Mentis
CONSULTING
Menschen zum Erfolg

Are you an expert in regulatory affairs seeking a challenging and rewarding, globally responsible and strategically important position in the medical device world?

Targeting top contract management business, German development and manufacturing OEM-partner is relying on your outstanding expertise, communication skills and drive.

highly competent - business-minded - assertive - cross-cultural

Head of Regulatory Affairs (m/f) - Medical Devices / IVD

Frankfurt/M. (Germany) or Montpellier (France)

The Company

BIT Analytical Instruments (www.BIT-group.com) is a profitably growing, renowned one-stop solution provider to the leading innovators of medical devices. BIT is part of the financially strong, family owned, 1.7 billion € turnover German Messer Group. Life Sciences is our home. Headquartered in Schwalbach near Frankfurt/M., we are present in all the relevant markets around the world. In our R&D and production sites in the USA, Europe and Asia some 350 qualified employees contribute to our growing success. We are building on the customer focus, expertise, enthusiasm and team spirit of our employees as well as on our constant thrive for excellence. Our flat organizational structure enables flexibility on all levels as well as fast decision-making processes and empowers our colleagues to actively get involved in shaping the future of the company. We have decades of experience in IVD, medical and life science automation – offering contract partnership in product development, manufacturing and after sales services. In vitro diagnostics is our home turf – hematology our particular strength. With our competencies along the innovation value chain we are an acknowledged partner of the international medical device OEM-industry. Our mission: To help our customers to improve their competitiveness and market position. Our targeted standards: Reducing time-to-market and time-to-volume, meeting feature and quality requirements as well as target prices by value engineering and last but not least providing top expertise in the world of regulatory affairs.

The Opportunity

Our strategic goal for the next years: We want to become one of the top 3 solution providers in our market segment worldwide. We are already on track - but there is still a lot to do. In order to achieve our challenging goal we have identified 'outstanding competency in regulatory affairs' as one of the key success factors. The urgency for our customers to cope with the rapidly growing complexity of the regulatory requirements around the world makes this area a top management issue. We therefore decided to substantially invest in that sector and to position a top expert as globally responsible Head of Regulatory Affairs (m/f). This cross-sectoral group function will be embedded in our matrix organization reporting directly to our CEO. Your personal goal: To strategically position BIT as THE knowhow center for regulatory affairs in medical devices/ IVD. The remuneration package for this position is in line with this particular focus: An attractive package that aims to entice a long-term perspective for highly competent candidates with convincing personalities. There is certain flexibility around the location of this position: You may choose to be located either at our headquarters near Frankfurt/M., Germany, or at our Hematology Center of Excellence in Montpellier, France.

As Global Head of Regulatory Affairs (m/f) you are the owner (and designer) of our overall global regulatory affairs approach and accountable for ensuring cross-functional alignment in planning and execution. Building on our existing competencies around the world you will form and coordinate a virtual interdisciplinary team of experts across various countries that deals with regulatory issues throughout product development, manufacturing and after sales services in the most pro-active, knowledgeable and effective way. By offering our customers and internal organization outstanding expertise and support in regulatory affairs you will also substantially contribute to developing future business.

Your Key Responsibilities:

- Provide guidance and training in order to foster our competency in regulatory affairs.
- Review and communicate current and emerging regulatory requirements for quality, design, manufacturing, preclinical and clinical programs to ensure compliance of all development activities with applicable US and international regulations and guidelines.
- Participate in the development of standard operating procedures (SOPs); ensure SOPs are in compliance with current regulatory requirements.
- Monitor company progress toward fulfilment of regulatory commitments.
- Prepare robust regulatory applications to achieve organizational objectives.
- Create, review and approve engineering change orders considering regulatory-related topics.
- Act as regulatory representative on product development teams, communicate regulatory requirements and impact of regulations to the development team.
- Provide guidance and expertise on risk analysis, quality system requirements, verification/validation testing, etc.
- Act as a balancing liaison between the company´s and clients´ interests.
- Act as liaison between the company and the various appropriate regulatory agencies, ensuring that communications on both sides are clear, specific and convey all necessary details.
- Maintain ongoing surveillance and analysis of pertinent domestic and international medical device regulations to ensure submission requirements world-wide are current and up-to-date.
- Interface with the FDA and other regulatory agencies.
- Support inspections by notified bodies, the FDA and other regulatory agencies.

Required Qualifications, Skills and Attributes

- BA/BSc or MA/MSc degree, scientific or engineering field preferred.
- Minimum 7-10 years of technical experience, including at least 7 years of regulatory experience in the medical device industry.
- Experience with 510(k) applications, PMA supplements and US device regulations (FDA) and/or experience with EU (MDD/MDR & IVDD/IVDR) and other international medical device regulations and submissions.
- Must have knowledge of U.S. and/or European/International regulations and standards like ISO 14971, IEC 62366, IEC 62304, IEC 61010, IEC 60101 etc., knowledge about CFDA requirements would be beneficial.
- Strong verbal and written communication skills (including good technical writing), fluent English mandatory, French and German would be ideal.
- Proficient in Microsoft Office.
- You are an acknowledged expert in your field, a demanding and convincing personality, a self-starter with strong business acumen.
- You are result-driven and persistent but also a good listener and integrator with natural leadership skills, assertiveness and intuition.
- You are rather task than career oriented, can identify with the culture of medium-sized companies and are capable of inspiring and motivating people.
- As a self-confident, independent thinker and pro-active manager you want to make things happen and approach complex situations with a solution-oriented and pragmatic attitude.

- Your systematic and target-focused approach is supplemented with excellent analytical skills.
- You enjoy intercultural and interdisciplinary collaboration and communicate in a direct and open manner at multiple levels in the organization, showing confidence when working in matrix structures.
- You are able to train and develop the organization in a smart and beneficial way in regards to all kinds of regulatory questions.
- You do not mind frequent international travel, have a positive attitude to your work, endurance and a good sense of humour.

If we were able to catch your interest then please send your complete application documents (letter of motivation, CV, references, salary expectations) - preferably by email to the below-mentioned address indicating our specific **assignment number: M-SB 180103.**

We look forward to receiving your application.

If you have any questions regarding this position please do not hesitate to get in touch with

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