

PERSONAL INFORMATION

Nanna Aaby Kruse

WORK EXPERIENCE

June 2001–Present

Team Manager, Pharmaceutical Quality, Biologics

Danish Medicines Agency (Denmark)

Chief consultant responsible for the Assessment of the Quality (CMC) Part of biological and biotech products. Primary focus is products approved through the Centralised Procedure.

April 1995–May 2001

Scientist in the Danish Medicines Agency Biological Control Laboratory

Danish Medicines Agency (Denmark)

Scientist with responsibility for evaluation of the Quality (CMC) part of dossiers and laboratory control of authorised biological products on the Danish / EU marked

August 1993–March 1995

Research assistant

Statens Seruminstitut, Biochemical Sector, Immunological department (Denmark)

Research assistant on a malaria vaccine research project

EDUCATION AND TRAINING

August 1986–July 1993

Master of Science, Pharmacy

The Danish University of Pharmaceutical Sciences (Denmark)

ADDITIONAL INFORMATION

Expertise

Quality (CMC) of Medicinal products manufactured by rDNA techniques especially insulins and monoclonal antibodies.

I have been on the Rapporteur /Co-Rapporteur team as Quality Assessor for the evaluation of several centralised authorised products like insulin's (8 products) monoclonal antibodies (12 products) and other recombinant proteins (12 products).

I have been involved in a number of Scientific Advices on a variety of products, including a great number of biosimilars

Publications

Ionic strength-dependent denaturation of Thermomyces lanuginosus lipase induced by SDS. Arch Biochem Biophys. 2011 Feb 1;506(1):92-8

Biosimilars: what clinicians should know. Blood. 2012 120:5111-5117. doi:10.1182/blood-2012-04-425744. Prepublished online October 23, 2012;

Projects**Memberships**

Danish member of the Committee for Advanced Therapies (CAT) since 2015, alternate member since 2012

Danish representative in CHMP's Biological Working Party (BWP) since 2002. Vice-Chair for BWP since April 2014

Expert member of CHMP's Biosimilar Medicines Working Party (BMWP) since 2010

Expert member of EMA's PAT Team since 2013

Danish representative in CHMP's Ad hoc Influenza Working Party since 2003

Member of Expert Working Group in ICH Q12

Other Relevant Information