Dr. Alfred Horak

Interim Head of Regulatory Affairs | Interim Manager Pharma and MedTech

Türkenkellerweg 9/5, 2413 Berg, Austria
+43 699 1002 0213 · info@horak-consulting.at · www.horak-consulting.at



Available at short notice for interim mandates in DACH and the EU – on site, hybrid or remote

PROFILE

Interim manager and senior regulatory affairs executive with more than 20 years of experience in pharmaceuticals, biologics, medical devices, combination products and digital health across Austria, Switzerland, Germany and the EU.

My focus is on situations where a regulatory function has to keep running without interruption: vacancies, spin-offs, acquisitions, the MDR transition or the introduction of new systems. I take responsibility from day one, secure compliance and hand over a documented, audit-ready function. Hands-on experience in CMC, labelling, lifecycle management, pharmacovigilance/QPPV, medical device technical documentation and regulatory IT (Veeva Vault, CSV).

TYPICAL INTERIM ASSIGNMENTS

- **Vacancy bridging:** Head of RA, RA Deputy, Information Officer, QPPV (Alnylam, Norgine, Krainer MedTech, Pharmaselect)
- **M&A, spin-offs and carve-outs:** separation of Sandoz from Novartis; integration following the transition from Spirig to Galderma and Nestlé; acquisition of Wyeth by Pfizer; RA and QM transfers for product acquisitions (Bichsel)
- **MDR transition and notified bodies:** implant recertifications, MDR/STED documentation, change of notified body; former TÜV SÜD assessor
- **Audits, inspections and remediation:** remediation plans for FDA and TÜV SÜD findings (DePuy Synthes); all audits and inspections passed (Galderma)
- **Digital regulatory transformation:** Veeva eDMS/RIM implementation, CSV (OQ/PQ), Gloria RCM, AI-based medical device software

KEY ACHIEVEMENTS

- Recertified 22 orthopaedic implant products with the notified body on schedule (Smith & Nephew).
- Completed OQ and PQ validation documentation for the regulatory eDMS (Veeva) during the separation of Sandoz from Novartis.
- Led the regulatory integration following two changes of ownership (Spirig, Galderma, Nestlé): all marketing authorisation transfers completed, all audits and inspections passed.
- Marketing authorisation for treprostinil via MRP (Amomed); approval of Enbrel in Russia and other CIS countries and an indication extension for methotrexate in Austria (Wyeth/Pfizer).
- Re-engaged by Norgine for a second interim mandate as regulatory lead DACH (2018–2019 and 2020–2021).
- Eight years as external QPPV with continuous pharmacovigilance compliance (Krainer MedTech, 2013–2021).

CORE COMPETENCIES

- Regulatory strategy (EU, CH, global)
- MAA, MRP/DCP, national procedures
- Variations, renewals, CCDS
- CMC (Module 3), labelling and artwork
- CTA, IMPD, medical writing
- Swissmedic, EMA, BfArM, PEI, FDA
- MDR/IVDR, technical documentation (STED)
- Notified body interaction
- ISO 13485, QMS, CAPA, change control
- GxP (GMP, GDP, GCP), audits and inspections
- Pharmacovigilance/QPPV, materiovigilance
- Combination products
- Interim leadership and structured handover
- M&A: due diligence, carve-outs, transfers
- SOP development
- Project and stakeholder management
- Veeva Vault (RIM, Submissions, PromoMats), CSV (IQ/OQ/PQ)
- Trained mediator: conflict and change

INTERIM MANDATES AND CONSULTING ASSIGNMENTS

Senior Consultant Regulatory Affairs DACH 08/2025 – 03/2026

Alnylam Pharmaceuticals · DACH · via Proclinical · siRNA therapies

Regulatory coverage for the DACH organisation, including the statutory Information Officer role.

- Information Officer DACH and RA Deputy.
- Wrote, reviewed and obtained approval of the new Information Officer SOPs.
- Reviewed Veeva PromoMats e-learning; trained the Medical and Marketing departments.
- Maintained regulatory and promotional compliance for the siRNA portfolio in DACH without interruption.

Senior Consultant Regulatory Affairs & Digital Solutions 03/2023 – 07/2025

Novartis / Sandoz · Kundl, AT · via Teccon Austria · global project

Set-up of a standalone, validated regulatory document management environment for the separation of Sandoz.

- Regulatory advisor for the Veeva eDMS implementation; authored and reviewed CSV documentation.
- Global project and interface management with business partners and functions; support of regulatory IT systems (e.g. Proton).
- OQ and PQ successfully completed; regulatory systems supported throughout the separation.

Senior Regulatory Affairs Consultant 05/2022 – 02/2023

Michor Consulting for GSK, CureVac and BioNTech · Vienna, AT / Germany · vaccines, biologics, small molecules

Short-term regulatory and medical writing capacity for German pandemic preparedness (ZEPAI at the Paul-Ehrlich-Institut) and ongoing COVID-19 vaccine submissions.

- Medical writing (IMPD, PSF, PSD) and clinical submissions, including Comirnaty; programmes for COVID-19, tuberculosis, malaria and mpox.
- Supported pandemic preparedness planning for Germany on behalf of GSK and CureVac.
- Change control, due diligence, global strategy for small molecules, medical device business development.

Senior Principal Regulatory Affairs Consultant 10/2021 – 04/2022

Synaptiq Technologies (start-up) · Software as a medical device · AI

Start-up developing AI-based contouring software for radiotherapy.

- Regulatory advice on software as a medical device during the set-up of the quality management system and the dossier assessment.

