



**DARK HORSE  
CONSULTING  
GROUP**

**BIO**TECH  
LOGIC

A DIVISION OF DARK HORSE CONSULTING GROUP

**DHC**

DARK HORSE CONSULTING

**CONVERGE  
CONSULTING**

A DIVISION OF DARK HORSE CONSULTING GROUP

## TABLE OF CONTENTS

DHCG overview .....	2
Our divisions .....	3
Domains & lifecycle .....	4-5
Range of modalities .....	6-7
CMC .....	8-13
Regulatory .....	14-17
Nonclinical .....	18-19
Clinical .....	20-23
Quality & Compliance .....	24-27
Supply Chain .....	28-31
Commercial Launch .....	32-34
ICMC, delivered by DHC .....	35
Business Analytics .....	36-37
Pegasi .....	38-39



darkhorseconsultinggroup.com



## DARK HORSE CONSULTING GROUP

**Dark Horse Consulting Group (DHCG)**, a worldwide consulting organization with offices in North America, Europe, and APAC, was founded in 2014 with the purpose of accelerating development and delivery of cell and gene therapies through unmatched expertise.

Since then, the Group's focus has expanded dramatically, with consulting team subject matter expertise encompassing strategy, operations, Quality, regulatory affairs, manufacturing, modeling, supply chain, commercial launch, and business optimization across the biopharma landscape.

DHCG's white-glove client service is grounded in rigorous scientific and technical expertise to support clients from early discovery through commercial launch.

The Group comprises three business units: DHC, BioTechLogic, and Converge Consulting, with Bruder Consulting & Venture Group forming a specialized Regenerative Medicine department within DHC as of early 2026.



**Dark Horse Consulting (DHC):** Since its founding in 2014, the scope and depth of DHC's capabilities has grown rapidly, offering unparalleled expert strategic advisory services with a particular focus on CGT for clients ranging from biopharma companies to tools and tech providers to venture capital and private equity investors.



**BioTechLogic (BTL):** For more than 20 years, BioTechLogic has been a leading partner for biopharmaceutical CMC and manufacturing consulting, augmenting their clients' technical, manufacturing, analytical, and regulatory capabilities through embedded practical and hands-on experience.



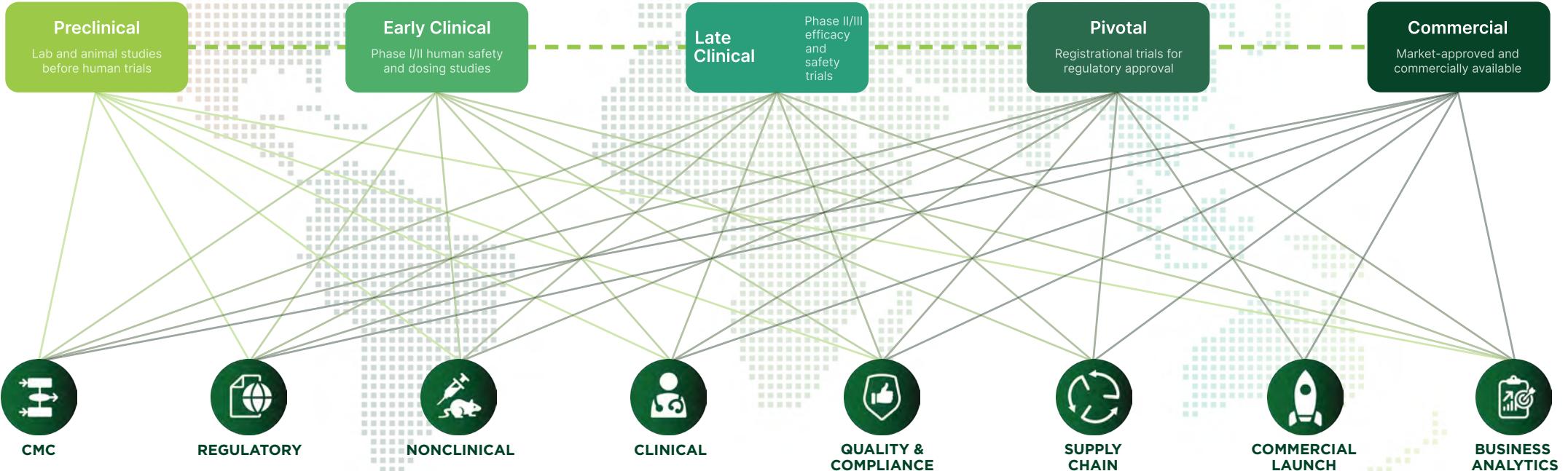
**Converge Consulting:** Converge Consulting serves the life sciences industry with strategy, operations, and execution expertise, collaborating with biotech, pharmaceutical, and CGT companies to achieve critical business objectives. Converge's approach focuses on bridging the gap between sound strategy and reliable execution.



