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CURRICULUM VITAE

Name: Margareta Svensson

Address: TFS Trial Form Suport AB
Box 165
SE-221 00 Lund
Sweden

Date of Birth: 1957-04-02

CURRENT POSITION

Date (most recent on the top)

Senior Safety Manager/Team Leader Drug Safety — 2004-05-01 -

EDUCATION

Date

Master of Science in Pharmacy, Uppsala University, 4 years — 1978 - 1982

CLINICAL RESEARCH EXPERIENCE (previous)

Date

Safety Manager, AstraZeneca — 1998 - 2003

Handling of AE/SAE in studies and post-marketing. Writing PSURs and other safety reports. Training of staff.

CLINICAL RESEARCH EXPERIENCE (TFS project)

Date

Clinical Drug Safety, including safety section in protocol and report writing
Handling of AE/SAE in clinical studies and post-marketing
Coding
Regulatory Affairs — 2004 -

RELEVANT PROFESSIONAL EXPERIENCE

Date

Safety Manager, AstraZeneca — 1998 – 2003
Product Manager, Astra Sverige — 1985 – 1998
Representative/Product Specialist, Draco/Tika — 1982 - 1985

THERAPEUTIC AREA

Date

Have been involved in many/most therapeutic areas, for example:
Respiratory — > 20 years
Gastro-Intestinal — > 10 years
Oncolgy — > 5 years
Infection — > 5 years

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COMPUTER SKILLS

Date

Word, excel, power point, access, ARISg, EudraVigilance EVWEB application

LANGUAGE QUALIFICATIONS

Date

Swedish (native), English (excellent)

OTHER MERITS

Date

2014 Risk Managment Plan (included in the course Basic in Pharmacovigilance), LÄkemeddelsakademin, Stockholm, 13 November 2014 (speaker)

2013 2nd Nordic Pharmacovigilance Conference, Helsinki, Finland, 29 January 2013

2012 Author of the chapter on adverse event reporting in the book "Handbok i genomförande av en klinisk prövning" (Handbook in the implementation of a clinical trials), Studentlitteratur, 2012

2011 Pharma Package - Pharmacovigilance in the Nordic Countries beyond 2012, Läkemdelsakademin, Stockholm 11 October 2011

2010 Clinical Trials, IBC Euroforum, Stockholm 17-18 March 2010 (Speaker of the subject "Adverse event reporting in clinical trials")

2009 Medical devices, TFS Academy, 02 June 2009, 1 day

2009 Electronic reporting of SAEs and the EudraVigilance System (included in the course Pharmacovigilance), IBC Euroforum, Copenhagen 30 April 2009 (Speaker).

2009, 2010, 2011, 2012, 2013, 2014 Periodic Safety Reports (included in the course Basic in Pharmacovigilance), Läkemedelsakademin, Stockholm, 01 April and 14 October 2009, 13 October 2010, 06 April and 16 November 2011, 14 November 2012, 29 May and 20 November 2013, 09 April and 12 november 2014 (Speaker)

2008 EudraVigilance User Training Course, EMEA, London, 17-19 September 2008

2008 GCP Good Clinical Practice Basic, TFS Academy, 27 May 2008, 1 day

2008 Audit and Inspections, TFS Academy, 27 May 2008, 1 day

2007 – 2011, Pharmacovigilance, TFS Academy, 1-day course held 1-4 time/year (Speaker)

2006 Pharmacovigilance, IBC Euroforum conference, Stockholm, 5-6 December 2006. (Chairman and speaker).

CURRICULUM VITAE

2006 Risk-Management Plan, IBC Euroforum Workshop, Stockholm 4 December 2006

2005 Grundkurs i Regulatory Affairs (Basic course Regulatory Affairs), Läkemedelsakademin, 2,5-day course

2004 Adverse Event Reporting & Pharmacovigilance, IIR, Stockholm (Chairman one day). 3-day conference.

2003 "Biverkningshantering" (Handling of Adverse Event), Apotekarsocieteten, Stockholm (Speaker). 1-day.

2001-2004 Good Clinical Practice course, AstraZeneca. Speaker of AE/SAE-handling, 2/year.

2002 "Chefskörkortet", AstraZeneca. 5-day course.

2002 Signal generation, Management Forum. 1-day.

2001 Periodic Safety Update Reports, Management Forum. 1-day.

2000 MedDRA, Essential and Coding, MSSO. 1-day.

2000 Läkemedelsepidemiologi (Epidemiology), SLEF. 2-day course.

1999 Good Clinical Practice, AstraZeneca. 2-day course.

1999 Rapportering av läkemedelsbiverkningar (Reporting of adverse drug reactions), Apotekarsocieteten. 1-day.

1998-1999 Läkemedelsbiverkningar; epidemiologi och klinik (Adverse Drug Reactions; Epidemiology and Clinic). Step 1 (4 days) and 2 (4 days), Medical Products Agency.

1999 Advanced english, Folkuniversitetet. 14 weeks.

1992 Project leading, AstraZeneca. 2-days.

1986 Läkemedelsvärdering (Drug evaluation), Apotekarsocieteten. 5-day course.

1986 Klinisk läkemedelsprövning (Clinical trials), Apotekarsocieteten. 5-day course.

1982 LIFs medicinska grundkurs (Medical basic course). 3 month course.

Date: 02-Mar-2015 Signature: .....

