EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

PERSONAL INFORMATION

Irene Agerkvist

WORK EXPERIENCE

May 2016- Present

Scientific Director Pharmaceutics and Biotechnology

Medical Products Agency (Sweden)

Scientific support responsibilities within quality (CMC) matters in the scientific advice procedures and regulatory assessment for marketing authorization applications e.g. heading quality assurance meetings peer-reviewing assessment reports and giving supervisory support to assessors.

May 2015-May 2016

Quality specialist

European Medicines Agency (Sweden)

Coordination of the quality (CMC) part of the centralized procedures for scientific advice and evaluation for market authorization within EU. Participated in BWP (Biological Working Party), QWP (Quality Working Party), PDCO FWG (Paediatric Committees Formulation Working Group) and CHMP (Committee for Medicinal Products for Human Use) for projects I coordinated.

January 2011-April 2015

Senior Consultant

REGA Consulting AB (Sweden)

Independent Consultant in various CMC management roles

September 2003-December 2010

Head of Biopharmaceutical Development

Octapharma AB (Sweden)

Management of a department for development and industrialization of recombinant protein products for heamophilia treatments.

January 2001-December 2004

Head Engineering & Process Development

Octapharma AB (Sweden)

Management of a department for the scientific and technical support functions to the commercial manufacturing of Plasma Protein Products.

November 1997-December 2000

Corporate Director Product Quality Development

AGA AB (Sweden)

Quality upgrading and GMP implementation of traditional Medical Gas Producs to comply with medicinal products legislation regarding quality systems and documentation for autority registration of the products.

November 1992-July 1997

Senior Scientist and Department Manager

Nycomed Imaging AS (Norway)

Senior Scientist and Department Management positions within formulation development, API as well as DP process development and upscaling to commercial manufacturing for Medical Contrast Agents.

September 1985-October 1992

Research Scientist

Institute of Surface and Colloid Chemistry (Sweden)

Academic studies and experimental research work leading to PhD degree

August 1984-August 1985

Process Scientist

Kabi Vitrum AB (Sweden)

Experimental work for process development of lipid substances to be used in Parenteral Lipd Emulsions

July 1982-August 1984

Process Scientist

ACO Läkemedel AB (Sweden)

Experimental laboratory and manufacturing work for process development and implementatiom for Parenteral Infusion Solutions.

EDUCATION AND TRAINING

September 1985-October 1992

PhD Biotechnology

The Royal Institute of Technology (Sweden)

Biotechnology, Biochemistry, Surface and Colloid Chemistr.

Thesis Title: "Characterization of and flocculation in Escherichia coli cell disintegrates".

September 1976-June 1982

MSc

Biotechnology (Sweden)

Biochemical Engineering and Biochemistry

ADDITIONAL INFORMATION

Expertise

Formulation development of lyophilized biologicals.
Immunoassay assessment.
Microbiological methods for quality control.
Development of therapeutic monoclonal antibodies.
Development of live biotherapeutic products.
Plasma product manufacturing and quality control.
Development of Heamophilia recombinant products multidisciplinary experience although focused on quality.
Full characterization for r-FVIII products.
Potency assays and Bioassays for r-FVIII products.
Process development and upscaling of biological products.
Clinical manufacturing, GMP inspections and logistics.
Manufacturing and Quality documentation Medicinal Gas Products
Pharmacopoeia quality standards

Publications

20 peer reviewed scientific publications

Projects

Memberships

PDA
ISPE

Other Relevant Information