

Regulatory Affairs Quality Analyst 3

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Company: Hyland

Location: Poland

Category: business-and-financial-operations

Overview

Hyland Software is widely known as a great company to work for and a great company to do business with. Being a leader in providing software solution for managing content, processes and cases for organizations across the globe we enabled more than 20,000 organizations to digitalize their workplaces and transform their operations.

We are **truly thrilled** to develop our **R&D Center in Katowice**, heart of Silesia region and enlarge **Hyland across the globe!** We hope to spread **#hylandlife** philosophy here, create a **vibrant culture** where employees can feel connected to each other regardless of their work location and where positive work environment is defined by **employees' happiness, health and engagement** .

Currently we are looking for a **Regulatory Affairs Quality Analyst 3** to join our Quality Engineering team.

What you will be doing

Aid in maintenance of the company's registrations for office licenses with federal state and international regulatory bodies including ISO certifications.

Manage regulatory processes prepare regulatory documentation regulatory submissions correspondence with regulatory agencies and regulatory tracking databases.

Assure team follows regulatory-required design related activities manage activities such as user needs document design input requirements (DIR) design history file (DHF) and verification and validation (V&V) etc.

Interact with all regulatory agencies notified bodies etc. on necessary matters.

Manage compliance against document control procedure record and change control procedures including adhering to document and part numbering protocols. Manage and support electronic quality management system (eQMS).

Manage the management review process.

Manage the change control process ensure change controls are followed per quality system procedure.

Prepare documentation requested in support of internal audits.

Assist in reviews of product labelling and intended for use (IFU) and co-approve product release.

Manage the corrective and preventive action process and assist with complaint process related activities.

Research interpret and stay abreast of current and emerging regulations and standards in the industry.

Establish implement and maintain production work instructions and SOPs and ensure personnel training.

Mentor coach train and provide feedback to other team members; may provide feedback to leadership on technical abilities of team.

What will make you successful

Bachelor's degree or equivalent experience

3 or 5 years of relevant experience

Strong English skills; **C1 level**

Strong knowledge of **FDA QSR ISO 13485:2016 MDD and MDR**

Ability to understand federal state and international regulations and laws concerning **medical devices**

Strong knowledge of industry standard compliance principles and best practices

Strong knowledge of systems administration

Ability to work with all departments within the organization

Strong facilitation and project management skill

Strong ability to develop and use engaging informative and compelling presentation methodologies

Strong interpersonal skills; able to maintain solid rapport with team members as well as maintain professionalism with those outside of department

Strong data gathering interviewing and analytical/problem solving skills

Attention to detail

Strong time management and multitasking skills

Strong written and verbal communication skills

Ability to use original thinking to translate goals into the implementation new ideas and design solutions

Self-motivated with the ability to manage projects to completion with oversight

Able to thrive in a fast paced deadline driven environment

Demonstrated ability to influence motivate and mobilize team members and business partners

Strong ability to handle sensitive information with discretion and tact

Strong ability to establish rapport and gain the trust of others; effective at gaining consensus

Ability to work independently and in a team environment

Strong understanding of core company products and technologies

Up to 5% travel time required

Hyland's Offering

We're proud of our culture and take employee engagement seriously. By listening to **employees' feedback**, we're able to provide meaningful benefits and programs to our workforce.

Learning & Development - development budget (used for certifications, conferences , tuition assistance program, 4,000+ self-paced online courses, instructor-led webinars, mentorship programs, structured on-boarding experience full of trainings, dedicated Learning & Development department supporting our employees

R&D focus – cutting edge technologies, constant modernization efforts, dynamic and innovative environment, dedicated R&D Education Services department to help you grow

Work-life balance culture – flexible work environment and working hours (we are working in task-based system!), possibility to work from home, we value trust and we believe efficiency does not depend on your actual location, however we would like to spend time together in the office!

Well-being - private medical healthcare, life insurance, gym reimbursement, psychologist & dietician consultation, wellness manager care, constant wellbeing programs

Community Engagement – Volunteer time off (24h/year), Hylanders for Hylanders relief fund, Mission fit giving, Dolars-for-doers matching gift programs

Diversity & Inclusion – employee resource groups, inclusion benefits and policies

Niceties & Events– quarterly profit sharing, culture & outings budgets, snacks and beverages, employee referral program, Christmas, birthday, baby gifts, constant incentives and employee programs

If you would like to join the company where **honesty, integrity and fairness** lie in the bottom of values, where people are truly passionate about technology and dedicated to their work and where **employees are called family** connect with us!

We are committed to a policy of Equal Employment Opportunity and will not discriminate against an applicant or employee on the basis of race, color, religion, creed, national origin or ancestry, sex, age, physical or mental disability, veteran or military status, genetic information, sexual orientation, marital status, gender identity, or any other legally recognized protected

basis under federal, state or local laws, regulations or ordinances. The information collected by this application is solely to determine suitability for employment, verify identity and maintain employment statistics on applicants.

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