



## *Ciba Expert Services*

### *CASE STUDY: Safety assessment for new medical device*

#### **Problem**

Noveko, a leading manufacturer of medical devices, wanted to market a new surgical mask that contained several plastic additives, including two antimicrobial compounds. The registration of products with antimicrobial properties can be very challenging in the US and all claims of performance, efficacy and labeling are closely scrutinized by the EPA and FDA. The safety of such articles must also be clearly demonstrated through a significant battery of analytical testing. Since the antimicrobials were being compounded into a face mask that would be worn by surgeons for up to 8 hours in a single usage, the FDA wanted to be certain that there would be no issues from volatile species and leachables that could enter the body through either the mouth or nose. The agency, therefore, requested that an inhalation study and an extractables and leachables test be performed.

#### **Solution**

Scientists from Ciba Expert Services were uniquely qualified to offer a total, one-stop solution for Noveko's issue. Toxicologists and regulatory compliance experts performed a comprehensive toxicological evaluation on the antimicrobials; filed several EPA use expansions for the antimicrobials; submitted Drug Master Files to the FDA for several of the additives contained in the mask; and ultimately defended the use of these compounds at a pre-notification meeting with the FDA in Washington, DC. The Testing Services group designed a protocol for the inhalation study and extractables and leachables testing; developed methods of analysis; and conducted the studies in accordance with GLP guidelines. The data generated provide the basis for the regulatory assessment and registration via the FDA's 510k submission process.

With the expert assistance of the Ciba Expert Services, leading surgical supply manufacturer Noveko was able to effectively bring their new antimicrobial surgical mask to market on-time and in compliance.



---

**Application/Use**

The Noveko™ 3xEZ antimicrobial surgical mask is a single use disposable device intended to be worn by medical and dental personnel to protect both the patient and the healthcare professionals from transfer of microorganisms, body fluids, aerosols, and particulate materials. As a special feature, the Noveko™ 3xEZ antimicrobial surgical mask contains a composition of Ciba® IRGAGUARD® B1000 and IRGAGUARD B-7000 incorporated into the synthetic fabric of all mask layers. By inhibiting the growth of the entrapped microorganisms from the surrounding air, this antimicrobial surgical mask may achieve above 99.9% reduction in the concentration of airborne pathogen captured on the mask in the first 30 to 60 minutes of exposure resulting in a mere transfer of 1-2% instead of the instead of the much higher values found in traditional surgical masks.

---

**Testimonial**

“Ciba Expert Services’ safety assessment was the most comprehensive document I read on the antimicrobial toxicology associated with our new Noveko Antimicrobial Surgical Mask. It was well written and clearly explained the safety aspects of the product. Moreover, the full spectrum of analytical and regulatory support allowed us to introduce an innovative new product to the competitive medical market within a year. What really surprised me was not only the excellent service but genuine dedication of the entire team - many researchers worked through consecutive weekends to overcome the challenges. Thank you for your professional assistance.”

*-- Dr. Konstantin Goranov, CTO, NOVEKO Inc.*

---

**Your Advantage**

Ciba Expert Services offers a broad range of support in highly regulated areas including Regulatory compliance, Analytical Testing, and Environmental, Health & Safety. Contact your local representative for more information.

---

© 2008 Ciba

**DISCLAIMER**

NOTHING IN THIS PUBLICATION MUST BE CONSTRUED AS A REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, OF FITNESS OF A PARTICULAR SOLUTION FOR A PARTICULAR PURPOSE. Any data or results given are based on controlled or laboratory work and must be confirmed by the Buyer by testing under its own conditions. Under no circumstances will Ciba Specialty Chemicals be liable for any damage.

**More information:**

Ciba Expert Services  
Testing Services  
540 White Plains Road  
Tarrytown, NY 10591 USA  
[www.ciba.com/expertservices](http://www.ciba.com/expertservices)

Mr. Dean Hamel  
Tel. +1 251 436 2397  
e-mail: [dean.hamel@ciba.com](mailto:dean.hamel@ciba.com)