

MedMAPSM

Medical Device Market Acceleration Program



sciessent



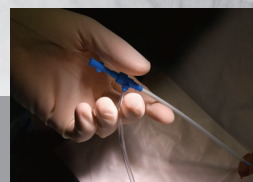
Medical Devices: The Next Generation

The market for antimicrobial treated medical devices is rapidly accelerating, driven by the desire to reduce bacterial colonization and biofilm accumulation on surfaces. The benefits of adding the antimicrobial feature have been accepted by the healthcare community including physicians, administrators and purchasing groups due to the proven performance and resulting economic savings.

Adding an antimicrobial feature to medical devices is viewed as a significant modification by regulatory bodies. Combining the expertise of the manufacturer's development team with the deep and specialized expertise of the Sciescent team of materials scientists, microbiologists, regulatory and marketing personnel can efficiently move products from concept to development, through regulatory approvals to commercialization.

Internal resources are often over-leveraged, making time to market a key concern - impacting competitive positioning, market share, and revenue. Integrating and outsourcing aspects of the development and regulatory program can prove to be the smartest course of action in today's device market.

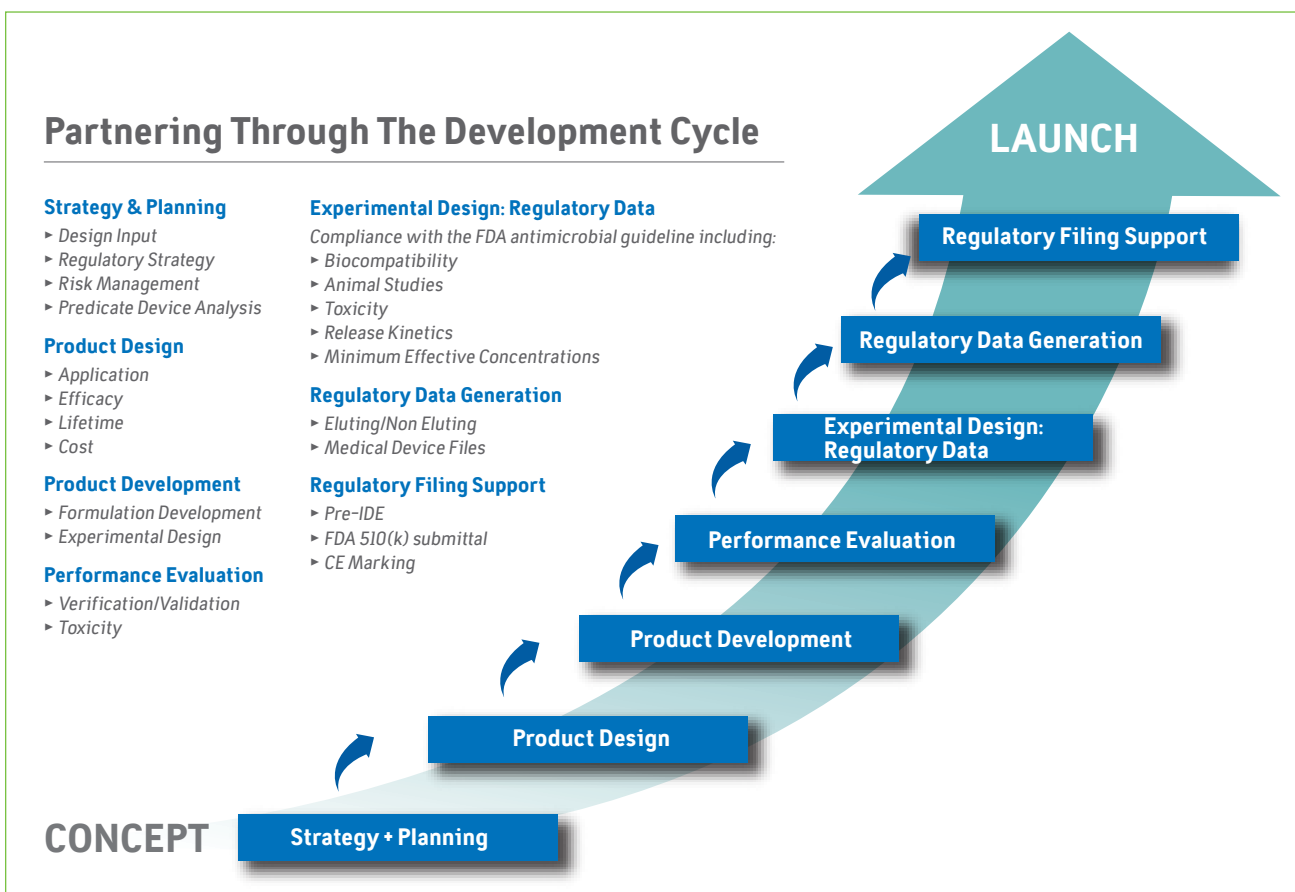
Although adding antimicrobial functionality is complex, Sciescent has a long history of partnering with manufacturers to develop, successfully file and gain global approvals for medical devices featuring the Agion branded silver-ion technology.



The Mark of Excellence

Agion inhibits the growth and propagation of bacteria on the surfaces of medical devices adding an important layer of protection to these vital products. Unlike common disinfectants and antibacterials, the Agion antimicrobial solution provides continuous protection against microbes by delivering silver ions to the surface at a slow and steady rate – for the life of the product. Working with customers from concept to implementation, through launch and beyond to brand awareness and building market demand, Sciescent delivers on a true partnership business model. Over the past 12 years, Sciescent has developed a proven track record and best practice methodologies to ensure customer success for medical device manufacturers.

MedMAP – Medical Device Market Acceleration Program



Accelerating time to market for devices with antimicrobial features is the goal of Scisessent’s MedMAP program.

Scisessent’s MedMAP program is designed specifically for medical device manufacturers – including a managed and accelerated FDA 510(k) management program. MedMAP is designed to make the launch of your 510(k) cleared medical device as seamless as possible by saving time, money and resources. Scisessent’s team of experts, an extensive catalogue of predicate devices and master device file availability combine to accelerate product development and launch.

The scope of characterization and evaluation of the device containing an antimicrobial agent depends on the type of antimicrobial, the device indications for use, and any predicate devices using the same, or similar, antimicrobial technology.

MedMAP includes product design, experimental design, formulation development, analytical and performance testing, and data interpretation support to fulfill the FDA and global requirements for medical devices containing antimicrobials. Medical devices featuring Agion branded protection that achieve FDA 510(k) clearance are allowed to be marketed in the U.S. and make the necessary documented health claims that speak to the importance of antimicrobial protection.

About Sciessent

Sciessent, located in Wakefield, Mass., is a leader in providing customized solutions that enhance the value of partners' products. Sciessent's Agion, Agion Active. And Agion Lava branded technologies are based on benign and beneficial elements and have been incorporated into a wide range of consumer, industrial and healthcare products, including apparel, footwear, keyboards, water filters, medical catheters and ice machines. Sciessent's customers include many leading brands such as Dell, Woolrich, Columbia, Adidas, Pentair, Carrier and DuPont.

For more information about Sciessent, please visit www.sciessent.com; for the Agion brand, please visit www.agion-tech.com and www.agionactive.com and follow the Agion brand's exciting consumer campaign on Facebook and/or Twitter.

Our Brands



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