COMMITTED TO YOUR SUCCESS IN JAPAN

FROM CONCEPT TO COMMERCIALIZATION

GLOBAL
REGULATORY PARTNERS

WHO WE ARE

We are a consulting firm that provides Regulatory Affairs, Quality, Clinical and Safety services to pharmaceutical and medical device companies worldwide.

In Japan, we are licensed to act as your:

- Marketing Authorization Holder (MAH) or Designated Marketing Authorization Holder (DMAH) and handle all your local regulatory and compliance activities.
- In-Country Caretaker (ICCC) and handle all your local clinical trials activities.
- In-Country Caretaker (ICC) and handle your DMF preparation and submission to PMDA Japan.

MARKET ACCESS

Our commercial team can help you define the perfect solution to access the Japanese market by providing the following services:

- Market-access, pricing, reimbursement strategies
- Due-diligence and asset evaluation
- Evidence-based portfolio prioritization
- Review of Target Product Profile (TPP) and label claims
- Evidence and economic needs assessment and evaluation
- Distributor selection
- Commercial and marketing strategies

SERVICES

REGULATORY AFFAIRS

- Regulatory Strategy
- Meeting with PMDA
- Product Registration
- Orphan Drug Application
- Annual Report
- Medical Writing
- Project Management
- Product Development
- DMF Writing
- DMF Maintenance

QUALITY

- Quality System Management (QMS)
- Good Quality Practice (GQP)
- QMS application to PMDA
- Preparation for PMDA Inspection
- Local Product Release
- SOP Writing
- Quality Manual Writing
- FMA application
- Due Diligence Audits

CLINICAL

- CRO Oversight and Management
- Product Development
- In-Country Caretaker (ICCC) for Clinical Trials in Japan
- Clinical Trial Notification (CTN)

SAFETY

- Receipt, review and coding of adverse events
- Safety Reports to PMDA
- Good Vigilance Practice (GVP)
- Post-Marketing Surveillance (PMS) Studies

We offer the perfect solution for you in Japan

- Regulatory affairs and clinical services that meet your needs and fit your budget.
- Efficient product registration.
- Compliance with PMDA regulatory requirements.
- Quick access and extension in Japanese market without local investment.
- Effective commercial and marketing strategy for your products in Japan.
- Control of your product registration and license.

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