



3Shape seeks a Regulatory Affairs Specialist

For the Quality Management department in Copenhagen we are looking for a Regulatory Affairs Specialist. You will be responsible of obtaining and maintaining regulatory approvals for our scanners, technical changes, and providing registration support to the organization. Furthermore, you will be critical in our ISO13485 process. The main internal customers are the Development Department, Production and Quality Department.

Your Profile

- A relevant theoretical background
- Min. 5 years of experience with key regulatory issues and developments affecting the healthcare industry
- Knowledge of key FDA, UL, ISO13485
- Excellent planning and project management skills
- Strong experience within document management
- Fluent in English
- Strong verbal and written communication skills
- Least but not least: A team player with a positive attitude

Your Responsibilities

- Propose regulatory strategies for establishment and technical registrations
- Develop state-of-the-art Regulatory Affairs processes for maintaining and enhancing the company's manufacturing and quality control registration dossiers
- Ownership and facilitation of our ISO13485 process together with the Quality Management Department

About us

3Shape A/S is a Danish company specializing in the development and marketing of **3D scanners and CAM/CAM software solutions** for the use, creation, processing, analysis and management of high quality 3D data.

Working at 3Shape

Become part of an international success, financially as well as product wise. As an employee, you have plenty of room to both **make a difference and fulfil personal ambitions** in a very knowledge intensive and challenging environment.

3Shape Technology

Through the relentless drive for new digital innovation by 3Shape, we claim to be **the most extensive and versatile CAD/CAM system** on the market.



Your Main Tasks

- You will work directly with administrative, operational and functional departments within the company to facilitate and manage all interactions with regulatory bodies worldwide
- Manage all activities related to the maintenance of establishment licenses and related to the submission of technical changes
- Prepare regulatory submissions
- Answer questions from health regulatory bodies and from the company affiliates and agencies concerning regulatory authority interactions
- Represents Regulatory Affairs on cross functional teams (e.g. task specific teams)
- Participate in interactions and negotiations with regulatory authorities regarding filings
- Responsible for maintaining up-to-date documentation for the company products

If this description corresponds to your profile and you would like to apply, please contact us preferably by e-mail at: recruit@3Shape.com. Please attach your Curriculum Vitae, grades and other relevant information. If you need more information, please contact Mikael Petersen at +45 7027 2620 or visit www.3shape.com

3Shape going Global

3Shape is headquartered in Copenhagen, with development teams in Denmark as well as the Ukraine and own production site in Poland. In early 2009 we opened Sales and Support Offices in New Jersey, USA and Shanghai, China.

Our People

Employing and developing the right people is an important key to 3Shape's success. We want to be the **best within our business**, an ambition which has created a true **fighting spirit** throughout the company - with lots of **commitment** and courage, and a **professional attitude** towards business.

Contact

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