

CURRICULUM VITAE

Name: Margareta Svensson

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

Date of Birth: 1957-04-02

<u>CURRENT POSITION</u>	Date (most recent on the top)
Senior Safety Manager/Team Leader Drug Safety	2004-05-01 -
<u>EDUCATION</u>	
Master of Science in Pharmacy, Uppsala University, 4 years	Date 1978 - 1982
<u>CLINICAL RESEARCH EXPERIENCE (previous)</u>	
Safety Manager, AstraZeneca	Date 1998 - 2003
Handling of AE/SAE in studies and post-marketing. Writing PSURs and other safety reports. Training of staff.	
<u>CLINICAL RESEARCH EXPERIENCE (TFS project)</u>	
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 -
<u>RELEVANT PROFESSIONAL EXPERIENCE</u>	
Safety Manager, AstraZeneca	Date 1998 - 2003
Product Manager, Astra Sverige	1985 - 1998
Representative/Product Specialist, Draco/Tika	1982 - 1985
<u>THERAPEUTIC AREA</u>	
Have been involved in many/most therapeutic areas, for example: Respiratory Gastro-Intestinal Oncolgy Infection	Date > 20 years > 10 years > 5 years > 5 years

CURRICULUM VITAE

COMPUTER SKILLS

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

Date

LANGUAGE QUALIFICATIONS

Swedish (native), English (excellent)

Date

OTHER MERITS

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

Date

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 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 (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).

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

CURRICULUM VITAE

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:.....

2014-03-25

Signature:.....



