Regulatory Affairs / Quality Manager (m/f)

OncoBeta is a manufacturer and service provider of innovative medical solutions targeting at the improvement of the quality of life. Our current field of action is brachytherapy, i.e. the treatment of lesions (tumors, scars, etc.) with radioactivity.
In concrete, OncoBeta currently offers solutions for personalized treatment of non-melanoma skin cancers and keloids. OncoBeta leads the patient from the detection of his/her illness to its cure and integrates all steps of the chain of values (R&D, clinical evaluation, certification, production, logistics, maintenance, marketing, sales, service, etc). As a result, OncoBeta is a stepping stone for career development of motivated individuals of any field of expertise. Joining OncoBeta you will start in a young, dynamic, interdisciplinary and international team maintaining a good working atmosphere and environment directly in Munich, one the best ranged cities to live in Europe.

For the beginning of April 2016, we are searching for a Regulatory Affairs / Quality Manager (m/f).

Main Assignments:

- Administer and maintain the Quality Management System (QMS)
- Organize, review, update, and/or initiate the writing of internal standard operating procedures (SOPs)
- Monitor the reporting and follow-up of incidents related to OncoBeta
- Organize internal quality and process audits: prepare for the audit, respond to findings, find root causes, and implement improvements
- Advise on the creation and updating of employee training records
- Schedule regular meetings, prepare the agenda & minutes and follow up on action items related to OncoBeta's QMS
- Prepare and follow-up submissions for product certifications worldwide
- Interact actively with R&D in the improvements of OncoBeta's products

Required Qualifications:

- Reliability, high motivation and willingness to learn
- Degree in engineering, computer or natural sciences, or if not experience in these fields
- Experience in communication with quality, risk and project management
- Experience with QMS and respective software solutions
- Previous roles in quality auditing and document management
- Fluent English and German (writing and speech)
- Power user level in Microsoft Word, PowerPoint and Excel (or equivalents)

Preferred Additional Qualifications:

- Previous roles in Quality Management and Regulatory Affairs
- Experience with CE certification, FDA, TGA or CDMR
- Experience with ISO9001 or ISO13485
- Experience in writing SOPs, preparing device master records (DMR), good manufacturer practices (GMP)
- Experience in Dermatology, Radiation Therapy or Plastic Surgery
- Italian or any Latin language
- Any major European language (French, Spanish, Russian, …)

If this challenging assignment is of your interest we would be happy to arrange a meeting with you. Please send your complete application (letter of motivation, CV and recommendations if available) as PDF by email to Dr. Thomas Wendler at career@oncobeta.com.