Mag. Dr. Alfred Horak

Address: Türkenkellerweg 9/5 Berg, AT
Tel: 0043 (699) 1002 0213
E-Mail: info@horak-consulting.at
Webpage: www.horak-consulting.at

Regulatory Affairs Manager

Highly dynamic and meticulous regulatory affairs executive with 15+ years' experience in overseeing product development and formulating global regulatory strategies.

Aptitude for providing regulatory support to project management on various projects, while executing quality assurance and ensuring successful transfer of technology. Adept at organizing and preparing submissions and pertinent dossiers for roll out of global products. Demonstrated capacity for coordinating with global partners, distributors, and consultancies to formulate strategies. Skilled at evaluating guidelines and regulations for project teams, and crafting solutions for project issues.

Areas of Expertise

- Project Management
- Drug Regulatory Affairs
- Medical Device Regulatory Affairs
- Food-supplement Regulatory Affairs
- Cosmetics Regulatory Affairs
- Medical Writing
- Submission Management: Swissmedic, EMA, and other national authorities
- Regulatory Compliance
- CMC Expertise
- Labelling Expertise
- Drug Research and Development
- Quality Assurance Expertise
- Change Control Expertise
- Remediation Planning
- Pharmaceutical Representative
- Information Officer
- Qualified Person Pharmacovigilance
- GxP (esp. GDP-responsible person)
- IT Systems & Digitals Regulatory Operations Management (IQs, OQs)
- Validation Management
- Marketing and Management
- Medical Writing

Accomplishments

- Attained authorization for MRP marketing of Treprostinil drug.
- Crafted SOP to enhance performance of workers, which led to more efficient operations.
- Prompted inclusion of new food supplements and medical devices into company portfolio.
- PQ writing and Proton testing for Gloria RCM and Veeva RIM
- Transfer of QM, Reg.Affairs, Pharmacovigilance and Compliance in the context of well-known company mergers and separations.

- Clinical submissions in the context of Covid-19 and pandemic preparedness planning.
- Various variation and renewal Submission and Approvals with SwissMedic, EMA and national authorities in RoW-countries

Career Experience

Horak-Consulting/Berg, AT **2026-today**

RA and GxP Consultant

Proclinical GmbH, Alnylam/DACH **2025-2026**

Information Officer DACH-region, Regulatory Affairs Deputy

Teccon Austria GmbH, Novartis/Sandoz (Kundl), Tirol, AT **2023-2025**

Manager Regulatory Operations- IT Systems & Digitals

Michor Consulting GmbH, Vienna, AT/Altran Austria, Gratkorn, AT **2022**

Interim Principal Regulatory Affairs Executive

Regulatory Strategy, Regulatory Procedures, Submissions, SOPs, Artwork and Labelling, CTD/eCTD, Agency Interactions, Drug Development, Pharmacovigilance, Technical Writing (IMPDs, PSD, PSF in context of Covid-19), Regulatory Intelligence, Post-approval & Life cycle management, Due diligence, Biologics, Clinical Submissions (Comirnaty, Tuberculosis, Malaria, Monkey pox etc.), PQ writing and Proton testing for Veeva RIM implementation, Pandemic Preparedness Planning for Germany etc.

Norgine GmbH, Vienna, AT/Wettenberg, DE **2019 – 2021**

Interim Principal Regulatory Affairs Executive

Oversaw implementation and regular updates of CCDSs and assessed packages for approval. Supervised MRP/DCP submissions for medical product authorization in Switzerlanda and EU Member States. Led change control process to ensure quality of products was maintained. Utilized eCTDs to submit Regulatory information to Health Authorities and ensured presented data aligned with medical department.

- Achieved regular drug renewals.
- Implemented essential variations and base-line CTD structure under deadline before new company chapter began.
- Engendered continuing lifecycle of lucrative product.

Alcon Grieshaber, Aargau, CH/Smith and Nephew Orthopaedics, Aargau, CH **2014 – 2018**

Senior External Consultant for Medical Devices

Guided life-cycle management of medical devices using Agile and Share-Point. Provided technical writing for various products (e.g. in STED file format according to MDR). Updated technical documentation of class 2b vitrectomy products in line with new MDR. Coordinated with notified bodies to assess conformity of medical devices and to attain new certificates (also for Drug-Device Combination Products). Spearheaded MD submissions in various countries, such as China, Canada, Australia and US. Documented clinical trials and research, and superintended projects for new product development.

- Initiated and finalized recertification for 22 implant products for notified body in timely manner.
- Engaged with QM, Clinical and Development Department to develop answers for notified body deficiency letters.

Depuy Synthes, Raron, CH/Johnson and Johnson, Zuchwil, CH **2013 – 2014**

Senior External Consultant

Directed quality assurance activities to ensure maintenance of orthopaedic implants. Collaborated with medical device developers and manufacturers to identify product defects and compliance with regulations. Advised distributors and clinical service providers on device and equipment use. Evaluated medical products and submitted products for regulatory approval.

- Developed legacy review documents for clients.
- Generated remediation plans for handling FDA and TÜV-Süd audit findings.

Laboratorium Dr. G. Bichsel AG, Interlaken, CH; Galderma Austria GmbH, AT **2010 – 2016**

Head of Regulatory Affairs

Regulated projects on new drug development, oversaw labelling activities, and ensured advertising material complied with local regulations and laws. Governed various registration activities (SwissMedic), such as medical device dialysis solutions (Citrasate) and "formula hospitalis" products, food supplements, and cosmetics (Daylong, Excipial etc.). Shared advice on drug-device combinations and cooperated with BfArM and EMA through consultation procedures. Conducted change of European notified body process. Offered regulatory support to clinical teams (internal and external laboratories) on development plans and trial requirements. Provided QM transfer documents within several company acquisitions.

- Initiated marketing authorization of Persiol Bichsel and ensure preparation of CTD sections for Cardioplexol.
- Engendered finalization of marketing authorization of Equibiserol, which is animal drug.

Additional Experience

Regulatory Affairs Manager, Amomed Pharma GmbH, Vienna, AT
Regulatory Affairs Officer, Wyeth-Whitehall Export GmbH, Vienna, AT
Regulatory Affairs Manager, Merck-Pharma GmbH, Vienna, AT
Regulatory Affairs Manager, Croma-Pharma GmbH, Korneuburg, AT

Education

PhD in Human Biology (final grade: excellent)
Institute of Human Biology, Vienna, AT

Master's Degree in Zoology (final grade: excellent)
Institute of Theoretical Biology, Vienna, AT

Licenses & Certifications

License for Trading of Medical Devices and Business Consulting, WKO, Vienna, AT
Licence of Technical Documentation Assessor of Non-Active Medical Devices (NAM-absorbable implants-TUEV-Süd) Munich, DE
Certificate for Conflict Management, ARGE, Vienna, AT
Certificate in Forms of Psychotherapy, University of Psychology, Klagenfurt, AT
Certificate for Pharmaceutical Sales Representative, BMGK, Vienna, AT