Dark Horse Consulting
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DARK HORSE CONSULTING

Premier consultants offer wide-ranging support in cell and gene therapy space

With extensive industry expertise, Dark Horse Consulting provides strategic and technical services to help clients realize their goals of bringing therapies to patients and commercialization.

Dark Horse Consulting (DHC) specializes in the development of cell and gene therapy products, applying pharmaceutical industry best practices to the unique challenges of this field. Deeply experienced consultants help clients achieve their strategic and operational objectives, spanning from high-level corporate strategy development to detailed technical implementation. Common services include process development, custom device development, project and program management, financing and diligence, manufacturing support, failure analysis, quality systems and regulatory support.

"Our goal is to be the premier provider of consulting services within the cell and gene therapy industry," said DHC founder and CEO Anthony Davies. "Our team is well equipped to apply the lessons learned from many decades in the industry to help clients in their daily work of bringing therapies to patients in need."

Ensuring a smooth process

The development of reproducible, cost-effective and current good manufacturing practice (cGMP)-compliant manufacturing processes is critical for clinical and commercial success. Failing to plan for and execute a phase-appropriate process development plan is a common source of product failures. To navigate this challenging path, DHC offers services such as process codification, evaluation and development planning.

DHC helps clients define their process for regulators and contract manufacturing organizations (CMOs), with a proven track record of success in regulatory filings and technology transfers. To assess process performance and trends, DHC consultants compile data into comprehensive tracking-and-trending databases and evaluate these data using statistical analysis software.

Through gap analysis of the client's current process, DHC develops a comprehensive product development roadmap that identifies key items to be addressed at each stage of clinical development. Moreover, DHC uses industry best practices to identify root causes of process failures and implement corrective and preventive actions to avoid them from reoccurring.

Manufacturing solutions

Many cell and gene therapy products require specialized devices for manufacturing, storage, transportation or delivery. Working with clients, DHC first determines whether an available device can meet their needs, and if none exists, DHC engineers will design a customized device solution. Moreover, DHC will provide project management oversight of device manufacturing and assist with regulatory documentation.

To overcome one of the greatest challenges faced by developers, DHC identifies and implements optimal cGMP manufacturing strategies. Quantitative capacity and cost models assess whether in-house or outsourced manufacturing best suits the needs of development programs.

The team at DHC also prepares requests for proposals, solicits responses from qualified CMOs, audits lead candidates and evaluates responses to select the optimal partner. Helping clients every step of the way, DHC oversees technology transfers to the selected CMO, and provides person-in-plant support for effective CMO management.

For clients that need assistance with facility design, DHC offers a tailored solution at each stage. Experienced scientists and engineers develop conceptual designs, and an architect translates those designs into comprehensive buildout plans. In addition, project management professionals solicit competitive quotes and oversee project timelines.

Providing optimal oversight

Program managers at DHC provide support for various needs, from tactical project management to strategic program and portfolio planning. DHC develops project timelines, identifies critical path items, and optimizes resource allocations. DHC oversees projects to timely achievement of milestones, develops product development plans, prioritizes development opportunities from platform technologies, and develops stage-gating processes for continuous portfolio management.

In addition, DHC develops stage-appropriate compliance systems that don't waste resources or generate excessive bureaucracy. To ensure quality standards are aligned with the unique needs of a program, DHC performs risk assessments and audits of critical raw material suppliers, contract manufacturers and analytical service providers. Moreover, DHC analyzes existing quality management systems, identifies any gaps, and provides stage-appropriate and resource-efficient solutions to address those gaps.

Putting your best foot forward

DHC is well equipped to provide both strategic and tactical regulatory assistance. The consultants are connected with current and former staffers of multiple worldwide regulatory bodies, and have written, reviewed and otherwise supported filings across a wide range of global jurisdictions and stages of development. DHC helps clients plan for long-term success while maintaining a pragmatic focus on near-term realities such as resource constraints and timeline objectives.

The financing and diligence team at DHC offers expertise to support companies seeking funding and investors interested in the cell and gene therapy space. DHC frequently performs due diligence on companies for investors and provides a mock diligence service to prepare companies seeking investment for questions investors may raise. Moreover, DHC provides candid assessments of programs and strategic planning to optimize pitches. Continuous awareness of motivated investors with interest in the cell and gene therapy space allows DHC to provide introductions to high-quality companies seeking funding. This investor relations and messaging capability can support all phases of funding, from seed through to initial public offering and beyond.

"With our depth of expertise and network of connections, we aim to exceed the expectations of our clients," Davies said. "We rigorously comply to the highest standards while recognizing practical limitations. In the end, our work to streamline efforts in the cell and gene therapy space may translate into benefits not only for our clients, but also for patients."

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