Senior Regulatory Affairs Manager (m/f/x) with an entrepreneurial mindset
Industry: Pharma

About the Company:

Our client is a family-owned healthcare company with a history stretching back more than 30 years. It markets over 200 products (Rx, OTC, medical devices, cosmetics and food supplements) and operates in over 30 markets around the world. Our client is looking to set up its first subsidiary in Western Europe, which will be based in the area of Munich, Germany. Our client is launching a novel product this year with best-in-market properties. We have been commissioned to look for a

Senior Regulatory Affairs Manager (m/f/x)

with the following profile:

Key Responsibilities & Tasks:

- To lead the regulatory affairs department (operational & disciplinary) and coordinate regulatory activities
- To ensure compliance with all relevant regulatory & statutory requirements covering manufacturing, registration and marketing
- To supervise pharmaceutical posts required by law (quality management, information, pharmacovigilance)
- To manage all regulatory issues
- To coordinate activities with the respective AFPL regulatory affairs departments
- To document any regulatory affairs issues
- To represent the company at specialist committees and events (e.g. regulatory affairs working groups at pharmaceutical industry associations, interactions with pharmacists/doctors associations, meetings/round tables organized by BfArM and/or local authorities such as the Upper Bavarian government authorities)
- Reporting line: General Manager

Requirements:

- A university degree in pharmacy, medicine or another scientific field
- Min. 5 years' experience of working in regulatory affairs in the pharma industry, ideally a family-run business (big pharma / freelancing also possible)
- Experience of handling regulatory affairs for Rx products, OTC products and medical devices
- Preferably experience of holding a comparable managerial position in a pharmaceutical company (i.e. personnel leadership skills; knowledge of how a pharmaceutical company functions (QM, approval cascades, regulatory demands and regulations), a robust personality with the relevant leadership and management skills to deal with internal and external bodies)
- Hands-on mentality
- Ability to work in a reliable, precise and independent manner
- Strong communication skills; ability to think and act in a target, solution and results-oriented manner
- Ability to collaborate closely with other departments
- Fluent in (business) English
- Proficient in all standard IT programs

About us:

Dr. Newzella Consulting and its 30+ employees have been operating in the management and personnel consultancy sector for 40 years. Our personnel consultants help our clients to fill a wide range of positions. Each year, we find approx. 80 specialist and managerial staff (m/f): from KAMs to CEOs. Our management consultants offer our clients a range of services from purchasing and selling companies, products and licences to developing business strategies.

Contact details:

Please send us your complete set of application documents including:

- CV incl. a photograph
- All letters of reference
- Last school certificate
- Certificates regarding seminars, further education courses, further training courses

We look forward to receiving your application. All information submitted will be treated confidentially.

Our project team can be contacted as follows:

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COMPETENCE IS OUR CONCEPT!