OZACK

REGULATORY EXECUTIVE

LEADER

DRIVER OF ACCOUNTABILITY

Entrepreneurs that move from research to clinical development phases and beyond go into a very regulated area with options as well as pit falls. Chances of success are increased significantly if a company is aware of all this.
Regulatory Affairs is a strategic prerequisite for the success of any pharmaceutical company. It will leverage the value of a development project through successful interactions with regulatory agencies.

ANN CHRISTINE KORSGAARD, MSc (PHARM.)

REGULATORY EXECUTIVE AND PROJECT LEADER, ACK@OZACK.DK

PROFILE: Senior Executive with a global strategic mindset at portfolio level. International regulatory execution and strategy across all phases of development. Collaboration in diverse partnerships and with stakeholders. Senior Management and Project Lead.

POSITIONS		KEY ACHIEVEMENTS
2018-current Afyx Therapeutics	**VP** Global Regulatory Affairs	Regulatory Strategies US and EU Enable First in Man trisl (phase 2) to start in US, CA, and EU.
2015 – 2016 Shionogi, UK	**VP** Regulatory Affairs Europe	Build regulatory organisation Strategic regulatory adviser for 6 development projects
2012 – 2015 UCB, Belgium	**VP** Regulatory Affairs Intl.	Early development products through to marketing Innovative Task Force with EMA Plan and execute outsourcing of 2000 licensees
2001-2019 Atrium/Cphg. University	Course Leader	Global regulatory strategy, Japanese Regulatory Affairs, Clinical Development
2006 – 2012 Genmab	**VP** Global Regulatory Affairs	Global regulatory strategies for the portfolio i.e. mainly phase 1 and 2 projects Lead and achievement of marketing approval for Arzerra™ in US and EU
2005 – 2006 Action Pharma	**VP** Regulatory Affairs & Project Management	Opened Action Pharmas first US IND Entered peptide product into First in Man trial
2005 Actavis	**Director** Intl. Regulatory Affairs	Streamline generic submissions in all Actavis markets from Icelandic HQ
1995 – 2004 LEO Pharma	Head of Regulatory Affairs.	Marketing approval in JP, EU and US of Dovonex and Dovobet Covered all early development projects
1992-1993 Norweigan Medicines Agency	**Clinical Assessor**	Evaluate clinical dossiers with focus on pharmacokinetics