United States Jobs Expertini®

(Senior) Director – Regulatory Affairs (Companion Diagnostics)

Apply Now

Company: QIAGEN

Location: United States

Category: other-general

Overview

At the heart of QIAGEN’s business is a vision to make improvements in life possible.

We are on an exciting mission to make a real difference in science and healthcare. We are still the entrepreneurial company we started out as and have today achieved a size where we can bring our full power to many initiatives and to our presence across the globe.

Our most valuable asset are our employees – more than 6000 in over 35 locations around the world. Our ambition is to ensure we have outstanding and passionate people working in the best teams and we are constantly looking for new talent to join us.

There are few players who have shaped the world of modern science and healthcare as much as QIAGEN, and we have only just started.

If you are looking to advance your career, are seeking new challenges and opportunities, enjoy working in dynamic and international, diverse teams and want to make a real impact on people’s lives, then QIAGEN is where you need to be.

Join us. At QIAGEN, you make a difference every day.

Position Description

- Serve as Global Regulatory Science Lead in support of QIAGEN Translational Science and Precision Diagnostics (TSPDx) Franchise responsible for developing and implementing the program's regional (i.e., U.S., E.U., and Canada) and global strategies for a comprehensive

portfolio of in vitro diagnostic (IVD) and companion diagnostic (CDx) devices, components and accessories.

- Lead TSPDx Regulatory Science Team to develop and deliver on competitive and innovative Regulatory Strategies and regulatory milestones, including an assessment of risks and mitigations, emerging data, and the probability of success of individual submissions.
- Serve as Regulatory Science Lead for individual Products and Projects, developing and directing competitive and innovative regulatory strategies and ensuring regulatory compliance through the product life cycle for in vitro diagnostic (IVD) and companion diagnostic (CDx) devices, components and accessories.
- Lead cross functional teams in major regulatory submissions, communications and meetings with regulatory authorities, securing clearances and approvals where required and owning negotiations with authorities, initiating and delivering key regulatory documents.
- Interact with external stakeholders and customers on regulatory issues to support CDx development and commercialization of products.
- Review partnership proposals and contracts to identify critical development and regulatory submission milestones, risks and opportunities.
- Support other QIAGEN functions in customer facing issues involving Regulatory Affairs aspects.
- Navigate complex topics regarding country specific regulations, guidelines, and precedents.
- Keep abreast of changing regulatory landscape; analyze and share information with stakeholders.
- Develop Regulatory Affairs processes and procedures for the Global Regulatory Affairs organization.
- Evaluate TSPDx Regulatory Science Team resource needs and contribute to Franchise and Global Regulatory Affairs budget planning activities.
- Other duties as assigned.

Position Requirements

- The ideal candidate will have 8-10 years of experience in regulatory affairs, including a minimum of 5 years in a team leadership role, for IVD companies, including successful pre-market submissions.
- Extensive knowledge of IVD medical device regulatory requirements and submission processes for U.S. and E.U. (Rest of World (RoW) knowledge is a plus).
- Strong knowledge of companion diagnostic and device development processes is essential.

- Strategic experience and ability, having demonstrated success related to the development and implementation of pre-clinical and clinical strategies for clinical IVD products, implementation of regulatory systems, and assuring compliance to all applicable regulations.
- Proven track record of success in problem solving and developing risk-based solutions.
- Prior responsibility for FDA submissions including Q-submissions, IDE, PMA, and 510(k), complaint review for reportability, and generating/submitting agency reports (e.g., Annual Reports, etc.).
- Understanding of global regulatory issues, FDA QSR, IVDR and ISO 13485 required.
- Well-developed cross-functional project and team management skills.
- Strong leadership and demonstrated experience in interfacing and working with external partners and regulatory agencies, including FDA.

