



IVANA GLATZOVA

Senior Regulatory Affairs Manager

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Nordre Fasanvej 215, 2000,
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ABOUT ME

- Regulatory professional with strategic and analytical mindset
- Experience as a submission lead in CTAs across EU and UK, and INDs to the US FDA
- Expertise in submission systems as CTIS, IRAS, IRIS or EudraVigilance
- Interactions with regulators (US FDA, EMA, EU National Agencies) on product development and pre-CTA plans

EDUCATION

**University of Copenhagen,
Denmark**

MSc. Pharmaceutical Sciences

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

2019 - 2021

**IMC University of Applied Sciences
Krems, Austria**

B.Sc. Medical and Pharmaceutical
Biotechnology

BSc Thesis: Role of STAT5 in stem cell
differentiation

2015 - 2018

Experience

September 2025 - Present

Ozack ApS | Copenhagen Denmark

Senior Regulatory Affairs Manager

Responsibilities

- Lead in preparation of CTA submissions dossiers within EU, and cross-disciplinary stakeholder management
- Co-ordination and compilation of IND submissions, including opening of an IND
- Regulatory intelligence and support on compliance with applicable regulatory requirements

July 2021

Regulatory Affairs Manager

Responsibilities

- Planning, 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

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

LANGUAGE

English Full Professional
Slovak Proficiency

German Elementary
Danish Proficiency

○ 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

- DIA
 - 2026 Mandatory use of ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on Training Course using the EudraVigilance System
- TOPRA
 - 2023 Drug Device Combinations and Other Technologies
- Atrium
 - 2023 Clinical Development and Documentation (Module 8)
 - 2024 Quality Drug Substance and Drug Product (Module 6)

Awards

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

Technical skills IT

- Microsoft Office Suite
- Submission system: IRIS, IRAS, CTIS, EudraVigilance
- Document Management systems; Veeva RIM

Laboratory skills

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

Soft skills

- Strategic & Analytical Thinking
- Problem solving
- Dependability
- Creativity
- Teamwork