EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

PERSONAL INFORMATION

Valgerdur Gudrun Gunnarsdottir

WORK EXPERIENCE

September 2000-May 2004

Specialist, Development Department, R&D

Omega Pharma/Actavis (Iceland)

Analytical method developmentGeneral R&D laboratory activities

May 2004-January 2008

Team leader, Analytical development, R&D

Actavis (Iceland)

-Supervised and managed analytical laboratory-Responsible for analytical technology transfers-Dossier compilation of chapter 3.2.P.5 in the registration process and answering deficiency questions

February 2008-April 2010

Technical Project Manager, Product Compliance, Global Quality

Actavis group (Iceland)

- Managed Stability transfers to a Centralized Stability Center.- Identified and implemented best practice processes.- Conducted corporate auditing and provided global quality support.- Introduced processes and tools for product stability transfers.- Worked with stakeholders to proactively and systematically resolve quality related issues.

May 2010-September 2012

Director, Product Compliance, Global Quality

Actavis group (Iceland)

- Maintained an overview of the Actavis stability program in order to secure regulatory compliance and maximum cost efficiency.- Conduced towards using selective, sensitive and robust analytical methods in Actavis stability studies according to modern requirements.- Introduced and implemented processes that will ensure that potential quality and compliance related issues are promptly addressed to ensure supply.- Monitored processes for resolving product related issues to ensure their robustness.- Worked with stakeholders to proactively and systematically resolve quality related issues.- Conducted corporate audits and provided global quality support.- Provided general Global Quality support to Actavis Central Stability Unit and quality related improvements.- Responsible for the overall Stability transfer projects to Central Stability Unit located in India

October 2012-December 2013

Director, Product Compliance, Quality Americas

Actavis group (Iceland)

-Maintained oversight of the implementation of Actavis centralized stability program (Americas and International) in order to secure regulatory compliance and maximum cost efficiency-Identified, harmonized and implemented best practice processes.

January 2014-July 2017

Director, Global Stability QA (GSQA), Global Quality

Actavis group (including Allergan & Teva) (Iceland)

-Accountable for development and implementation of an effective and efficient QA system with procedures to monitor and provide oversight of the quality status and regulatory compliance of the companys stability programs and studies.- Maintaining oversight of Allergan global stability programs.- Liaise and collaborate with cross functional units and stability system process owners.- Provide leadership and professional guidance to the GSQA team.

September 2017-December 2017

Change and Project Manager

Icelandic Medicine Agency (Iceland)

January 2018-August 2018

Head of Marketing Authorisation Division

Icelandic Medicine Agency (Iceland)

September 2018- Present

Head of Inspection Unit

Icelandic Medicine Agency (Iceland)

EDUCATION AND TRAINING

September 1994-June 2000

MSc, Pharmacy / Cand. pharm.

University of Iceland (Iceland)

ADDITIONAL INFORMATION

Expertise

Publications

Projects

Memberships

Other Relevant Information