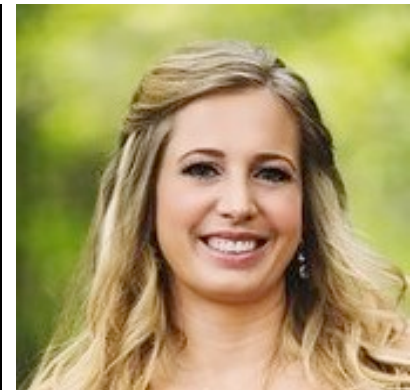


Nicole Palluck
Consultant, Ethylene Oxide

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CONSULTANT INTRODUCTION

Nicole Palluck joined Sterigenics International in 2014 as a SteriPro Consultant with focus in Ethylene Oxide (EO). She is responsibility for leading and overseeing diverse, comprehensive analytical studies on medical device and pharmaceutical based products. She has become well versed in the ISO Standards and their requirements. At Sterigenics seminars, she is a lecturer on EO sterilization topics.

Nicole has over 10 years of experience in the medical device industry and began her career working for a Fortune 500 health care services company that specializes in distribution of pharmaceuticals and medical products. While with the company she was responsible for supplier management of the company's southwest region Ethylene Oxide (EO) and irradiation (gamma) contract sterilizers.

AREAS OF EXPERTISE

- Ethylene Oxide Sterilization Validation and Requalification
Cycle design and development, cycle optimization studies, process definition and performance qualification studies, Process Challenge Device (PCD) development, D-value determination, and EO residual evaluation.
- Relative Resistance Evaluation including Product Adoption
Evaluation of new or changed products and of changes to the load configuration (including packaging). Perform comparative resistance studies for product adoption.
- Ethylene Oxide Single Lot Batch Releases
Release of small product batches used for clinical studies or research & development of new products.
- Parametric Release
Evaluate the consistency of the sterilization process to establish minimum specifications for release of product during routine sterilization.

AREAS OF EXPERTISE (continued)

- **Process Equivalency**
Evaluate validated sterilization process through examination and analysis of records associated with equipment, historical test/product data, and current test/production data.
- **Supplier Management of Contract Sterilizer**
Perform quality and technical audits for contact sterilizers (EO and Irradiation) and contract labs, analyze process deviations and develop justification for release of sterilized product, assist with customer complaints, ensure compliance with regulatory standards.

EDUCATION & CERTIFICATIONS

Bachelor of Science (BS) in Microbiology

University of Iowa, Iowa City, IA,