



IVANA GLATZOVA

Regulatory Affairs Manager

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Ole Maaløes Vej 3, 2200 Copenhagen N, Denmark

ABOUT ME

- Submission lead in 7+ CTAs in Europe and UK.
- Contributed to 10+ Agency meetings with European National Agencies/FDA.
- Expertise in submission systems as CTIS, IRIS, IRAS and EudraCT.

EDUCATION

University of Copenhagen, Denmark
MSc. Pharmaceutical Sciences

MSc Thesis: "Impact of CTR (No 536/2014) on SMEs"

Courses: Methods and Procedures in Clinical Drug Development, Pharmaceutical Policy, Pharmacology: From Physiology to Therapy

2019 - 2021

**IMC University of Applied Sciences
Krems, Austria**
B.Sc. Medical and Pharmaceutical Biotechnology

BSc Thesis: Role of STAT5 in stem cell differentiation

Courses: Project management in Life Sciences, Clinical studies and GCP

2015 -2018

LANGUAGE

English	Full Professional
Slovak	Proficiency

Experience

July 2021- Present

Ozack ApS | Copenhagen Denmark

Regulatory Affairs Manager

Responsibilities

- Planing, compilation, and submission of Regulatory Dossiers as CTAs, INDs, and briefing materials for meeting with Regulatory Agencies
- Regulatory Intelligence and extracts preparation
- Preparation of communication tools on Regulatory Topics

November 2019 - June 2021

Ozack ApS | Copenhagen Denmark

Student Regulatory Affairs Associate

Responsibilities

- Gathering and compilation of regulatory intelligence for clients on potential competitors
- Assistance with completion and submission of FastTrack/Scientific advice/CT application documentation to competent authorities
- Collaboration on Master's thesis - Impact of Clinical Trial Regulation on SMEs

Research projects

September 2018- June 2019

Institute of Science and Technology of Austria

Group of Calin Guet

Pathogenicity of E.coli in urinary tract infections

Achievements

- Established a novel dendritic cell-line generation protocol
- Performed FACS analysis, and migration and maturation assays to assess the effect of various generated bacterial mutants on the dendritic cells

September 2017 - February 2018

Institute of Pharmacology and Toxicology

University of Veterinary Medicine in Vienna

Group of Veronica Sexl

Role of STAT5 in stem cell differentiation

Achievements

- Analysed data from serial bone-marrow transplantation assays of three different genotypes
- Generated shRNA mediated loss of function cell culture models and performed subsequent analysis of the impact to their life cycle

Additional Information

Professional courses

- Atrium (2022)
Clinical Development and Documentation (Module 8)
- TOPRA (2023)
Drug Device Combinations and Other Technologies

Awards

- FEMtech Fellowship Grant (2018) The Austrian Research Promotion Agency FFG of Austria
- Merit Scholarship (2016) IMC University of Applied Sciences

Technical skills IT

- EudraCT
- CTIS
- Veeva RIM

Laboratory skills

- Cell culture
- Migration assays
- Molecular assays (ELISA, PCR, DNA/RNA extraction, FACS)

Soft skills

- Problem solving
- Dependability
- Flexibility
- Creativity
- Teamwork