LOOK 2024 BACK

DHC
DARK HORSE CONSULTING

BIO TECH LOGIC
A DIVISION OF DARK HORSE CONSULTING GROUP

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Welcome to our 2024 Lookback, the Dark Horse Consulting Group annual year-in-review.

2024 was a milestone year across the board: we marked our tenth anniversary, acquired BioTechLogic, added a new department (Clinical), launched ICMC™, and increased our content libraries by another five expert webinars (page 27) and seven case studies (pages 20-26).

Our tenth anniversary began on March 15th, the date on which Anthony Davies founded DHCG in 2014. See the facing page for a look at how our footprint and that of the industry have changed in the intervening ten years.

The biggest news in our very big year came in October, when we announced our acquisition of BioTechLogic, Inc., a 20+ year success story and recognized forerunner in technical operations, manufacturing, quality, and regulatory CMC consulting. BioTechLogic's dozen consultants (pages 18-19) expand the availability and expertise of our consulting teams while further optimizing efficiencies of cost, timeline, and resources.

What does this mean for current and future clients of either practice? As a fully integrated global consulting practice, Dark Horse Consulting Group now has two business units with two distinct business models: Dark Horse Consulting (DHC) and BioTechLogic (BTL). We jointly offer a wide range of biopharma services. Turn the page for details on how DHC and BTL will interface with one another.

The fall of 2024 also gave us the Initiative for Certification of Manufacturing Capabilities (ICMC), a groundbreaking offering delivered by DHC (pages 30-31). With an industry-leading track record in supporting both CGT therapeutic developers and manufacturing organizations, we are uniquely positioned to deliver credible and unbiased evaluations to help drug developers make informed decisions in selecting their manufacturing partner.

In 2024 we brought on two medical experts to form our new Clinical Department: Adnan Jaigirdar, M.D., FACS (page 9) and Kristin Baird, M.D. (page 10). Common client requests in this area currently include clinical strategy and trial design, integrated regulatory authorship, and support in convening a medical advisory board. Pages 20-21 include case studies specific to this department.

Be sure to follow us on social media so you can hear all our latest news as it happens: search for "@darkhorsecagt" on X and "Dark Horse Consulting Group Inc." or "BioTechLogic, Inc." on LinkedIn. If you're not yet receiving The Quarter Horse newsletter, subscribe via darkhorseconsultinggroup.com/newsletter-signup.

As always, reach out with any questions or to schedule an initial consultation: details on the back page. We look forward to keeping in touch.

Anthony Davies, Ph.D.
FOUNDER & CEO

Katy Spink, Ph.D.
COO & MANAGING PARTNER

Robert Allen, Ph.D.
MANAGING PARTNER & GENERAL MANAGER, DHC EUROPE

DHC 10 YEARS
DARK HORSE CONSULTING

2024 marked double-digits for Dark Horse Consulting Group. A lot has changed between then and now!

	THEN (2014)	NOW (2024)
EMPLOYEES	1	63
GLOBAL OFFICES	1	4
PROJECTS	1	1,000+
APPROVED CGTs IN THE U.S.	1	34*†

* not counting cord blood product
† Source: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products

Dark Horse Consulting Welcomes BioTechLogic

On October 2, 2024, we were thrilled to announce our acquisition of BioTechLogic, Inc. As Greg Thomas, Partner at WestView and DHC Board Director, said at the time, "Combining BioTechLogic with DHC will create a powerhouse in the biopharma consulting space, while retaining a critical focus on advanced therapies."

Our fully integrated global consulting practice, Dark Horse Consulting Group, Inc., is now comprised of two business units with two distinct business models: Dark Horse Consulting (DHC) and BioTechLogic (BTL). We jointly offer services across nearly all biopharma markets.

DHC's business model is structured, staffed, priced, and positioned around leveraging industry-leading experience to close gaps in our clients' knowledge or expertise, enabling them to accelerate their strategic objectives. This support typically takes the form of short- to mid-term engagements.

BTL's business model is structured, staffed, priced, and positioned around leveraging two decades of operational experience and expertise to close capability gaps for our clients, enabling achievement of operational and development objectives…typically through embedded mid- to long-term engagements.

Through our two business units, we are uniquely positioned to address a wide range of client types and challenges, offering tailored combination of relevant expertise, resources, and engagement types.

On the facing page, see examples of BTL's areas of focus and most popular service offerings. And then, turn the page to see the Core Capabilities and common service offerings from the DHC team.

