



KNOWLEDGE.  
ACCELERATED.  
confidence beyond compliance

# MEDICAL DEVICE SERVICES:

# OUTSOURCING

## CUSTOMIZED TO MEET YOUR NEEDS

- ▶ We will work with you to develop an outsourcing solution that is right for your organization
- ▶ Assigned Account Manager to manage your unique requests and communications

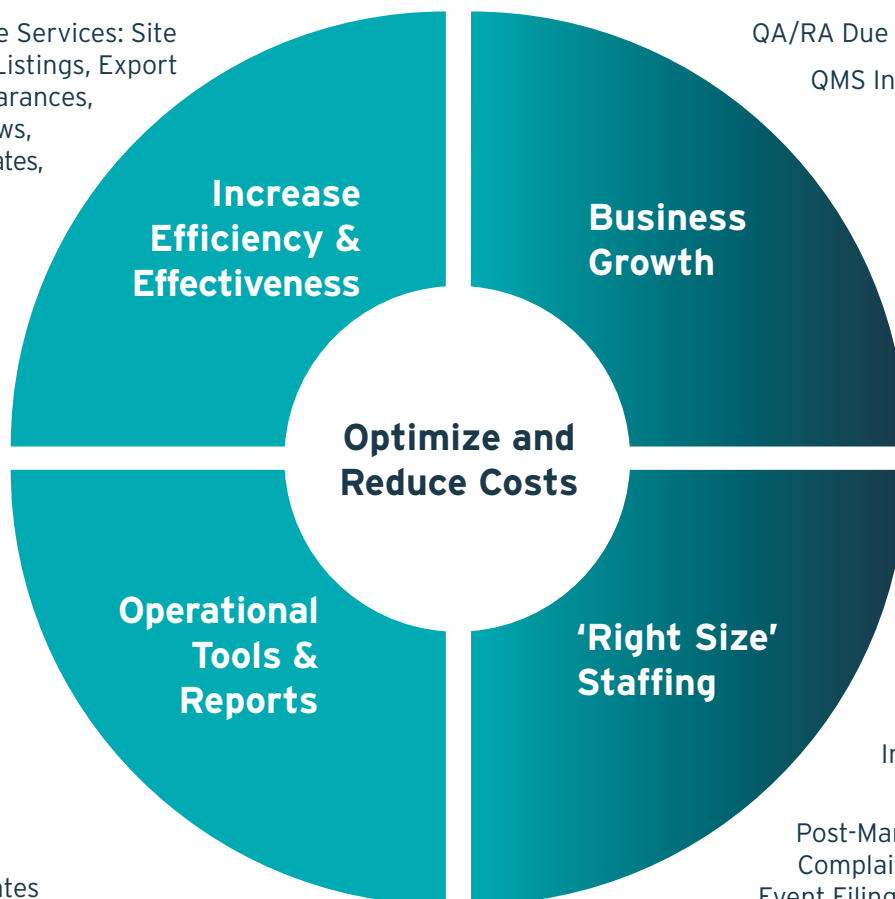
Regulatory Maintenance Services: Site Registrations, Product Listings, Export Certificates, Import Clearances, Product Labeling Reviews, Technical File/CER Updates, Post-Market Surveillance Reports.

Quality Auditing (QSR, ISO13485, GLP, ISO15189, CLIA, CAP, ISO17025, GCP)

QA/RA Employee Training

Computer Software Validation (CSV) Maintenance Services

Regulatory Intelligence  
QMS Procedural Templates



QA/RA Due Diligence for Acquisitions  
QMS Integration across business

US Agent/Official Correspondent  
QA/Compliance & RA On-going Advice

Interim Staffing for RA/QA leadership positions

Post-Market Surveillance Staffing: Complaint Handling Unit, Adverse Event Filings, Recall Mailing/Tracking

# Safis

MEDICAL DEVICE SERVICES  
A ▶ PHARMALEX Company

Ask us about our other individual  
QA/RA Consulting Services

## CONTACT US

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