Richard Angelo, PhD
Executive Consultant

Executive Consultant

Clinical, quality and regulatory consultant to the pharmaceutical,
biotechnology and medical device industries

Employment

Executive Consultant
NOVA Clinical Research Support, LLC
Overland Park, KS
2004 - Present

Director, Executive Consultant
Cardinal Health Regulatory Sciences
Overland Park, KS
2005 - 2017

Project Director, Group Leader
PRA International
Lenexa, KS
1998 - 2004

Director, Clinical Affairs
Maxim Pharmaceuticals, Inc.
San Diego, CA
1997 - 1998

Senior Scientist, Clinical Affairs
Gen-Probe, Inc.
San Diego, CA
1995 - 1996

Clinical Research Scientist, Infectious Diseases and Oncology
Marion Merrell Dow
Kansas City, MO
1990 - 1995

Senior Immunologist
Marion Merrell Dow
Kansas City, MO
1988 - 1990

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NOVA Clinical Research Support
Angelo.rick@novacrs.com

Diagnostic Microbiologist
Marion Merrell Dow
Kansas City, MO
1987 - 1988

Education

Purdue University, Postdoctoral Research Fellow, 1987

University of Kansas, PhD Microbiology, 1986

University of Missouri, MS Microbiology, 1981

University of Missouri, BS Biology, 1975

Professional Experience

Compliance Oversight and Management

- Development and implementation of quality management systems
- Compliance assessment of pre- and post-market safety management and pharmacovigilance activities
- Compliance assessments of medical device products with the Quality System Regulation and other regulatory standards
- Investigator audits (investigator qualification/capabilities, protocol compliance, GCP compliance, patient consent, source data verification, clinical study processes, data quality, facilities, adverse event reporting, control and disposition of investigational product, etc.)
- Vendor audits (general capabilities and compliance of CROs, clinical laboratories, clinical supplies manufacturing and distribution, medical service providers)
- Due diligence audits (key safety and efficacy variables, data accuracy/integrity, data authentication, patient authentication, for-cause audits)
- Quality systems audits (organization, operations, quality assurance unit, employee training, vendor selection and management, manufacturing controls, clinical trial management, regulatory compliance, drug safety and safety reporting, etc.)
- Computer systems and electronic source data compliance audits (21 CFR Part 11)
- FDA readiness inspections (pre-approval and post-approval; CROs, corporate sponsors, investigator sites, contract service providers) for compliance with FDA statutes, regulations and guidance documents, harmonized international standards, protocols, and applicable standard operating procedures

Strategic Planning

- Regulatory and financial planning for the commercialization of therapeutic and in vitro diagnostic products in areas of analgesia, dermatology, infectious diseases, neurology, oncology, and pulmonology
- Steering committee and executive oversight of product development programs
- Development, preparation, and implementation of Risk Evaluation and Mitigation Strategies

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Clinical Development

- Organization and leadership of regional, national, and international multidisciplinary clinical trial project teams
- Program risk management and contingency planning
- Organization, charter development, and leadership of data monitoring committees
- Assessment, qualification, and management of outsourcing partners
- Establishment and oversight of clinical program compliance standards, performance standards and operating procedures

Medical Devices

- Point of care diagnostic tests (including CLIA-waived tests for diabetes, glucose monitoring, hemoglobin A1c monitoring, pregnancy, illicit drug use, alcohol use, etc.) (Class I, II)
- Nucleic acid amplification-based immunodiagnostic devices (Class II)
- In vitro diagnostic devices (Class I, II)
- Metered dose inhalers (Class II)
- Post-capture medical imaging management software products and applicable Class II special controls/voluntary standards, including Digital Imaging and Communications in Medicine (DICOM) standard; Joint Photographic Experts Group (JPEG) standard; Society of Motion Picture and Television Engineers (SMPTE) Test Pattern standard
- Diagnostic imaging software from multiple modalities such as DICOM PET, ECAT PET, SPECT, CT and MRI. Software packages typically provide the means to display, register and integrate medical images, and perform semi- to fully-automated quantitative and statistical analyses (Class II)
- Radiolabeled diagnostic imaging agents for PET scanning (Class II)
- Quantitative automated differential cell counter products in vitro diagnostic use (Class II devices and reagents)
- Gene-based Class III molecular diagnostic tests for infectious agents such as Human Immunodeficiency Virus (HIV), Human Papillomavirus (HPV)
- Chloridometers (Class II)
- Central venous catheter (CVC) devices (Class II)
- Neurological therapeutic devices that provide visual or auditory signals corresponding to patient physiological components such as brain waves, muscle activity, skin temperature, etc. (Class II)
- Laser devices - general surgical and ophthalmic (posterior capsulotomy, peripheral iridotomy) (Class II)
- Resorbable bone-void filler devices (Class II)
- Transdermal drug delivery systems (Class II)
- Stomal appliance cements (Class I)

