gSource, LLC
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Job Requirements

Job Title:	Regulatory Affairs Specialist
Wage Category:	RAS I, II, III
Department:	Quality
Reporting to:	Quality Manager

1. Strong working knowledge of medical device regulations and terminologies required
2. Ability to lead and coach staff members required
3. Excellent written and oral communication, technical writing and editing skills required
4. Ability to write clear, understandable technical documentation required
5. Skilled at analyzing and summarizing data required
6. Proficient with Microsoft Office required
7. Ability to manage and prioritize multiple projects required
8. Ability to follow verbal and/or written instructions such as part drawings, traveler, work instructions, process specifications, and direction from the supervisor in completing tasks effectively and efficiently required

9. Strong knowledge of QSRs and ISO 13485, MDD, EU MDR, GMP and 21 CFR preferred
10. Bachelor's degree in Engineering, Law, Business Administration or relevant field preferred
11. Minimum of 3 years experience in regulatory medical device environment preferred

12. Reliable and responsible
13. Organized, detail oriented, accurate, thorough
14. Outgoing, enthusiastic and persuasive
15. Proactive and able to make decisions
16. Work well under pressure and tight deadlines, maintain composure in difficult situations
17. Work independently with minimal or no supervision

18. Position: Full time
19. non-exempt
20. Working hours per week: 40
21. Hours gSource open: 7:30 am to 6:00 pm