ANN CHRISTINE KORSGAARD

Global Leadership and Regulatory Affairs

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ABOUT ME

- Senior executive with global strategic mind set at portfolio level
- Leadership of up to 80 FTEs internationally, in line/matrix
- Global Regulatory Strategy and execution across all phases of development
- Negotiation and collaboration in diverse partnerships and with stakeholders
- Communication with beliefs in trust, respect and freedom to innovate
- The person behind the CV see: https://www.youtube.com/watch?v=jmSZd6TDptE

EDUCATION

Orchestrate Leadership Program at UCB, Belgium, Transitioning from functional to business wide leadership
2014

SIMI Scandinavian International Management Institute, Copenhagen Denmark, Managing Medical Product Innovation Degree (part-time MBA awarded).
1999

Royal Danish School of Pharmacy, University of Copenhagen Denmark, M.Sc. Pharmacy.
1985-1990

Hasseris Gymnasium, Ålborg, Denmark, Natural science/mathematics examination High School
1994

Experience

2016- Present
Ozack ApS I Copenhagen Denmark
CEO and founder

Responsibilities
Increase progress in development of medicinal products through providing knowledge on how to navigate the regulatory maze and agency interactions through development of medicine within all phases of drug development.

- Advice numerous SMEs in the early phases of clinical development and pre-phase 1 clinical phase
- Prepare regulatory strategy and Agency Communication plan
- Lead companies through meetings and interactions with regulatory agencies such as EMA SME Briefing Meetings, EMA Scientific Advice, FDA meetings
- Role as VP Regulatory Affairs for several clients
- Regulatory responsible person at a number of biotech companies

2016 - 2017
Biotrack ApS I Copenhagen Denmark
Managing Director, Global Regulatory Affairs & Development Strategy

Responsibilities

- Biotech consultancy: Navigate, Execute, Communicate
- Global Regulatory Affairs Strategy for 8 clients
- Clinical trial applications submission & approval to start clinical trial
- Agency meetings with EMA (SME briefing meetings and Scientific Advice)

2015 - 2016
Shionogi Europe I London United Kingdom
Vice President, Regulatory Affairs Europe - ad interim

Responsibilities

- European Regulatory Team Head also reporting to Japanese Head Quarter
- Build Regulatory organisation to be fit for purpose
- Structure process and operations to increased efficiency
- Strategic regulatory advise for 6 development projects
- Competence mapping for future global regulatory vision
- Educating Head Quarter colleagues in Japan on European Regulatory Environment

2013 - 2015
UCB S.A HQ I Brussels Belgium
Vice President, Regulatory Affairs Europe & Early Development Projects

Responsibilities

- Global Regulatory Affairs Lead for Europe and all early development projects
- Cross country leadership of employees based in Belgium, Germany, and UK
- Organizational transformation from 80 to 40 FTEs
- Strategic outsourcing of global regulatory operations for 2000 licensees of UCBs established brand portfolio. Value of portfolio was about 30% of UCB revenue.

LANGUAGE

English	Full Professional
Danish	Proficiency
German	Limited Professional
French	Proficiency

ADDITIONAL INFORMATION

Several Regulatory Affairs specific conferences and training during all years of employment. Also trained in GCP at previous employment at LEO Pharma, Genmab, UCB, Symphogen, and through acting as course leader several times at the Atrium Clinical Development module.

Leadership training at companies like LEO Pharma, Genmab, and UCB.

Articles
Strategic Mindset is needed within Regulatory Affairs

Setting up informal networking groups within Regulatory Affairs

Professional memberships: EFPIA (EBE, ERLC, SRMPC), DIA (Drug Information Association), TOPRA, Danish Biotech, Danish Association for GCP

OTHER ACTIVITIES

University of Copenhagen, Teaching for the Masters in New Drug Development
2007-2011

Atrium before called Medicademy (part of LIF i.e. Pharmaceutical Industry Association), Course Leader and speaker for the Masters of Regulatory Affairs on topics like Japanese regulatory environment, global regulatory strategies, and clinical development.
2003 - 2016

SIMI Scandinavian International Management Institute, Copenhagen Denmark, Acting as Industry Executive Advisor
2007

2012 - 2013
UCB S.A HQ I Brussels Belgium
Vice President and Sr. Dir., Regulatory Affairs EU/Intl

