation. To date over 100,000 NovaKill™/scCO<sub>2</sub>-sterilized allograft transplants have been performed with no adverse reports. This sterilization technology has also been validated for sterilization of two medical devices with regulatory approval. NovaSterilis licenses processes utilizing a larger 100 liter scCO<sub>2</sub> sterilization unit, the Nova8800™, to meet the high throughput needs of larger tissue processors and medical device manufacturers. NovaSterilis' scCO<sub>2</sub> process provides the medical materials industry with a safe and effective, in house, low-cost terminal sterilization alternative.

For more information on NovaSterilis and supercritical carbon dioxide visit [www.novasterilis.com](http://www.novasterilis.com) or call 607-330-2772.