Annick Gillet

Director SteriPro consulting (Pharma services)

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CONSULTANT INTRODUCTION

Mrs. Gillet began his career at Sterigenics 10 years ago as Quality Manager for the Belgian Petit-Rechain plant, managing the quality system, the QC team as well as the validation team. She was in charge to review and approve validation protocols and reports. She acted as the main contact during customers and regulatory inspections (FDA, European Authorities …etc.).

SteriPro® consultant for 1 year, she's leading ethylene oxide sterilization projects in different Sterigenics plants and is supporting the plants as technical expert. She provides Specific follow-up of pharmaceutical projects.

Mrs. Gillet gets ten years of experience in Medical Device industry (wound dressings) in R&D, Quality, and consultancy.

She also worked for about two years in Pharmaceutical industry (Manufacturing of terminally sterilized hormonal Intra Uterine device) in quality department, equipment and process validation. She was SME in Sterilization.

AREAS OF EXPERTISE

- Ethylene Oxide Sterilization Validation of Medical devices or Pharma applications
  Cycle design and development, process definition and performance qualification studies, PCD development, D-value determination, EO residues
- Gas chromatography method validation
- Failure investigations

LANGUAGES

French
English
(Dutch)

PROFESSIONAL ASSOCIATIONS

A3P Pharma trade Association (France, Belgium, Switzerland, North Africa)

EDUCATION & CERTIFICATIONS

- Biochemistry Graduate _ Liège (B) IPESPA Beeckman (1993)
- DES Total Quality: FMEA- Faculté Polytechnique Mons (2005-2006)
- Certified trainer (Allergan- 2015)
- Management of Pharmaceutical Quality systems (ECA – 2014)
- Ethylene Oxide sterilization Validation - STERIGENICS (2016)

PUBLICATIONS

"Why use ethylene oxide (EO) for sterilizing medical devices" – Medical Design & Outsourcing 2016 - G. Grams / A. Gillet/ M. Padilla