BioTechLogic's Areas of Focus

PRODUCT & PROCESS DEVELOPMENT

- Process characterization and risk assessment
- Quality Target Product Profiles (QTPP) and Critical Quality Attribute (CQA) assessments
- Process development descriptions, documentation, and reports
- Process material evaluations
- Process development, qualification, and validation

ANALYTICAL DEVELOPMENT

- Analytical method development and validation
- Product characterization
- Method transfer
- Regulatory compliance, SOP generation, and submission support
- Analytical method troubleshooting

FACILITIES, MFG, & COMPLIANCE

- Facility assessment/design optimization
- Contract services selection and mgmt
- Tech transfer and process scale up
- Person-in-Plant and suite mgmt
- Internal and external audits
- Inspection readiness
- Troubleshooting/ongoing optimization
- Aseptic fill/finish
- Combination product mfg support

QUALITY ASSURANCE

- Establishing quality management systems excellence
- Internal and external audits
- Global FDA/EMA remediation projects
- Combination products quality support

PROJECT & PROGRAM MANAGEMENT

- Project and program creation
- Project execution and communications planning
- Project execution, tracking, reporting, and document management
- Mitigation and problem resolution

REGULATORY AFFAIRS

- Regulatory filing, planning, & readiness
- Filing preparation, review, & publishing
- Regulatory body liaison
- Accelerated filing support
- Combination products regulatory support

Dark Horse Consulting's Core Capabilities

PRODUCT & PROCESS DEVELOPMENT

- Process evaluation
- Process codification
- Product & process development planning
- Comparability studies
- Process & test remediation
- Interim functional leadership

ANALYTICAL DEVELOPMENT

- Method development
- Specification setting
- Qualification and validation
- Method transfer
- Comparability testing
- Next-gen sequencing & off-target analysis
- Interim functional leadership

DEVICE DEVELOPMENT

- URS development
- Landscape scan and gap analysis
- Custom device design
- Contract manufacturing management
- Regulatory documentation

REGULATORY AFFAIRS

- Regulatory strategy
- Regulatory gap analysis
- Meeting assistance
- U.S. FDA Agent
- Integrated regulatory authorship
- Interim functional leadership

NONCLINICAL DEVELOPMENT

- Preclinical/nonclinical strategy
- Technical writing
- Vendor selection
- Study design and oversight

CLINICAL REGULATORY

- Clinical strategy and trial design
- Integrated regulatory authorship
- Medical advisory board

OUR NEWEST CORE CAPABILITY

FACILITIES, MANUFACTURING, & COMPLIANCE

- Ops and capacity planning
- CDMO selection
- Tech transfer/CDMO oversight
- Facility design
- Failure analysis
- Mock audits and remediation
- Interim functional leadership

QUALITY ASSURANCE

- QMS design
- QMS gap assessment
- Document authoring/review/revision
- Supplier oversight
- Audits
- QP support
- Interim functional leadership

PROJECT & PROGRAM MANAGEMENT

- Timeline analysis
- Project management
- Program development planning
- Strategic portfolio prioritization
- Interim functional leadership

QUANTITATIVE MODELING

- Capacity planning
- Cost of goods (COGs) analysis
- Build vs. buy analytics
- Market analysis
- Profit margins/business use case
- Pegasi

MARKET EXPERTISE

- Needs assessment/market research
- Voice of customer (VoC) surveys
- Marketing strategy

DILIGENCE & BUSINESS STRATEGY

- Due diligence technical assessments
- Landscape scanning
- Teach-ins
- Message optimization and market positioning

Meet the DHC Team

In 2024, we added four new Horses to our team, all of whom are called out with a light green outline around their pictures. The rest of our team's images are within orange circles, designating those who have been with us since 2023 or before. Each Principal, Practice Expert, and Consultant has underneath their name one or more icons to indicate their core capabilities (pages 6-7).

