PharmEng Technology

THE LEADER IN GLOBAL ENGINEERING AND CONSULTING SERVICES FOR THE LIFE SCIENCES INDUSTRIES

QUALIFICATIONS

- Six Sigma
- RAC
- CQA

REGULATORY AFFAIRS

PharmEng Technology will work alongside you to provide regulatory affairs services to meet client needs globally. Our consultants average over 15 years of experience and are equipped to facilitate the optimum regulatory interactions with the health authorities worldwide.

CONTACT US

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SERVICES WE OFFER

General

- Project Management
- Application & Transfers
- Establishment Registration
- Manufacturer Site Inspection
- Import and Wholesale License Application
- Outsourcing Solutions
- In and Out Licensing
- Technology Transfer
- Medical Device Submissions
- ANDA/NDA Submissions
- Label Reviews
- Drug Submissions – Notice of Compliance (NOC)
- Notice of Non-compliance (NON) Support

ASEAN/Asia Pacific Countries:

- Single Window to Multiple Markets
- Virtual Regulatory Affairs Representation
- Local Authorization Representation
- Product Registration Holder
- Product License Holding
- Cosmetic Notification Holder
- Marketing Authorization Holder
- Application & Transfers
- Establishment Registration
- Manufacturer Site Inspection
- Pharmacist License
- Local Person for Pharmacovigilance
- Import and Wholesale License Application
- Outsourcing Solutions
- In and Out Licensing
- Technology Transfer

PharmEng Technology has provided regulatory affairs services with a support team of Subject Matter Experts (SMEs) to offer technical expertise across the spectrum of product development, registration, and commercialization, ensuring compliance along the way. Our team offers customized expertise according to the country of interest.

Our team offers companies many benefits and assurance with not only cost savings, but also professional review, and continuity of projects to see through the product's life cycle management from product development to approval.