

Diamond BioPharm

Diamond BioPharm Limited is one of very few European regulatory companies which has experience in clinical and regulatory development programmes within the gene therapy sector, to an advanced stage of development. Its first European Marketing Authorisation Application submission for a gene therapy product will be in 2009.

Diamond BioPharm Limited was founded in 2005, by Maureen Graham. Formerly Director of European Regulatory Affairs at Amgen, Maureen has a huge amount of experience in the biotechnology field and was later engaged (as Diamond BioPharm Limited) to lead the regulatory development of a pioneering gene therapy treatment. Supported by an experienced team of regulatory experts, Diamond is now a leader in this field.

“Bridging the Gap ... from invention to the market place”

What can Diamond BioPharm do for your Gene Therapy programme?

Bring expertise and experience through direct project involvement

Prepare high quality documentation to support Clinical Trial Applications (IMPD, IND, CTA)

Links with North American regulatory specialists to support global development programme

Manage regulatory dossier life-cycle from project initiation to submission, MA approval and beyond

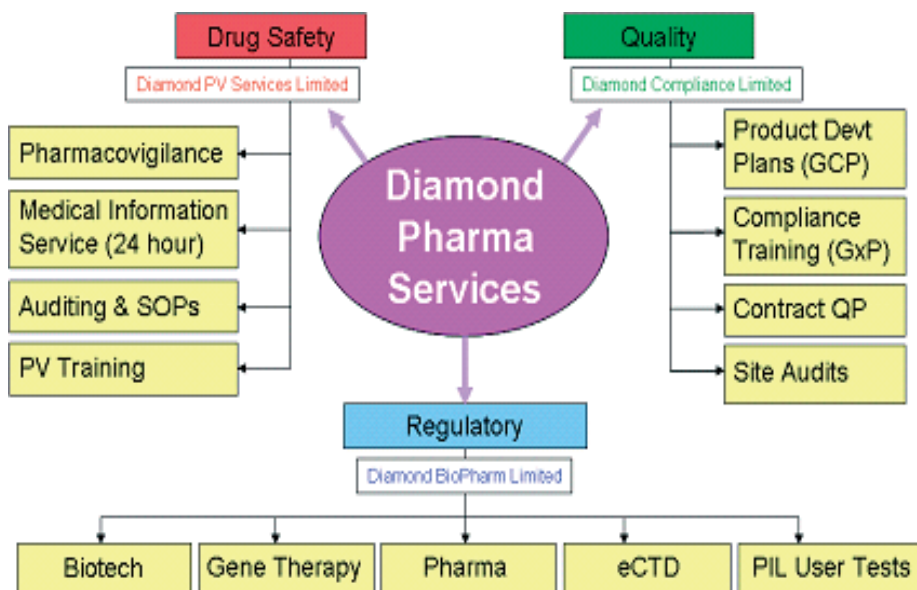
Assist with writing, editing and reviewing Modules 3, 4 and 5 of the CTD dossier

eCTD-ready documentation and publishing

Act as legal representative in the EU for clinical trials

Be the central point for communication with regulatory agencies

SME status means lower fees for Scientific Advice meetings and regulatory submission fees



Critical Issues that Diamond BioPharm can assess and add value to the product development include:

Comparability studies for changes in production processes

Characterisation studies

Viral safety evaluation

Non-clinical ... choice of animal models

Germ line transmission

Integration

Environmental risk

Clinical protocol design

Risk management planning

Pharmacovigilance

Diamond BioPharm Ltd

No4 Eastwing Gemini House

Flex Meadow

Harlow

Essex, CM19 5TJ

U.K.

tel.: +44(0)1279 406 751

fax: +44(0)1279 418 964

info@diamondpharmaservices.com

<http://www.diamondpharmaservices.com>

Examples of Diamond BioPharm Limited's major successes

Orphan Drug designation approvals

Approval of Paediatric Investigation Plan

Scientific Advice and Product Strategy meetings

Successful Clinical Trial Applications in more than 20 countries

10+ Centralised Marketing Authorisation approvals

Diamond Pharma Services is a group of companies which provides technical support to the pharmaceutical industry, focusing on specialised services such as Regulatory, Quality and Drug Safety.