Bringing a new product from its development upto marketing approval is an expensive and lengthy process. If unanticipated delays occur, costs in both time and money can rapidly escalate. The staff at G7 Synergon

is well experienced to support clients through the entire drug development program, from early consultations to clinical trials and marketing authorisation submissions. Our experience in handling a wide variety of regulatory challenges helps the client to meet exigent timelines. We have the ability to provide regulatory services as a complete study management and/or as customized services.

Clinical Regulatory services include:

- Preparation and submission of Clinical Trial Agreement (CTA)
- Local accompanying of the approval process and communication with regulatory authorities
- Clinical Trial Registry India (CTRI) Entry
- Import / Export licenses from DGFT
- T - License procurement
- Approval from Genetic Engineering Approval Committee (GEAC) for Biotech products

Pharma Regulatory services include:

- Dossier Development and submission (CTD and e-CTD)
- DMF preparation
- Conversion review of old dossiers from general format to CTD format
- Import/Export licenses from DGFT
- CMC documentations and submissions
- Variation filings