Professor Steffen Thirstrup
CURRICULUM VITAE

Personal details

Name	Steffen Thirstrup
Education	MD, PhD

Professional experience

Current position

- Member, NDA Advisory Board
- Adjunct Professor University of Copenhagen, Faculty of Health Sciences, School of Pharmacy

Previous positions

- 2012-2013, Head of Division Medicines Assessment and Clinical Trials Danish Health and Medicines Authority
- 2011-2012, Director of Licensing Division Danish Medicines Agency
- 2009-2011, Head of Institute for Rational Pharmacotherapy Danish Medicines Agency
- 2004-2009, Chief Medical Officer Danish Medicines Agency
- 2003-2004, Specialist Registrar (Internal medicine), Department of Respiratory Medicine, H:S Hvidovre Hospital, Denmark
- 2001-2003 Specialist Training in Internal medicine: Respiratory Medicine, Nephrology and Geriatrics (Senior House Officer), H:S Hvidovre Hospital, Denmark
- 2000-2001 Medical Officer, Institute for Rational Pharmacology, Danish Medicines Agency
- 1999 Senior House Officer, Department of Gastroenterology and Hepatology, University Hospital Aarhus, Denmark
- 1995-1998 PhD study at The Institute of Pharmacology, University of Aarhus, Denmark
- 1993-1995 Basic Medical Training (House Officer)

Areas of Expertise

- Clinical background in general internal medicine with a special interest in respiratory medicine
- In-depth knowledge of clinical pharmacology and therapeutics

- Detailed knowledge of the European approval system including European Medicines Agency (EMA).
- Clinical documentation requirements to support European Clinical Trial Applications (CTA) and Marketing Authorisation Applications (MAA)
- Regulatory aspects during Post-authorisation phase including variations, line extensions as well as routine and urgent pharmacovigilance issues
- Design of clinical development plans: Scientific and strategic aspects
- Biosimilars
- Advanced Therapies (cell and gene therapies and tissue engineering)
- Pharmacogenomics, biomarkers and personalised medicine
- Detailed knowledge of the Danish health technology assessment and drug utilisation of new medicinal products
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Scientific specialty

- Pharmacology, clinical pharmacology, Respiratory area, Biosimilars

Major projects

As Regulator

- 2004-2009 CHMP member, EMA
- 2005-2009 BioSim: Active participant on behalf of the Danish Medicines Agency in the network of excellence financed by the European Commission under its 6th framework program
- 2008-2009 CAT member, EMA
- 2009-2013: Protect: Key scientific contact for the management entity of the IMI beneficiaries for the PROTECT collaboration (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium).
- 2011-2013 Chair-person of the CHMP Respiratory Drafting Group
- 2011-2013 Co-Chair-person of EC Working Group on Market Access of Biosimilars under the EU Platform on Market Access of Medicines in EU

Associations

Danish Doctors Association (Lægeforeningen), Danish Society for Clinical Pharmacology

Publications

Publications and conference presentations on aspects of Pharmacology and Regulatory Affairs of medicinal products.
The complete list can be provided upon request.