Executive Leadership Team

Anthony Davies, Ph.D.
FOUNDER & CEO

Katy Spink, Ph.D.
COO & MANAGING PARTNER

Robert Allen, Ph.D.
MANAGING PARTNER &
GENERAL MANAGER
DHC EUROPE

John Ng
GENERAL MANAGER
DHC ASIA PACIFIC

Sanjin Zvonić, Ph.D.
SVP,
BUSINESS DEVELOPMENT

Department Heads

Kimberly Benton, Ph.D.
MASTER PRINCIPAL;
HEAD OF REGULATORY

Heath Coats, M.S.
SENIOR PRINCIPAL;
HEAD OF FACILITIES &
ENGINEERING COMPLIANCE

Stephan Croft, MSc., Eligible QP
SENIOR PRINCIPAL;
HEAD OF QUALITY

Scott Cross, M.S.
SENIOR PRINCIPAL;
HEAD OF GENE THERAPY CMC

HEAD OF OUR NEW DEPARTMENT

Adnan Jaigirdar, M.D., FACS
SENIOR PRINCIPAL;
HEAD OF CLINICAL

Nathan Manley, Ph.D.
SENIOR PRINCIPAL;
HEAD OF NONCLINICAL

Practice Experts and Principals

Kristin Baird, M.D.
MASTER PRACTICE EXPERT

Donald Fink, Ph.D.
MASTER PRACTICE EXPERT, REGULATORY

Richard Grant
MASTER PRACTICE EXPERT

Tal Salz, Ph.D.
SENIOR PRACTICE EXPERT

Liz Cauldwell
PRINCIPAL

Michael Kinzie
PRINCIPAL

Amanda Mack, Ph.D.
PRINCIPAL

Sara Masterson, MBA
PRINCIPAL

Brent Morse, M.S.
PRINCIPAL

Jacob Staudhammer
PRINCIPAL

Senior Consultants and Consultants

Joshua Beckett
SENIOR CONSULTANT

Blake Bergam
SENIOR CONSULTANT

Liam Breen, MChem, MRSC
SENIOR CONSULTANT

Deborah Chen, Ph.D.
SENIOR CONSULTANT

CONGRATULATIONS
to Carrie on her 2025 promotion to Practice Expert!

Catherine Colandro
SENIOR CONSULTANT

Allyson Davidson, Ph.D.
SENIOR CONSULTANT

Elizabeth Figueroa, Ph.D.
SENIOR CONSULTANT

Carrie Fitzgerald, CQA
SENIOR CONSULTANT

Senior Consultants and Consultant

Christina Fuentes, Ph.D.
SENIOR CONSULTANT

Liying Guay, M.S.
SENIOR CONSULTANT

Anne Lamontagne, M.S.
SENIOR CONSULTANT

Wendy Liang
SENIOR CONSULTANT

Lyndsey Treacher
SENIOR CONSULTANT

Melissa Triggiano, M.S.
SENIOR CONSULTANT

Sean O'Farrell, Ph.D.
SENIOR CONSULTANT

Uzma Shoukat-Mumtaz, PMP
SENIOR CONSULTANT

Madeline St. Onge, MBA
SENIOR CONSULTANT

Heather Todd, M.S.
SENIOR CONSULTANT

Malachi Wickman, M.S.
SENIOR CONSULTANT

Sam Blackford, Ph.D.
CONSULTANT

In 2024, our Client Satisfaction ratings reached an all-time high:

How well did DHC **understand your business needs?**
4.80/5

How satisfied were you with DHC's **communication?**
4.73/5

How well did the **deliverables meet your business needs?**
4.73/5

How would you rate the **quality of the deliverables?**
4.87/5

How well does DHC deliver **good value for money?**
4.4/5

What is the likelihood you would **use DHC again?**
4.73/5

How would you rate your experience with DHC overall?
4.87/5

Enabling Functions Team

FINANCE

Sheryl Andersen
VICE PRESIDENT, FINANCE

Germina Jackson
STAFF ACCOUNTANT

LEGAL

Mohammed Hill, J.D.
GENERAL COUNSEL &
CORPORATE SECRETARY

Cecilia Sohi
CONTRACTS ADMINISTRATOR &
LEGAL ASSISTANT

ADMINISTRATIVE

Jessi Rubbicco
DIRECTOR
ADMINISTRATION

Ebby Niyazi
EXECUTIVE ADMINISTRATOR/
OFFICE MANAGER

Kathleen Farrance, MFA
EXECUTIVE ASSISTANT/
OFFICE MANAGER

Business Development

Sanjin Zvonić, Ph.D.
SVP,
BUSINESS DEVELOPMENT

Oliver Ball, MSc.
DIRECTOR,
BUSINESS DEVELOPMENT

Alex Gibb
DIRECTOR,
BUSINESS DEVELOPMENT

Alex joined the BD team when BioTechLogic merged with DHC

Rachel Luarte
MANAGER,
BUSINESS OPERATIONS

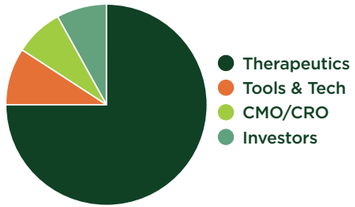
While DHC and BioTechLogic are independent companies under the Dark Horse Consulting Group umbrella, we share a joint Business Development group. We will collectively respond to your request, whether it comes in through the DHC or BTL site.