# Throughout the full lifecycle



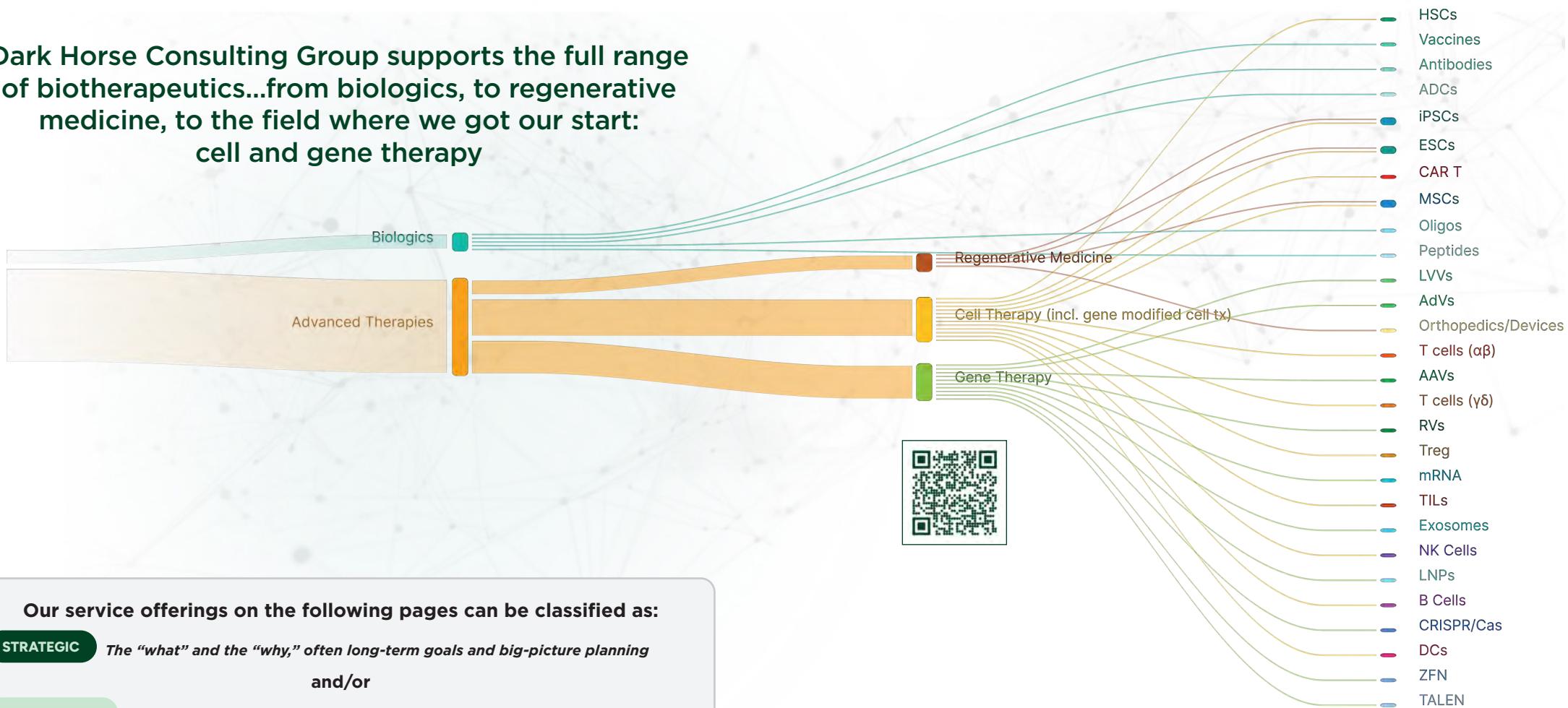
# Around the world



# Across our eight service domains

# Dark Horse Consulting Group supports the full range of biotherapeutics...from biologics, to regenerative medicine, to the field where we got our start: cell and gene therapy

Biopharmaceuticals



Our service offerings on the following pages can be classified as:

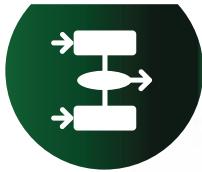
**STRATEGIC**

*The “what” and the “why,” often long-term goals and big-picture planning*

and/or

**OPERATIONAL**

*Tactics and day-to-day activities/processes to achieve operational objectives*



## CMC

CMC can make or break a CGT approval, as our experts know well. Time spent on getting CMC development right will nearly always pay dividends by streamlining next steps towards regulatory approval and commercialization.

Our divisions have robust teams of CMC experts available to develop, optimize, and validate thorough, scalable, cost-effective, and compliant manufacturing processes. We offer hands-on phase-appropriate development support for all aspects of CMC and biopharmaceutical development under R&D and GMP conditions.

### STRATEGIC

#### Process and analytical development support

Our team's depth and breadth of experience helps you navigate and overcome various challenge, including:

- Root cause investigation and failure analysis of processes or assays
- Analytical method and/or assay development, transfer, qualification, codification, and validation
- Process and assay evaluation and codification for formal documentation
- NGS data interpretation and off-target analysis
- Feedback on suitability of CQA (and ranges)
- Potency assay strategy development
- Stability testing support including reports
- Assay development gap analysis
- Comparability strategy review including study design and execution
- Advice on matrixed potency panels
- Remediation of analytical test failures
- GLP assays

### STRATEGIC

#### Device development support

Our team provides support across the full lifecycle of device development, including:

- User Requirement Specification (URS) development
- Competitive landscape scan/analysis of existing devices
- Early-stage concept design and product strategy
- Search and selection of outsourced engineering partners
- Oversight of prototype development and testing
- Authorship of Design History Files (DHF), Device Master Files (MAFs), and Device Master Records (DMRs)
- Generation of submission-ready technical documentation

### OPERATIONAL

#### Analytical method troubleshooting

We work with you on-site or virtually to identify, diagnose, and resolve analytical problems or inconsistencies.

### STRATEGIC

#### Analytical method development & validation

Essential to CMC program success, we design, optimize, and validate phase-appropriate analytical methods tailored to your product and processes. We recommend the utilization of fit-for-purpose assays and advanced statistical approaches to support the identification of your product's critical quality attributes (CQAs).

### OPERATIONAL

#### Regulatory compliance, SOP generation, & submission support

We support end-to-end traceability of analytical data from collection and analysis to data management for your quality system, regulatory filings, CMC submission summaries, and beyond. Additionally, we assist with SOP generation and management to ensure excellence in analytical execution.

### OPERATIONAL

#### Facility assessment, capacity planning, & optimization support

We offer site development and capacity planning support if you plan to scale in-house manufacturing, and support cleanroom validation and personnel training. If you are working with a CMO partner operating multi-product facilities, we assess the facility and conduct a cross-contamination risk assessment. We're experienced in assessing and qualifying systems such as WFI/purified water, clean steam, and air handlers. If new products are being brought onsite in anticipation of audits/PAI, we assess for regulatory compliance and capacity.

### OPERATIONAL

#### Combination products CMC support

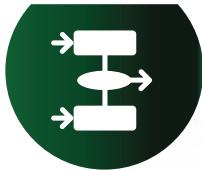
The following are examples of services to help support combination products throughout product development and into commercialization:

- Generate a Design and Development SOP or plan including templates for documentation of design inputs, design outputs, design reviews, and design verification
- Generate a Design History File SOP including a Design History File Index
- Support the generation of: User Requirements, Design Input, Design Output, and Design Verification Traceability Matrix, Design Verifications, and Design Validations
- Facilitate design reviews, act as an independent reviewer, and prepare design review documentation
- Generate a biocompatibility risk assessment
- Prepare design FMEAs (dFMEA), User Requirement Risk Assessment (URRA), and other device risk assessment

### OPERATIONAL

#### Method transfer

Preparation, documentation, and oversight to ensure the seamless transfer of your method to CROs, CDMOs, and other service organization partners.



## CMC continued

### STRATEGIC

#### Full lifecycle product development planning

Our team's unmatched multi-disciplinary expertise is available to support you throughout the full lifecycle of your product development.

