

Niki Fidopiastis RM (NRM)

Director, Sterilization Consulting Group

Professional Experience

Niki Fidopiastis joined Sterigenics International in 1998 as the primary consultant for SteriPro® Consulting.

- In her current position, she is responsible for leading the SteriPro Consulting team in the development and management of ISO- and FDA-compliant sterilization validations for electron beam, gamma and ethylene oxide processing.
- Prior to joining Sterigenics, Ms. Fidopiastis served for nine years with North American Science Associates (NAMSA) where she held various laboratory supervisory positions.

Professional Activities

Ms. Fidopiastis is an active member of ISO/AAMI/TC 198 where she serves as a working group member of the following committees:

- WG2, Radiation Sterilization
- WG08, Microbiology Methods
- WG93, Cleaning of Reusable Medical Devices
- WG90, Microbial Quality (SAL) of Process Medical Devices.

She is also a registered Microbiologist with the National Registry of Microbiologists (ASM).

Education

Ms. Fidopiastis holds a Bachelor of Science in Biology and a Bachelor of Science in Chemistry from California State University at Fullerton.

*“My goal is to meet
the customer’s needs,
quickly and accurately,
and to have a
customer for life.”*



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Mike Rahn

Director, SteriPro® Labs

Professional Experience

Michael Rahn began his medical device career at Sterigenics International (then Griffith Micro Science) in 1994 following 13 years in the OTC pharmaceutical manufacturing industry, with experience that included various technical roles in quality, R&D and laboratory operations.

- Throughout his tenure at Sterigenics, Mr. Rahn has held positions within Quality and the Laboratory, beginning as a Corporate Quality Engineer.
- In 1997, Mr. Rahn moved to SteriPro® Labs and in 2002 was named Lab Director.

Professional Activities

Mr. Rahn is an active participant in the Association for the Advancement of Medical Instrumentation where he has served as a member of the Ethylene Oxide Engineering Task Group, contributing to the development of TIR 15, *EO Sterilization Equipment, Process Considerations, and Pertinent Calculations.*

Education

Mr. Rahn holds a Bachelor of Science in Biological Sciences from Northern Illinois University, and an MBA in Operations Management from DePaul University, Chicago Illinois. His expertise includes sterilization process development and validation, statistical process analysis, Quality System design and implementation, laboratory operations and testing methodologies.

“I particularly like the problem-solving aspect...working with customers who have specific goals targeted, but need help in attaining them.”



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