A Resource for Life Science Innovators

The Cerneos Group Mission

Our Deep Scientific Knowledge + Our Regulatory Experience = YOUR SUCCESS!

Cerneos Group provides comprehensive consulting services with expertise in regulatory affairs, life sciences, product and business development strategies.

We provide in-house services or connect you with professionals to help in every step throughout the bench to body continuum.

Whether you are a first-time entrepreneur or an established firm, our mission is to help you achieve your goals by providing end-to-end solutions for life science innovators.

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Our Service Offerings

- Regulatory Affairs
- Clinical Trial Strategies
- Business Development
- Strategic Solutions
- Financial Resources
- Grant Writing and Submissions
- Market Research
- Product Launches

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Why Choose the Cerneos Group?

OUR SINGLE FOCUS IS YOUR SUCCESS

You work directly with experts with decades of experience in drug, biologics & medical devices

Regulatory Affairs

505(b)(2)	Type A, B, C Meetings	IDE	FDA Liaison & Advisory
Pre-IND	ANDA	510K	Establishment Registration
IND	CTA	PMA	Global Product Registrations
NDA	Product Dossiers	Q-Sub	Expedited Access Program (EAP)
BLA		CE Mark	Device Class I, II, III & *De Novo*

Business Acumen

Asset Valuation	Fundraising	Reimbursement Analysis	Grant Writing & Review
Market Analysis	Project Management	CRO/CMO Coordination	Clinical Strategy

Life Science, Biotech & Pharmaceutical Expertise

Immunology	Analytical Chemistry	Microbiology	Infection Prevention
Molecular Biology	Engineering	Antibiotic Discovery	Literature Review
Biochemistry	Diagnostics	Vaccine Development	Statistics
Cell Biology	*In Vitro* Assays	Environmental Health & Safety	

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Ten Years of Success: Cerneos by the Numbers

Accomplishments Since 2013

- 20 Biologic Submissions
- 10 Vaccine BLAs
- 10 Small Molecule NDA
- 10 Large Molecule NDA & BLA
- 10 EU- MDR/IVDR Cleared Products
- 150+ Medical Device 510(k)
- 75 Diagnostics – IVD
- 25 Electromechanical Devices
- 25 Therapeutic Aids
- 10 Food Products and Nutritional Supplements

Global Reach:

US, Canada, Australia, UK, EU, APAC, Brazil, LATAM, Israel, and other global product requirements

Therapeutic Areas Include: CNS, Oncology, Infectious Disease, Gene Therapy, Telemedicine, Orthopedics

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Historic Projects

Medical Device Technology

Developed a quality system for a metals smelter for surgical implantable devices. Instituted quality systems, training programs and certifications. Obtained adoption by ISO certified medical device manufacturer.

Expedited Access Program for Parkinson's Device

Developed regulatory strategy, clinical strategy, and documentation for a *DeNovo* device to stop freezing gait syndrome in Parkinson's disease patients.

COVID Treatment

Prepared NIH STTR Grant for a biotech-based cell biology COVID treatment product. Research is ongoing for new therapeutic applications for Long COVID.

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Historic Projects Continued

Women's Health Trial

Regulatory strategy development for maternal nutrition and counseling programs to prevent gestational diabetes. Trained team on regulatory strategy and recruitment procedures for clinical trial participants.

Rapid Diagnostics

Developed 510(k)s for rapid diagnostic kits for home and institutional use for infectious disease and drugs of abuse testing. Bundled 510(k) submissions for FDA clearance and expanded client's marketing capacity by 100%.

Telemedicine

Developed regulatory strategy, registered products and companies, and obtained market clearance for a telemedicine device to encourage at home connectivity & HIPAA compliant telemedicine visits.

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Testimonials

"They have been so wonderful at explaining and tailoring their approach to our needs, and they provided regular and thorough feedback and updates to keep us on top of our game. Cerneos attends weekly briefings from our science and marketing teams to stay on point with our product's registration, applications required, we feel great about the results and milestones that we have accomplished."

Principal Investigator, Maternal Microbiome Clinical Trial at Long Island University

"Richard's understanding of regulatory affairs is both detailed and strategic, and his ability to relate to and work with people at all levels is truly remarkable. Any organization that brings him on board will be lucky to have him."

Director, Product Development, Diagnostics for All

"I would strongly recommend Richard to any company. He is the consummate regulatory professional. Extremely knowledgeable on regulatory regulations as well as other areas within Regulatory Affairs."

Joeseph S., Supplier Quality Engineer, Insulet Corporation

"Richard is highly knowledgeable and very detail-oriented. I am impressed with how quickly he grasps the medical application details of the technology, how well he devises a plan for regulatory strategy and executes each step."

C-G (Carmen) Stefanita, Ph.D., P.Eng., Medical Device Development

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