Responsibilities
- Global UCB target markets outside US and Canada, including Brazil, Russia, India, and China (BRIC)
- Managed team of up to 55 employees and 25 insourced contractors
- Talentpool mapping and organisational plan

2010 - 2012
Genmab HQ I Copenhagen Denmark
Vice President, Global Regulatory Affairs

Responsibilities
- Target to market global regulatory strategies development for all Genmab products
- Communication strategies with regulatory agencies
- Risk management evaluation
- 3-7 employees
- Member of Global Executive Management Team of Genmab
- FDA approval and EMA approval of the product Arzerra by the FDA. Arzerra in Q1 2015 totaled net sales of DKK 111 billion.

2008 - 2009
Genmab HQ I Copenhagen Denmark
Senior Director, Global Regulatory Affairs

Responsibilities
- 20 employees leadership
- Global regulatory strategies with US and EU focus
- Joint Development Team with our partner GSK
- Genmab's first Marketing Authorization submission and approval of the product Arzerra in both EU and US
- Conditional approval, accelerated approval respectively and with priority review in US
- Outsourcing strategy planned and implemented for any non-key regulatory activities

2007 - 2008
Genmab HQ I Copenhagen Denmark
Director, Global Regulatory Affairs

Responsibilities
- Led department of 20 FTEs being Global Regulatory Affairs & Operations.
- Regulatory co-development with external partner (GSK) and the Genmab submission management team for Arzerra Regulatory dossier (BLA/MAA)

2006 - 2007
Genmab HQ I Copenhagen Denmark
Global Regulatory Lead, Global Regulatory Affairs

Responsibilities
- Global Submission Management Team leadership for Arzerra at Genmab
- Global orphan regulatory strategy for Genmabs most advanced oncology product in Clinical Phase 3.

2005 - 2006
Action Pharma & Incuba Venture I Holte Denmark
Vice President, Project Management & Regulatory Affairs

Responsibilities
- 6 small virtual biotech companies in Incuba Venture Portfolio
- Regulatory strategic advice and Global Project management
- Agency communication strategy linked to key investor decision points
- Development & manufacturing plans of the drug substances and drug products
- Non-clinical (pharmacology & toxicology) and clinical plans across numerous CROs/CMOs.

2005 - 2005

Actavis I Hørsholm Denmark

Director International Registration, Sales & Marketing International

Responsibilities

- Actavis Sales & Marketing International leadership of Regulatory Affairs
- Pharmacovigilance function to ensure European compliance
- International regulatory team leadership of 30 FTEs
- Markets included the Scandinavian area, Baltic's, CEE, Turkey, Serbia, Russia, Ukraine and C.I.S

2000 - 2004

Leo Pharma A/S HQ I Ballerup Denmark

Head of Department, Regulatory Affairs Initial Filing

Responsibilities

- First submission and achievement of the Marketing Authorization in each of the ICH regions , i.e., EU, US and Japan for entire LEO Pharma portfolio
- Global Regulatory Affairs Lead for quality, non-clinical and clinical development
- 15 R&D projects and 6 in-licensed products for dermatology, oncology and respiratory indications
- US and EU oncology development plans aligned through leadership of FDA and EMEA Agency Advice meetings
- EMA pre-submission meetings for Orphan Drug Applications and Scientific Advice

1995 - 2000

Leo Pharma A/S HQ I Ballerup Denmark

Group Manager, Regulatory Affairs Department

Responsibilities

- EU, US, JP and 24 other major countries
- All development stages and life cycle management
- 10 projects Global regulatory strategies
- 2 US New Drug Applications, 2 EU Mutual Recognition Procedures in the early days of this in EU
- Pre-IND, EoP2 and pre-NDA meetings led with FDA in US

1993 - 1995

Dumex (ex Alpharma A/S) I Copenhagen Denmark

Regulatory Affairs Officer

Generic regulatory dossiers for EU and project manager for development project.

1992 - 1993

Norwegian Medicines Agency (SLK) I Oslo Norway

Medical Assessor in Department of Pharmacotherapy

Generic dossiers evaluated for applicability to Norwegian legislation.

1990 - 1991

Pharmacy Ryparken I Copenhagen Denmark

Head Dispenser

Management of Delivery of medicine in Pharmacy