

OUTSOURCED REGULATORY DEPARTMENT

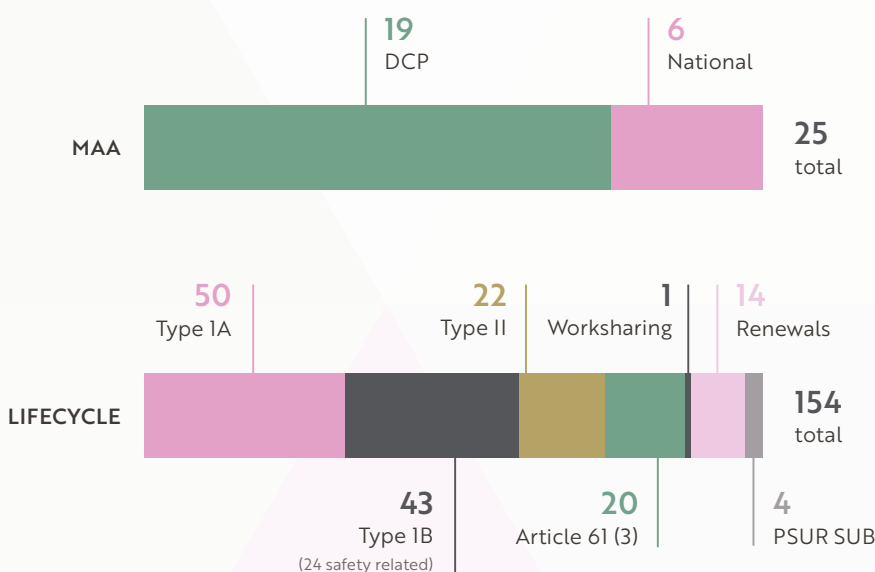
Sometimes there is sound logic for a pharmaceutical company to outsource a significant part of their regulatory tasks to a stable and experienced team. Diamond Pharma Services has been a trusted resource for a variety of companies looking to:

- Overcome a significant workload increase
- Place regulatory lifecycle management in safe hands whilst internal reorganisations take place
- Increase workflow efficiency
- Keep internal headcount 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:



OUR 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.