**Wanted – Regulatory Affairs Professionals Needed to Drive Healthcare Product Development**

**The Cerneos Group, LLC is seeking Regulatory Affairs Professionals to drive innovation programs in healthcare product development. We are a life science consultancy in the fields of product development, scientific consulting, regulatory affairs and clinical development. We are a village for development. We reduce pain by providing clarity.**

**It’s a chance to work with the brightest entrepreneurs in the Biotech, Medical Device and Diagnostic innovators and drive international regulatory efforts:**

**Benefits:**

* **100% Remote work and flexible scheduling**
* **Thought leadership in a variety of fields**
* **Develop your portfolio of science and regulatory skills**
* **Be “in the room” when important healthcare decisions are made**
* **Recognition from the scientific community and industry**
* **Opportunities to network, publish and be a thought leader**
* **Introductions to the leaders in healthcare innovation**
* **Academic freedom and control of your projects**
* **Encouragement of diversity in all programs**
* **Competitive rates for consulting**

**Cerneos needs regulatory affairs professionals in the fields of:**

|  |  |  |
| --- | --- | --- |
| * **Gene Therapy**
 | * **In-Vitro Diagnostics**
 | * **Oncology**
 |
| * **Cell Biology**
 | * **Women’s Health**
 | * **Microbiome Science**
 |
| * **Immunology**
 | * **Nutrition**
 | * **Public Health**
 |
| * **Infectious Diseases**
 | * **Cardiology**
 | * **Epidemiology**
 |
| * **Autoimmune Disease**
 | * **Endocrinology**
 | * **Personalized Medicine**
 |
| * **Neurobiology**
 | * **Behavioral Health**
 | * **Bioprocess**
 |
| * **Biochemistry**
 | * **Biochemistry**
 | * **Pharmacology**
 |

**Cerneos needs Regulatory Affairs consultants to oversee consulting activities for Cerneos Group.**

**Roles Available:**

**Chief Regulatory Consultant:**

**Leadership for Cerneos Regulatory Affairs programs. Responsible for global regulatory strategies, client management, service delivery, regulatory intelligence, staff coordination and competent authority liaison. Expert in global regulatory standards including ISO, EMEA, GxP, MDR/IVDR, ICH. Requires excellent client management, negotiation, contract negotiation and business development skills.**

**Regulatory Project Manager:**

**Coordinates regulatory, clinical, quality and all stakeholders on client projects. Responsible for project management, service delivery and client coordination. May be responsible for multiple client projects and regulatory submissions as Cerneos, client and international competent authority contact.**

**Senior Regulatory CMC Consultant:**

**Prepares CMC documentation for INDs, BLAs and NDAs for drug, biologic, biotech and combination product submissions, briefing books and FDA meeting requests. Responsible for stakeholder coordination with clients and acts as client FDA liaison. May work with multiple clients in multiple regions.**

**Senior Regulatory Device Consultant:**

**Develops regulatory and product development strategy for combination, diagnostic, electro-mechanical and non-invasive devices. Responsible for coordinating international strategies including ISO, EMEA, GxP, MDR and IVDR compliance. Coordinates design control, development and device dossier documentation to meet international requirements. May handle multiple projects including 510(k), Q-Sub and PMA filings.**

**Science/Medical/Technical Writer/Literature Researcher:**

**Independent writer and publisher on a variety of topics. Will support client projects, regulatory consultants and Cerneos leadership on an as-needed contract basis. Will carry our independent projects in the forms of:**

* **Biomedical literature research**
* **Public health documentation**
* **Briefing books**
* **Clinical dossiers**
* **Clinical compliance documentation and consent forms**
* **Science and engineering research in support of product development**
* **Instructions for use and usability documentation**

**Flexible hourly and project rates depending on experience and client and Cerneos requirements.**

**Quality Systems & Compliance Specialists/Managers:**

**Responsible for developing quality systems documentation, conducting client and supplier audits, reviewing compliance documentation for production, lab analysis, clinical, manufacturing and all operations regulated by ISO, GxP and EMEA requirements. May develop documentation in support of regulatory and quality programs such as:**

