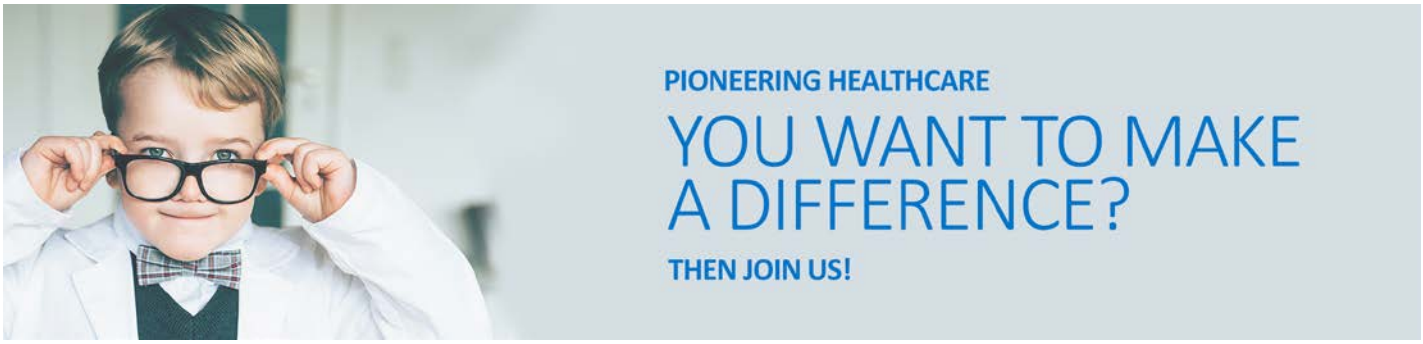
TIEFENBACHER GROUP




## We are Tiefenbacher Group – Health Pioneers since 1963.

100% family owned since 1963, we are a leading healthcare company providing innovative and best-in-class solutions along the entire pharmaceutical value chain. The distribution of APIs and the development, manufacturing, and registration of finished dosage forms are our core competencies. The world´s most trusted brands count on our pioneer spirit as well as our pharmaceutical excellence. Leveraging our global presence, including own laboratories and manufacturing sites, we are driven to make pharmaceuticals more affordable, more available, and better than before. There is one purpose driving our about 600 employees day by day: improving the life of millions of patients worldwide.

Your expertise and commitment can make a difference to patients all over the world. Join us at our global headquarters in Hamburg (fulltime) and become a part of our FDF-Business Unit AET at the earliest possible date.

We look forward to hearing from you!

Send your resume and letter of motivation including your salary expectations and availability to our HR department (jobs@aet.eu).

Check out our website www.aet.eu for more information!

# ENGINEER (M/F/D)
# FOR MEDICAL DEVICE ENGINEERING

### YOUR RESPONSIBILITIES

- Developing, configuring and optimizing medical device product designs – from inception to industrialization
- Assessing product designs, processes, taking measurements and interpreting data
- Supporting the qualification procedures including IQ/OQ/PQ – e.g. of injection mould tools, other equipment and assembly processes
- Carry out risk analyses including failure mode and effects analysis (FMEA) and support design and process changes
- Manage and execute verification and validation activities associated with design or process changes through our partners
- Identify process deficiencies and non-conformances in manufacturing processes and support the development of corrective actions
- Support internal audits and QA related activities under ISO 13485 and MDR
- Working with product development teams throughout the development and the regulatory pathway in the USA and Europe
- Product scopes: Drug Inhalers, further Drug Delivery Devices currently in preparation

### YOUR SKILLS & QUALIFICATIONS

- You have successfully completed your (medical) engineering studies and have relevant professional experience (more than three years) within a regulated area in the field of Medical Device Engineering, in particular in product development, process validation and/or automation of production
- You are confident in applying relevant standards and regulations (ISO 13485 as well as 21 CFR 820, ISO 14971 and MDR)
- You are motivated to work both in a team and independently and enjoy complex tasks and "pioneering work”
- With your strong communication skills and solution-oriented mindset, you will master business contacts with people from different backgrounds and cultures
- You are characterized by a high degree of commitment, sense of responsibility and assertiveness
- You have a profound technical understanding and confident use of 3D-CAD software as well as the MS-Office, especially Excel
- Very good knowledge of German and English complete your profile

### LOOK FORWARD TO

- working for an internationally established company in the pharmaceutical industry.
- our modern offices in the buzzing heart of Hamburg right at the Elbe river.
- the opportunity to implement your own ideas in solving challenging tasks.
- flexible working hours