Julliana Bauer

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PROFESSIONAL SUMMARY

Dedicated and **motivated Regulatory Affairs Manager** with over **8 years** of experience with extensive background developing and implementing regulatory strategy, for top-tier medical devices companies worldwide.

Also possess outstanding **regulatory strategic thinking** and **risk assessment**. Excellent **interpersonal**, **team-management** and **organizational skills**. Experience in **regulatory lead** on **project teams** as well as guidance and **mentoring** to less experienced colleagues and **cross-functional team** members.

WORK EXPERIENCE

Portomed – Orthopedic Implants Importer and Distributor
Regulatory Affairs Manager
November 2014 – Current

- Created the Regulatory Affairs Department, previously outsourced, reducing company's costs, being the major responsible for the regulatory submissions of Medical Devices, critical reviewing product labelling, product recalls and assessing applicable regulations and international standards.
- Played key role in the design, implementation, management and training of employees in a Compliance Program and company policies, resulting in mitigating any regulatory risks, creating awareness and consistently improving client and employee confidence in the company.
- Increased company regulatory reliability and reduced time spent with product labelling errors by reviewing and maintaining accurate regulatory data in the Company's Management System.
- Build Relationship and interface with relevant regulatory authorities, clients and worldwide suppliers.

Oriens – Regulatory Affairs Consulting
Senior Regulatory Affairs Specialist
April 2009 – October 2014

- Improved company's competitive market position nationally and helped achieve international recognition by implementing and managing the Orthopedic Regulatory Submissions Division. Redesigning critical analysis and regulatory assessment procedures, notably increasing the quality levels of Medical Devices submissions.
- Played a key role on the team that developed and launched the company's submissions management web system, which consistently improved regulatory process efficiency, reduced time for customer inquiries and significantly decreased the loss of information and data.
- Consistently achieved a high level of client's satisfaction by reducing the time required to respond requests, building trust, exceeding expectations and effectively resolving inquiries and providing the best strategic solutions with the skills, knowledge and authority needed.
- Supervised complex regulatory submissions projects for top-tier Medical Devices companies worldwide, prioritizing and organizing workloads in a constantly changing environment to meet daily and weekly schedules.
- Build Relationship and interface with relevant regulatory authorities.
- Trained new and less experienced colleagues providing guidance and mentoring.

Latini – Regulatory Affairs Consulting
Junior Regulatory Affairs Specialist
September 2008 – April 2009

- Reduced the time in the preparation of regulatory submissions by effectively reviewing submission documents, to ensure consistency with related filings and critical regulatory requirements.

- Performed interface with relevant regulatory authorities.
- Achieved a high level of client's satisfaction by reducing the time required to respond requests, building trust and effectively resolving enquiries.

EDUCATION DEVELOPMENT

MBA in Strategic Management
Educational Institute of Rio Grande do Sul - IERGS, Porto Alegre/RS - Brazil
Graduated 2011

Postgraduate Diploma in Pharmaceutical Medicine
Federal University of Sao Paulo - UNIFESP, Sao Paulo - Brazil
Graduated 2009

Undergraduate Bachelor of Biomedicine
Feevale University, Novo Hamburgo/RS - Brazil
Graduated 2007

TECHNICAL SKILLS

Medical Device
Mentoring and Training
Evaluation of Risks and Problem Solving
Project Management
Ability to Multi-Task
International Regulatory Affairs
Regulatory Filings and Submissions
Critical Analysis of Technical Documentation
Ability to Prioritize
Critical Thinking
Regulatory Requirements
Presentation and Communications Skills
Regulatory Strategy
Cross-Functional Team Work
ANVISA
Knowledge of Orthopedic Industry
Medical Technology
Creative

ADDITIONAL SKILLS AND INTERESTS

- Advanced Knowledge of Microsoft Office (Microsoft Word, Microsoft Powerpoint, Microsoft Excel)
- Intermediate Knowledge of Adobe Suites (Photoshop, Illustrator)
- Internal Auditor ISO 9001 Certification
- English – Fluent
- Spanish – Intermediate
- Portuguese – Native
- Martial Arts Black Belt
- Hobbies: Digital Design, Photography, Web Development and Programming
- Willing to Relocate