Visit **darkhorseconsultinggroup.com/consult/** or scan this QR code to request a complimentary initial consultation.

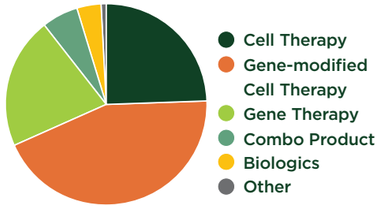
Visit **biotechlogic.com/request-consultation** or scan this QR code to request a complimentary initial consultation.

DHC at a Glance

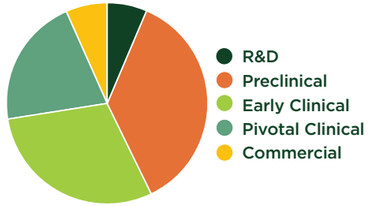
Clients by Industry



Products by Modality



Products by Phase



Select Therapeutic Competencies:

- Primary cells and tissues
- iPSCs, ESCs (incl. gene-modified)
- HSCs, MSCs (incl. gene-modified)
- T cells (αβ, γδ, Treg), TILs, NK cells, B cells, DCs (incl. gene-modified)
- Viral gene delivery (LVV, AdV, AAVs, RVs)
- Non-viral gene delivery (mRNA, exosomes, LNPs, etc.)
- Gene editing (CRISPR/Cas, ZFN, TALEN, etc.)

Regulatory Support

18	INTERACT & ITF	17	TYPE A-D & SA
39	PRE-IND	4	CLINICAL HOLD RESPONSE
58	IND & CTA	25	BLA & MAA
5	CATT & AMT		

BTL at a Glance

Projects by Therapeutic Types

- Gene Therapies
- Cell Therapies
- Combination Products
- Biosimilars
- Recombinant Proteins
- Complex Antibodies (incl. bispecific, ADC, etc.)
- Oligonucleotides & Peptides
- Vaccines
- Blood-Based Products

BioTechLogic's select therapeutic competencies include:

- AAV Vector
- AAV Sf9 Baculovirus
- LV Vector
- CRISPR/Cas
- CAR T cells
- Stem and progenitor cells
- iPS cells
- UCMSC's
- Recombinant proteins
- Complex antibodies
- Oligonucleotides and peptides
- Vaccines
- Blood-based products
- Fusion proteins
- Synthesized macromolecules

Regulatory Submission Experience

Served as the primary CMC author for 102+ submissions.

48	INDs	2	NDAs
6	IMPDs	7	MAAs
26	BLAs	1	PMA
3	BLA/315(K)s	9	CTAs

BIO TECH LOGIC
A DIVISION OF DARK HORSE CONSULTING GROUP

Meet the BTL Team

BioTechLogic's highly skilled professionals work alongside your staff and resources throughout the course of your project. We blend as teammates into your organization; not only serving as the technical expert and consultant, but also providing hands-on leadership to drive and successfully execute the plan. Icons underneath each team member indicate their areas of focus (page 5).

Co-Founders/ Department Heads

Patrick Giljum
CO-FOUNDER,
HEAD OF OPERATIONS

Tracy TreDenick
CO-FOUNDER:
HEAD OF REGULATORY & QUALITY

Vice Presidents

Eileen Choi, Ph.D.
VP OF MFG SCIENCE & TECHNOLOGY

David Fetterolf, MBA
VP OF
TECHNICAL OPERATIONS

Julie Spyrison
VP OF
REGULATORY OPERATIONS

Directors and Consultants

Rachel Houp
SENIOR DIRECTOR

John Kandl
SENIOR DIRECTOR

Ashley Gucinski, Ph.D.
EXPERT CONSULTANT

Ariel Bornstein
SENIOR CONSULTANT

Samantha Burton
SENIOR CONSULTANT

Haleigh Wetzel
SENIOR CONSULTANT

Brittany McConnell
CONSULTANT

This year we added seven new entries to our case study library, which provides examples of our Core Capabilities in practice. View full case study library here:

These first two case study examples are from our new Clinical department.

