Jazz Pharmaceuticals	Job Description	
Document Number **JV-QDOC-203141**	**Name** **Global Job Description Template**	**Version** **2.0**

Job Description

JOB TITLE:	***Intern, Global Regulatory Publishing***	COUNTRY:	***US***
LOCATION:	***Philadelphia***	ALT LOCATION:	***N/A***
DEPT NAME:	***Regulatory Affairs***	DEPT NO:	***20710 Regulatory Operations***
REPORTS TO:	***Andrew White***	FLSA STATUS:	***Exempt***
JOB TYPE:	***Temporary***	WORK LOCATION TYPE:	***Home Based***
IS POSITION SUPERVISORY?	***NO***	BUDGET NUMBER:	***Enter Budget Number***
% OF TRAVEL:	***<10%***	TRAVEL TYPE:	***Both National/International***
JOB LEVEL:	***Choose Drop Down***	DATE WRITTEN/REVISED	***17Dec2024***

This Job Description provides a summary of the duties and/or characteristic of work performed and is not inclusive of every detail of the job for every individual assigned to the position. This description will be reviewed periodically and revised as duties and responsibilities change with business demands. Other duties not listed above may be assigned as needed.

Brief Description:

The Global Regulatory Operations Publishing Intern prepares and delivers high quality, timely, and compliant regulatory submissions to global health authorities. The Publishing Intern represents Global Regulatory Publishing in cross-functional project teams, provides regulatory submission support for Jazz Pharmaceuticals products and contributes to regulatory initiatives..

Essential Functions/Responsibilities

- Collaborate in submission teams, to assist planning and execution of timely regulatory submissions primarily in eCTD format in support of investigational and marketed products.
- Represent Global Regulatory Publishing as subject matter expert on regulatory teams and project teams
- Ensure compliance with global health authority regulations, guidelines, and specifications including FDA, EMA, Health Canada, and ICH for regulatory submissions.
- Contribute to submission plans to develop, track, and report on submission deliverables for all submissions
- Facilitate submission QC and issue resolution for regulatory submissions and documents with stakeholders
- Identify potential risks to submission plans, escalating appropriately
- Support report publishing, QC, and signoff utilizing templates and eSignature technology in accordance with Jazz Pharmaceuticals process and standards
- Assist in development of documentation including job aids or best practices.
- Maintain records and data in Regulatory Information Management (RIM) system
- Performs other regulatory related duties as assigned
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Required Knowledge, Skills, and Abilities

- Interest in creating and publishing of regulatory submissions for Investigational (IND, CTA, etc.) or New Drug Applications (NDA, BLA, MAA, etc.) to Global Health Authorities in eCTD format
- Ability to research and interpret global health authority regulations, guidelines, and specifications including FDA, EMA, Health Canada and ICH
- Technical proficiency that would position candidate to quickly learn industry recognized tools including eSubmission gateway, DXC ToolBox, , Lorenz docuBridge, Accenture Starting Point templates, and Veeva Vault
- Excellent verbal and written communication skills
- Ability to work independently with moderate supervision on multiple projects simultaneously
- Strong team building skills and exemplary written and verbal communication skills.
- Detail oriented with creative problem solving and troubleshooting skills.

Required/Preferred Education and Licenses

- Enrolled in program progressing toward BS/BA.

Signed: _____ **Date:** _____
Position Holder, Position Title

Signed: _____ **Date:** _____
Line Manager, Line Manager Title