- CMC and nonclinical gap analysis
- Product Development Plan (PDP) and roadmap creation
- Detailed Process and Analytical Development Plans
- Raw material strategy and critical supplier selection
- Milestone-based planning from FIH through to BLA readiness ('roadmap to BLA')
- Coordination of cross-functional activities

### STRATEGIC

#### Quality Target Product Profiles (QTPP) & Critical Quality Attribute (CQA)

Creating a foundation for your product and process development program, we utilize a QbD framework to thoroughly understand the quality characteristics essential for ensuring consistent, reliable, and reproducible execution and product quality, as well as for safely delivering your drug product's intended therapeutic effect.

### STRATEGIC

#### Process characterization & risk assessment

Leveraging design of experiments (DOE), we perform a systematic evaluation of your manufacturing process, establishing an understanding of how critical process parameters (CPPs) influence your final product's critical quality attributes (CQAs). Our process parameter risk assessments identify highest risk to your production process to support risk mitigation planning.

### STRATEGIC

#### Full lifecycle CMC strategy

We leverage our extensive experience gained from working on thousands of projects at all stages of development to support you with:

- Process Flow Diagram (PFD) authorship
- CMC gap analysis
- Portfolio prioritization
- High-level manufacturing strategy definition
- Capacity planning using custom quantitative models
- Supply chain strategy development including redundancy, sourcing, and lead-time risk
- Cross-program CMC governance support
- Alignment of manufacturing timelines with clinical and regulatory strategy
- CMC roadmap
- Critical path identification

### OPERATIONAL

#### Process development, qualification, & validation

Our experience managing pre-qualification, validation, optimization, and CPV for all modalities and production technologies includes managing laboratory scale processes, pilot plants, and large-scale processes up to 30,000 L scale. This includes the development and validation of the following: precipitation, centrifugation, microfiltration, depth filtration, cell disruption (microfluidization, homogenization), and periplasmic extraction.

- We have expertise in upstream and downstream manufacturing of: PEGylated and non-PEGylated proteins, antibody fragments, oligonucleotides, mAbs, recombinant proteins, gene therapies, and blood products.
- We have developed work processes, provided on-site manufacturing support and designed process steps using the following purification technologies: laboratory and industrial-scale liquid chromatography, high-pressure liquid chromatography, ultrafiltration/diafiltration, rotary evaporation, sterile filtration, Tangential Flow Filtration, centrifugation, chromatography, and virus inactivation & removal.
- We also manage microbial fermentation, mammalian cell culture and oligonucleotide synthesis processes for the production of biopharmaceutical products, as well as plasmid production or selection, cell expansion and plasmid transfection, and viral vector production for gene therapy.

### OPERATIONAL

#### Process material evaluations

We do a complete analysis, often including an extractables and leachables risk assessment, of the impact of raw materials, excipients, consumables, and intermediates on process performance and product quality. This includes program design, procedure creations, external laboratory identification, results review, and mitigation strategies.

### OPERATIONAL

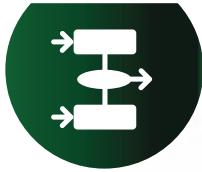
#### Project execution, tracking, reporting, communication, & document management

We track and report progress throughout your project, including maintaining up-to-date project timelines, organizing team meetings, capturing meeting minutes, establishing RACI (responsible, accountable, consulted, informed) matrices, and detailing communication plans, ensuring transparent and accurate communication. and follow-up on achievement of action items. Our PMs carefully track and expedite the resolution of action items, highlight critical project issues and risks, and facilitate the development of mitigation action plans.

### STRATEGIC

#### Product characterization

Our consultants have a thorough command of diverse analytical techniques supporting comprehensive characterization, including functional and physicochemical assays, of your drug substance and/or drug product.



**CMC**

continued

STRATEGIC

### Process development descriptions, documentation & reports

We support and execute the authoring of comprehensive documentation, process descriptions, data trend analysis, and supporting study reports for your product's process development and optimization journey, as well as regulatory filings.

### Manufacturing operational support

We expeditiously address operational challenges and bottlenecks, including:

- Remediation of manufacturing/testing failures (especially at CDMOs, CROs)
- Facility design consultation (for scale-up, compliance, etc.)
- Quantitative capacity planning and throughput modeling
- Workforce development and technical training programs
- PM support across tech transfer, scale-up, and vendor onboarding
- Interim functional leadership, e.g., QA lead, CMC director, operations head
- Support for internal GMP facility planning
- CDMO selection and evaluation support

### Interim functional leadership

Senior DHC experts can provide interim expertise and leadership with the goal of enabling the clients to identify, hire, and onboard internal candidates in a timely manner.

### Contract services partner selection & management

Since CDMO selection is unique for every client, we assist based on specific project objectives and variables, including process development assistance required, needed capacity, development timelines, and tech transfer costs. If desired, we can also manage contract partner programs. Our proprietary CDMO database and established methodologies ensure a good fit for your program.

- Access to a proprietary CDMO database with selection filters by modality, scale, geography, and tech capability
- Proprietary quantitative CDMO selection methodology
- Design and management of the CDMO selection process
- Support for vendor audits, including on-site inspections and capability assessments
- Contract negotiation support (terms, deliverables, risk-sharing, etc.) including Quality Technical Agreement (QTA)
- Oversight of tech transfer activities (protocols, knowledge hand-off)
- Management of ongoing manufacturing operations at selected sites

### Technology transfer & process scale up

Whether you will be scaling up your process within your own facilities or working with a contract services partner, we'll support your technology transfer plans, including technology transfer protocols, scale-up feasibility assessments, risk management plans, commercialization master plans, and guide associated studies.

### Person-in-Plant & suite management

If you require real-time, on-the-ground oversight, troubleshooting, and/or remediation, we oversee execution and ensure compliance with regulations and procedures, as well as supporting gap identification. We also offer GMP training services and can be on the ground at your CMO facility during manufacturing runs.

### Manufacturing troubleshooting & ongoing optimization

Grounded in sound scientific principles, decades of hands-on execution experience, and sound science-based root cause analysis, our team supports operational performance and process troubleshooting initiatives. Additionally, we support ongoing process optimization to improve product quality, yield, and efficiency, and reduce deviation recurrence.

### Mitigation & problem resolution

Even the best-managed projects and programs encounter challenges. Our project managers ensure clear, honest, and transparent communications as issues are explored, effectively prioritized, and resolved.

### Aseptic fill/finish

Our overall production expertise includes compounding, sterile filtration, component and equipment preparation, aseptic filling and stoppering, lyophilization, capping, labeling and packaging operations. We have supported and managed drug product production for various biologic compounds including PEGylated proteins, PEGylated antibody fragments, vaccines, blood products recombinant proteins, and gene therapies in various forms and presentations (liquid, lyophilized products, and suspensions in vials and syringes). We can also assess & improve or implement visual inspection and inspector qualification programs for drug product manufacturers.

