

Medical Device Development Services

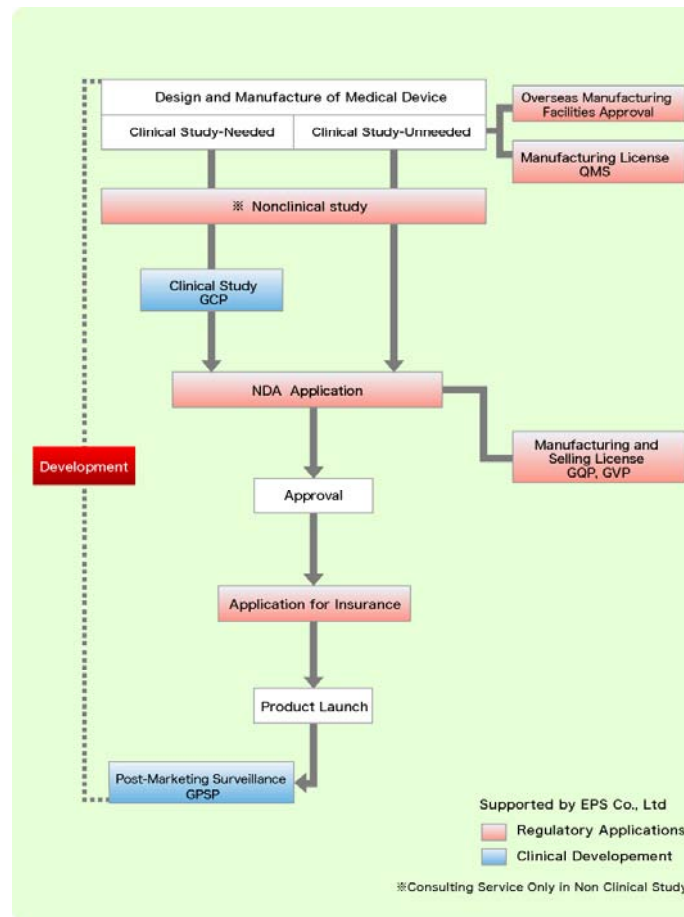
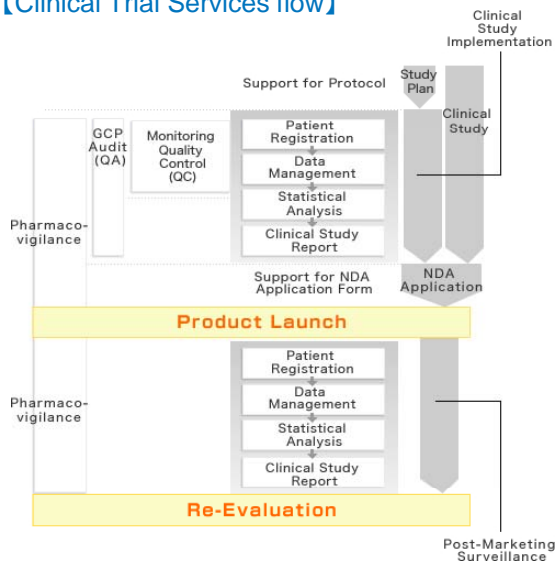
We Provide Speedy Application of Approval and License through our Enhanced Experiences in Medical Device Clinical Development

After revision of Pharmaceutical Affairs Law, safety, efficacy, quality control, safety precautions at manufacturing companies are more required strictly. As such NDA (PMA or 510k) requires more expertise knowledge and procedures. In high-controlled medical device, information collected from post-marketing surveillance on efficacy and safety shall be scientific and ethical sound. EPS supports medical device regulatory, clinical study and post-marketing surveillance widely by knowledgeable experienced staff.

Clinical Development and Consulting

1. Clinical Study-related Operations and Consulting (Protocol, Monitoring etc)
2. Post-Marketing Surveillance-related Operations (Case Report Form Collection, Drug Use Investigation)
3. Quality Control Service for Overseas Clinical Study
4. Consulting Service (Clinical Design Analysis, Set Up Clinical Study Framework)

Clinical Trial Services flow



Regulatory Applications and Consulting Services

1. Support for Regulatory (Investigation of Classification of Drugs, Design of Effective Pharmaceutical Affairs Strategies)
2. Application and Registration of Approval and Licenses (Documentation Support etc)
3. Operations-related Applications of Licenses (Support for each License, Procedure)
4. Insurance Application

Medical Devices Studies

Radiation Therapy Device, Diagnostic Imaging Apparatus, Catheter, Low Frequency Therapy Device, Gastrointestinal System Device, Orthopedic Device, Circulatory System Device, Dental Unit, Ophthalmology Device, Other Inspection Devices

ADVANTAGE of EPS

- Medical device team provides full-service support from clinical development to all application.
- All services are performed in compliance with GCP(GPSP).
- All services are supported by professional experts having electrical engineering, biology and chemistry backgrounds.
- Efficient supports by well organized teamworks.