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1. JOB TITLE: Senior Regulatory Affairs Operations Specialist

2. REPORTING TO: RA Manager

3. PRIMARY ROLE DESCRIPTION:


The Regulatory Affairs Operations Specialist will be responsible for overseeing operational aspects of all Amryt regulatory submissions, ensuring that the submissions are of highest quality, delivered on-time, and within established budget. The position is also responsible for overseeing the effective and appropriate management of Amryt's regulatory documentation.

4. DUTIES:

- Manage document publishing for regulatory submissions from all areas of company, in support of global regulatory submissions which may include both paper and e-filings
- Manage publishing activities for marketing applications in eCTD format; formatting, publishing, submitting, lifecycle activit, and archiving sequences
- Oversee the management of electronic and/or paper-based regulatory records
- Provide recommendations on resource needs for regulatory operations and records management activities including the need for outsourcing (e.g., eCTD vendor, SPL vendor)
- Provide oversight for the selection and management of any outsourced publishing and records management vendors
- Create and manage submission plans, in conjunction with Regulatory colleagues
- Represent Regulatory Operations in project teams to support submission planning and ensure coordination of system development activities
- Manage selection, implementation, validation (as applicable) and maintenance of IT tools for regulatory team
- Develop proposals for continuous improvement of internal systems and processes related to publication, submissions, and archiving of regulatory dossiers in a secure and readily-accessible manner
- Apply knowledge of electronic publishing requirements to ensure compliance with agency submission requirements and remain current with evolving standards for electronic submissions and inform other staff of these standards

5. KEY REQUIREMENTS AND QUALIFICATIONS:

Bachelor's degree with a minimum of 5 years' experience in a Regulatory Operations role; ability to work independently with moderate supervision; ability to communicate and interact with a variety of personnel, including management and external vendors; ability to direct operational staff to achieve submission publishing timelines successfully. Excellent organizational skills, sufficient to multi-task and manage project timelines in an extremely fast-paced environment with changing priorities. Knowledge expert regarding global regulatory submission standards, software validation concepts, and publishing best practices. Excellent knowledge of Word and Adobe Acrobat Pro required. Demonstrated expertise with

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submission publishing tools (eCTD building tools); hands-on experience with publishing, validating, and submitting a full marketing application in CTD format in the US/EU required.

6. REVIEW AND APPROVAL:

Reviewed by person in role	Name	Signature	Date
Approved by Manager	Name	Signature	Date