Convening a Medical Advisory Board

Why DHC?

- Expand Client Bandwidth
- **Provide Additional Technical Expertise**
- Solve Existing Problem (Remediate)

The Ask

A therapeutic development company sought investment to enable further clinical development of a mid-stage candidate cell therapy, including funding for a licensure-enabling trial. In combination with the findings and recommendations identified and developed through DHC's due diligence of the therapeutic candidate's Chemistry, Manufacturing and Controls (CMC) and Regulatory position, the practice was appointed to recruit, convene and chair a Clinical Advisory Board to provide independent evaluation of existing clinical data to enable an informed view to be developed regarding the readiness and near-term potential for evaluation within a licensure-enabling trial.

The Impact

DHC's leadership and expertise in executing a first-rate Clinical Advisory Board afforded our client an unparalleled opportunity to optimally inform their investment decision, appropriately based on the development of an impartial, multi-factorial evidence-based position.

View this case study in full here:

Clinical Regulatory Writing and Focusing Regulatory Strategy

Why DHC?

- Expand Client Bandwidth
- **Provide Additional Technical Expertise**
- Solve Existing Problem (Remediate)

The Ask

Sometimes a client comes to DHC with a request that shifts dramatically upon our experts' evaluation of available documents and gathering of additional information. In this instance, a small-to-midsize company with an understanding of clinical needs (but with limited regulatory experience) initially came to DHC for document review and help with providing a list of pre-IND questions. Their goals included an expansive vision for their product development and an urgency to get a pre-IND meeting accepted within 30 days of project initiation for investor/fundraising purposes. In addition to the time constraints, the original goal was ambitious because the product is intended to be used in combination with various other products and could also be used to treat patients across multiple disease indications. The client was originally planning to send a package proposing this full range of treatment options to FDA.

Prior to engaging with DHC, another consultancy had begun this work for the client. The client came to DHC because they were experiencing concerns about timelines and the lack of attention that they felt that their project was receiving. Upon receipt, DHC recognized that the package as prepared by the other consulting practice was inadequate for submission to FDA and that the regulatory advice was inappropriate for the development pathway. DHC consultants identified the regulatory challenges: a meeting package with this wide of a developmental scope would not make it through regulatory review in the time available, and likely would not be possible without a step-wise development plan.

The Impact

The client achieved their first business goal: a timely and concise FDA submission. Successful completion of the meeting provided the client with responses clarifying FDA's expectations for launching the first clinical trial. The client also now has a detailed understanding of how to segment their goals in order to maximize each opportunity before moving on to the next.

View this case study in full here:

Interim Functional Leadership

Why DHC?

- Expand Client Bandwidth
- Provide Additional Technical Expertise
- Solve Existing Problem (Remediate)

The Ask

DHC has encountered a variety of examples in which a client requires a temporary personnel solution, a sort of strategically savvy SME-on-demand, and the approach we take to those varying situations can differ.

Senior leaders at DHC have held leadership positions at numerous companies in the past. Because our experts continuously collaborate on projects for gene, gene-modified, and cell therapies across multiple modalities, encompassing all stages of development (nonclinical through to commercial), we're uniquely equipped to provide as much or as little support as any given situation requires.

This support could be in the form of leadership (Chief Technology, Manufacturing, or Regulatory Officer) or technical expertise in the areas of CMC, manufacturing, quality, regulatory, analytical, non-clinical, project management, and/or regulatory writing.

The Impact

DHC's goal is to progress the field of CGT by assisting organizations get to their next step(s) in a timely and effective manner while planning for future growth. In any of these situations, the impact is to keep each client's product or process on track and moving forward for as long as the client requires support (engagements have ranged from a few weeks to several years), stepping back and handing operations off to the client once they find themselves in a self-sufficient position. Embedding our experts can be extraordinarily helpful in minimizing disruption during change but these needs rarely, if ever, require a permanent DHC-based solution. Our emphasis is always on helping each client operate as efficiently, effectively, and independently as possible.

View this case study in full here:

Transforming an Academic Nonclinical Data Package for IND Readiness

Why DHC?

