



### *Analyst, Product Performance*

#### **Position Description**

Analyzes customer complaints to determine which are regulatory reportable and coordinates activities with internal, field, and end use customers. Responsible for adherence to Good Manufacturing Practices (GMPs) and proper complaint handling per the Code of Federal Register (CFR) and other governmental regulations. Communicates event investigation results via regulatory reports and written communications, as appropriate.

#### **Key Responsibilities**

- Review complaint communications and assess for regulatory compliance, reportability, and potential impact to patient safety and business operations.
- Apply clinical knowledge, as related to product application, to evaluate identified complaints. Investigate complaints by gathering sufficient data from clinical staff, field representatives, internal employees, and laboratory analysis.
- Establish regulatory reportability decisions using event investigation and regulatory decision models.
- Participate in development and modification of these decision models with changes in product advances/therapies to uphold consistent compliance with government mandated regulations.
- Write Medical Device Reports (MDRs), MedWatch, Vigilance, and other regulatory reports, ensuring timely transmission to the appropriate regulatory authorities.

#### **Skills/Experience Requirements**

Solid understanding and application of business concepts, procedures and practices. Will perform this job in a quality system environment. Failure to adequately perform tasks can result in noncompliance with governmental regulations. Works on problems of diverse scope where analysis of data requires evaluation of identifiable factors. Exercises judgment within generally defined practices and policies in selecting methods and techniques for obtaining solutions. Has a sound knowledge of a variety of alternatives and their impact on their business unit. Experience in post market regulatory reporting to FDA for medical devices, pharmaceuticals and biologics. Working knowledge of business concepts, procedures and practices.

#### **Education Requirements**

Bachelor's degree plus 6+ years of related work experience with a strong understanding of specified functional area, or an equivalent combination of education and work experience. Advanced degree preferred.

Affinity Scientific, LLC  
4660 La Jolla Village Drive  
Suite 500  
San Diego, CA 92122  
(858) 535-4870  
[www.affinityscientific.com](http://www.affinityscientific.com)