McCormick LifeScience Consultants, LLC

Bridging the gap between discovery and market with efficient execution of the approval process

Our services include:

Regulatory Affairs

We work with client companies to ensure they comply with all rules and regulations related to drug and product submission and approval.

- CMC, Nonclinical and Clinical RA program support (operational & strategy)
- Direct contract/correspondence with FDA and other agencies
- Regulatory submissions (IND/CTA, NDA/MAA, DMF, ANDA, BLA, 510K/PMA)
- Risk Management Planning
- Response to agency queries
- Agency meetings
- Advisory Committee preparation
- Scientific Advice and Protocol assistance
- Lifecycle management
- Operations; Submission compilation & publishing (paper and/or eCTD)
- Post-approval support/maintenance

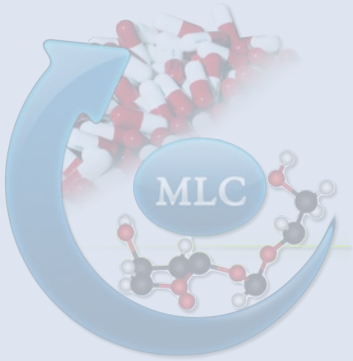
Clinical

We support client companies throughout the clinical phase, as they move to using human subjects to generate efficacy and safety data for their drugs and products.

- Clinical medical writing (protocols, amendments, study reports, case report forms, investigator brochures, SOPs, informed consents, regulatory submission sections, etc.)
- Protocol design
- Biostats and statistical programing
- Program Management
- Trial Management
- Monitoring (investigator selection, IRB selection and management, site contract, budget negotiation, and grant administration, site qualification, initiation, and closeout, drug accountability, on-site training)
- Clinical Safety: Adverse events reporting & Medical Monitoring
- Data Management

Our mission is simple: We partner with pharmaceutical, biologic and medical device companies to help them bring products to market.

Drawing on an elite, hand-picked network of contract consultants – all of whom we know through firsthand experience – we provide expert services in five areas: Regulatory Affairs, Quality, NonClinical, Clinical and CMC.



Client Testimonial

My company has worked closely and continuously with Kelsey over the past six years. During the initial years, Kelsey provided regulatory project leadership and assumed responsibility for regulatory affairs/operations to support opening two IND's. More recently, as McCormick LifeScience Consultants has expanded capabilities, we have expanded our relationship to take advantage of her team's expertise in a range of other areas including intellectual property and pharmacovigilance. Kelsey has broad expertise, is incredibly competent and is a consummate professional. What really sets Kelsey apart however is that she truly considers herself, and has become, an integral member of our team. She is always fully engaged and aligned with our goals. Drug development is never a linear process and we are incredibly fortunate, when the unexpected event leads to crunch time, to have McCormick LifeScience Consultants, LLC on our team.

Randall Carpenter, MD, *CEO / Seaside Therapeutics*

NonClinical

Our consultants partner with client companies during the nonclinical phase as they determine a drug or product's potential efficacy and final safety profile.

- Nonclinical medical writing (study protocols, reports, regulatory submission sections, conference materials, publications etc.)
- Developing, planning nonclinical *in vitro* & *in vivo* studies
- Animal model development
- Histology
- Data analysis, compilation & presentation
- CRO assessments, selection, management

Quality

We support and advise clients in the three intertwined areas of Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP).

- Quality system (GMP, GLP, GCP) development, implementation and/or assessment
- Compliance GAP analysis
- QA Management
- Quality Manual development
- SOP/Procedure development and review
- Batch Record review and approval
- GMP, GLP, GCP audits
- Mock FDA audits
- Risk Management
- Change Control Program
- FDA 483 response support
- CAPA development/support
- Equipment/Utility validation
- Process validation
- Vendor qualification, selection & management
- Vendor audits
- Training

Chemistry, Manufacturing and Controls (CMC)

We work with client companies to optimize the process by which chemicals are made – from lab, to clinic, to market.

- Cost and process modeling, including new technologies
- Process development
- Drug Formulation
- Analytical Methods/ development & validation
- Stability services
- Class 100 Aseptic Processes / Terminal Sterilization
- GMP Auditing of API and drug product manufacturers
- Technology transfer and scale-up
- CMO management
- Process validation and Master Validation Plans
- Draft, write, review and/or compile CMC sections of regulatory submissions
- Drug substance and drug product clinical and commercial manufacturing
- Commercialization
- Supply Chain
- Product life-cycle management

Kelsey McCormick, MS,
President

Phone:
978-448-0953

Email:
kelsey@
mccormicklifescience.com