### Project & program creation

Every project must have a defined goal, detailed plans, and an established schedule. We define and document team structures, roles, responsibilities, and what will be accomplished upon completing the project.



## REGULATORY

A comprehensive regulatory strategy is key to the efficient development of complex Cell and Gene Therapies, Biologics, and Devices. Our regulatory experts integrate with our SMEs in CMC, Clinical, Nonclinical, and Quality & Compliance to provide regulatory solutions customized to our clients' unique needs and regulatory challenges. We bring full spectrum strategic and operational support to guide clients through the product lifecycle from discovery to clinical trials, marketing authorization, and post market.

### STRATEGIC

#### Global regulatory support

We are uniquely positioned to provide both strategic and tactical regulatory assistance to our clients for their global regulatory needs. We are connected with current and former staffers of multiple worldwide regulatory bodies and have supported filings for clients across a wide range of global jurisdictions and stages of development.

We work with regulatory bodies around the globe, including:



US FDA



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EU (EMA and National  
Competent Authorities)



UK MHRA



Health Canada



PMDA (Japan)



ANVISA (Brazil)



TGA (Australia)



Israel Ministries  
of Health

### OPERATIONAL

### STRATEGIC

#### Regulatory strategy

We help you plan for long-term success, while maintaining a pragmatic focus on near-term realities such as resource constraints and timeline objectives. We can develop your regulatory timelines for submissions and meetings and identify data that will be required for optimal outcomes at each development milestone. We provide recommendations on the programs and designations applicable to your program, such as US FDA designations and FDA expedited programs or EU special procedures and programs.

#### US FDA

- Orphan drug designation (ODD)
- Rare pediatric disease (RPD)
- Fast track (FT)
- Breakthrough therapy (BT)
- RMAT designation
- Post-designation initial comprehensive multidisciplinary meeting
- CMC Readiness Pilot applications
- Advanced Manufacturing Technology designation (AMT)
- Commissioner's National Priority Voucher request

#### EU (EMA and National Competent Authorities) and UK MHRA

- Innovative licensing and access pathway (ILAP)
- PRIME (Priority Medicines) designation
- Classification as Advanced Therapy Medicinal Product
- Certification of quality and nonclinical data
- Orphan Medicinal Product

### STRATEGIC

#### Accelerated development & filing support

In addition to increased therapeutic complexity, leading regulatory bodies now offer many more options for accelerating development of products meeting critical unmet medical needs. We provide the expertise to navigate the multitude of approval options and manage drastically accelerated programs.

### STRATEGIC

#### Regulatory gap analysis, filing planning, and readiness

Our support includes in-depth analysis of your current status and/or existing plan relative to requirements for your targeted milestones (e.g., readiness for INTERACT, pre-IND, Scientific Advice, IND/CTA, BLA/MAA). We can also provide you with a detailed report summarizing all identified gaps complete with severity rating and suggested remediations.

- CMC & preclinical gap analysis to IND/CTA & first-in-human readiness
- BLA documentation gap analysis
- Readiness assessments ahead of other regulatory submissions (e.g., designation requests, meetings)



## REGULATORY

continued

OPERATIONAL

### Project management

We oversee your project to achieve your milestones in a timely fashion, including maintaining up-to-date project timelines, organizing project team meetings, capturing meeting minutes, establishing RACI (responsible, accountable, consulted, informed) matrices, and following up on achievement of action items.

OPERATIONAL

### Integrated regulatory authorship

Our experienced technical writers can provide a full range of support for your filing needs, from individual sections to authorship of full dossiers. We support the full range of contents: Administrative, CMC, Nonclinical, Clinical (Modules 1-5 of the eCTD).

We also offer review, gap analysis, and editing of your existing draft documents.

In terms of publishing, our team's diverse experience spans a wide range of global jurisdictions and stages of development, from preclinical (INTERACT, pre-IND, Scientific Advice, IND, IMPD, CTA) through clinical (meeting packages, designation requests, IND protocol documents, DSUR), marketing approval (BLA, MAA), and post approval (supplements, request for variation).

OPERATIONAL

### Interim functional leadership

For clients currently without internal leadership in this domain, our experts can provide interim expertise and leadership with the goal of enabling the clients to identify, hire, and onboard internal candidates in a timely manner.

OPERATIONAL

### US FDA Agent

We act as the US FDA Agent for clients based outside the US.

OPERATIONAL

### Regulatory body liaison

We offer full support, whether in response to a request for information or in managing an FDA warning letter or other communication.

OPERATIONAL

### Expert witness services

Our regulatory and technical experts are available to serve as expert witness services for law firms. *(Please note: DHCG does not provide legal advice.)*

OPERATIONAL

### Combination products regulatory support

Regulatory Support for combination products includes the following:

- Generate and review the CMC sections of regulatory submissions that support combination products [e.g., 3.2.P.2.4, 3.2.P.3.3, 3.2.P.7, and 3.2.R.4: Medical Devices (Device Design Controls), etc.]

OPERATIONAL

### EU combination product support

- Prepare General Safety and Performance Requirements (GSPR) reports
- Obtain the opinion of a notified body

OPERATIONAL

### Teaching/training

To provide support for a remediation or to ensure future compliance, we offer customized teach-ins.

### Regulatory meeting assistance

We organize and lead internal preparatory sessions for all types of regulatory meetings and also frequently attend regulatory meetings with our clients to assist them in putting their best foot forward with regulators. We provide briefing book support, pre-meeting preparatory workshops with mock regulatory authority response options, direct meeting assistance & participation, and meeting minuting.

- INTERACT meetings
- Pre-IND meetings
- Innovation Task Force (ITF)
- Scientific advice (SA) meetings
- CATT meetings
- Type A meetings
- Type B meetings
- Type C meetings
- Type D meetings
- BLA meetings
- MAA meetings



## NONCLINICAL

Generating a robust, focused, and convincing nonclinical (sometimes called ‘preclinical’) data package is critical. Failure to appropriately plan and execute a suitable nonclinical development program is a common source of regulatory application failures and delays. DHC can provide extensive, in-house subject matter expertise to assist you in successfully planning and executing your program.

### STRATEGIC

#### Preclinical/nonclinical strategy

We help you to define and describe your nonclinical development plan as well as related safety and efficacy endpoints to optimally support your regulatory and clinical strategies.

