

**Diamond Pharma Services**  
PHARMACEUTICAL CONSULTANTS



USER TESTING



COMPLIANCE



PHARMACOVIGILANCE



REGULATORY

**Light entering a diamond ricochets around until it can find a way out...**

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We have the expertise and want to help your company in resolving any regulatory or licensing issues. Whatever your needs, Diamond Pharma Services can find the way forward for you. We aim to bring a fresh and dynamic approach to the area of Regulatory Affairs, Pharmacovigilance & Compliance.

We have the expertise and professionalism and will ensure that your requirements are handled to the highest possible standards.



## **Diamond BioPharm Limited**

**REGULATORY CONSULTANTS**

Diamond BioPharm Limited is a Regulatory Consultancy company which was founded in October 2005. Our staff have extensive and wide experience in all aspects of European Regulatory Affairs including New Chemicals, Biotechnology, Gene Therapy and Generic products. We can provide you with high quality services in:

- ✓ Experts in Gene Therapy and Biotechnology
- ✓ Preparing for and arranging Scientific Advice meetings
- ✓ Preparation of IMPDs/Clinical Trial Application submission and management
- ✓ Preparation and submission of Orphan Drug Applications
- ✓ SME status for ex-EU companies
- ✓ POM to P reclassification applications
- ✓ Regulatory Strategic Advice
- ✓ Dossier and development gap analysis
- ✓ CTD conversions/Routine Maintenance
- ✓ Preparation and submission of EDMFs/CEPs
- ✓ Assistance with Mutual Recognition, Decentralised and Centralised Applications
- ✓ e-CTD and Document Management



## **Diamond PV Services Limited**

PHARMACOVIGILANCE CONSULTANTS

Diamond PV Services Limited is a young and newly formed operation offering a broad range of world-wide Pharmacovigilance services. Through our enthusiastic staff we can offer high quality and cost effective services covering all aspects in Volumes 9A and 10, for example:

- ✓ Full electronic adverse event management via the ArisG database
- ✓ Adverse event management for clinical trials and marketed products
- ✓ Adverse event reporting, collection and follow up
- ✓ European Qualified Person (QP) for Pharmacovigilance
- ✓ Expedited reporting in accordance with regulatory requirements
- ✓ Medical assessment of cases
- ✓ Assistance with signal detection
- ✓ Periodic Safety Update Report preparation
- ✓ Annual Safety Report preparation
- ✓ Assistance with writing SOPs and developing your own PV systems
- ✓ Writing Risk Management Plans (RMP)
- ✓ Training in PV practices



## **Diamond Compliance Limited**

PHARMACEUTICAL QUALITY CONSULTANTS

Diamond Compliance Limited is a newly formed company. Our staff has in excess of 20 years experience within most areas of the Pharmaceutical Industry. Irrespective of what aspect of our services you may be interested in you can be assured that it will be to a high standard in compliance with all legislative requirements. Our level of expertise allows us to offer a complete range of services covering all aspects of GxP compliance, including:

- ✓ Auditing of Primary (API) and Secondary (Dose Form) manufacturing sites
- ✓ Quality Systems Review
- ✓ Validation activities including computer validation
- ✓ Study monitoring for bioavailability studies
- ✓ Qualified Person (QP) service – including batch release
- ✓ Liaison with Regulatory Authorities on all aspects of compliance
- ✓ Arranging Quality-focused meetings through Regulatory Authority contacts
- ✓ Organising and leading, on behalf of Sponsor Companies, Regulatory Authority GxP inspections
- ✓ Training across the spectrum of compliance activities



## **Diamond Clear PILs Limited**

**PATIENT INFORMATION LEAFLET TESTING**

Diamond Clear PILs Limited was set up as a separate entity in order to assist companies in meeting the legislative requirements for Patient Information Leaflet testing. An area that we are especially enthusiastic about; therefore, all of the personnel are highly experienced in their field and are drawn together to offer you a PIL User Testing service which is second to none. We will provide you with a high quality service, supported by an enthusiastic and friendly team to:

- ✓ Prepare your new leaflets
- ✓ Review and amend your existing leaflets
- ✓ Medical input into lay language leaflet text
- ✓ Input into layout and design of leaflets
- ✓ Carry out full User Testing to achieve satisfactory PILs for Regulatory Authority submission
- ✓ Compile final reports for submission
- ✓ Assistance through Regulatory Authority review
- ✓ Assessment of all of your existing leaflets with the aim of 'grouping' specific therapeutic classes, hence avoiding the need to test all leaflets

# Our successes

- Regulatory Authority approval of Pharmaceutical Manufacturing Operations
- 46 PILs tested; positive Regulatory Authority feedback
- Diamond Clear PILs Limited is the first company to gain approval for a PLPI patient leaflet
- Project Leadership with companies involved in:
  - New Chemical Entities
  - Biotechnology
  - Generics
  - Gene Therapy
  - Biosimilars
- Working with global-based companies in:
  - USA
  - Turkey
  - Europe
  - India
  - United Kingdom
- Installation of International Company standard for electronic PV reporting

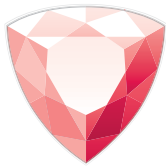


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