

Be the new

# CMC Submission Specialist

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

Zealand Pharma A/S (Zealand) is looking for an experienced CMC and Device Submission Specialist who in collaboration with CMC scientists will be responsible for the writing and reviewing of CMC submission documentation that lives up to Authorities' expectations from a content perspective.

You will be part of an innovative and agile Biotech company focused on the discovery, design, development and commercialization of innovative peptide-based medicines.

You will be part of Commercial Manufacturing which is responsible for late-stage development and manufacturing activities. You will be working in a project team together with other development functions, and you will be working on several drug-device combination product submissions.

Since Zealand is using Contract Development and Manufacturing Organizations, coordination and alignment with external partners are a key part of the job alongside internal Zealand collaboration.

## Job Profile

The successful candidate will be responsible for the CMC and Device content of initial NDAs, during Q&A and subsequent lifecycle management activities:

- Drive the CMC and Device regulatory documentation gap analysis and plan mitigation strategies together with your regulatory affairs counterparts
- Coordinate CMC and device writing activities with several CMC scientists (API, DP, Device, Analytical and CMO Manufacturing)
- Be key writer to ensure content and storyline of the CMC and Device sections of submissions and authority questions/answers.

## Candidate Profile

The successful candidate will have:

- A Life Science degree within chemistry, biochemistry, pharmaceutical sciences, or another relevant field
- 10 years' experience from the Pharmaceutical Industry
- Extensive experience with regulatory requirements for late stage CMC development and content of regulatory submissions (NDA/BLA/MAA)
- Hands-on technical writing experience from major regulatory submissions
- Experience with drug development processes



- Experience with contract development and manufacturing organizations
- Experience with participating in cross functional project teams
- Strong written communication skills in English
- Stakeholder management skills
- The ability and engagement to “walk the extra mile”
- Interest in working in a dynamic environment and taking on new challenges

### What we offer

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

At Zealand, we understand the value of a diverse workforce. 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/](http://www.zealandpharma.com/zealand-as-a-work-place/)

[www.zealandpharma.com/video-about-zealand-new/](http://www.zealandpharma.com/video-about-zealand-new/)

### Application

Please send your application and CV no later than October 3, 2018 to:

[career@zealandpharma.com](mailto:career@zealandpharma.com)

or

**Zealand Pharma A/S**  
**Att.: HR**  
**Smedeland 36**  
**DK-2600 Glostrup**

For further information, please contact Vice President, Commercial Manufacturing, Jakob Gjelstrup Kristensen at +45 5060 3772 or [jgk@zealandpharma.com](mailto:jgk@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 and development of innovative peptide-based medicines. More than 10 drug candidates invented by Zealand have advanced into clinical development, of which two have reached the market. Zealand's current pipeline of internal product candidates focus on specialty gastrointestinal and metabolic diseases. Zealand's portfolio also includes two clinical license collaborations 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](http://www.zealandpharma.com) or follow Zealand on LinkedIn or Twitter @ZealandPharma.