PHARMALEX MEDICAL DEVICE SERVICES

PROVEN METHODOLOGY FOR LONG TERM SUCCESS

CONTACT US

EMAIL

contact@pharmalex.com

WEB

www.pharmalex.com/meddevice

PHARMALEX
MEDICAL DEVICE SERVICES

OVER 20 YEARS OF GLOBAL MEDICAL DEVICE EXPERIENCE

PharmaLex leverages over 20 years of Medical Device experience and expertise coupled with proven methodologies and hands-on support to optimize and customize QA and RA solutions which are delivered on time, in budget and with the highest quality. Our comprehensive services portfolio provides end-to-end compliance support throughout the product lifecycle.

Pre-Market Services

- Regulatory Strategy
- Project Management
- Device Design Control Consultation
- Combination Product Device Support
- Medical Device Regulatory Submission Support (PMA, 510(k), IDE, CE Mark, etc.)
- Regulatory Agency / Notified Body Inquiry
- Response Support

Quality Management System Support Service

- QMS Gap Analysis for ISO 13485, ISO 14971, 21 CFR Part 820, EUMDR 2017 / 745, EUIVDR 2017 / 746
- Creation, Revision, Updates to Quality System Management Policies and Procedures
- Perform Third Party Referral Audits
- Regulatory Agency Inspection Preparation / Audit Preparation
- Regulatory Agency / Notified Body Enforcement Action Response Support
- QMS Remediation Services
- Project Management for QMS Remediation
- Training Services for QMS subsystems and cGxP

QMS / Post-Market Services

- Surveillance System Review
- Surveillance System Maintenance
- Incident Management and Reporting
- Preparation of Post-Marketing Reports