

*Combining Drug Delivery with Medical Device Technology**A Anderson**SurModics, Eden Prairie, Minnesota, USA*

Controlled, local delivery of pharmaceuticals in vivo is recognized as an efficient and effective means of treating disease. SurModics is actively developing and testing strategies to combine local drug delivery with medical devices or other implantable platforms. The intent of this approach is to provide local delivery of bioactive agents to enhance the performance or biocompatibility of medical devices or to provide local delivery of therapeutic agents which are not readily bioavailable if administered systemically. It is believed that combining drug delivery polymer matrix technology with implantable device platforms will serve as an effective therapeutic approach.

SurModics is developing a variety of drug delivery matrix materials that span both biostable and biodegradable polymer systems. We have been successful at creating systems to control the delivery of low molecular weight pharmaceuticals and are currently expanding our capabilities in the delivery of large molecules, like peptides, proteins, and nucleic acid polymers. The time profile of drug delivery from these matrices can be controlled from days to many months with changes to matrix chemistry and composition, but also processing methods.

One example of a combined drug delivery/device platform is the drug eluting stent. SurModics developed the coating for the first-to-market drug eluting stent. The coating on this stent provides three month delivery of the drug sirolimus to the wall of a blood vessel after implantation, to control the occurrence of restenosis. SurModics is also developing and testing a helical ophthalmic implant which is designed to deliver drugs to treat retinal diseases, like diabetic macular edema (DME) and age-related macular degeneration. The current version of this device is in Phase I clinical testing for treatment of DME.

In an alternative approach to controlled delivery of a pharmaceutical agent, SurModics is developing encapsulated cell technology to allow the local or systemic delivery of cell-synthesized proteins. In the first application of this now in development,

we are encapsulating islet cells with a polymer matrix so that they can be implanted in patients to treat diabetes. The polymer matrix surrounding the individual islets is designed to allow nutrients and insulin to diffuse through freely, but to keep antibodies and other proteins and cells of the native immune system from reaching the implanted islet cells. Results in animal models have been very encouraging and Phase I/II clinical implants have recently started.

SurModics is taking a variety of approaches to combine local delivery of bioactive agents with implantable devices or polymer systems. It is expected that these development activities and the resulting products will lead to novel, effective tools for improving pharmaceutical therapies.