

DAVY DIERICKX

Senior Manager Quality Assurance Qualification & Validation, JANSSEN PHARMACEUTICA

University degree in Applied biological sciences – IR Cell- and gene therapy

Started working for Janssen Pharmaceutica (a J&J pharma company) in 1999. Janssen Pharmaceutica has an important Research & Development and Production site in Belgium. Production is focused on Liquids & Creams, Transdermal systems and Steriles (ampoules, vials, syringes, eye drops). The steriles plant is FDA approved.

Until today held several positions:

- Quality Assurance – liquids & creams plant (non sterile): responsible for deviation & complaint handling, batch release
- Pharmaceutical Engineering – Steriles
- Qualification/Validation department: responsible for sterilization validation & media fills
- Qualification/Validation department: Manager of the Process & Cleaning Validation group – activities of this group include process validation, cleaning validation and sterilization validation
- Qualification/Validation department: Head of the Qualification & Validation department – activities of this group include Equipment & Utility qualification, process validation, cleaning validation and sterilization validation

Participated in the project to implement parametric release for our terminally sterilized ampoules. For parametric release, responsible sterility assurance engineer on the site.