Personal Requirements

- Excellent verbal and written communications skills and the ability to convey complex regulatory requirements in a straightforward and practical manner.
- Passionate leader, enthusiastic and able to inspire others to drive results while helping members at all sites feel competent, challenged, and supported.
- A strong sense of ethics and a commitment to uncompromising integrity.
- Ability to work well cross-functionally, to work well in team settings and independently, to take a stand and ensure completion of time-critical projects.
- Strategic thinker, with ability to interpret and find novel solutions to complex regulatory and business challenges.
- Structured and well organized.
- Confident with excellent cross-functional influencing skills.
- Good business acumen, pragmatic and business oriented.
- Able to proactively identify and focus on the key priorities.
- 10% travel (willing to travel to Manchester, UK site).

What we offer

At the heart of QIAGEN are our people who drive our success. We act with passion, always challenging the status quo to drive innovation and continuous improvement. We inspire with our leadership and make an impact with our actions. We create a collaborative, safe and engaging workplace which forms the basis for high performing individuals and teams. We drive accountability and entrepreneurial decision-making and want you to excel your growth and shape the future of QIAGEN.

QIAGEN is committed to creating a diverse environment and is proud to be an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, sex, age, national origin, religion, sexual orientation, gender identity, status as a veteran, or disability.

Apply Now

Cross References and Citations:

1. (Senior) Director – Regulatory Affairs (Companion Diagnostics) ElectricianjobsJobs United States Electricianjobs↗

2. (Senior) Director – Regulatory Affairs (Companion Diagnostics) LebanonjobsJobs United States Lebanonjobs↗

3. (Senior) Director – Regulatory Affairs (Companion Diagnostics) Chemistryjobs Jobs United States Chemistryjobs↗

4. (Senior) Director – Regulatory Affairs (Companion Diagnostics) Trademethejobs Jobs United States Trademethejobs ↗

5. (Senior) Director – Regulatory Affairs (Companion Diagnostics) Erpjobs Jobs United StatesErpjobs ↗

6. (Senior) Director – Regulatory Affairs (Companion Diagnostics) Searchamericanjobs Jobs United States Searchamericanjobs ↗

7. (Senior) Director – Regulatory Affairs (Companion Diagnostics) Phpjobs Jobs United StatesPhpjobs↗

8. (Senior) Director – Regulatory Affairs (Companion Diagnostics) Educareer Jobs United StatesEducareer↗

9. (Senior) Director – Regulatory Affairs (Companion Diagnostics) Ophthalmologistjobs Jobs United States Ophthalmologistjobs↗

10. (Senior) Director – Regulatory Affairs (Companion Diagnostics) Supplychainjobs Jobs United States Supplychainjobs↗

11. (Senior) Director – Regulatory Affairs (Companion Diagnostics)

Servicemanagementjobs Jobs United States Servicemanagementjobs ↗

12. (Senior) Director – Regulatory Affairs (Companion Diagnostics) Schooljobsnearme Jobs United States Schooljobsnearme ↗

13. (Senior) Director – Regulatory Affairs (Companion Diagnostics) Mathematicsjobs Jobs United States Mathematicsjobs ↗

14. (Senior) Director – Regulatory Affairs (Companion Diagnostics) Polandjobs Jobs United States Polandjobs ↗

15. (Senior) Director – Regulatory Affairs (Companion Diagnostics) Ukjobscareer Jobs United States Ukjobscareer ↗

16. (Senior) Director – Regulatory Affairs (Companion Diagnostics) Petsjobs Jobs United States Petsjobs ↗

17. (Senior) Director – Regulatory Affairs (Companion Diagnostics) Lawyerjobs Jobs United States Lawyerjobs ↗

18. (Senior) Director – Regulatory Affairs (Companion Diagnostics) Jobsinnigeria Jobs United States Jobsinnigeria ↗

19. (senior) director – regulatory affairs (companion diagnostics) Jobs United states ↗
20. AMP Version of (senior) director – regulatory affairs (companion diagnostics) ↗
21. (senior) director – regulatory affairs (companion diagnostics) United states Jobs ↗
22. (senior) director – regulatory affairs (companion diagnostics) Jobs United states ↗
23. (senior) director – regulatory affairs (companion diagnostics) Job Search ↗
24. (senior) director – regulatory affairs (companion diagnostics) Search ↗
25. (senior) director – regulatory affairs (companion diagnostics) Find Jobs ↗