LIGHTDECK® DIAGNOSTICS
5603 Arapahoe Avenue, Suite 1
Boulder, CO 80303
303-952-2905 • www.LightDeckDx.com

Laboratory Quality Control Lead

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:

Qualify incoming lots of chemicals and biologics

Experienced in performance of sandwich and competitive immunoassays and analysis of the resulting data

Experience in using and maintaining various analytical equipment (HPLC, spectrophotometers, fluorescence plate readers)

Demonstrated success in development of analytical QC methods for biologics (antibodies, protein conjugates, oligonucleotides)

- Solid understanding of statistics and other lab data protocols (i.e. Westguard Rules, etc.)
- Method transfer and validation
- Perform assay performance quality control for manufactured lots of disposable cartridges.
- Process release or rejection of materials and product in accordance with LightDeck procedures
- Investigate and report on nonconformities
- Generate calibration for manufactured lots of disposable cartridges.
- Work with Assay Transfer Lead to develop methods and processes
- Analyze and report on QC data trends
- Communicate with Manufacturing, Assay, and Quality Teams
- Hands-on position with potential for growth and additional leadership opportunities
- Candidate should have a background in FDA in vitro diagnostics, specifically POC and CLIA-waived devices.

Requirements

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.

- Quality Control
- Laboratory Operations

- Process/method development and transfer
- Handling of blood-based products
- Statistics and lab protocols
- ISO 13485:2016 MDSAP
- IVD medical device
- CLIA-waived device
- Point-of-Care
- Science background such as biology, chemistry, or medical
- Education and Experience: ·
- Bachelor’s or higher degree in life sciences field.
- A minimum of 7 years IVD / medical device industry experience with a minimum of 5 years in laboratory quality control.

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.