A Regulatory & Clinical Resource for Life Science Innovators

The Cerneos Group Mission

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

Cerneos Group provides consulting services with expertise in:

- **Regulatory Affairs**
- **Clinical Affairs**
- **Scientific Consulting**
- **Business Development**

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

CERNEOS GROUP

Why Choose the Cerneos Group?

You will work with experienced consultants in biotech, drugs & devices that will meet and exceed your expectations. We offer a personalized approach to your projects.

Regulatory Affairs & Clinical Services

- ANDA Submissions
- Biosimilars
- BLA Submissions
- 505(b)(2) Applications
- Pre-IND Meetings
- IND Submissions
- NDA Submissions
- In-Vitro Diagnostics
- Type A, B, C Meetings
- ANDA Submissions
- Clinical Trial Applications
- Product Dossiers
- Clinical Trial Strategy
- CRO / Site Coordination
- IDE Submissions
- 510K Submissions
- PMA Submissions
- Q-Sub Meetings
- CE Mark- Devices
- FDA Liaison & Advisory
- Establishment Registration
- Global Product Registrations
- Expedited Access Program (EAP)
- Device Class I, II, III & *De Novo*

Business Services

- Asset Valuation
- Market Analysis
- Investor introductions
- Project Management
- Reimbursement Analysis
- CRO/CMO Coordination
- Grant Writing & Review
- Government Liaison

CERNEOS GROUP

Our Expertise

Therapeutic Area Experience

Arteriosclerosis	Diabetes	Neurobiology	Rare Diseases
Atrial Fibrillation	Digital Health	Orthopedics	Sleep Apnea
Blood Disorders	Emergency Medicine	Ophthalmology	Surgical Technology
Cell Therapies	Epidemiology	Parkinson's Disease	Vaccine Development
CNS Disorders	Gene Therapy	Personalized Medicine	Veterinary Medicine
Dental Therapies	Heart Disease	Pulmonary Disorders	

Scientific Expertise

Analytical Chemistry	Engineering	Molecular Biology	Orthopedics
Assay Development	Hematology	Molecular Genetics	Pulmonology
Biochemistry	Histology	Neurobiology	Tissue Biology
Cell Biology	Immunology	Ophthalmology	Virology
Endocrinology	Microbiology	Orthopedics	

CERNEOS GROUP

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

20 EU- MDR/IVDR Cleared Products

150+ Medical Device 510(k)

150 Diagnostics – IVD

25 Electromechanical Devices

25 Therapeutic Aids

20 Food Products & Nutritional Supplements

CERNEOS GROUP

Our Global Reach

We have extensive experience in meeting regulatory, product development and launch requirements in the following regions

- USA – Food and Drug Administration (FDA), Centers for Medicare and Medicaid (CMS)
- EU – EMEA
- Canada – Health Canada
- UK – National Health Service
- Israel – Ministry of Health
- Brazil – ANVISA
- Asia Pacific
  - South Korea – KFDA
  - Japan – MHLW
  - Australia – Therapeutic Goods Administration
  - China – CFDA

CERNEOS GROUP

High Impact 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.

CERNEOS GROUP

High Impact 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.

CERNEOS GROUP

Testimonials

Clinical Trial Expertise

"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

Diagnostic IVD Development Experience

"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

IVD / Diabetes Expertise

"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."

Joseph S., Supplier Quality Engineer, Insulet Corporation

Device and Combination Product Experience

"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

CERNEOS GROUP

Richard Tharin, MS, RAC
Chief Executive Officer

rtharin@cerneos.com

https://www.linkedin.com/in/rctcerneos/

CERNEOS GROUP

Joseph Kavanagh
BSc, MBA
Senior Consultant
Business & Development Strategy, Market Analytics, Medicare & Reimbursement

Richard Reeves
BASc, MBA
Senior Regulatory Affairs & Quality Assurance Consultant

Thomas Catalano PhD
Scientist/Senior Regulatory Affairs Consultant

831 Beacon Street #325, Newton, MA 02459 USA
http://cerneos.com