- Expand Client Bandwidth
- Provide Additional Technical Expertise
- Solve Existing Problem (Remediate)

The Ask

The discovery of cutting-edge cell and gene therapy modalities often stems from innovative academic centers, who may then seek to partner with a biotech organization to engage in formal product development and to advance these promising drug candidates to patients. In this instance, a client developing a CAR-T cell therapy licensed from an academic institution hired DHC to provide full support in developing a pre-IND and subsequent IND-enabling nonclinical strategy based predominantly on *in vitro* and *in vivo* studies conducted at the academic center. In addition, and as is typical in these scenarios, the nonclinical studies were performed using drug product generated with an earlier production process that was being developed for GMP-readiness in parallel to the aforementioned regulatory activities. This engagement combined four of DHC's core capabilities, namely nonclinical development, regulatory affairs, process development, and analytical development.

The Impact

By working with Dark Horse, the client submitted a well-crafted pre-IND package, which enabled actionable Agency feedback and a clear roadmap to IND submission. Subsequently, DHC and the client worked in collaboration to craft a robust and detailed nonclinical narrative for the IND, which resulted in its clearance with no hold comments or information requests from the Agency.

View this case study in full here:

Interim CMC Lead Helps Address an LNP-based Drug Product Shortage

Why DHC?

- Expand Client Bandwidth
- Provide Additional Technical Expertise
- Solve Existing Problem (Remediate)

The Ask

This client was experiencing a critical shortage of drug product to supply ongoing clinical trials and were about to run out of clinical material. A number of contributing variables were at play. First, the client had recently changed the CDMO that was manufacturing the LNP component of their drug product (DP), while additionally modifying its manufacturing process so that a tech transfer was not feasible. Secondly, drug product stability issues were being investigated. Thirdly, relationships with multiple drug substance (DS), critical component, and DP manufacturers were broken. Lastly, several lots of DP had failed to meet acceptance criteria and were therefore unusable to resupply the clinical inventory. The loss of these DP lots compounded the already tense relationship between leadership and the CMC/MSAT groups and brought the client perilously close to reaching the end of product shelf life and product availability for the current inventory. With only a few months of clinical supply remaining, and a 3-4 month manufacturing process timeline, the client reached out to DHC for help.

The Impact

DHC sped up and improved the client's manufacturing process, generating material suitable for drug product manufacture to successfully release clinical GMP drug product with little to no impact on the clinical supply. This allowed patients currently enrolled to continue with treatment as well as the enrollment of additional subjects. DHC also established a manufacturing forecast to ensure that future clinical supply would continue to be met; additionally, DHC identified, prioritized, and implemented further manufacturing improvements and analytical strategy for support as the client transitions to later stage clinical trials.

View this case study in full here:

Market Analysis for a Manufacturing Reagent

Why DHC?

- Expand Client Bandwidth
- Provide Additional Technical Expertise
- Solve Existing Problem (Remediate)

The Ask

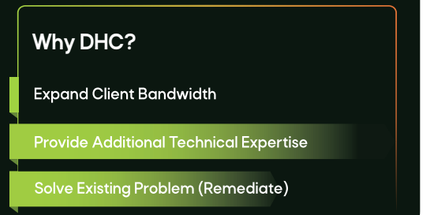
This client was considering acquisition of a company with a critical reagent used in the manufacture of viral vectors. To understand the market opportunity, DHC was asked to estimate current and future market sizes for this material as it pertained to its use in Adeno-Associated Virus (AAV) and Lentiviral Vector (LVV) manufacturing processes. This market size assessment was one piece of a broader diligence project conducted for this client.

The Impact

In addition to providing comprehensive diligence support, DHC provided a detailed overview of market size for the reagent in question to build a better understanding of whether this potential opportunity aligned with the client's investment thesis. The analysis performed provided the necessary details—including a consideration of the magnitude of potentially obtainable market share for this target—to allow the client to make a solid data-driven decision on future investments.

View this case study in full here:

Strategic Support for Next-Generation CGT Platform



The Ask

The client asked for a review of the development status of equipment and disposables in addition to the projected timeline for the manufacture and readiness of GMP ready systems with the output being a gap analysis and recommended remediations.

DHC's Approach

First, DHC reviewed the foundational requirements documents (URS, FRS, SRS etc.) for the system design to check for maturity, clarity, and conciseness, as well as any duplication, all by way of ensuring that requirements were testable and traceable/trackable to a verifiable source.

Next, the team studied the project GANTT chart with the client's PM to thoroughly understand the reported status to promised timelines and management's future expectations at a sub-system and system level for the program.

