AGUSTA GUDJONSDOTTIR

Global Regulatory Affairs Director

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ABOUT ME

- Regulatory affair manager with more than 25 years of experience within all phases of drug development.
- Experience from both big pharmaceutical companies and small biotechnology companies.
- Respectful teamplayer as drug development requires many different skills.
- Goal orientiated and work hard to meet the set timelines.
- Highly interested in products that can improve patients life, especially where there is an unmet medical need.

EDUCATION

Master in Pharmacy
Royal Danish School of Pharmacy
1987

Bachelor in Pharmacy
Icelandic University
1983

Experience

December 2023 - Present
Ozack ApS I Copenhagen Denmark
Global Regulatory Affairs Director

Regulatory consultant for both pharmaceutical and biotechnology companies.

August 2021 - November 2023
Galecto Biotech A/S I Copenhagen Denmark
Director of Regulatory Affairs

Responsibilities

- Regulatory strategy for Idiopathic Pulmonary Fibrosis (IPF) project and supporting oncology project.
- Preparation, execution and follow-up of Scientific Advice Meetings at Health Authorities.
- Regulatory intelligence to relevant teams.
- Preparation of regulatory submission packs to Health Authorities in Australia, US, Canada, Israel and Europe (including East European countries)and regulatory submissions in cooperation with external partners.
- Regulatory input to CMC documentation, protocols, IBs, CSRs and DSURs.
- Maintenance of all regulatory submissions, planned regulatory submissions and Health Authority commitments.

June 2018 - August 2021
Symphogen I Copenhagen Denmark
Director of Regulatory Affairs

Responsibilities

- Regulatory strategies for oncology projects.
- Preparation, execution and follow up of Scientific Advice Meetings at Health Authorities.
- Regulatory intelligence to relevant teams.
- Preparation of regulatory submissions to Health Authorities in US; Canada, Europe and regulatory submissions in cooperation with external partners.
- Regulatory input to CMC documentations, potocols, IBs, CSRs and DSURs.
- Maintenance of Standard Operating Procedures, Work instructions and Guidance Documents within RA.
- Regulatory input in change control cases and regulatory approval of these.

November 2011 - May 2018
Roche A/S I Copenhagen Denmark
Deputy Head of Drug Regulatory Affairs (DRA) and back up for quality

Responsibilities

- Responsible for several cancer products and immunotherapy.
- Planning and participate in Scientific Advice Meetings for several centralised products (both pre-marketing and post-marketing (new indications).

LANGUAGE

English Danish Icelandic	Full Professional Proficiency
Swedish Norwegian	Limited Professional Proficiency

ADDITIONAL INFORMATION

- Several Regulatory Affairs specific conferences (DIA EU and DIA US), and oncology conferences (ASCO). Company training during all years of employment
- Atrium courses: The US Regulatory Environment
- Clinical development and Documentation
- Good Regulatory Practise Marketing Compliance
- Pharmakon courses within GMP, GDP and Regulatory
- Trained in GCP at Symphogen and Galecto

- Regulatory input to launch preparation, input to Summary of Product Characteristics and educational materials.
- Responsible for Compassionate Use Programs.
- Responsible for Direct Healthcare Professional Communications.
- Regulatory submissions for national products and decentralised products
- Local implementation of regulatory database, artwork database and implementing touchpoint sites.
- Back up for quality task as complaints, recalls, national release of products and control of repackaging.
- User of quality databases, SAP and other systems.
- Maintenance of Standard Operating Procedures, Work instructions and Guidance Documents for the affiliate.

August 2011 - November 2011
Leo Pharma I Copenhagen Denmark
Drug Regulatory Manager

Responsibilities
- Regulatory maintenance of older products that were planned to be divested.

January 2011 - August 2011
McNeil I Copenhagen Denmark
Drug Regulatory Manager

Responsibilities
Regulatory submissions for decentralised products and national products.

August 2008 - January 2011
ALK-Abelló I Hørsholm Denmark
Drug Regulatory Manager

Responsibilities
- Preparation and submissions of CMC variations in EU in cooperation with different departments for approximately 1 year.
- Preparation and submissions of renewals in EU for approx. 1 year.
- Preparation and submission of clinical variations in EU in cooperation with different departments.
- Member of project teams for both diagnostic products and medicinal products.
- Established a tool for collecting Regulatory Information regarding competitor clinical trial programs.

April 2004 - August 2008
Bristol Myers Squibb I Virum Denmark
Head of Regulatory Affairs Science, QU Manager & Compliance Manager

Responsibilities
- Member of the Danish Management Group.
- Member and later vice president of the Regulatory Committee at The Danish Association of the Pharmaceutical Industry (LIF).
- Planning and participating in Scientific Advice Meetings for centralized product Regulatory input to launch preparation.
- Regulatory submissions for decentralised and national products.
- Responsible for Compassionate Use Programs Responsible for Direct Healthcare Professional Communications.
- Responsible for fulfilling the GDP regulation.
- Quality tasks as complaints and recalls.
- Maintenance of Standard Operating Procedures, Work instructions and Guidance Documents for the affiliate.
- Preparing and submission of tenders.
- Approval of promotional materials.

August 2001 - April 2004
Organon A/S I Copenhagen Denmark
Head of Drug Regulatory Affairs & Qualified Person

Responsibilities
- Regulatory input to launch preparation.
- Regulatory submissions for decentralised products and national products.
- Life cycle management for a decentralised product at EU level.
- Member of global regulatory database working group.
- Established a local regulatory database.
- Responsible for Direct Healthcare Professional Communication.
- Qualified Person and responsible for the local warehouse.
- Responsible for fulfilling GMP and GDP regulations.
- Quality tasks as complaints , recalls, repacking activities.
- Maintenance of Standard Operating Procedures, Work instructions and Guidance Documentss for the affiliate.

August 2000 - August 2001
Novartis l Copenhagen Denmark
Drug Regulatory Manager

Responsibilities

- Back up for Head of Regulatory Director in transition period.
- Regulatory input to launch preparation.
- Translation of Summary of Product Characteristics for centralized products.
- Regulatory submissions for decentralised products and national products.
- Clinical trial submissions to the Danish Agency.
- Responsible for Direct Healthcare Professional Communications.
- Responsible for fulfilling the GDP regulation.
- Responsible for quality tasks as complaints and recalls

August 1998 - August 2000
MSD ApS l Copenhagen Denmark
Drug Regulatory Affairs Associate

Responsibilities

- Translation of Summary of Product Characteristics for centralized products.
- Regulatory submissions for decentralised products and national products.
- Control of repackaging.

May 1990 - August 1998
The Royal School of Pharmacy
Ph. D. student in pharmacokinetics and Academic secretary for education in clinical pharmacy.