Dark Horse Consulting Group
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Dark Horse: the cell and gene industry experts

With unmatched industry expertise, Dark Horse Consulting provides strategic and technical services to help clients realize their goals of bringing therapies to patients and commercialization. Those seeking services from Dark Horse Consulting range from biopharmaceutical companies to tools and tech providers to investment firms.

Dark Horse Consulting (DHC) specializes in the development of cell and gene therapy products, applying pharmaceutical industry best practices to this dynamic field. Deeply experienced consultants help clients achieve their strategic and operational objectives, spanning from high-level corporate strategy development to detailed technical implementation. There are twelve typical service areas in demand: manufacturing support, process development and comparability, analytical development, quantitative modeling, device development, preclinical, project and program management, financing and diligence, market research, intellectual property, quality systems, and regulatory support.

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 these challenging paths, 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, the company uses industry best practices to identify root causes of process failures and implement corrective and preventive actions to prevent recurrence.

Assessing and supporting manufacturing, modeling, and management

To overcome one of the greatest challenges faced by developers, DHC identifies and implements optimal cGMP manufacturing strategies. Quantitative capacity and cost modeling considers the needs of development programs, providing a window into future planning.

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. DHC can oversee technology transfers to the selected CMO, and/or provide 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 project management professionals solicit competitive quotes and oversee project timelines.

Many cell and gene therapy products require specialized devices for manufacturing, storage, transportation or delivery. DHC firstly determines whether an available device can meet client needs, and if none exist, DHC engineers will design a customized device solution. Moreover, DHC provides project management oversight of device manufacturing and assists with regulatory documentation.

Providing à la carte program management, quality, and regulatory support

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. In addition, the company analyzes existing quality management systems, identifies any gaps, and provides relevant solutions.

DHC is equipped to provide both strategic and tactical regulatory assistance. The consultant team has unrivaled experience with multiple worldwide regulatory bodies, and has 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.

Supporting investor relations, from market research to diligence to IP

The financing/diligence and IP (intellectual property) teams at DHC offer expertise to support companies seeking funding and investors interested in cell and gene therapy. 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. Additionally, DHC's extensive technical and scientific background in cell and gene therapy as well as its deep network of industry contacts allows for an informed, in-depth ability to perform effective market research (landscape scans, voice-of-customer surveys, and needs assessments). The company also offers scientifically-informed intellectual property expertise: ensuring that appropriate IP coverage exists and identifying new IP opportunities.

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

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