With an understanding of the development baseline and the upcoming milestones, our team performed a deep dive into the status of each of the development disciplines with the respective design leaders including an assessment of the maturity of the system design: assessing the existing prototype equipment and consumables as well as the proposed changes for inclusion in the next generation system.

Our review also included a resource assessment to map required effort with the current company resource profile.

The Impact

The client received a gap analysis and an action list, with detailed supporting analysis and recommendations identifying specific remediation necessary to achieve their challenging launch timetable.

View this case study in full here:

Unbridled Excellence webinars

2024 brought us another five Unbridled Excellence expert webinars. Each one takes a deep dive into a particular topic of interest to those in the CGT industry. View the entire library on-demand by scanning the QR code.

#6: Navigating Route to Market for CGT Enabling Technologies

This webinar provided a practical discussion on how to understand and navigate key issues. Our team has deep experience in supporting CGT enabling technology companies as they successfully commercialize their products, from which we shared lessons learned and best practices.

#7: Navigating Nonclinical Development for CGT Products

As an increasing number of CGT products reach the clinic, we can look back on their preclinical paths to identify common pitfalls and how to overcome them. This webinar explored the current state of nonclinical development for CGT products, focusing on big picture questions such as selection of suitable model systems, dose determination, and design of GLP tox studies.

#8: Practical Considerations for Implementing Advanced Characterization Techniques into rAAV Release Panels

This webinar focused on best practices and trends for implementing advanced methods for empty/full analysis, next-generation sequencing, and post translational modification analysis...as well as technical hurdles, regulatory considerations, industry trends, and advantages for implementing novel methods.

#9: Recommendations for IND Authorship

While providing phase-appropriate considerations and recommendations for IND authorship, our hosts included a survey of the recommended general structure of a CGT IND, discussed defining and codifying drug substance and drug product, reviewed best practices for streamlining authorship, and provided insight into what to expect after IND submission.

#10: Unique Considerations for Development of IND Strategy for Viral and Non-Viral Gene Editing

This webinar addressed unique product development considerations for the evolving gene editing and delivery landscape, including viral and non-viral delivery vectors such as LNPs and AAV. Topics included clinical progress, creation of a modular IND roadmap, and specific product development challenges.

UNBRIDLED EXCELLENCE

Office Locations

As a global consulting firm, we benefit from having footholds around the world.

DHC BAY AREA

Our San Francisco Bay Area office now serves as the global headquarters for all of Dark Horse Consulting Group: both DHC and BioTechLogic. It is also the home office of COO Katy Spink, Ph.D.

DHC ROCKY MOUNTAINS

In 2023 we opened a new office in Denver, CO, located at 1200 17th Street, Suite 650; Denver, CO 80202. This is the home office for our CEO, Anthony Davies, Ph.D.

DHC EUROPE

DHC Europe's new address is The ClubHouse St. James; 8 St. James's Square; London SW1Y 4JU and is run by MP and GM of DHC Europe, Robert Allen, Ph.D.

DHC ASIA PACIFIC

In 2023 we proudly incorporated DHC Asia Pacific and opened an office in Singapore under GM John Ng. This office is located at 9 North Buona Vista Drive; #02-01, The Metropolis Tower One; Singapore 138588.

Remote by Design

Dark Horse Consulting Group is "Remote by Design" (RbD), meaning that our team members are distributed across the globe, on purpose. Being location-agnostic allows us to seek out top talent, but it also means that we have a range of cultural fluency. Critically, we're also versed in variations across global regulatory bodies. Plus, being RbD builds a practice-wide resilience that serves us well in uncertain times.

DHC OUT & ABOUT

2024 was, as always, a busy year of conferences around the world. We have already completed our 2nd Annual CGT Landscape Forum at #JPM25 as well as this year's Advanced Therapies Week with Phacilitate. Here's a sampling of some conferences we have on deck for the rest of 2025. If you're planning to attend these or any other CGT conference, please make a note to connect with our BD team at **bdteam@darkhorseconsultinggroup.com.**

For updates, please visit **darkhorseconsultinggroup.com/conferences.**

MARCH 2025
BioCentury East-West Summit
Singapore

APRIL 2025
Meeting on the Med
Rome

CGT Asia 2025
Shanghai

MAY 2025
BioKorea
Seoul

ISCT
New Orleans

ASGCT
New Orleans

SEPT 2025
Phacilitate's Advanced Therapies Europe
Lisbon

OCT 2025
Meeting on the Mesa
Phoenix, AZ

Closing a Critical Gap in the CGT CDMO Market

WHY ICMC?

