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## Professional experience summary

**Consultancy assignments**
Update of training manual on therapeutic area, review and update of internal clinical training slides on product and disease area, review of speakers slides for international conference. Sharing experience and knowledge of the device end-user's needs, limitations and challenges as well as training strategies and needs relevant for the end-user. Compilation of Human factor study report for FDA submission.

**Device development**
Member of device development teams contributing to the target product profiles and design input requirements as well as to all other aspects of the device design. This include user and technical failure mode and effect analysis (FMEA's) and collaboration with pen developers and manufactures. Engaged in design, planning and execution of user studies and publication of the results hereof.
One of the device development team received the Red dot design award 2012 and the German Design Award Special Mention 2014 for the design and usability of a prefilled, multi dose, disposable pen

**Communication**
In charge of development of communication plans and responsible for presentation of clinical trial design and results internally as well as externally. Participating in the design and creation of intranet pages. Evaluating and reviewing local trial protocols and investigator initiated trial proposals as well as contributing to publications and review of publication drafts. Speaker at international meetings and press conferences.

Developing training manuals and material (IFU, PIL, brochures and videos) as well as material for product-, hotline - and device training.

**Training experience**
Responsible for the training of trial teams, affiliates, vendors and investigators on therapeutic areas, products, injection devices and technique, as well as post market surveillance and vigilance, protocols and CRF completion. Performing annual therapeutic area training for non-medical global staff.

**Clinical Trials**
Leading clinical trial teams and clinical sub teams within the therapeutic areas osteoporosis, post stroke cognitive impairment and tissue sealing. Designing, overseeing and reporting clinical trials from phase II to phase IV and coordinating up to 10 different clinical trials at a time within osteoporosis and rheumatoid arthritis.

Responsible for Clinical Development Plans, evaluation of new indications and in-licensing opportunities, planning and execution of investigator meetings, protocol and scientific advisory board meetings.

**Work experience**

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| **2015-** | **Independent consultant,** owner of Hyldstrup Medical, Virum, Copenhagen |
| **2014-** | **Study coordinator,** Glostrup Hospital, rheumatology research department |
| **2005-2014** | **International Medical Adviser,** Nycomed Aps now Takeda Pharmaceuticals Research and Development, Medical Marketing and Device Development |

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| **2004-2005** | **Clinical Project Manager,** Nycomed Aps |
| **1994- 2004** | **Study coordinator** at the Osteoporosis Research Clinic Aarhus Hospital, Gynecological Clinic, Anette Peen, Aarhus and Sexology Clinic, Rigshospitalet |
| **1986-1994** | M**edical and surgical outpatient wards,** Aarhus Hospital |
| **1981-1982** | **Medical and surgical wards,** Tuolumne General Hospital, California, USA. |

**Education**

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| 2015 | LEAN six sigma black belt, Compass |
| 2010 | Master of Professional Communication (MPC), Roskilde University |
| 1986 | Registered Nurse (RN), Aarhus Amtssygehus Nursing School |
| 1981 | Licensed Vocational Nurse (LVN), Columbia College, California, USA |
| **Languages** | Danish and English: full professional including medical terminology<br>Norwegian and Swedish languages: good understanding |
| **IT** | Microsoft Office 2010 & Document handling systems |

**Relevant courses**

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| 2013 | Usability and Human Factors Engineering in Drug Delivery Products workshop, Management Forum |
| | Effective Stakeholder Management, Matchett |
| | GCP refresher |
| | Professional Communication Seminar |
| | Post marked surveillance and vigilance of medical devices, Delta Device academy, DTU |
| 2012 | Medical Oversight in Clinical Trials Course |
| 2009 | SharePoint server 2007 3-day course |
| | Boye Intranet-day (including presentation on intranet sites and collaboration) |
| | Building value into the Product Development Process, 2 day course |
| | Patient Reported Outcomes (PRO) |
| | Health Economics, 2-day course |
| 2008 | Statistic for the non-statisticians |
| 2006 | Int. Osteoporosis Foundation (IOF) Advanced Training Course on Osteoporosis |
| | Statistics in clinical drug development Part I |
| | Injection Device Course, development, TPU |
| 2005 | Project management and project participation. The Competence Center |
| | GCP advanced Brookwood International Academy |

**References** Upon request