

Diamond Pharma Services
PHARMACEUTICAL CONSULTANTS



COMPLIANCE



PHARMACOVIGILANCE



REGULATORY



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

Diamond Pharma Services is a company which provides leading-edge technical services to the biotech and pharmaceutical industries, through its experienced panel of 25 employees and consultants in the fields of Regulatory Affairs, Pharmacovigilance and Compliance.

We aim to set ourselves apart from the rest by focusing at all times on providing a high-quality service that meets our customer's needs, and by acting at all times with integrity and professionalism to ensure that our customers feel that they have received good value for money and will return to Diamond again.

Our job is to make your job easier.



Diamond BioPharm Limited

REGULATORY CONSULTANTS

Diamond BioPharm Limited is a Regulatory consultancy company which is a leading provider of dedicated services to the biotech and pharmaceutical industries.

Diamond BioPharm was the first of the Diamond Pharma Services group of companies to be established when it was founded in 2005. Diamond BioPharm Limited has EMA SME status.

Under the leadership of Maureen Graham (ex-Amgen and IVAX), our team has extensive experience across most aspects of European Regulatory Affairs including New Chemicals, Biotechnology, Gene Therapy and Generic products.

Within Diamond BioPharm our customer is our number 1 priority.

So, how can Diamond BioPharm provide value and support for your company?

- ✓ Experts in Gene therapy and Biotechnology fields
- ✓ Experts in navigating the Centralised Procedure
- ✓ Prepare and manage Scientific Advice meetings (EMA, EU national)
- ✓ Dossier and product development gap analysis
- ✓ Prepare IMPDs and Clinical Trial Applications (CTA)
- ✓ Prepare and submit Orphan Drug applications, PIPs, RMPs
- ✓ Full e-CTD publishing and document management services
- ✓ Regulatory strategy advice and guidance (in CMC, nonclinical, clinical)
- ✓ POM to P switch (reclassification)
- ✓ Assist with MRP, DCP and National applications
- ✓ Patient Information Leaflet (PIL) user testing
- ✓ Linguistic Review Process of Product Information



Diamond BioPharm Limited
REGULATORY CONSULTANTS



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Diamond PV Services Limited

PHARMACOVIGILANCE CONSULTANTS

Diamond PV Services Limited was founded in June 2007.

Diamond PV Services provides a full global pharmacovigilance service to customers, from within Europe and overseas.

Through an experienced team of permanent staff and additional members that help to manage peak workloads, we can provide advice, insight and support across a wide range of areas and can provide out-sourced solutions for clients in the post-authorisation, clinical trials, named patient and compassionate use environments.

Our staff have extensive experience in all aspects of pharmacovigilance for new molecular entities and generic products as well as in Device Vigilance for medical devices and Medical Information.

Diamond PV Services is committed to providing its customers with a flexible range of high quality solutions which meet all current regulatory and legal standards, at an affordable price. Services include:

- ✓ Full electronic case management, using the ARISg database
- ✓ Pharmacovigilance project management for clinical trials and authorised products
- ✓ Qualified Person for Pharmacovigilance (QPPV) in EU, and Deputy QPPV
- ✓ Responsible Person for EudraVigilance
- ✓ 24 hour pharmacovigilance hotline
- ✓ Expedited reporting capabilities across EU member states via EudraVigilance and ex-EEA countries globally
- ✓ Signal detection
- ✓ Global literature search and review
- ✓ Periodic Safety Update Report (PSUR) preparation
- ✓ Clinical trial cumulative report preparation, including Development Safety Update Reports (DSUR)
- ✓ Medical Information services, including 24 hour hotline
- ✓ Risk Management Plan (RMP) preparation
- ✓ PV Training
- ✓ Review of internal systems (audits) for improvement of regulatory compliance
- ✓ Case Processing – legacy cases and clearing work backlogs



Diamond PV Services Limited

PHARMACOVIGILANCE CONSULTANTS



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Diamond Compliance Limited

PHARMACEUTICAL QUALITY CONSULTANTS

Diamond Compliance Limited was founded in 2006.

