

# Genzyme Pharmaceuticals

## REGULATORY SERVICES

Genzyme Pharmaceuticals, a business unit of Genzyme Corporation, offers customers a comprehensive support package which includes a complete range of Regulatory Services at all stages of development, from concept to launch and beyond.

### AN INTEGRATED SERVICE OF OUR CUSTOM MANUFACTURING:

#### CLOSE RELATIONSHIP WITH PRODUCTION AND DEVELOPMENT

- > Experienced, on-site RA team ensuring regulatory compliance
- > Proactive discussions of CMC development and regulatory status
- > Shorter time to submission by early involvement of regulatory affairs
- > Pragmatic and achievable solutions ensured by coordinating with the facility at every stage of the project lifecycle

#### INTEGRATED PROJECT MANAGEMENT

- > Direct integration with project management and technical development
- > Open communication with external customers
- > Tied in with Quality Assurance, Validation and Stability Management

#### SUPPORT AND ADVICE ON REQUIREMENTS AND PLANNING FOR REGISTRATION

- > Development and registration strategies
- > Registration in Europe, US, Canada or Japan

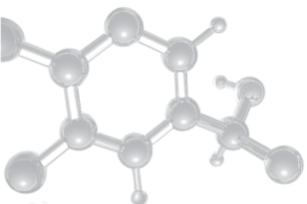
### REGULATORY SERVICES INCLUDE:

#### COMPILING OF REGISTRATION DOSSIERS

- > Collecting data necessary in registration dossiers for APIs or Excipients used in your development or marketed product applications
- > Preparing CMC Quality module documentation in CTD format suitable for the submission of IND, IMPD, NDA and MAA dossiers
- > Submission and maintenance of Drug Master Files (DMFs in USA, Europe, Japan, Canada, etc)
- > Converting existing data into the CTD format – reformatting and review

#### CUSTOMIZED SUPPORT

- > Gap analysis of available CMC information
- > Quality agreements with customer, defining the desired support
- > Evaluation of proposed changes for dossier impact - change notifications
- > PQR compiling providing reliable data reports to applicants
- > Coordination and evaluation of stability studies





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