Therapeutic Specialties

- Analgesia (OTC and scheduled products)
- Anti-Infection (Pre-operative and pre-injection topical antiseptics, antibiotics, vaccines)
- Dermatology (Skin structure infections, wound healing)

- Infectious diseases (Acute and chronic osteomyelitis, hepatitis C virus, human immunodeficiency virus, *Mycobacterium avium* complex, *Mycobacterium* sp., skin/skin structure infections)
- Microbial diagnostic devices (Immunodiagnostic devices, nucleic acid amplification assays)
- Neurology (Alzheimer's disease, general anxiety disorder, medical imaging devices)
- Oncology (Locally advanced and metastatic breast cancer, metastatic malignant melanoma, acute myelogenous leukemia, cutaneous T-cell lymphoma)
- Pulmonary (Allergy drug/device combination products, asthma, seasonal allergic rhinitis)

Publications

Richard Angelo, PhD. Chapter 16, Medical Device Compliance and Postmarketing Activities, in Fundamentals of US Regulatory Affairs, Seventh Edition, 2011, a Regulatory Affairs Professionals Society (RAPS) publication.

Ronald E. Esser, Alan R. Hildebrand, Richard A. Angelo, Lynnetta M. Watts, Mark D. Murphey and Larry E. Baugh. Measurement or Radiographic Changes in Adjuvant-Induced Arthritis in Rats by Quantitative Image Analysis. Arthritis and Rheumatism, June 1994.

Ronald E. Esser, Richard A. Angelo, Mark D. Murphey, Lynnetta M. Watts, Larry P. Thornburg, James T. Palmer, Jamil W. Talhouk and Robert E. Smith. Cysteine Proteinase Inhibitors Decrease Articular Cartilage and Bone Destruction in Chronic Inflammatory Arthritis. Arthritis and Rheumatism 37(2):236 1994.

Ronald E. Esser, Lynnetta M. Watts, Richard A. Angelo, Larry P. Thornburg, Jeffrey J. Prior and James T. Palmer. The Effects of Peptidyl Fluoromethyl Ketone Inhibitors of Cathespin B on Adjuvant Induced Arthritis. J. Rheumatology 20(7):1176 1993.

Ronald E. Esser, Richard A. Angelo and Alan Hildebrand. Measurement of Bony Changes in Experimental Arthritis by Quantitative Image Analysis In Proceedings of the Electronic Imaging Conference, p. 151-8, Miller Freeman, Inc. publisher, Dallas, Texas. September 1992.

Henry Weiner, Richard A. Angelo and Suzanne C. Cunningham. N-Terminal Acetylated Matrix Space Aldehyde Dehydrogenase. Journal of Protien Chemistry 9(3):247 1990.

R. Angelo, K.C. Voepel and C.S. Buller. Isolation and Characterization of a New Strain of Cellulomonas flavigena. Journal of Industrial Microbiology 5:125 1990.

R.A. Angelo and C.S. Buller. Production and Characterization of a Xylanase Produced by Cellulomonas flavigena. Abstract, Missouri/Missouri Valley Society for Microbiology, Annual Meeting. Kansas City, Missouri. April 1986.

R.A. Angelo and C.S. Buller. Xylanolytic Activity of Cellulomonas flavigena. Abstract, Society for Industrial Microbiology, Annual Meeting, SIM News 344(4):53 1984.

F.A. Pacheco, R.A. Angelo, E.K.C. Chang and E.J. Hsu. Optimization of Production and Thermostability of Alpha-Amylase in Bacillus amyloliquefasciens. Abstract, Amercian Society for Microbiology, Annual Meeting. Abstracts of the Annual Meeting. 1981.

R.A. Angelo, E.K. Chang, F.A. Pacheco and E.J. Hsu. Ethanol Producing Cells of Clostridium thermosaccharolyticum. Abstract, American Society for Microbiology, Annual Meeting. Abstracts of the Annual Meeting, 1980.

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Presentations and Webinars

FDA Inspection Readiness
R. Angelo, PhD (Speaker)
December 2014
Heart of America Research Professionals Association Presentation
Accredited by the Association of Clinical Research Professionals (ACRP) Accreditation Committee

FDA Inspection Readiness – A Compliance Primer
R. Angelo, PhD (Instructor)
May 2016
Life Science Training Institute Webinar

Responding Effectively to FDA Form 483 Observations – Strategies to Ensure Compliance
R. Angelo, PhD (Instructor)
December 2016
Life Science Training Institute Webinar

Contact

Email angelo.rick@novacrs.com
Direct 913.402.4520
Mobile 913.530.8638
Web www.novacrs.com

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