

Dr. Alfred Horak

Interim Head of Regulatory Affairs | Interim Manager Pharma & MedTech

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Available for interim mandates at short notice · DACH & 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. Brought in when a regulatory function must keep running through a vacancy, spin-off, acquisition, MDR transition or system implementation: takes responsibility from day one, stabilizes compliance and hands over a documented, audit-ready function. Hands-on across 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 & carve-outs:** Sandoz separation from Novartis; Spirig → Galderma → Nestlé; RA/QM transfers in acquisitions (Bichsel)
- **MDR transition & notified bodies:** implant recertifications, MDR/STED documentation, change of notified body; former TÜV SÜD assessor
- **Audit, inspection readiness & remediation:** FDA and TÜV SÜD remediation plans (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 orthopedic implant products with the notified body on schedule and ahead of competitors (Smith & Nephew).
- Completed OQ and PQ validation documentation for the regulatory eDMS (Veeva) during the separation of Sandoz from Novartis.
- Led regulatory affairs through two changes of ownership (Spirig → Galderma → Nestlé); all audits and inspections passed.
- Secured marketing authorization for Treprostinil via MRP (Amomed); approval of Enbrel in Russia and further CIS markets and an indication extension for methotrexate in Austria (Wyeth/Pfizer).
- Re-engaged by Norgine for a second interim mandate as regulatory lead DACH (2018–19 and 2020–21).
- Eight years as external QPPV with continuous pharmacovigilance compliance (Krainer MedTech, 2013–2021).

CORE COMPETENCIES

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

INTERIM MANDATES & CONSULTING ASSIGNMENTS

Senior Consultant Regulatory Affairs DACH — Alnylam Pharmaceuticals

08/2025 – 03/2026

DACH · via Proclinical · siRNA therapies

Situation: The DACH organization for innovative siRNA therapies required regulatory coverage, including the statutory Information Officer role.

Mandate: Information Officer DACH and RA Deputy; author and reviewer of the new Information Officer SOPs; reviewer of Veeva PromoMats e-learning (incl. training for the Medical and Marketing departments).

Result: Regulatory and promotional compliance for the siRNA portfolio in DACH maintained without interruption; SOPs created and approved.

Senior Consultant Regulatory Affairs & Digital Solutions — Novartis / Sandoz

03/2023 – 07/2025

Kundl, AT · via Teccon Austria · global project

Situation: The separation of Sandoz from Novartis required a standalone, validated regulatory document management environment.

Mandate: Regulatory advisor for the Veeva eDMS implementation; CSV documentation and review; global project and interface management with business partners and functions; support of regulatory IT systems (e.g. Proton).

Result: OQ and PQ successfully completed; regulatory systems supported through the separation.

Senior Regulatory Affairs Consultant — Michor Consulting for GSK, CureVac and BioNTech**05/2022 – 02/2023***Vienna, AT / Germany · vaccines, biologics, small molecules*

Situation: German pandemic preparedness planning (ZEPAL at Paul-Ehrlich-Institute) and ongoing COVID-19 vaccine submissions required rapid regulatory and medical writing capacity.

Mandate: Medical writing (IMPD, PSF, PSD), clinical submissions (incl. Comirnaty), change control, due diligence, global strategy for small molecules, medical device business development.

Result: Submission documentation delivered for COVID-19 and other programmes (tuberculosis, malaria, mpox); pandemic preparedness planning for Germany supported on behalf of GSK and CureVac.

Interim Principal Regulatory Affairs Executive DACH — Norgine**07/2018 – 02/2019 · 04/2020 – 09/2021***Vienna, AT / Wetttenberg, DE · two mandates · Rx, OTC, medical devices*

Situation: The DACH affiliate needed interim regulatory leadership, including Rx-to-OTC transfers and a regulatory baseline check under deadline before a new company chapter.

Mandate: Regulatory lead DACH for medicinal products and medical devices; CCDS implementation and guidance; DCP variations; Veeva RIM compliance; project management.

Result: Essential variations and a baseline CTD structure implemented on deadline; numerous variation approvals and regular renewals; re-engaged for a second mandate.

Senior Principal Regulatory Affairs Consultant — Synaptiq Technologies (start-up)**10/2021 – 04/2022***Software as a medical device · AI*

Situation: A start-up developing AI-based contouring software for radiotherapy needed regulatory expertise for medical device software.

