LIGHTDECK® DIAGNOSTICS
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Boulder, CO 80303
303-952-2905 • www.LightDeckDx.com

Regulatory Manager

LightDeck Diagnostics believes in a new approach to healthcare where fast, accurate, simple, low-cost diagnostic tests will be run wherever and whenever they are needed, without compromise. Our proprietary LightDeck® platform combines an advanced laser waveguide with novel materials and patented manufacturing techniques to deliver lab-quality results anywhere, in minutes. We are introducing a portfolio of in vitro diagnostic panels; the first is an on-the-spot test for COVID-19. The LightDeck platform is currently commercialized in veterinary diagnostics and for environmental testing.

Job Duties:

- Responsible for the activities related to regulatory compliance of all products at LightDeck Diagnostics, with a heavy emphasis on IVD products
- Contribute to and execute upon regulatory strategy for the organization
- Ensure regulatory compliance of devices and activities at LightDeck
- Work closely with Quality, Clinical, and R&D teams to ensure alignment
- Participate in audits and inspections
- Draft, revise with the team, and support regulatory submissions including 510(k)s, pre-submissions, Emergency Use Authorizations, CE Mark Technical Files, Device License Applications, and other submissions based upon business needs
- Guide and support V&V plan development, including clinical studies
- Review and advise on design changes to ensure proper change control and regulatory submissions are made, as appropriate
- Support investigations and own reporting requirements related to product issues and customer complaints
- Develop and support implementation of post market surveillance activities
- Candidate should have a background in FDA in vitro diagnostics regulations, specifically POC and CLIA-waived devices. Experience in veterinary (USDA) and/or environmental (EPA) regulations is also valuable.

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No single candidate is expected to have demonstrated skill in all functions listed below, but candidates should highlight relative experience in a brief cover letter.

- Proven working experience
    - As a quality engineer, preferably within the IVD or medical device industry

- Working knowledge of ISO 13485:2016 standard
- Working knowledge of FDA and EU IVD regulations
- Experience related to the above listed Job Duty categories
- Proficient and experienced in spreadsheets, MS Office, statistical software, and other QMS software applications
- Outstanding technical writing and communication skills

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Education and Experience:

- Bachelor's or higher degree in life sciences field.
- A minimum of 5 years IVD medical device industry experience with a minimum of 3 years in regulatory affairs.

Applicant must have authorization to work in the U.S. Resumes must be accompanied by a cover letter explaining how the applicant meets the job requirements and desired skills. Please apply via Workable; or you may email a cover letter and resume to Jobs@LightDeckDx.com with applicant name and the job title listing in the subject line.

No phone calls, please. Note: no third-party recruiters will be enlisted for this search.

LightDeck Diagnostics is an Equal Opportunity Employer committed to a culturally diverse workforce.