

REGULATORY DEPARTMENT OVERFLOW

Maintaining a headcount balance in regulatory affairs departments in the pharmaceutical industry is a perennial headache for any senior management team. The workflow in regulatory groups can undergo periods of extreme pressure as unexpected projects or structural reorganisations create the need for fast action. Recruiting skilled staff to meet these demands is not straightforward, and new staff take time to understand the historical perspective for a product portfolio.

At Diamond Pharma Services we understand this pressure. Over the years we have provided overflow regulatory department coverage to a range of clients including:

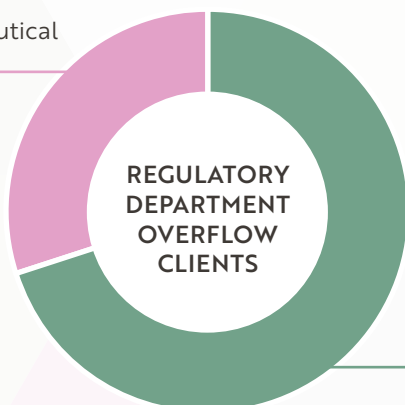
- Global generics companies
- Top 10 global pharmaceutical companies
- Virtual generics companies
- Generics companies with no EU or UK regulatory trained staff.

We are specialists in providing bespoke cover to companies either via the provision of dedicated full time equivalent coverage, or ad hoc emergency support.

STATISTICS

30%

Top 100 pharmaceutical



70%

Other

OUR CASE STUDIES

Top 40 Pharmaceutical Company:

- Post-marketing variations in EU member states via centralised and national procedures.
- Dedicated project leader with access to regulatory pool of staff.
- Ongoing long term project (3 years+).
- MAA support, lifecycle management, ad hoc overflow variations.
- Flexible overflow resource within an adaptable team with retained knowledge of products, licenses and variation history.
- Eliminate peaks in headcount and resource needs with an efficient knowledgeable partner.

Multinational Healthcare Organisation:

- Managed site transfer variations and lifecycle support during a major site rationalisation.
- 2 dedicated staff provided.
- 2 year project.
- Integrated into the internal project team to support various sites undergoing structural change.
- Offered a stable hub to direct activities across sites and maintain global licenses for 5 assigned products.
- Stable external resource during a time of internal flux.