- Development of regulatory positioning and early interaction strategy
- General planning for FIH (first-in-human) readiness such as gap analysis of current state and remediation planning
- Animal model selection and study design
- Strategic interim leadership
- Identification of minimum viable nonclinical data package to support FIH
- Drafting or consolidation of TPP documents for regulatory filings

### STRATEGIC

#### Roadmap to FIH

An effective roadmap to FIH (first-in-human) considers both efficacy and safety through the lens of the client’s business strategy and risk tolerance. It addresses timeline and budget, including an in-depth expectation of what the client’s future capital needs will be over time.

- FIH roadmap delivery
- Gantt chart: fully-loaded and board-ready formats
- Timeline analysis
- Critical path identification
- Resource planning
- CRO/CDMO/vendor selection

### STRATEGIC

#### Technical writing

We write and/or review your study protocols, reports, and regulatory submissions, ensuring that essential items are thoroughly and appropriately addressed as well as clearly communicated.

Includes preparation of briefing books.

- Review of draft regulatory documentation
- Briefing book support and authorship for pre-IND, INTERACT, and Scientific Advice meeting interactions
- Study report and protocol content review and authorship
- Analytical methods and justification review and authorship documentation edits
- Authorship of full IND: Module 1, Module 2, Module 3, Module 4, Module 5
- Management of eCTD publishing and submission

### STRATEGIC

#### Study design and oversight

Study design and oversight can take many forms, from package design to execution, data compilation to analysis, and more.

- Design of nonclinical proof-of-concept studies
- Feedback on non-clinical test article selection and testing
- Compilation and review of nonclinical assay data
- Advisory on *in vivo* model selection and suitability
- Nonclinical study endpoint selection and study design
- Study report authorship
- De novo nonclinical package design
- Oversight of nonclinical study execution
- Nonclinical package/study gap analysis
- Quality oversight for non-GLP safety studies

### OPERATIONAL

#### Project management

We oversee your project to achieve your milestones in a timely fashion, including maintaining up-to-date project timelines, organizing project team meetings, capturing meeting minutes, establishing RACI (responsible, accountable, consulted, informed) matrices, and following up on achievement of action items.

### STRATEGIC

#### CRO oversight

We work with you to understand your development strategy, pipeline asset, Agency interaction timelines, geographical considerations, and operating budget, all with the end goal of identifying, appraising, auditing, and recommending the most appropriate vendor(s) to successfully achieve your objectives.

- Vendor/CRO selection
- Cross-functional vendor oversight with technical program management
- CRO audit planning and performance monitoring



#### WHITE PAPER

#### Roadmap to FIH: Charting a Path to Success (Part 1)

Nathan Manley, Ph.D.

DHC MASTER PRINCIPAL & HEAD OF NONCLINICAL



## CLINICAL

Strategic and tactical support are critical to a robust and comprehensive clinical trial program in preparation for application for licensure to regulatory bodies. Without a thoughtfully structured program, regulatory applications are more subject to delays or rejection. We offer support from a range of clinical development SMEs in strategic clinical development, strategic clinical quality and risk management, and clinical business development.

### STRATEGIC

#### Clinical development strategy, trial design, and ongoing regulatory support

We help you to define and strategize your clinical trial structure from first-in-human (FIH/Phase 1/IIT) through to Registrational (Phase 3) & FDA expedited programs or EU special procedures and programs. We can also assess the program's readiness for optimal timing of your submission. Example client requests include:

- Clinical trial design regulatory readiness assessment, including indication and patient population selection support as well as endpoint determination support
- Clinical data review and regulatory expedited designation support
- Embedded clinical regulatory support from experts working closely with your regulatory team in an ongoing partnership
- Clinical supply chain

### STRATEGIC

#### Clinical advisory boards with KOLs (Key Opinion Leaders)

When convening an Advisory Board, it's necessary to select an appropriate group of KOLs who understand both the indication in question and the unique challenges and considerations of developing a product for that indication. Working with the right group of advisors is critically important to allow for proactive identification of strengths and weaknesses in a clinical development program so as to catch any potential limitations early. Our experts work with many KOLs in biopharma and have supported convening and running of advisory boards for a range of purposes, from indication selection and clinical protocol development for therapeutics developers to opining on strength of clinical data in due diligence projects.

- Support with identification, selection, and engagement of KOLs
- Directly acting as KOLs for Scientific Advisory Boards

### OPERATIONAL

#### Clinical Quality Assurance

We bring our deep expertise in developing and implementing phase-appropriate, fit for purpose, bespoke clinical quality systems to advance CGT programs from preclinical to PoC.

Examples include BIMO and Global (EMA/PMDA) GCP Inspections, CRO Selection & Compliance Audits, Establishing CRO Governance & Oversight Programs Aligned With ICH E6(R3).

### OPERATIONAL

#### Interim functional leadership

For clients currently without internal leadership in this domain, our senior experts can provide interim expertise and hands-on leadership with the goal of enabling the clients to identify, hire, and onboard internal candidates in a timely manner.

### OPERATIONAL

#### Project management

We oversee your project to achieve your milestones in a timely fashion, including maintaining up-to-date project timelines, organizing project team meetings, capturing meeting minutes, establishing RACI (responsible, accountable, consulted, informed) matrices, and following up on achievement of action items.

### OPERATIONAL

#### Integrated regulatory authorship

Our experienced technical writers can provide a full range of support for your filing needs, from individual sections to authorship of full dossiers. We also offer review, gap analysis, and editing of your existing draft documents. Our team's diverse experience spans a wide range of global jurisdictions and stages of development, including clinical.

Examples include:

- Clinical Synopsis, Clinical Protocol, Informed Consent Form (ICF), Long-term Followup (LTFU) Protocol, and Clinical Study Report (CSRs)
- Investigator Brochure (IB), Development Safety Update Report (DSUR), Annual Report
- Fast Track Designation or FTD, Regenerative Medicine Advanced Therapy (RMAT), Breakthrough Therapy Designation (BTD) Orphan Drug Designation (ODD), Rare Pediatric Disease Designation (RPDD), RPD, iPSP, Clinical Special protocol assessment (SPA) request
- Meeting Packages: e.g. INTERACT, pre-IND, EOP1, EOP2, pre-BLA, Type A, B, C, D
- Authoring, Review, Gap Analysis, and/or editing of existing draft documents



## CLINICAL continued

### Option to Embed Fractional Personnel



#### WHITE PAPER

#### Roadmap to FIH: Clinical Readiness on the Path to First-in-Human (Part 2)

Kristin Baird, M.D., DHC MASTER PRACTICE EXPERT

Eric Humes, RQAP-GLP, M.D., DHC SENIOR PRACTICE EXPERT

Matthew Spear, M.D., DHC CHIEF MEDICAL OFFICER



## QUALITY & COMPLIANCE

We help you ensure that phase-appropriate compliant systems are in place so your program stays aligned with “Quality by Design” principles and ahead of the curve—without wasting resources, capital, or generating excessive bureaucracy.