Interim Principal Regulatory Affairs Executive DACH 07/2018 – 02/2019 · 04/2020 – 09/2021

Norgine · Vienna, AT / Wettenberg, DE · two mandates · Rx, OTC, medical devices

Interim regulatory leadership for the DACH affiliate, including Rx-to-OTC switches and a regulatory baseline check under deadline pressure.

- Regulatory lead DACH for medicinal products and medical devices; CCDS implementation and guidance; DCP variations; Veeva RIM compliance; project management.
- Implemented key variations and a baseline CTD structure on time; numerous variation approvals and regular renewals.

External QPPV 03/2013 – 08/2021

Krainer MedTech · Austria · part-time mandate alongside other assignments

- Introduction and maintenance of the marketing authorisation and marketing of Perisol; eight years of continuous pharmacovigilance compliance.

International Regulatory Affairs Manager 05/2019 – 12/2019

Amomed Pharma · Vienna, AT · generics

- MRP/DCP and national submissions for generic medicines in several EU markets; authored CTD Modules 1–3 (CMC, labelling); pharmacovigilance documents.
- Secured the marketing authorisation for treprostinil via MRP.

Senior External Consultant Medical Devices 04/2014 – 01/2015

Smith & Nephew Orthopaedics · Aargau, CH · implants (MD scope 0202)

- Led the recertification of a portfolio of orthopaedic implants under time pressure.
- Coordinated QM, Clinical and Development to answer notified body deficiency letters.
- 22 implant products recertified on schedule.

Senior External Consultant Medical Devices 08/2013 – 03/2014

DePuy Synthes (Johnson & Johnson) · Raron / Zuchwil, CH · implants

- Legacy reviews and remediation plans for FDA and TÜV SÜD audit findings on orthopaedic implants.
- Product assessment and regulatory submissions.

Further assignments

- **Alcon / Grieshaber, CH** (04–06/2018): MDR technical documentation (STED) for class IIb ophthalmic surgery devices.
- **Pharmaselect, AT** (08–09/2017): Head of Regulatory Affairs for medicinal products and medical devices.
- **TÜV SÜD, DE** (02–06/2017): Technical Documentation Assessor for non-active medical devices (absorbable implants); all qualifications passed.

LEADERSHIP POSITIONS

Regulatory Affairs Manager (regulatory lead Austria) 02/2015 – 12/2016

Galderma Austria (formerly Spirig) · Vienna, AT · medicinal products, aesthetic fillers, cosmetics, food supplements

Acquisition of Spirig by Galderma, which subsequently became part of Nestlé Skin Health.

- Regulatory lead for the integration after both changes of ownership; EU, MRP and national procedures.
- Local Safety Officer, GDP Responsible Person and Information Officer.

- All audits and inspections passed during the integration; all marketing authorisation transfers completed.

Head of Regulatory Affairs 07/2010 – 03/2013
Laboratorium Dr. G. Bichsel AG · Interlaken, CH · medicinal products, medical devices, biocides
Successor to the departing Head of RA; there was no independent vigilance department.

- Responsible for regulatory affairs, vigilance, risk management and advertising compliance; Swissmedic, MRP and national procedures.
- Medical devices (e.g. Citrasate dialysis solution, lubricants, contact lens products); BfArM and EMA consultations on drug-device combinations; RA/QM transfer documents for product acquisitions.
- Numerous approvals; change of notified body completed; CTD for Cardioplexol prepared; authorisation of the veterinary product Equibiserol completed.

Regulatory Affairs Officer 08/2008 – 06/2010
Wyeth Whitehall Export (now Pfizer) · Vienna, AT

- EU, CIS and national procedures; CCDS implementation; submission of new clinical studies supported by CTASURs.
- Approval of Enbrel in Russia and other CIS countries; indication extension for methotrexate in Austria approved.
- Regulatory work during Pfizer's acquisition of Wyeth (closed 10/2009) and the subsequent integration.

Regulatory Affairs Manager 11/2007 – 07/2008
Merck · Vienna, AT

- Medicinal products (Rx/OTC; CMC, labelling; MRP/DCP), medical devices and food supplements.

Regulatory Affairs Manager 09/2006 – 10/2007
Croma Pharma · Korneuburg, AT

- Medical devices (intraocular tamponades, contact lenses) and food supplements; reimbursement applications; numerous registrations in the Middle East.

Earlier career (2000–2006): Regulatory affairs trainee (Faromed); pharmaceutical and hospital sales representative (Novartis, Sigmapharm); product specialist diagnostics (Instrumentation Laboratory/Werfen).

EDUCATION

2000	**Doctorate in Human Biology**, University of Vienna (Dr. rer. nat., with distinction)
1996	**Master's degree in Zoology**, University of Vienna (Mag. rer. nat., with distinction)
2001 – 2003	**Postgraduate training** in drug development and drug safety, Austria

CERTIFICATIONS AND QUALIFICATIONS

2021	WKO (Austrian Economic Chamber): qualification examination in management consulting
2018	WKO: qualification examination for medical device trade (managing director)
2017	TÜV SÜD: MDR and ISO 13485:2016; qualification as Technical Documentation Assessor for non-active medical devices
2001 – 2004	Mediator training, ARGE Vienna
1995	WKO: pharmaceutical sales representative examination

LANGUAGES, IT AND OTHER

Languages	German (native), English (business fluent), French (basic)
Systems	Veeva Vault (RIM, Submissions, QualityDocs, PromoMats, MedComms), DocuBridge, Lorenz eValidator, Gloria RCM, Proton, TrackWise, Adonis, Jira, MS Office, Articulate 360
Other	Publications on the regulation of genetic testing in Europe (1998–2000, OECD); author of novels and short stories; member of the Austrian Writers' Association