Denmark Jobs Expertini®

Sr. Regulatory Professional, CDx

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Company: Agilent

Location: Copenhagen

Category: business-and-financial-operations

Description

This is an exciting opportunity to be part of the future of Precision Medicine! Our mission is to improve the human condition by bringing the power of precision medicine to laboratories, partners, and patients globally. Our employees are passionate about their contributions because there is a very direct connection to helping patients with cancer.

In the Companion Diagnostics Business (CDx), our team partners with leading pharmaceutical companies to develop, manufacture, and commercialize highly regulated medical devices which are critical for physicians to help select therapies for their patients.

As the Regulatory Companion Diagnostics Professional, you will ensure compliance to medical device and CDx IVD regulations globally. In conjunction with Enterprise Global Regulatory Affairs, the CDx Regulatory Affairs Department communicates with worldwide health authorities in the licensing of all products in development or currently marketed globally. The Regulatory Professional integrates broad business concepts and strategies into structured projects leading design and delivery of new products and solutions as a key technical contributor. The ability to tackle complex, high-impact project design problems is required.

Main Responsibilities

Develops and implements programs and processes to ensure that company products are safe, legal and meet or exceed customer expectations for compliance with national/regional/global regulations.

Prepares document packages for regulatory submissions for new and mature products to

ensure alignment and compliance with local and regional registration requirements and company policies.

Compiles materials required in submissions, license renewal, and annual registrations and maintains updated information about national/regional/global regulatory requirements.

Proactively manages the changing regulatory environment for company products, prevents barriers to trade, eliminates duplication of effort, and identifies and mitigates areas of risk.

Reviews product labeling and marketing materials for accuracy and compliance with regulations.

Response to customers and/or authorities' requests/inquiries dealing with regulations and product compliance.

Represents the company in external bodies dealing with standards and/or product regulations at the national/regional/global level.

May assess requirements and identify strategies for the earliest possible approvals of clinical trials applications.

Determines and develops approaches to assignments.

Leads regulatory projects requiring coordination with other functions, third parties.

Solves a broad range of problems of varying scope and complexity.

Qualifications

Bachelor’s or Master’s Degree or equivalent

At least 8+ years relevant experience for entry to this level.

Possess proven experience in an advanced medical devices regulatory role.

Requires in-depth knowledge and experience in the job and the ability to work independently.

Apart from these more technical skills, we are also looking for:

Excellent written and verbal communication skills, the ability to coordinate and prioritize efficiently.

Strong attention to detail and processes, ensuring compliance with Agilent's Quality standards, ability to handle customer expectations and balance customer requirements with business needs.

Experience with clinical trials will be a highly preferred skill.

#LI-PK1

What we offer:

The full-time, permanent position, based anywhere in the US or in Europe, is available as soon as possible. The role won't be head-office based but working remotely.

We will make sure you get all the training and development opportunities you need to become the best in your field.

Agilent offers core global benefits to all staff - but in addition to these, the business offers Agilent Result Bonus, Stock Purchase Plan, Life Insurance, Pension, Healthcare, Employee Assistance Program, Holiday, Company activities.

The US pay range for this full-time position is $ 114, - $210, /yr, plus eligibility for bonus, stock and benefits. Our pay ranges are determined by role, level, and location. The range displayed on each job posting reflects the minimum and maximum new hire pay for the position across the relevant US locations. Within the range, individual pay is determined by work location and additional factors, including job-related skills, experience, and relevant education or training. During the hiring process, a recruiter can share more about the specific pay range for a preferred location. Additional details are available at: .

Agilent Technologies, Inc. is an Equal Employment Opportunity and Affirmative Action employer. We value diversity at all levels. All individuals, regardless of personal characteristics, are encouraged to apply. All qualified applicants will receive consideration for employment without regard to sex, pregnancy, race, religion or religious creed, color, gender, gender identity, gender expression, national origin, ancestry, physical or mental disability, medical condition, genetic information, marital status, registered domestic partner status, age, sexual orientation, military or veteran status, protected veteran status, or any other basis protected by federal, state, local law, ordinance, or regulation and will not be discriminated against on these bases.Agilent Technologies, Inc., is committed to diversity in the workplace and strives to support candidates with disabilities. If you have a disability and need assistance with any part of the application or interview process or have questions about workplace accessibility, please email or contact +1-262-754-5030.For more information

about equal employment opportunity protections, please visit

Option to Work Remote

Yes

Travel Required

Occasional

Shift

Day

Duration

No End Date

Job Function

Quality/Regulatory

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