Our industry-experienced experts have implemented dozens of quality systems within the biopharmaceutical, pharmaceutical, medical device, and combination product industries. We assist with organizational activities, plans, policies, procedures, and processes and provide the resources to design, implement, and maintain a quality system that delivers quality, compliant drug products.

### We develop and implement quality systems in accordance with:

- FDA Phase 1 GMPs
- Good Manufacturing Practices (21 CFR 210 and 211, 600, 601, 610, 820 and 1271)
- Combination Products GMPs (21 CFR 4)
- Pharmaceutical Development (ICH Q8)
- Risk Management (ICH Q9)
- Quality Systems (ICH Q10)
- Good Manufacturing Practices for Active Pharmaceutical Ingredients (ICH Q7A)
- EU Good Manufacturing Practices (Eudralex Volume 4) and EU Annex 1.
- PIC/S Guide to Good Manufacturing Practices

#### STRATEGIC

### Strategic QMS design

We help you develop a Quality Management System (QMS) that meets the unique needs of your program and phase of development.

#### STRATEGIC

### QMS gap assessment & roadmap

We analyze your existing QMS, identify any gaps, and provide phase-appropriate and resource-efficient solutions to address them.

#### OPERATIONAL

### QMS remediation

QMS remediation addresses gaps in US, EU, and ANVISA GMP based on guidances, regulations, directives, and norms from these regions. This includes performance of a gap assessment, a subsequent report, and preparation of inspection sub-system remediation quality plans to focus work efforts and prioritization. This can apply to any or all of the six inspection subsystems: quality system, production controls, facilities and equipment, laboratory controls, materials control, and packaging and labeling.

#### OPERATIONAL

### Document authoring, review, and revision

We write your SOPs, policies, and other controlled documents, or provide expert review and revision of existing documents.

- Standard operating procedure (SOP) authorship
- Quality system documentation authorship
- Quality system documentation review

#### OPERATIONAL

### Supplier oversight

We perform evaluations, risk assessments, and/or audits of critical raw material suppliers, contract manufacturers, and analytical service providers to ensure their quality standards are aligned with your needs.

- Follow-on work from audit findings
- Supplier audits
- Tech transfer oversight and management
- Person-in-plant support

#### OPERATIONAL

### Project management

We oversee your project to achieve your milestones in a timely fashion, including maintaining up-to-date project timelines, organizing project team meetings, capturing meeting minutes, establishing RACI (responsible, accountable, consulted, informed) matrices, and following up on achievement of action items.

#### OPERATIONAL

### Internal & external audits

The generation and execution of a comprehensive phase-appropriate audit program is critical for regulatory and developmental success. We combine specialized in-house experience and the use of a proprietary toolkit when customizing an audit for your program. Whether preparing for and supporting an external GMP audit by a global regulator [pre-approval inspection (PAI), pre-licensing inspection (PLI)] or planning and executing an internal audit, our team offers comprehensive capabilities in support of agency audits. We also plan and execute audits of 3rd parties (e.g., suppliers and contract testing/manufacturing sites) on behalf of client sponsors. Common requests include:

- Vendor audits
- CDMO audits
- Mock pre-licensure inspection (PLI) support
- Other mock audits, including FDA inspection dress rehearsal, clinical phase GMP audit, or strategic session.

#### OPERATIONAL

### Interim functional leadership

For clients currently without internal leadership in this domain, our senior experts can provide interim expertise and leadership with the goal of enabling the clients to identify, hire, and onboard internal candidates in a timely manner.



## QUALITY & COMPLIANCE

continued

OPERATIONAL

### QP support

Our eligible QPs are experts in global regulatory standards. Common eligible QP client requests include training and education on the roles of QP as well as QP audits and remediation.

Please contact us for further discussion should you require batch certification or licensing support.

- QP audits and inspections
- QP batch review, certification and release
- Import/export support

OPERATIONAL

### Quality operations

Hands-on operational quality support

- Investigation, impact assessment, resolution of GMP-related adverse issues such as environmental events, deviations, out of specification results, non-conformities, process failures
- Execution of records and administrative activities within the QMS
- Provide quality oversight representation to external stakeholders
- Support PM of quality operations
- Good clinical practice (GCP) support
- Good laboratory practice (GLP) support

OPERATIONAL

### Global FDA/EMA remediation projects

We support comprehensive global inspection readiness remediation projects, whether a 483 remediation, clinical hold, product complaint/adverse event, CRL, etc.

- Quality plans for Six-System inspection readiness
- Remediation team leadership
- Conduct mock inspections
- Remediation services for GMP depts
- Reorganization and establishment of a high-performance management team
- On-site support and team augmentation
- Gap assessment and reporting
- Quality remediation plans and execution

OPERATIONAL



This phase-appropriate, timeline- and cost-efficient turnkey solution is for Sponsors needing to establish a Quality Management System (QMS). Three signs that it's time:

- 1 Identifying and engaging CROs and CDMOs (Vendor Management)
- 2 Initiating ND-enabling toxicology studies (QA oversight of GLP product)
- 3 Commencing preparation for the manufacture of FIH clinical product (DS/DP) batch (QA oversight and release of GMP product)

OPERATIONAL

### Establishing QMS excellence

Our team designs and implements quality system procedures and instructions in line with client objectives and the requirements of the leading regulatory bodies. Elements of our quality management system programs include the establishment and/or management of:

- Document control program
- Electronic document management system
- Deviation and CAPA SOPs
- External audit SOP
- Performance of GMP and GLP audits
- Establish phase-appropriate training SOP and program
- Vendor qualification, audits, and materials management programs
- Change control program
- Quality risk management (e.g., microbial control, quality risk assessment, etc.)
- Implementation of phase-appropriate quality systems from scratch
- Support for and implementation of electronic quality management systems

OPERATIONAL

### Teaching/training

To provide support for a remediation or to ensure future compliance, we offer customized teach-ins.

