

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

Master of Science in Pharmacy, Uppsala University, 4 years

Date
1978 - 1982

CLINICAL RESEARCH EXPERIENCE (previous)

Safety Manager, AstraZeneca

Date
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)

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

Date
2004 -

RELEVANT PROFESSIONAL EXPERIENCE

Safety Manager, AstraZeneca
Product Manager, Astra Sverige
Representative/Product Specialist, Draco/Tika

Date
1998 - 2003
1985 - 1998
1982 - 1985

THERAPEUTIC AREA

Have been involved in many/most therapeutic areas, for example:
Respiratory
Gastro-Intestinal
Oncology
Infection

Date
> 20 years
> 10 years
> 5 years
> 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 Management Plan (included in the course Basic in Pharmacovigilance), Läkemedelsakademin, 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, Läkemedelsakademin, 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).

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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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