* **Quality Manuals**
* **SOPs**
* **Specifications**
* **Audit strategies, schedules and reports**
* **Validation and Commissioning documentation**
* **Management Review**
* **CAPA**
* **Batch Record Development and Review**
* **Training programs and records**

**Will support Regulatory Project Managers and clients on active Cerneos projects. Must be able to conduct audits and compliance tasks independently and work closely with client management. Requires excellent communications skills, attention to detail, diplomacy, writing, training and investigative skills. Level of responsibility will depend on client needs and candidate expertise.**

**Our Needs:**

* **Provide regulatory strategy, scientific content and advising to Cerneos clients**
* **Scientific, CMC and Medical Writing in support of FDA and international regulatory filings**
* **Conduct literature searches in support of client development projects**
* **Oversight of scientific and clinical investigations in support regulatory projects**
* **Coordination with other service providers on projects**
* **Be client facing and maintain market and regulatory intelligence functions**
* **Identify gaps in scientific and clinical data from client product documentation.**
* **Must be eligible to work in the USA for any employer.**

**Regulatory Affairs Proficiencies Needed: (A combination of several proficiencies desired)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Biologic and Drug CMC Preparation** | **510(k) Prep / Submissions** | **MDR/IVDR compliance** | **Regulatory Project Management** |
| **FDA Briefing Books** | **Design Control & Design Dossiers** | **EMEA/UK/MHRA/MHLW Compliance** | **GCP & Clinical Affairs compliance** |
| **IND, BLA and NDA Submissions** | **Risk Management** | **Pre-submission Package Development** | **GxP, ISO 13485, ISO 14971 compliance** |
| **CTA Preparation** | **Technical Writing** | **Training & Development** | **Compliance Auditing** |

**Qualifications:**

* **Life Science background with industry experience**
* **Advanced Degree and RAC Certification preferred**
* **Strong diplomatic, writing, presentation, negotiation & communications skills**
* **Corporate and consulting experience preferred**
* **Understanding of product & regulatory needs in biotech & devices**
* **Willing to learn new product areas and extend into new business areas**
* **Drive to implement new programs and execute marketing plans**

**Immediate needs projects:**

* **Help develop educational webinars and podcasts**
* **Carry out regulatory consulting projects on COVID, MDR and IVDR compliance.**
* **Support research in CNS, immunology, microbiome and infectious diseases.**

**The Package:**

* **Independence on scheduling and operations**
* **Remote operations and virtual business**
* **Training, personal development and networking opportunities**
* **Support for RAC Certification and professional certifications**
* **Coverage of educational networking programs**
* **Key scientific person on all accounts**
* **Competitive rates depending on candidate experience, client needs, and candidate skill proficiency.**
* **Travel and expenses covered for events**
* **Potential for partnership in Cerneos for most senior positions**

**The Terms:**

* **Contract -1099 or Corp to Corp relationship**
* **Maintain confidentiality on all operations and client programs**
* **Maintain eligibility to work in the USA for any employer**
* **Maintain contract integrity with all clients**
* **Agree to abide by RAPS Code of Ethics**

[Code of Ethics | RAPS](https://www.raps.org/who-we-are/advancing-the-profession/code-of-ethics)

* **Re-Evaluation after 1 year**
* **Provide 2 Week notice if you need a break or to terminate contract**

**Please contact:**

**Richard Tharin, MS, RAC**

**CEO/Founder**

**The Cerneos Group, LLC**

**info@cerneos.com**

**Please provide resume and/or professional profile and Linkedin profile and/or professional website links**

**No Phone Calls Please**

**WELCOME TO CERNEOS GROUP**

***To see and to solve***

***New solutions for life science & medical products***

***A Village for Development***

***We reduce pain by providing clarity***

[***http://cerneos.com***](http://cerneos.com)

****