OPERATIONAL

### Combination products quality support

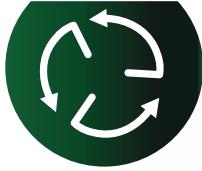
We assist companies by supporting the registration of drug-device combination products; our team can guide you through the matrix of requirements. The following are examples of services to help support combination products throughout product development and into commercialization:

- Quality System Mapping and Quality Planning for products, gaps in the quality system, or transitions to new regulatory requirements
- Establish new QMS in accordance with GMP for Combination Products (21 CFR Part 4)
- Provide on and off-site quality system support including reviewing documentation, generation of system procedures and forms, corrective and/or preventive action recommendations, management review system and training.

OPERATIONAL

### Inspection readiness

To ensure successful inspections, conduct a risk evaluation well in advance of your inspection window to identify high-risk areas in your supply chain, and inform an inspection readiness plan and effective resource allocation. This also runs to gap assessment against the FDA System Approach, European and other international regulations, as well as more specialty regulations, like Annex 1. We also plan and execute these for 3rd parties.



## SUPPLY CHAIN

Each stage of a company's lifecycle presents distinct supply chain challenges—regulatory requirements, clinical and commercial uncertainty, constrained capacity, evolving logistics models, and increasing complexity in reaching new points of patient care. These challenges must be navigated while maintaining quality, compliance, and uninterrupted supply.

DHCG helps clients manage this complexity by designing and operating stage-appropriate clinical and commercial supply chains that are reliable, compliant, and scalable. From early clinical planning through global commercial expansion, we help organizations reduce risk, maintain focus on patient outcomes, and translate strategy into executable supply.

### STRATEGIC

#### Operational process design

We help clients design, implement, and operate fit-for-purpose supply chain and operational processes, with flexibility to engage at the strategic design level, the execution level, or both.

##### Strategic services include:

- End-to-end process design and mapping
- Definition of roles, responsibilities, and RACIs
- Development of guidance documents and conceptual operating models

##### Operational services include:

- Drafting SOPs and work instructions
- Supporting or running processes such as supplier risk monitoring, capacity planning, or materials management
- Continuous improvement of live operational processes quality, and commercial stakeholders

### OPERATIONAL

#### Commercial supply chain buildout

We offer execution-focused support that follows strategic launch planning.

- CMO selection, tech transfer, and ongoing management
- 3PL and FTZ selection, onboarding, and setup
- Packaging, labeling, and artwork management
- Commercial supply and quality agreements
- S&OP and inventory planning processes
- DSCSA/serialization and enterprise system enablement
- Shipping solution design and qualification

### OPERATIONAL

### STRATEGIC

#### Clinical Supply Chain Strategy & Execution

Our consultants support clinical programs across the full spectrum of strategy and execution. Many engagements begin with hands-on operational support and can be complemented by targeted strategic assessments and roadmaps.

##### Strategic services include:

- Clinical supply chain gap and operating model assessments
- Strategic roadmaps aligned to development plans and trial complexity
- Scenario planning to address enrollment uncertainty, protocol changes, and scale transitions

##### Operational services include:

- Clinical supply planning, forecasting, and inventory management
- IRT setup, script execution, UAT, and ongoing trial support
- Packaging, labeling, shipment coordination, depot oversight, and returns
- End-to-end management of clinical supply operations without diverting internal scientific resources
- Creation of a phased roadmap to guide downstream commercialization activities

### OPERATIONAL

### STRATEGIC

#### Commercial Supply Chain Strategy & Execution

Similar to clinical supply chain, commercial supply chain engagements often begin with a strategic assessment and evolve into execution through launch and early commercialization.

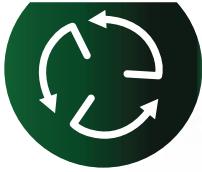
##### Strategic services include:

- Commercial supply chain operating model and gap assessments
- Commercial supply chain strategy and roadmap development
- Make-buy decisions, virtual vs. integrated supply chain models, and investment timing

##### Operational services include:

- Activation and execution of the commercial supply chain during launch
- Ongoing supply, inventory, and S&OP process support
- Coordination across CMOs, 3PLs, quality, and commercial stakeholders

### OPERATIONAL



## SUPPLY CHAIN continued

STRATEGIC

### IT & enterprise systems

We support the business side enablement of enterprise system initiatives without acting as a technical integrator.

**Strategic services include:**

- IT landscape and system assessments
- Solution selection for ERP, QMS, EDMS, serialization, COI/COC, MES, and analytics
- Business and user requirements definition

**Operational services include:**

- Project management and PMO support during system implementations
- Test script creation, execution support, and UAT coordination
- Cross-functional coordination alongside third-party integrators

OPERATIONAL

OPERATIONAL

### Project management

We oversee your project to achieve your milestones in a timely fashion, including maintaining up-to-date project timelines, organizing project team meetings, capturing meeting minutes, establishing RACI (responsible, accountable, consulted, informed) matrices, and following up on achievement of action items.

OPERATIONAL

### Interim functional leadership

For clients currently without internal leadership in this domain, our experts can provide interim expertise and leadership with the goal of enabling the clients to identify, hire, and onboard internal candidates in a timely manner.

STRATEGIC

### Logistics & global trade compliance

Engagements typically begin with a focused strategic assessment and transition into long-term operational support.

**Strategic services include:**

- Global logistics and trade compliance gap assessments
- Evaluation of import/export practices, cold-chain readiness, and compliance risk
- Development of global logistics and trade compliance strategies and roadmaps

**Operational services include:**

- Acting as the client's logistics and trade compliance function
- Day-to-day import/export execution for DP, DS, API, and R&D materials
- Building and maintaining trade compliance infrastructure, procedures, and supplier relationships
- Cold-chain and cryogenic logistics solution design and shipping qualification

OPERATIONAL

## Read Converge's two most recent Perspectives on supply chain:



### Quarantines, Complaints, Temperature Excursions & Other Debacles: Mitigating the Impact of Clinical Supply

By Steve Sinclair

CLINICAL SUPPLY CHAIN CONSULTANT



### Event Recap: Successful Gating Strategies When Building Your Commercial Supply Chain

By June Stevens

BUSINESS DEVELOPMENT/OPERATIONS ASSOCIATE



## COMMERCIAL LAUNCH

Commercializing innovative therapies requires navigating technical complexity, evolving regulatory expectations, and significant capital investment well before product success is assured. Misalignment across functions, immature processes, or late-stage surprises can materially delay launch and erode value.

We support companies from early commercial strategy through launch execution by aligning organizations, scaling processes and systems, and reducing launch risk through disciplined, stage-appropriate planning and execution.

### STRATEGIC

#### Commercial launch strategy & roadmap

Typically initiated ~36 months pre-launch, this is the earliest and most strategic commercial launch engagement.

