

CURRICULUM VITAE



PERSONAL DATA

Anne Sørensen (131268)

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PROFESSIONEL EXPERIENCE

2014 Oct. Senior GxP Consultant, Pharmac
2010 Apr. Head of Production, Region Sjælland Sygehusapoteket (Region Zealand, Hospital Pharmacy)
2007 Feb. Director, Quality Assurance. Qualified Person. Egalet a/s
2003 Jan. Director of Analysis and QA/QC and Qualified Person. Egalet a/s
2002 Feb. Manager of Analysis and QA/QC and Qualified Person. Egalet a/s
1997 Jan. Production Manager Non sterile liquids at Leo Pharma.
1995 Jan. Head of section Tablet Production at Leo Pharma
1994 Oct. Pharmacist in Finished Product Packaging at Leo Pharma
1993 - 1994 Pharmacy Technician at Nærum Pharmacy

EDUCATION / EXAMS

1994 Aug. Master of Science in Pharmacy
1994 Accomplishment of Masters Thesis at AstraZeneca, Sweden
Title: Studies of drug release and drug loading from hydrophilic polymers
1989 Jun. The Royal Danish School of Pharmacy
1987 Jun. Næstved State School
High school graduation, A-level, the mathematical-chemical side

COURSES / TRAINING

2016 May Cleaning validation strategy, techniques and regulations, Key2Compliance, Copenhagen
2015 Dec. Mettler Toledo GWP and minimumweighing training, Denmark
2015 Nov. GMP latest news, Pharmakon a/s, Denmark
2015 Feb. GMP in the laboratory, Mads Friis Sørensen, Pharmac at Riemann A/S Hillerød
2014 Dec. ICH Q7 Compliance for APIs (including special session on APIs Manufactured by Cell Culture/Fermentation, ECA, Berlin
2014 Nov. GMP latest news, Pharmakon a/s, Denmark

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- 2013 Nov. GMP latest news, Pharmakon a/s, Denmark
- 2013 Jun. Contamination Control in clean rooms, GMP requirements and industrial practice (EU and FDA), Key2Compliance, Copenhagen
- 2013 Jan. LEAN and Strategy Map, Lars Dyrby Johansen, Management Consultant - Valcon
- 2012 Nov. Strategic communication and Culture development, Region Zealand, Denmark
- 2012 Okt. Introduction to Quality Risk Management jf. EU GMP Vol IV Part III, Hjorth Kvalitetsudvikling, Denmark
- 2011 Nov. Manufacturing and Validation of Sterile Drugs, Pharmakon a/s, Denmark
- 2011 Mar. Support for the process of change - a leadership development for managers in Region Zealand (3x2 days)
- 2010 Mar. Hands on Risk Assessment with Case Studies. IFF. Symbion Denmark
- 2009 Nov. Workshop on An Incremental Approach to GMP from early to late phase Product Development including Responsibility for Release of Clinical Batches. IFF. Symbion Denmark
- 2009 May Workshop CAPA, IFF and Karen Ginsbury, Symbion Denmark
- 2009 Feb. Change Control Management, IFF and Karen Ginsbury, Symbion Denmark
- 2009 Jan. GMP – trends, IFF and David Begg Associates, Symbion Denmark
- 2008 Nov. Recommendations on how to apply ICH Q8/Q9/Q10 during audits, Key2Compliance, Copenhagen
- 2008 Sep. Validation and Qualification Compliance Requirements, Key2Compliance, Copenhagen
- 2007 Nov. Management of clinical trials - GMP meets GCP, ECA, Berlin
- 2007 Okt. ICH Quality Guidelines Q1-10 an overview, Pharmakon a/s, Denmark
- 2007 May Practical Approaches to Global GMP for Investigational Medicinal Products, Key2Compliance, Stockholm, Sweden
- 2005 May Role of the European Qualified Person, IIR, London
- 2005 Mar. The Mechanics of Preparing INDs & NDAs & FDA Regulations, The center for Professional Advancement, Amsterdam
- 2004 Sep. NLP – the road to self-management, DIEU, Denmark
- 2004 Apr. Contract Manufacturing, Pharmaceutical post graduation course, Hillerød
- 2003 Mar. The role of the Qualified Person in EU Clinical Trials, IIR, London
- 2002 Sep. Stability Documentation, Pharmaceutical post graduation course, Hillerød
- 2002 Apr. Quality Assurance and GMP in Clinical Trials manufacture and supply, David Begg, York
- 2002 Apr. Workshop on GCP inspection and audit, Pharmaceutical post graduation course, Hillerød
- 2001 Nov. Economics for the non-economist, Teknologisk Institut, Denmark
- 2001 Okt. GMP Compliance Auditing, John Lee, Novo Nordisk
- 2000 Feb. Managing Production Teams, Modul I & II, DI
- 1999 Jun. Cleaning Validation, Symbion
- 1999 Mar. Cleaning Validation, Pharmaceutical post graduation course, Hillerød
- 1999 Mar. Pharmaceutical Packaging and End product use, David Begg, Denmark
- 1999 Feb. cGMP Interpretation and Application, John Lee, Novo Nordisk

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SCIENTIFIC CONFERENCES/WORKSHOPS

- 2014 Mar. EAHP Congress (European Association Hospital Pharmacists), Barcelona
- 2012 Mar. EAHP Congress (European Association Hospital Pharmacists), Milan
- 2009 May Speaker presentation ISPE Baseline Guideline Vol. 12 and FDA Process Validation, IFF Copenhagen
- 2009 May Speaker presentation ASTM E2500 standard, Risk based Verification, IFF Copenhagen
- 2009 Feb. Workshop Change Control/Management, IFF Copenhagen
- 2009 Jan. Workshop GMP-trends, IFF Copenhagen
- 2008 May Workshop CAPA, IFF Copenhagen
- 2006 Apr. Integrating Development and Manufacturing , ISPE Copenhagen conference
- 2004 Oct. 4th Annual Life Science Symposium, Process Analytical Technology, Copenhagen
- 2003 Dec. Information Day, Danish Medicine Agency
- 2003 Nov. ISPE Nordic Annual Meeting, Copenhagen
- 2002 Sep. Inspectorate Information Day, IMB, Ireland