Freelance Senior Regulatory Affairs Consultant (m/w/d)

Dear Network,

I am urgently looking for a Freelance Senior Regulatory Affairs Consultant (m/w/d) who can support my client remotely.

Frame Data:
Start: ASAP
Duration: 6 months +
Work volume: 30-40h/ week
Location: Remote
Languages: Excellent verbal and written communication skills in English

Tasks:
- Develop regulatory strategies for regulatory submissions, including the development of paediatric development plans (PIPs, iPSP)
- Independently support planning and submission of clinical trial applications (CTA) phase III in cooperation with CROs
- External cooperation with the regulatory authorities of the external production partners
- Review and advice on approval of quality documentation for IMPDs, INDs and MAA dossiers (eCTDs)
- Regulatory contact with EU and USA, China and UK in CP
- Independent monitoring of regulatory SOPs
- External consulting to ensure regulatory compliance
- Independently plan and develop regulatory documents for submission to regulatory authorities
- Provide regulatory input to product development teams and other internal projects
- Establish active networks with internal and external experts to support the activities of the Regulatory Affairs department
- External contact person for regulatory issues

Requirements:
- Authority contact with EU and USA, China and UK in CP
- Pharmaceutical background/ drug development (coming from CRO not sufficient)
- Marketing authorisation strategy
- Organisational and communication skills in English (oral and written)
- Hands-on mentality
- Nice to have: in-vitro diagnostics experience

I am looking forward to your feedback. Please do not hesitate to call me for further details or to share it with your network.
Kind regards
Milena Heidinger
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