



DAGMARA GRZADZIELA

Senior Regulatory Affairs Manager

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Nordre Fasanvej 215, 2000
Frederiksberg, Denmark

ABOUT ME

- Life science professional with a strong interest in regulatory affairs, driven by challenges of new technologies and interest in bringing new treatment options to patients
- Experience with early and late-stage pharmaceutical and biotech products
- Interactions with regulators (US FDA, EMA, PDMA, etc.) on specific developments and general trends in life science
- Experienced cross-disciplinary and multicultural team lead

EDUCATION

University of Vienna, Austria

MSc. Molecular Biology

MSc Thesis: "Reprogramming Social Behavior in *C.elegans*" in collaboration with Cori Bargmann, head of the Lulu and Anthony Wang Laboratory of Neural Circuits and Behavior, Rockefeller University

2010 - 2013

University of Vienna, Austria

B.Sc. Molecular Biology

2008 -2010

University of La Coruna, Spain

Erasmus Semester (MSc programme)

2010

Experience

2022- Present

Ozack ApS | Copenhagen Denmark

Senior Regulatory Affairs Manager

Responsibilities

- Regulatory Strategy development and execution in line with business strategy
- Regulatory Support across all areas of development
- Regulatory Meetings (EMA, FDA, PDMA, National regulatory agencies), Submissions (IND, BLA, CTAs in EU and UK, etc.) and Regulatory Intelligence

2020 - 2022

ExpreS2ion Biotechnologies | Copenhagen Denmark

Project Manager

Responsibilities

- Management of ABNCov2, a Covid-19 vaccine in Clinical Phase 3, fully out-licensed to Bavarian Nordic, a global vaccine manufacturer
- Program lead of preclinical ES2B-C001 development, a HER2+ breast cancer vaccine
- Management of development of next-generation influenza vaccines as part of INDIGO consortium (17 partners from EU, US and India), funded by H2020
- Key driver and contributor of MucoVax consortium establishment and successful grant application (IFD grant of 29 mio DKK)
- Driver of change management at ExpreS2ion Biotechnologies, leading change from CRO business model to pipeline

2017 - 2020

Jakob and Partners | Copenhagen Denmark

Project Manager and Team Lead

Responsibilities

- Deep-dive and tailored market research & analysis on global and regional pharma and biotech markets (very early to late stage products)
- Team Lead of cross-cultural (Denmark-India- US) specialized teams: regulatory, biologics, and clinical

2014 - 2017

Rex&Lindeborgh | Copenhagen Denmark

Scientific and Pharmaceutical Event Assistant

Responsibilities

- Planning and organization of scientific and pharmaceutical congresses, conferences, and events (ESMO, EADV, PH forum)
- On site management and personnel oversight

LANGUAGE

English

Danish Full Professional

German Proficiency

Polish

Spanish Professional Proficiency

Russian Limited Professional Proficiency

2013 - 2014

Research Institute of Molecular Pathology | Vienna Austria

Research Technician, Circuit Neuroscience

Responsibilities

- Investigation of the role of GAP junctions in a neuronal circuit coupling social and chemotactic behaviour in *C.elegans*
- Analysis, interpretation, and presentation of data internally and to external collaborators in various formats

Additional Information

Publications

- F. Ruzzi et al, Prevention and therapy of metastatic HER-2+ mammary carcinoma with a human candidate HER-2 virus-like particle vaccine, submitted to Biomedicines

Courses

- GCP certificate (Klifo, DK)
- Non-clinical development and Documentation (Atrium, DK)
- GMP Certificate (Key2Compliance, SE)

Technical skills IT

- Microsoft Office Suit
- Various project management tools
- Basic programming in R and MatLab

Laboratory skills

- Experimental design, including DOE
- Microscopic methods
- Molecular assays (ELISA, PCR, DNA/RNA extraction, etc.)

Soft skills

- Various communication techniques
- Teamwork and teambuilding