

Russell Gonsiorowski

Consultant

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CONSULTANT INTRODUCTION

Russell Gonsiorowski joined Sterigenics International in 2000 as a Microbiologist for the Itasca, IL laboratory. Throughout his tenure, he has held various positions within the company including EO Consultant, EO Validation Coordinator, Microbiology Technician, and Microbiology Laboratory Supervisor.

In his current role as SteriPro Consultant since 2009, he is leading ethylene oxide sterilization projects in different North America plants, supporting the facilities as technical expert and holding training sessions on EO Sterilization for Customers and Notified Bodies.

AREAS OF EXPERTISE

- Ethylene Oxide Sterilization Validation
Cycle design and development, process definition and performance qualification studies, PCD development, D-value determination, EO residues
- Product Adoption
Evaluation of new or modified products for adoption into a validated sterilization process and written technical review comparison of the candidate product and existing products or internal PCD for adoption into the product family or processing category
- Single Lot Batch Release
Performance of the requirements for the release of product from a sterilization process where there is only sufficient product to comprise a single sterilization load, for example, during research and development of new product or for clinical trial product

- Parametric Release
Assessment of the sterilization process to determine the value and tolerances for chamber humidity by direct measurement during conditioning and the value and tolerances for the EO concentration determined from direct analysis of chamber atmosphere using analytical methods to establish the process specification for routine processing

EDUCATION & CERTIFICATIONS

B.S. in Biology (1995)
Iowa State University, Ames, Iowa

Medical Device Directives and CE Mark