ANN CHRISTINE KORSGAARD

Global Leadership and Regulatory Affairs

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Nordre Fasanvej 215, 2000, Frederiksberg, Denmark

ABOUT ME

- Senior executive with global strategic mind set at portfolio level
- Leadership of up to 80 FTEs across countries, in line/matrix
- International 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 at Afyx Therapeutics ApS and at Symphogen ApS
- Role as Head of Regulatory Affairs at RhoVac ApS
- 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

Main achievements:
- Global Regulatory Affairs Strategy for 8 clients
- Clinical trial applications submission & approval to start clinical study
- Agency meetings with EMA (SME briefing meetings and Scientific Advice)

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

Responsibilities
- European Regulatory Team Head
- Build Regulatory organisation to be fit for purpose
- Structure process and operations to increased efficiency

Main achievements
- Structure growth enabling Regulatory Organization for Europe
- Strategic regulatory advise for 6 development projects
- Competence mapping for future global regulatory vision
- Educating Head Quarter colleagues in Japan on European Regulatory Environment

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

May 2013 - June 2015
UCB S.A HQ l 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

Main achievements
- Strategic outsourcing of global regulatory operations for 2000 licensees of UCBs established brand portfolio. Value of portfolio was about 30% of UCB revenue.
- 10% increase in employee engagement
- European HUB regulatory organisation developed
- Global Regulatory Strategy tool established for all projects

September 2012 - April 2013
UCB S.A HQ l Brussels Belgium

Vice President, 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

Main achievements
- Reorganized Global Regulatory Affairs into a Patient Solution Team structure with dedicated reporting lines into projects instead of functions.
- Reorganizing to separate out the international regulatory part of the organization into a separate unit.

June 2012 - August 2012
UCB S.A HQ l Brussels Belgium

Senior Director, Regulatory Affairs EU/Intl

Responsibilities
- Same as above

Main achievements
- Talentpool mapping and organisational plan
- Global Regulatory Leads and Regulatory Liaisons roles clarified
- Knowledge management improvements.

January 2010 - May 2012
Genmab HQ l 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

Main achievements
- Downsized department from 20 to 3 FTEs in line with new Company Strategy
- Outsourcing strategy for 70 % of required Regulatory Affairs activities
- FDA approval and EMA approval of the product Arzerra by the FDA.
- Arzerra in Q1 2015 totaled net sales of DKK 111 billion.
- Turnaround from full licensing organization to focus on drug discovery and development

June 2008 - December 2009
Genmab HQ l 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

Main achievements
- 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
- From 20 to 7 employees downsized the department

October 2007 -May 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)

Main achievements

- Aligned Genmab Strategy with GSK
- Successful teamwork established across Genmab and GSK
- Reorganized department to match project needs

November 2006 - October 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.

Main achievements

- Regulatory frame implemented for Genmab's first Biologic License Application (BLA) to FDA and Marketing Authorization Application to EU
- Project plan that accurately predicted completion for submission 2 years ahead and even after partnering with GSK
- "BLA house" planned and implemented in 2007.

December 2005 - October 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.

Main achievements

- Development plan for AP214 – a hormone analogue for prevention of acute kidney injury associated with major cardiac surgery being Action Pharmas first product going into human.
- Pre-IND FDA meeting with subsequent IND opening
- First in Patients study to start in US enabled.
- AP214 was in 2012 sold to Abbott for a cash payment of $110 million
- Found and established agreement with Contract Manufacturer for a peptide (a small molecule AP1030 with anti-diabetic and anti-obesity effects)
- Regulatory path and project plan to the Board of Action Pharma

January 2005 - September 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

Main achievements

- Fastest possible approval of generic dossiers from HQ in Iceland
- Integrated a new country per month into the International organization of Actavis
- Global Regulatory Team seminar with all 30 international employees

October 2000 - December 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
- Dermatology (psoriasis, dermatitis & acne), a biological lung surfactant, oncology and rheumatoid arthritis

Main achievements

- 15 R&D projects and 6 in-licensed products for dermatology, oncology and respiratory indications
- Japanese NDA filed for dermatological product working with partner in Japan
- 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
- Expanded department from 5 to 12 Regulatory Professionals

November 1995 - September 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
- Dermatology (psoriasis, dermatitis & acne), biological lung surfactant, oncology, and rheumatoid arthritis

Main achievements

- 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
- EU variations (quality, non-clinical, and clinical); annual updates of US DMFs, NDAs and INDs and EU DMFs.

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