



McCormick

LifeScience Consultants, LLC

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

MLC, LLC partners with clients to provide compliant, high-quality and cost-effective pharmaceutical, biotechnology and medical device integrated product development services. We offer flexible arrangements to fit your specific needs including onsite and/or offsite services. From small engagements to large contract/consulting projects, we specialize in providing expert services in the following areas:

REGULATORY AFFAIRS

- CMC, Nonclinical and Clinical RA program support (operational & strategy)
- Regulatory submission management (writing, review, coordination)
- Submission compilation & publishing (paper and/or eCTD)

CLINICAL

- Clinical medical writing (protocols, amendments, study reports, case report forms, investigator brochures, SOPs, informed consents, regulatory submission sections, etc.)
- Program Management/ Trial Management
- Monitoring
- Clinical Safety: Adverse events reporting & Medical Monitoring
- Data Management

NONCLINICAL

- Nonclinical medical writing (study protocols, reports, regulatory submission sections, conference materials, publications etc.)
- Developing, planning nonclinical *in vitro* & *in vivo* studies
- Data analysis, compilation & presentation

CHEMISTRY, MANUFACTURING & CONTROLS

- Authoring/reviewing CMC sections of regulatory submissions
- Method/process transfer
- Batch record review
- Selecting & managing CROs
- Drug Substance & Drug Product support
- Facility audits

QUALITY ASSURANCE/ GXP COMPLIANCE

- Quality system development and/or assessment
- GMP, GLP, GCP audits
- GMP, GLP, GCP program development & maintenance
- Equipment & process validation
- Vendor selection & management
- SOP & protocol development & review

INTELLECTUAL PROPERTY

- Prior art searches, patentability & freedom-to-operate analysis
- Intellectual property strategy
- Competitive surveillance
- Patent drafting & prosecution
- Review of collaboration, research and/or licensing agreement(s)

SALES, MARKETING & BUSINESS DEVELOPMENT

- Program support
- Commercial launch

TRAINING

- Customized trainings per request

LITERATURE SEARCHES

- Medical, medicolegal, & scientific data research, retrieval and analysis
- Literature, patent, trademark searches



MLC, LLC, a Massachusetts based Consulting company, is comprised of >100 results-driven, career-oriented professionals with up to 30+ years of expertise in the pharmaceutical, biotechnology and medical device industries.

“My company has worked closely and continuously with Kelsey over the past three 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 C., MD, Co-Founder, President & CEO of small pharmaceutical company



Kelsey McCormick, MS
Founder & Principal Consultant

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