Regulatory Operations E-Submission Specialist (f/m/d)

Would you like to be part of a joint effort to undertake submission for our various products to international health authorities? Are you ready to join the effort to further accelerate timelines and strengthen processes in a growing company? Do you enjoy working hand-in-hand with a diverse team, all dedicated to handle submissions in a timely and precise manner? Then we would like to meet you.

Join our transformative journey

At Bavarian Nordic, we aspire to save and improve lives by developing innovative vaccines that are designed to unlock the power of the immune system. We are a global leader in smallpox vaccines and our commercial product portfolio contains market-leading vaccines against rabies and tick-borne encephalitis as well as an Ebola vaccine, licensed to Janssen.
We have embarked upon a truly transformative journey towards becoming one of the largest pure play vaccine companies by excelling in R&D innovation, manufacturing and commercialization, and are looking for more talent to help drive the change. Come on board our journey and let's change more lives, together.

Our Regulatory Affairs Department

Our Regulatory Affairs Department heads up all submissions to international health authorities for Bavarian Nordics' products, ensuring their access to and success on diverse markets. Become part of a dedicated team that works to its highest standards while still having fun together.

Your tasks

- Planning, preparing, tracking and publishing as well as the timely submission of global eCTD applications (e.g. IND, CTA, BLA, MAA, post-authorisation life-cycle management MRP/DCP)
- Publishing and archiving various metrics as well as the submission process to global health authorities (eCTD publishing and electronic document management system)
- Administrating our Document Management System "Veeva"

About you

Your qualifications

- Commercial apprenticeship and relevant work experience within regulatory affairs or an adjacent field within the healthcare industry
- At least 2 years of experience in electronic document management (e.g. ERP systems such as SAGE, SAP, DB, Extedo, SARA and/or Veeva RIM)
- Basic knowledge of regulations and industry standards regarding eCTD requirements and document formats/ standards
- Good written and verbal communication skills in English
- Ideally a background in IDMP and XEVMPD
- Experience with EMA, FDA, CA and ROW authorities would be an advantage

We offer

A chance to work in an international company with unique technology and a dedicated work force. We offer a dynamic work environment and an opportunity to develop both your personal and academic competencies.

Caught your interest?

If you are interested in the position, we look forward to receiving your application in English with your annual salary expectations and your earliest possible start date via our internal system.
Just click here and you will be redirected to our application site.

We kindly ask recruitment agencies/headhunters to refrain from contacting Bavarian Nordic GmbH. Unsolicited documents will not be considered.

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