



OUTSOURCED REGULATORY DEPARTMENT

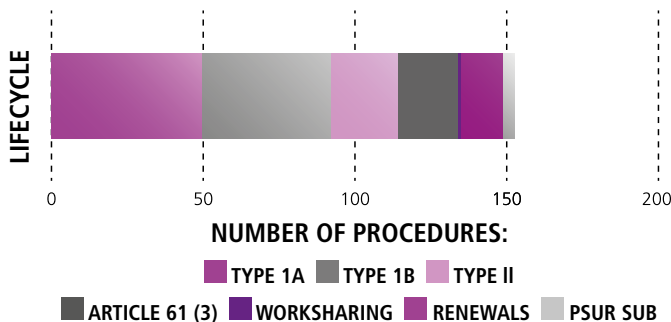
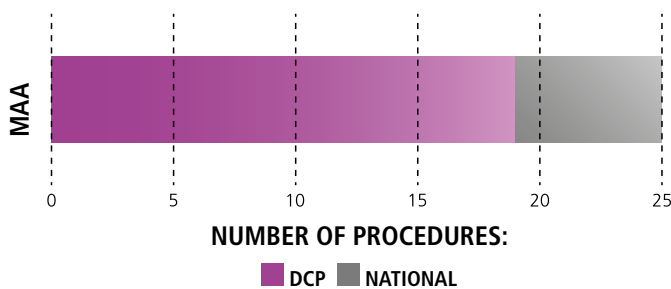
Sometimes there is sound logic for a pharmaceutical company to outsource a significant part of their regulatory tasks to a stable and experienced team. Diamond Pharma Services has been a trusted resource for a variety of companies looking to:

- *OVERCOME A SIGNIFICANT WORKLOAD INCREASE.*
- *PLACE REGULATORY LIFECYCLE MANAGEMENT IN SAFE HANDS WHILST INTERNAL REORGANISATIONS TAKE PLACE.*
- *INCREASE WORKFLOW EFFICIENCY.*
- *KEEP INTERNAL HEAD COUNT TO A MINIMUM IN SMALL GENERICS PHARMACEUTICAL COMPANIES.*
- *SUPPORT NON-EU PHARMACEUTICAL COMPANIES ENTERING THE EU MARKET.*

Diamond Pharma Services can build a bespoke regulatory team for any company and provide a reliable regulatory workflow with appropriately qualified staff available for each task. The outsourced model can work as either dedicated FTE or task-based contracts.

STATISTICS:

Outsourced Department Case Study For A Top 100 Pharma Company:



CASE STUDIES:

Top 100 Pharmaceutical Company:

- *Fully outsourced regulatory department provided to support major corporate restructure.*
- *Team assembled with 1 director, 2 managers and access to 5 officers.*
- *2 year project.*
- *Full control of a portfolio of products.*
- *Provided a safe harbour for product licences and lifecycle maintenance during a restructuring exercise.*
- *On completion the client retained Diamond for Regulatory Department Overflow services.*

Mid-sized UK Based Generics Pharmaceutical Company:

- *To provide outsourced regulatory services for MAA and post-marketing variations. Assistance for in-licensed products providing regulatory strategy and associated lifecycle and transfer of ownership management*
- *Long term project leader with access to regulatory pool of staff.*
- *Ongoing long term project (4 years+).*
- *Cost-efficient and flexible resource providing full regulatory support to several national markets.*
- *Ad hoc regulatory trouble shooting for complex and urgent regulatory issues.*
- *Keeping products on the market in the face of challenging situations.*

