



Poul Schmidt-Andersen

Experience	Credentials
<ul style="list-style-type: none">• Have in Scandinavian conducted several voluntary inspections with respect to FDA QRS 21CFR 820• Over ten years regulatory affairs and compliance experience in the medical and in vitro diagnostic devices industry• Extensive experience in EU regulatory MDD submissions for CE-marking. (Annex II, III, IV, VI and V)• Experience in FDA regulatory submissions (510(k), PMA, IDE)• Expert in software driven device submissions under the Medical Devices Directive (MDD)• Expert in design control, complaint handling and the European Vigilance system• Provided regulatory support and defined requirements for new product development projects to facilitate compliance and effective submission for CE-marking• MDD Quality System Regulation, Design Control, Complaint Handling and General Regulatory Requirements training• Have worked with different European Notified Bodies for assessment and selection of suitable partner for medical devices manufacturer• Have in Scandinavian conducted inspections on behalf of FDA under the MRA agreement (Mutual Recognition Agreement)• Have worldwide conducted numerous inspections for compliance with the MDD quality system requirements as defined by Annex II, IV and V• Extensive experience in the review and approval of labeling and promotional materials with respect to the MDD and national laws of the EU member states.• Extensive experience in the review and approval of Annex III EC type-examination and Annex II §4 Design Dossier.	<ul style="list-style-type: none">• Passed the exam on US regulatory requirements held by FDA. 1999• Trained as FDA Medical Devices inspector between 1999 and 2001• Regulatory affairs consultant for the medical and in vitro diagnostic devices industry since 2001• Convener of the taskforce for Notified Body recommendation on Software. 1999 to 2001• Certified by FDA as a reviewer of 510(k) under the MRA agreement (Mutual Recognition Agreement) between EU and US. 1998• Vice Chairman for the European Notified Bodies between 1997 and 1999• Lead instructor on Medical Devices Directive and In Vitro Diagnostic Medical Devices Directive training courses.• Certified auditor for EN 46001:1996; ISO 13485:2003 and ISO 9001.2000• Certified auditor for GMP/QRS quality systems. AAMI/EU/US Mutual Recognition Agreement• Managing Director and CEO of the national Danish Notified Body: DGM, Danish Medical Devices Certification Between 1994 and 2001• Managing Director and CEO of S&W Medico Teknik AB. A Gothenburg, Sweden. Company owned by Vickers, PLC, UK. The company specialized in neonatal care. Between 1987 and 1994• Head of Engineering for more that 15 years in different Danish companies concerning active medical devices in class IIb..• Aarhus Technical College B.Sc in Electronic Engineering, 1964• Copenhagen Commercial College, Denmark B.Comm in Business Administration, 1974