We have over 50 years combined experience within pharmaceutical, generic and specialty fields and within regulatory, development, compliance and quality functions, including a number of years within the UK Regulatory Authority (MHRA).

All services are provided to a high standard and in compliance with all current legislative requirements.

Our experience and qualifications allow 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

Testimonials

“Diamond Pharma Services is an ideal partner, with immense experience in European regulatory affairs and pharmacovigilance. Fortunately, they still retain the ability to be creative and flexible in strategy and in understanding client needs and business realities. These are key advantages and differentiators.”

Managing Director, Flynn Pharma

“Working with Diamond PV Services is a pleasure. Their representatives are extremely knowledgeable about pharmacovigilance and have been able to train our customer-facing staff ... I have no hesitation in recommending Diamond PV Services as a provider of pharmacovigilance services.”

Technical Director, Moorfields Pharmaceuticals

“My company is engaged in gene therapy, a cutting-edge technology whose regulatory guidelines are still evolving. Diamond has supported us on matters of regulatory strategy and compliance across the board – manufacturing, quality, non-clinical, clinical, and pharmacovigilance. Their service has always been outstanding.”

Chief Operating Officer, Amsterdam Molecular Therapeutics

“Diamond Compliance has always provided us with reliable and accurate advice and high quality services. Their strong points being a team of friendly professional people from the industry with many years of practical experience.”

Regulatory Affairs Director, Medochemie

“Diamond PV Services have provided us with excellent service and support ... I can confidently recommend Diamond as a solid and reliable consultancy service providing experts in their field.”

Deputy Head of Pharmacovigilance, Gedeon Richter

“I have been working with Diamond BioPharm for over 2 years and have found their services to be professional, thorough and most supportive.”

Project Manager, Goldshield

“It has been a great comfort to know that Amdipharm can and will continue to request assistance in its Pharmacovigilance activities from Diamond PV and as they offer a wide range of services it feels like an extension of the existing Company resource, which makes working with Diamond PV effective and easily manageable.”

Medical Services Manager, Amdipharm

“We have been working with Diamond BioPham Limited and Diamond PV Services Limited on European wide Regulatory and Pharmacovigilance issues for some time. They have proved first class both in terms of professional strategic advice as well as full operational support. They have managed the interactions with our executive teams in a most personable and professional way. I have no hesitation in recommending Diamond to others.”

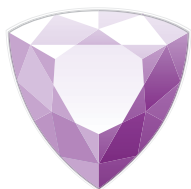
CEO, Forest Laboratories Europe

“The ability to think strategically and then implement the strategies operationally has proved invaluable to the development of our products. We continue to be impressed by the creative and innovative solutions presented allowing us to stay on track with our regulatory, product development and corporate goals.”

CEO, PCI Biotech AS, Norway

Track record

- European experts providing solutions within 3 critical disciplines
 - Regulatory, Pharmacovigilance, Compliance
- **NEWS...** e-CTD system (Extedo) installed and fully validated
- Excellent EMA credentials and reputation:
 - 50+ Scientific Advice Meetings
 - 3 Centralised Procedure applications
 - ...plus much more experience through previous roles
- 20+ clients for Pharmacovigilance services, covering 100+ molecules
- Broad experience across Biotechnology and Advanced Therapy fields
 - Monoclonal antibodies
 - Recombinant DNA products
 - Gene Therapy
- 120+ PILs tested, with 100% positive Regulatory Authority feedback
- Working with international companies based in:
 - USA & Canada
 - European Union
 - Switzerland
 - India
 - Republic of Korea



Diamond Pharma Services

PHARMACEUTICAL CONSULTANTS

Commercial Development

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Diamond BioPharm Limited

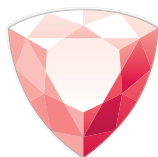
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Diamond PV Services Limited

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Diamond Compliance Limited

PHARMACEUTICAL QUALITY CONSULTANTS

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