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CURRICULUM VITAE

Personal data

Name: **Anna Karlsson**
Birthday: **710202 – 0307**
Present employment: **Manager Regulatory Affairs**

Summary

7 years experience as a Medical Secretary/Secretary to the Management Group.

(Uppsala University Hospital).

1 year experience of being an Assistant to the President, CEO. (Orexo AB).

13 years of experience within Regulatory Affairs, with product development, maintenance and adverse event reporting.

Earlier employments

ICA-Krysset in Almunge

ICA-Knuten in Knutby – First responsible person for the colonial department, fruit & vegetable department and later on for the charcuteri department.

Employments

Medical secretary	Uppsala University Hospital	1994 - 1999
- " -	Knutby Health Care Centre	1999
- " -	Norrtälje Hospital	1999
Secretary to the Management Group	Department of Anaesthesiology and Surgical Institution at Uppsala University Hospital	2000-2001
Assistant to the President, CEO	Orexo AB	2001-04 to 2001-10
Assistant Regulatory Affairs	Orexo AB	2001-11 to 2003-06
Associate Manager Regulatory Affairs	Orexo AB	2003-07 to 2007-03
Manager Regulatory Affairs (Ongoing)	Kibion AB	2007-03 to
Deputy QPPV (Ongoing)	Kibion AB & Orexo AB	2009-06 to

Education

Distribution- and office Education	Senior High School	1988-1989

Medical Secretary Education (Health documentation)	Post Senior High school	1993-1994
IT-Support Education	Community University	1998
Basic course in Business Laws	Post Senior High school	1999
Business Economics A and B	Post Senior High school	1999

Training

Introductory course in Regulatory Affairs	Läkemedelsakademin	2002
Basic course in Regulatory Affairs	Läkemedelsakademin	2002
Internal Education in Regulatory Affairs	Sinéad Breen, Director	2002
Internal Education in Clinical Trials	Katarina Andersson, Manager	2002
Education in maintenance product process	Läkemedelsakademin	2002
Biotech Content Management Workshop and document Management System	First Consulting Group - John Wise	2003
Pharmacovigilance	Läkemedelsakademin	2003
Basic course in Pharmacology	Annelie Svensson, BMC	2003
Education in the English language, 2 hours per week	Cross Cultural International Group (Eddie Farrelly)	2001-04 to 2003-06
Introduction/preparation for FDA-Meetings and Registrations Procedures	Biologics Consulting Group - Karin Sewerin	2004
Pharmacovigilance – Wisper (Database for pharmacovigilance)	Transmed – Solveig Andréen	2004
The Clinical Program in Regulatory Affairs Perspective	Läkemedelsakademin	2004
Establishing product document's	LIF –Johan Eklund	2004
Advanced course in Exceel	QD-System AB	2004
Introduction to Clinical Trial's	Läkemedelsakademin	2005
Eudravigilance-database	EMEA	2005
The New Medical Legislation	Medical Products Agency	2005
The Pharmacovigilance Day	Medical Products Agency	2006
Pharmacovigilance	Läkemedelsakademin	2006
Education in the English language, 2 hours per week	BBi Språkproducenterna AB, Mr Gwyn Williams	2006
Variations – Variation Applications within Regulatory Affairs	Läkemedelsakademin	2007

Negotiation technique	MarketWatch Management A/S, Denmark	2008
Presentation of the Quality System & Documentation at Orexo AB	Anne-Marie Ciupitu, Head of QA/QC Orexo AB	2008
Pharmacovigilance symposium	Medical Products Agency	2009
Basic course in communication with NLP; (Neuro-Lingvistic Programming) – Influence by communication	Peder Wroldsen, Interaction Consulting Group, Norway & Anna Pia Hellstedt, Heart in Business, Sweden	2009
Variations within Regulatory Affairs	Läkemedelsakademin	2009
Pharmacovigilance symposium	Medical Product Agency	2010
The Medical Device Directive	Medical Product Agency	2010
The Medical Device Directive	Swedish Standards Institute – Stockholm	2010
Quality System for Medical Devices	Swedish Standards Institute – Stockholm	2010
Internal Audits for Medical Devices	Swedish Standards Institute – Stockholm	2010
Risk Management for Medical devices, essential requirements	Swedish Standards Institute – Stockholm	2011
Risk Management for Medical devices, advanced practical applicability	Swedish Standards Institute- Stockholm	2011
Pharma Package – Pharmacovigilance in the Nordic Countries beyond 2012	Medical Product Agency	2011
FASS-business competence test for administrators using the FASS-tool.	IT-based test (FASS.se, LIF)	2012
Pharmacovigilance symposium	Läkemedelsakademin	2012
Education in using the PV-system - ArisGlobal	TFS (Trial Form Support) in Lund	2012
What about drugs and Med Tek	Medical Product Agency 2013 (TOPRA- meeting)	
Terms and regulatory issues	Medical Product Agency (together with Uppsala BIO)	2013
Pharmacovigilance from a Regulatory perspective	Medical Product Agency (TOPRA- meeting)	2013
Variations from a Regulatory perspective	Läkemedelsakademin	2014

GDP-education	Internally at Kibion AB	2014

2014-12-03 .....

Date **Signature**