NSF Health Sciences Medical Devices

The right people. The right solution. The first time.™

International Services: European Expertise

NSF Health Sciences Medical Devices has European based experts that support our clients in their CE Marking and European Medical Device Training needs. Our experts have extensive professional experience in both European Regulatory agencies (Competent authority and Notified body) and EU regulated industry.

Our Services Include:

Regulatory and Clinical Services

- European regulatory body interactions
- CE Marking expertise including classification decisions and competent authority briefings
- European Clinical Trial Design, Investigation and Clinical Evaluations
- Technical file/ design dossier development and review including Regulatory Science Expert reports

Quality Systems and compliance

- ISO13485 Quality System Implementation
- Notified body audit preparation
- Supply Chain approval as part of a CE marked device
- CE Marking and ISO13485 audits
- EU safeguarding and Notified body CE marking withdrawal remediation

Training and Medical Device QARA professional qualifications

- Company-Wide Quality and Regulatory awareness modules
- Professional Certificates and Post-Graduate Qualifications in Quality Assurance and Regulatory affairs
- Lead and Internal Auditing training program
- Industry and Regulator focused Study days covering a range of Regulatory, Quality and Medical Device professional topics

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Our People

James Pink

Vice President, Europe

Mr. Pink has 16 years' experience in the medical devices industry including 10 years as a HealthCare Technology Expert and Lead Auditor for a leading European Notified body. His industry experience includes managing development and quality assurance programs for Orthopedic, Cardiovascular, Wound and Combination products. He has a team of experts based in Europe who have over 20 years' individual experience in both Competent Authority and Notified body leadership. James has coordinated and presented to EU competent authorities and expert working groups relating to classification decisions, clinical study design, scientific and technical briefings as well as EU remediation strategies.

Yvonne Middlefell, BA Hons RAC FRAPS

Executive Director

Ms. Middlefell leads our European Regulatory Strategy and Clinical services having extensive experience in Global Medical Device Regulatory Affairs. She has worked for a number of key multinational corporations. These include Amersham Nycomed, Eastman Kodak, Bausch and Lomb and a 25 year tenure at Johnson and Johnson. Her RA experience includes developing Global Regulatory strategies for IVD's, Medical Devices, OTC products, Biologics and Pharmaceuticals. Ms. Middlefell has written and filed multiple CE Technical files and US 510(k)'s for a range of products that include immunoassays, clinical chemistry analyzers, infectious disease products, contact lenses and solutions. In addition she has successfully managed a full PMA for an IVD US product submission. She was her company's primary interface with regulatory agencies and industry bodies such as AdvaMed (USA) and EDMA (EU).

For more information about NSF Health Sciences Medical Devices, visit our website at www.nsf.org/info/medicaldevices.

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LMD-704-1014