

Contact

www.linkedin.com/in/gregory-m-hockel-ph-d-3b65938 (LinkedIn)

Top Skills

Clinical Trials
CTMS
CRO

Gregory M. Hockel, Ph.D.

Founder at Hockel & Associates, Regulatory Consulting
Baltimore, Maryland Area

Summary

I have 40 years of experience in the pharmaceutical industry (large pharma, biotech companies, and contract research organizations), including both drug discovery and development. I have supervised the planning, submission, and maintenance of numerous INDs and NDAs/BLAs to both CDER and CBER and have organized and conducted well over 100 meetings (Pre-IND, End-of-Phase 2, Pre-NDA/BLA) with the Food and Drug Administration and Health Canada. From a submissions perspective, I have submitted and maintained over 200 INDs, involving all therapeutic Divisions within CDER and CBER, and provided strategic input into and the compilation of over 50 NDAs/BLAs (both 505(b)(1) and 505(b)(2) applications), more recently in the Common Technical Document format. I have provided input into Fast Track applications, Special Protocol (nonclinical and clinical) Assessment submissions, and have written and submitted numerous Orphan Drug Applications, “gap analyses”, due diligence, and portfolio review. During my career, I have been responsible for Regulatory Operations, Drug Safety and Pharmacovigilance, Clinical Trial Supply Management, Quality Assurance, and Medical Writing. Over the course of my career, I have established a large network of associates capable of addressing all facets of product development. I have presented at numerous symposia and DIA meetings on a variety of regulatory issues and hold a Ph.D. degree in renal physiology from Indiana University School of Medicine and an M.B.A. degree from Rensselaer Polytechnic University.

Experience

Hockel & Associates, Regulatory Consulting
Founder
May 2015 - Present (5 years 1 month)

INC Research

Sr. Vice President, Regulatory Consulting
October 2013 - April 2015 (1 year 7 months)
Raleigh, North Carolina

PharmaNet
Executive Vice President, Regulatory Affairs
1999 - October 2013 (14 years)

Guilford Pharmaceuticals
Vice President
1998 - 1999 (1 year)
Baltimore, Maryland

British Biotech
Vice President
1994 - 1998 (4 years)
Annapolis, Maryland

G. H. Besselaar & Associates
Executive Director
1989 - 1994 (5 years)
Princeton, New Jersey

Pfizer
Assistant Director
1980 - 1989 (9 years)
Groton, CT

Education

Rensselaer Polytechnic Institute
Master of Business Administration (M.B.A.) · (1985 - 1987)

Indiana University School of Medicine
Doctor of Philosophy (Ph.D.), Physiology · (1973 - 1977)

California State University-Long Beach
Bachelor of Arts (BA), Biology, General · (1970 - 1972)

Long Beach City College
Associate of Science, Biology · (1968 - 1970)

