



Darcy Consulting: Best SME Life Sciences Compliance Consultancy - North East USA

Drawing upon the expertise and industry knowledge of its team, Darcy Consulting is a niche compliance consulting company that helps start-up companies navigate the complex path of regulatory approval. We profiled the firm to find out more about how it came to win one of this year's coveted Healthcare and Pharmaceutical Awards.

Since it first started in 2014, Darcy Consulting has focused on helping clients, predominantly start-ups, plan and prepare for regulatory approval of their first product.

The firm's founder Catherine Arthey brings many years of experience working in Pharma as well as the main consulting firms. During this time, she realized that for small companies, specifically start-ups that are planning to file their first IND, there are few vendors that provide the 'nurturing and supportive environment' that these fledgling companies need. This is the focus of Darcy Consulting and with an impressive suite of offerings to support such emerging life science companies, they are making a name in this space.

Thanks to its small size, the firm has been able to establish an intimate working relationship with clients and this has been central to Darcy's success in the marketplace. Darcy's approach is very hands on. They have deep expertise, knowledge and experience and this comes across very quickly. They are intimate yet flexible with their clients and can very quickly blend in with client teams. For many start-ups, the focus is on securing funding, developing the science and preparing the market. Having

adequate quality expertise or oversight, whether in planning a clinical trial or preparing for a filing, is often a luxury that few start-ups can afford. This is where Darcy excels. They create great partnerships and work seamlessly with their clients to get the job done.

Within the life sciences market, recent changes in the industry, particularly ICH E6(R2), have caused a stir in the industry and forced companies to assess where they are at. This, according to Arthey, has been very positive. Clients want to know that they are following the regulations. In addition, the focus on areas such as risk, vendors and quality has forced companies to look at their internal processes, this in the long run will ultimately make companies more efficient and effective.

Incorporating regulatory updates is a critical component of any service that Darcy Consulting provides, and remains its focus moving forward. The firm's extensive knowledge of the industry and its singular focus on start-ups has given them a unique advantage among their peers. Working across biotech companies, device companies and small CROs, they have been able to identify common themes and typical pitfalls for any start-up. In effect, they know exactly what to look for. This focus has been core

to their success and with so many start-ups seeking accelerated approval, this will help drive the company to even greater success over the years to come.

With a team of four full time employees and a network of over eight consultants, Darcy Consulting is growing. The firm's new clients come in predominantly through referral and they have no problem providing names of very satisfied clients. Indeed, for one client, the FDA Inspector commented on the quality of the client's quality system, which the firm helped establish. Darcy's clients are start-ups, many are rare disease companies including gene therapy and stem cell companies. The firm currently works with a range of clients throughout the US, UK and Japan. With a growing list of clients in Philadelphia as well as the life science hubs of San Francisco and Boston, the company is well positioned to grow its expertise and reach.

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