

PERSONAL INFORMATION **Nicolas Lee**

WORK EXPERIENCE

- December 2010- Present **Executive Pharmaceutical Assessor**
HPRA (Ireland)
Assessment of Medicinal Products, Clinical Trials. Quality lead for Drug-Device Combinations and HPRA lead for Continuous Manufacturing. EWG member for ICH Q13 IE delegate to QWP and member of PAT Team
- August 2008-December 2010 **Director, R&D**
Innocoll Pharmaceuticals (Ireland)
Responsible for Corporate R&D of medicinal products, medical devices and drug-device combination products
- July 2005-July 2008 **Head of R&D, Ireland**
Gerard Laboratories (Ireland)
Responsible for R&D (Ireland) of generic medicinal products
- April 2004-June 2005 **Director, Analytical Operations**
OSI Pharmaceuticals (Ireland)
Responsible for all analytical activities within OSI
- April 2001-April 2004 **Section Manager, Analytical Development**
Pathon PDS (United Kingdom)
Responsible for all analytical activities on client projects Responsible for establishing and commissioning laboratory, processes and equipment.

EDUCATION AND TRAINING

- **PhD**
Brunel University (United Kingdom)
Oxidation Profiles of ZDDPs in Hydrocarbon Solvents
- **BSc (Hons)**
Loughborough Univeristy (United Kingdom)
Medicinal and Pharmaceutical Chemistry

ADDITIONAL INFORMATION

- Expertise** Drug development/pharmaceutics/delivery Analytical and Formulation development Manufacturing and QC Stability ASMF Drug-Device Combination Products Continuous Manufacturing and PAT New technologies and their application
- Publications**
- Projects**
- Memberships** FRSC, C.Chem
- Other Relevant Information**