

Be the new

Regulatory CMC & Drug/Device Specialist

in a biotech company focused on the discovery, design and development of innovative peptide-based medicines ●

Zealand Pharma A/S (Zealand) is seeking a Regulatory CMC and drug-device specialist who will be responsible for Regulatory CMC and device tasks related to our development projects.

Job Profile

The successful candidate will:

- Be an experienced and proactive Regulatory CMC expert with late stage drug and drug-device development experience who can enable our fast to patient strategy through close liaison with our pharmaceutical development and commercial manufacturing departments
- As part of the CMC project teams find the best regulatory strategy and pathways for CMC plans and know the potential shortcuts and pitfalls
- Advice on regulatory and non-CMC consequences of CMC/device decisions
- Drive Agency interactions on CMC and device issues
- Be involved in inspection Q&As ensuring proper response to Agencies
- Review all CMC and device regulatory documents from a regulatory strategic perspective
- Generate regulatory risk assessments for CMC and device changes.

Candidate Profile

The successful candidate will have:

- CMC and preferably drug-device regulatory expert knowledge
- A solid CMC regulatory network especially in the US and especially on drug-device requirements
- Experience with the US and EU drug-device regulatory environment including FDA and EU Regulatory Agency interactions
- Experience with NDA and MAA submissions
- The wish to make a difference in our fast-paced development projects.



The department

You will be part of the Regulatory Affairs team in the Regulatory, Medical Writing & Pharmacovigilance department. We are a small regulatory team that emphasizes supporting and challenging each other in order to find the best regulatory strategies for the Zealand projects. We are high-performing, ambitious, work independently and take responsibility for our own projects while focusing on functioning and delivering as a team. We aim to make a difference for the project teams and for the development and approval of our products. We are busy but we make sure we have fun in our daily work. While we lay out the regulatory strategies internally, we collaborate with external regulatory contractors.

What we offer

Zealand's employees are one of the company's most important assets, and we strive to attract, develop and retain the best talents, and to be a company where employees thrive.

At Zealand, we understand the value of a diverse workforce, and as an employee, you will be part of an innovative cross-disciplinary and cross-cultural working environment.

We offer a combined salary package including pension scheme and health insurance, as well as the option of joining the company lunch program, and use of massage, fitness and social facilities.

To find out more about working at Zealand, visit our careers site and view our company video at:

www.zealandpharma.com/zealand-as-a-work-place/

www.zealandpharma.com/video-about-zealand-new/

Application

Please send your application and CV no later than July 31, 2018 to:

career@zealandpharma.com

or

Zealand Pharma A/S
Att.: Charlotte Madsen
Smedeland 36
DK-2600 Glostrup

For further information, please contact
Trine Moulvad: tbm@zealandpharma.com or
Mette Clausen: mcl@zealandpharma.com

About Zealand Pharma A/S

Zealand Pharma A/S (Nasdaq Copenhagen and New York: ZEAL) ("Zealand") is a biotechnology company focused on the discovery, design and development of innovative peptide-based medicines. Zealand has a late stage clinical portfolio of proprietary product candidates focusing on specialty gastrointestinal and metabolic diseases. In addition, it has two marketed products, commercialized by Sanofi, and two product candidates under license collaboration with Boehringer Ingelheim.

Zealand is based in Copenhagen (Glostrup), Denmark. For further information about the Company's business and activities, please visit www.zealandpharma.com or follow Zealand on LinkedIn or Twitter @ZealandPharma.