The current Cell and Gene Therapy (CGT) CDMO landscape is rapidly expanding. Contract Development and Manufacturing Organization (CDMO) claims about ability to provide compliant and scalable manufacturing services are typically not proactively verified by the relevant regulatory bodies, leaving therapeutic developers challenged with evaluating credibility of prospective CDMO partners. This is causing fragmentation and a perception of diminished value in the CDMO market.

WHY PARTICIPATE?

Certification of CDMO capability claims by a credible independent party allows therapeutic developers to more robustly evaluate CDMO partners. Additionally, it allows CDMOs to build credibility and differentiation in the marketplace and introduces a level of standardization that is currently lacking.

WHY DHC?

With an industry-leading track record of cross-functional experience and expertise in supporting both CGT therapeutic developers and manufacturing organizations, Dark Horse Consulting Group (DHC) is uniquely positioned to act as the credible, expert, and unbiased party to perform such evaluations, as evidenced by the success and recognition of our global CDMO database and CDMO selection service offerings.

CERTIFIED MEMBER DIRECTORY

STATUS: Fully Certified | Conditionally Certified | Certification in Progress | Not Certified | Commercially Ready

CDMO Name / Location / Product Type	Service Business	Quality	Digital	Facilities and Equipment	Materials	Production	Packaging and Labeling	Laboratory Control	Commercial Readiness
AGC Biologics S.p.A. Milan, Italy Viral gene delivery products Cell therapy products Cell banking	Jan 2025	Jan 2025	Jan 2025	Jan 2025	Jan 2025	Jan 2025	Jan 2025	Jan 2025	Jan 2025
Andelyn Corporate Center (ACC) Columbus, OH, USA Viral gene delivery products	Oct 2024	Oct 2024	Oct 2024	Oct 2024	Oct 2024	Oct 2024	Oct 2024	Oct 2024	Oct 2024
ElevateBio BaseCamp, Waltham Waltham, MA, USA Viral gene delivery products Non-viral gene delivery products Cell therapy products	Oct 2024	Oct 2024	Oct 2024	Oct 2024	Oct 2024	Oct 2024	Oct 2024	Oct 2024	Oct 2024

CERTIFIED MEMBER

ICMC Certification is a paid “opt-in” program, intended to verify capability and compliance claims of participating CDMOs by a credible, expert, and unbiased independent party. The scope of the certifications is focused on Quality and Operational capabilities required to manufacture the various types of CGT therapeutic products in a compliant and scalable manner.

Certified Member Directory lists the certification status of the participating program members. Additional members will be added and certified on an ongoing basis. Scan the above QR code or navigate to https://www.icmcprogram.com/certified-member-directory to bookmark the Directory for your reference.

DARK HORSE CONSULTING

Since DHC's founding in 2014 we have remained focused on the field of CGT. Over the last decade, the range and depth of the collective strategic and tactical knowledge of DHC's hand-picked consulting team has grown rapidly. We apply best practices from across this and other industries to address the varied needs of our clients, who range from biopharmaceutical companies to tools & tech providers to venture capital and private equity investors. All of our services are tailored to meet specific client needs, providing as much or as little support as each client requests to effectively complement the existing expertise and bandwidth of each in-house team.

WEB: **darkhorseconsultinggroup.com**
EMAIL: **contactus@darkhorseconsultinggroup.com**
PHONE: **408.680.2527**

BIOTECHLOGIC
A DIVISION OF DARK HORSE CONSULTING GROUP

Dark Horse Consulting Group is excited to welcome BioTechLogic to the stable!

For more than 20 years, BioTechLogic has been a leading industry voice for biopharmaceutical CMC and manufacturing consulting excellence. BTL offers strategic, practical, and hands-on experience to help clients bring products to market quickly and successfully by augmenting and optimizing each organization's technical, manufacturing, analytical, and regulatory resources.

WEB: **biotechlogic.com**
EMAIL: **contact@biotechlogic.com**
PHONE: **303.775.9264**

Our joint Dark Horse Consulting Group Business Development team will respond to your request, whether it comes in through the DHC or BTL site.

Visit **darkhorseconsultinggroup.com/consult/** or scan this QR code to request a complimentary initial consultation.

Visit **biotechlogic.com/request-consultation** or scan this QR code to request a complimentary initial consultation.

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