Everyone can achieve great things at BioNTech! We develop revolutionary approaches in the fight against cancer and other diseases. BioNTech wants to become the world's leading biotechnology company for individualized cancer medicine. Over 1000 dedicated, passionate pioneers achieve sensational success and promising breakthroughs time and again by forging new paths – and ensure people all around the world have hope for the future. You too can become a pioneer!

(Senior) Director* Regulatory Affairs CMC

Here, you'll achieve greatness. At BioNTech, you will be responsible for leading the day-to-day CMC Regulatory Affairs operations to include managing a global team as well as building/driving strategy and regulatory/compliance filings. Your primary duties in detail:

- Strategic development and optimization of the Regulatory Affairs CMC team, including the respective processes/procedures/SOPs for market approval (Phase I to Phase IV)
- Strategic planning of the Regulatory Affairs CMC activities for all clinical projects at BioNTech (i.e., mRNA, antibodies, CARs, small molecules)
- Regulatory evaluation of CMC development activities and data
- Oversight of regulatory dossiers (e.g., creation; modification; submission) for market approval and beyond
- Lead, manage, develop, mentor and hire global team members

What you have to offer.

- Scientific degree is highly preferred, along with at least 10 years of relevant academic/government/CRO/industry experience
- A minimum of 5 years of direct CMC regulatory experience, to include a global background, is required
- Significant management and leadership background is required
- Significant experience working with national agencies in Europe as well as EMA and FDA is required; Further regions (Japan, China, Rest of World (RoW)) is preferred
- Experience managing and overseeing of regulatory documents/dossiers for market approval and beyond is required
- Experience with biologics and drug development is required; Gene and/or cell therapies experience is preferred
- Adaptability, strategic mindset, innovative yet pragmatic/solution-oriented thinking, and attention to detail with a strong orientation to quality required
- Fluent English language skills and professional-level communication skills (i.e., oral, written, presentation) required

Benefits for you.

- Jobticket
- Child Care
- Company Bike
- Fitness
- Pension
- Relocation
- and much more.

Have we kindled your pioneering spirit?

Then apply now for our location Mainz and simply send us your application documents using our online form.

If you have any further questions, Andy Wingstrom will be happy to answer them on + 49 (0) 6131-9084-1291 (Monday-Friday, from 12 noon).

*BioNTech does not discriminate on the basis of gender, race, religion, color, origin, sexual orientation, disability, age and other protected status as required by applicable law. We are committed to creating a diverse environment and are proud to be an equal opportunity employer.

BioNTech - As unique as you

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