SIF ORMARSDÓTTIR, MD, PHD
CURRICULUM VITAE

Personal details

Name:
Sif Ormarsdóttir

Education:

- Cand. med. et chir, University of Iceland 1988
- Foreign medical graduate examination in the medical sciences (FMGEMS) and the English Language (ECFMG)
- Basic medical sciences examination completed 1988 and Clinical sciences completed 1989
- PhD, University of Uppsala, Sweden 2001
- Diploma in Pharmaceutical Medicine (corresponding to 20 weeks full time studies), The Karolinska Institute 2004
- Completed MBA course "Organisational Behaviour", Edinburgh Business School 2014

General physicians license 1990

Board certification Internal Medicine 1996

Board certification Gastroenterology and Hepatology 1998

Professional experience

Current position:

- Member, NDA Advisory Board
- Consultant, Dpt. Gastroenterology and Hepatology, University Hospital, Iceland
- Private practice as gastroenterologist, Læknasetrid Mjódd, Reykjavik, Iceland

Previous positions:

- Associate Director, Liver Safety Expert Physician, AstraZeneca, Sweden (50%) 2011 – 2016
- Global Safety Physician, AstraZeneca, Sweden (50%) 2011 – 2016
- Consultancy since 2016; AstraZeneca, Pfizer
- Senior Medical Officer 2007-2010, Icelandic Medicines Agency, Reykjavik, Iceland

- Senior expert, Icelandic Medicines Agency, Reykjavik, Iceland 2003-2006
- Private practice as gastroenterologist, Læknasetrid Mjódd, Reykjavik, Iceland 2004-2010
- Company doctor NimbleGen Systems of Iceland Inc 2009-2010
- Clinical assessor, Medical Products Agency, Uppsala, Sweden 2001-2003
- Consultant, IBD Unit, Sophiahemmet, Stockholm, Sweden 2002-2003
- Consultant, Dept. Gastroenterology and Hepatology, Akademiska University hospital, Uppsala, Sweden 1998-2001
- Specialist training in Internal Medicine and Gastroenterology and Hepatology, Akademiska University Hospital, Uppsala, Sweden (including rotation at Dept's Endocrinology, Tumour endocrinology, Cardiology, and Infectious diseases) 1992-1998
- Internship and residency, Landspitali University Hospital, Iceland and Länssjukhuset Kalmar, Sweden 1988-1991
- Member of the Expert Advisory Committee, Icelandic Medicines Agency 2003-2010
- Member of the Committee for Medicinal Products for Human Use (CHMP) at
- EMA 2004-2010
- Member of the Scientific Advice Working Party (SAWP) at EMA 2004-2010
- Member of the Efficacy Working Party (EWP) at EMA 2004-2008
- Chair Gastroenterology Drafting Group at EMA 2010
- Member of Steering Committee for Clinical Guidelines, Directorate of Health,
- Iceland 2004-2010
- Chair working group for clinical guidelines on dyspepsia, Directorate of Health, Iceland 2004
- Chair and clinical lead, Hepatotoxicity Safety Knowledge Group, AstraZeneca 2011 - 2016
- AstraZeneca representative on IMI SAFE-T consortium 2011 - 2015 (DILI WP3 co-lead and member of the Steering Committee)
- Main author of AstraZeneca´s Safety Biomarker Strategy 2016 – 2020
- Teaching position (50%) for medical students, Faculty of Medicine, University of Uppsala,
- Sweden 1994-1995, 1997-1998, 2000-2001; theoretical and clinical, including Problem Based Learning (PBL)
- Lectures in Gastroenterology at the Faculty of Pharmacy and the Faculty of Social Sciences 1995-2001

Area of Expertise

Clinical background in general medicine with a special interest and in-depth knowledge of internal medicine, gastroenterology and hepatology

- Expert knowledge and experience in liver safety (drug-induced liver injury) at all stages of drug development, including forward and reverse translation of pre-clinical liver toxicity issues and liver safety biomarkers
- Detailed knowledge of the European approval system including the European Medicines Agency (EMA).
- Design of clinical development plans: Scientific and strategic aspects
- Routine pharmacovigilance, including RMP, PSUR/PBRER, DSUR preparation

Scientific regulatory speciality

Gastroenterology, hepatology, internal medicine (endocrinology in particular)

Major projects

- 2001 – 2010: Clinical Assessor involved in the evaluation of registration of new medicinal products in gastroenterology, osteoporosis and respiratory diseases at the European and national level
- 2001 – 2010: Clinical Assessor involved in the evaluation of scientific advice both at the European and national level
- 2004 – 2010: CPMP/CHMP Member and SAWP member, EMA
- 2004-2008: EWP member, co-ordinator for three scientific guidelines in the field of gastroenterology
- Chair and clinical lead, Hepatotoxicity Safety Knowledge Group, AstraZeneca 2011 - 2016
- AstraZeneca representative on IMI SAFE-T consortium 2011 - 2015 (DILI WP3 co-lead and member of the Steering Committee)
    - Main author of Briefing books submitted to EMA and FDA, face to face meetings with SAWP and FDA on behalf of the consortium
- Main author of AstraZeneca´s Safety Biomarker Strategy 2016 – 2020
- Global Safety physician for a fixed combination product as well as early stage oncology products

Associations

- Member of the Icelandic Medical Association
- Member of the Icelandic Society of Gastroenterology
- Member of the European Association for the Study of Liver Disease
- Member of the American Association for the Study of Liver Disease

Publications

Full list of publications available on request