

PERSONAL INFORMATION **Tone Agasoster**WORK EXPERIENCE

- January 1995-December 1995 **Adviser at QC laboratory**
The Norwegian Association for Proprietor Pharmacists (Norway)
Control of analyses and some work on monographs
- January 1996-December 1997 **Senior lecturer in pharmaceutical analytical chemistry**
University of Tromsø (Norway)
Laboratory course and some lectures
- January 1998- Present **Senior adviser**
Norwegian Medicines Agency (Norway)
Assessment of quality dossiers (MAAs) including the centralised procedure and control activities for assessment reports from other assessors. Assessment of IMPDs for clinical trials
- January 1999- Present **member**
European Medicines Agency (United Kingdom)
CHMP/CVMP Quality Working Party, Harmonisation of pharmaceutical quality requirements within applications for marketing authorisation
- August 2012- Present **member**
European Medicines Agency (United Kingdom)
CHMP/CVMP Quality Working Party Core Team, Product specific issues for Human products within applications for Marketing Authorisation/Scientific Advice
- October 2013- Present **QWP observer to Group 7**
European Pharmacopoeia (France)
Elaboration of pharmacopoeial monographs
- September 2018- Present **Topic Leader ICH Q2(R2)/Q14 EWG**
European Commission (Belgium)
Analytical Procedure Development and Revision of Q2(R1) Analytical Validation

EDUCATION AND TRAINING

- August 1985-June 1990 **MScPharm**
University of Oslo (Norway)
Pharmaceutical education of 5 years. Different fundamental and pharmaceutical subjects. Thesis: same topic as for PhD degree
- June 1990-October 1994 **Ph.D.**
University of Oslo (Norway)
Thesis: Development of automated HPLC methods for determination of some antibacterial drugs in fish and other foodstuffs of animal origin using dialysis for on-line sample preparation

ADDITIONAL INFORMATION

Expertise - Assessment of chemical-pharmaceutical part of different centralised applications
-Assessment of applications for clinical trials
-Rapporteur for Guideline on setting specifications for related impurities in antibiotics

Publications

Projects

Memberships Member of the Norwegian Pharmaceutical Society

Other Relevant Information Mother tongue: Norwegian
Other languages: English (very good), German (basic/good)