Mandate: Regulatory affairs support for the software as a medical device.

Result: Advisory services based on experience regarding medical devices during sensitive QM and dossier evaluation phase.

International Regulatory Affairs Manager — Amomed Pharma**05/2019 – 12/2019***Vienna, AT · generics*

Situation: Generic medicinal products were to be registered in several EU markets.

Mandate: MRP/DCP and national submissions; authoring of CTD Modules 1–3 (CMC, labelling); pharmacovigilance materials.

Result: Marketing authorization for Treprostinil secured via MRP.

External QPPV — Krainer MedTech**03/2013 – 08/2021***Austria · long-term part-time mandate alongside other assignments*

Situation: The marketing authorization holder required a qualified person responsible for pharmacovigilance for the Austrian market.

Mandate: External QPPV; introduction and maintenance of the marketing authorization and marketing of Perisol in Austria.

Result: Perisol introduced and kept on the Austrian market with continuous pharmacovigilance compliance for eight years.

Senior External Consultant Medical Devices — Smith & Nephew Orthopedics**04/2014 – 01/2015***Aargau, CH · implants (MD scope 0202)*

Situation: Certificates for a portfolio of orthopedic implants were due for recertification under time and competitive pressure.

Mandate: Led the recertification; coordinated QM, Clinical and Development to answer notified body deficiency letters.

Result: 22 implant products recertified on schedule, faster than any of the competitors.

Senior External Consultant Medical Devices — DePuy Synthes (Johnson & Johnson)**08/2013 – 03/2014***Raron / Zuchwil, CH · implants*

Situation: FDA and TÜV SÜD audit findings on orthopedic implants required structured remediation.

Mandate: Legacy reviews and remediation plans; product evaluation and regulatory submissions.

Result: Legacy review documents and remediation plans delivered for the FDA and TÜV SÜD findings.

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 (NAM, absorbable implants); all qualifications passed.

LEADERSHIP POSITIONS**Regulatory Affairs Manager (regulatory lead Austria) — Galderma Austria (formerly Spirig)****02/2015 – 12/2016***Vienna, AT · pharma, aesthetic fillers, cosmetics, food supplements*

Situation: Spirig was acquired by Galderma, which subsequently became part of Nestlé Skin Health.

Mandate: Regulatory lead through both transitions; Local Safety Officer, GDP Responsible Person and Information Officer; EU, MRP and national procedures.

Result: All audits and inspections passed during both changes of ownership. All transfers successfully completed.

Situation: The former Head of RA had resigned. There was no independent vigilance department.

Mandate: Responsible for regulatory affairs, vigilance and risk management and advertising compliance; Swissmedic, MRP and national procedures; medical devices (e.g. dialysis solution Citrasate, lubricants, contact lens products); BfArM/EMA consultations on drug-device combinations; RA/QM transfer documents in acquisitions.

Result: Numerous approvals; change of notified body completed; CTD for Cardioplexol prepared; authorization of the veterinary product Equibiserol finalized.

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

Situation: Enbrel was to be registered in the CIS countries. New clinical studies were to be submitted, supported by CTASURs; additionally an extension of the indication for methotrexate was sought.

Mandate: EU, CIS and national procedures, CCDS implementation; approval of Enbrel in Russia and further markets; indication extension for methotrexate in Austria.

Result: Enbrel has been registered in numerous CIS countries, including Russia; the extension of indication for use with methotrexate has also been approved.

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

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

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

Medical devices (intraocular tamponades, contact lenses) and food supplements; reimbursement submissions; 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

PhD in Human Biology (Dr. rer. nat., excellent) — University of Vienna

2000

Master's degree in Zoology (Mag. rer. nat., excellent) — University of Vienna

1996

Postgraduate training in drug development and drug safety — Austria

2001 – 2003

CERTIFICATIONS & LICENCES

- TÜV SÜD: MDR and ISO 13485:2016; Technical Documentation Assessor for non-active medical devices (2017)
- WKO trade licences: Management Consulting (2021) and Medical Devices (2018)
- Certified Mediator, ARGE Vienna (2001–2004)

LANGUAGES & IT

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 etc.

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.