- Development of preliminary commercial strategies
- Cross-functional information gathering and assumption alignment
- Documentation of key interdependencies, risks, and decision points
- Creation of a phased roadmap to guide downstream commercialization activities

### STRATEGIC

#### Commercialization gap analysis

This offering is often conducted ~24 months pre-launch, either standalone or in conjunction with a roadmap.

- Assessment of progress against internal plans, milestones, and company goals
- Benchmarking against industry peers and best practices
- Identification of gaps, risks, and critical dependencies
- Practical mitigation recommendations to de-risk the path to launch

### STRATEGIC

#### Launch readiness assessment

Typically performed ~12 months pre-launch to confirm readiness and surface late-stage risks.

- Evaluation of launch preparedness across functions
- Assessment of governance, decision-making, and accountability
- Alignment of stakeholders on critical success factors
- Development of accelerated action plans to close gaps and reduce risk

### OPERATIONAL

#### Commercial supply chain buildout

We offer execution-focused support that follows strategic launch planning.

- CMO selection, tech transfer, and ongoing management
- 3PL and FTZ selection, onboarding, and setup
- Packaging, labeling, and artwork management
- Commercial supply and quality agreements
- S&OP and inventory planning processes
- DSCSA/serialization and enterprise system enablement
- Shipping solution design and qualification

### STRATEGIC

### OPERATIONAL

#### Logistics & global trade compliance

Engagements typically begin with a focused strategic assessment and transition into long-term operational support.

##### Strategic services include:

- Global logistics and trade compliance gap assessments
- Evaluation of import/export practices, cold-chain readiness, and compliance risk
- Development of global logistics and trade compliance strategies and roadmaps

##### Operational services include:

- Acting as the client's logistics and trade compliance function
- Day-to-day import/export execution for DP, DS, API, and R&D materials
- Building and maintaining trade compliance infrastructure, procedures, and supplier relationships
- Cold-chain and cryogenic logistics solution design and shipping qualification



## COMMERCIAL LAUNCH continued

STRATEGIC

### IT & enterprise systems

We support the business side enablement of enterprise system initiatives without acting as a technical integrator.

**Strategic services include:**

- IT landscape and system assessments
- Solution selection for ERP, QMS, EDMS, serialization, COI/COC, MES, and analytics
- Business and user requirements definition

**Operational services include:**

- Project management and PMO support during system implementations
- Test script creation, execution support, and UAT coordination
- Cross-functional coordination alongside third-party integrators

OPERATIONAL

OPERATIONAL

### Interim functional leadership

For clients currently without internal leadership in this domain, our experts can provide interim expertise and leadership with the goal of enabling the clients to identify, hire, and onboard internal candidates in a timely manner.

OPERATIONAL

### Project management

We oversee your project to achieve your milestones in a timely fashion, including maintaining up-to-date project timelines, organizing project team meetings, capturing meeting minutes, establishing RACI (responsible, accountable, consulted, informed) matrices, and following up on achievement of action items.

DELIVERED BY DARK HORSE CONSULTING

# ICMC™: Initiative for Certification of Manufacturing Capabilities

## 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 DHCG?

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 (DHCG) 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.



Learn More



## BUSINESS ANALYTICS

Whether you're in the process of developing a tools & tech offering, are a company seeking funding, or are an investor considering investing in the CGT or biopharma spaces, our experts are available to provide due diligence, strategy support, market research, and quantitative modeling services.

STRATEGIC

### Landscape scanning

Our knowledge of the biopharma landscape can help you identify investment targets that are well-aligned with your portfolio objectives.

STRATEGIC

### Due diligence technical assessments

We are frequently called upon by investors to perform due diligence on companies in the CGT space. Alternatively, for companies seeking investment, our mock diligence service can help ensure you are prepared for questions investors may raise.

STRATEGIC

### Teach-ins

Are you an experienced investor who is new to the complex world of CGT? Or an existing pharma or biotech company that has recently acquired a cell and gene asset? We provide customized teach-ins.

STRATEGIC

### Message optimization and market positioning

Our unique combination of deep technical expertise and investor relations experience allows us to provide a candid assessment of your program and strategic planning for an optimal 'pitch.'

STRATEGIC

### Voice-of-customer (VOC) surveys

Knowing the right questions to ask is the secret to getting actionable survey results that speak specifically to your product and the market. Dark Horse experts have more combined years of experience in the CGT field than any other consulting practice; in fact, many of us have been in the space since the very beginning. There is no substitute for direct experience and meaningful connections when building a survey or a set of respondents.



Would you like to lend us your voice? Join our VOC community here!



STRATEGIC

### Needs assessment/market research

Our unmatched experience in this industry means that we have a deeper understanding of existing offerings and competitive environments than your company can get anywhere else. An informed assessment of market needs gets far beyond the buzzwords and the latest trends, considering instead the long-term trajectory for future therapies and the tools & tech necessary to create those therapies. Having watched this industry for decades, we've also seen a range of typical pitfalls and oversights and are equipped to help you avoid those.

STRATEGIC

### Commercial (marketing) strategy

We both are your target customers and work with your target customers every day. Living amidst the technical details of this space has provided us with an understanding of what your customers are looking for, what their pain points are, and what messaging will resonate with them. We aren't marketers. But we absolutely know how to strategize effectively in biopharma, no matter what your stage of market readiness may be.

*These offerings are delivered via Pegasi, DHCG's proprietary data-modeling application, which is designed to model uncertainty.*

STRATEGIC

### Capacity planning

Predict facility size requirements, instrumentation needs, and FTE by department over time under the full range of reasonable input assumptions to enable robust scenario planning even in environments of great uncertainty.

STRATEGIC

### Cost of goods (COGs) analysis

Evaluate the range of likely product COGs over time and evaluate key levers for cost reduction based on the impact of various input assumption on overall product COGs.

STRATEGIC

### Market analysis

Determine current and project future market size for your product or services based on inputs such as patient/user/customer type, indication prevalence, and assumed market penetration.

STRATEGIC

### Profit margins/business use case

Model profitability scenarios based on COGs, OpEx, CapEx, and market size inputs.



Our proprietary quantitative modeling platform helps model uncertainty by applying customized input assumptions to quantitatively describe a range of probable outcomes.



### for Tools & Tech Developers

**Use cases include market forecasting and COGs modeling**

- Understand potential market size for a product
- Understand size of potential customer base by therapeutic area
- Understand impact of product on client's COGs

### for Therapeutic Developers

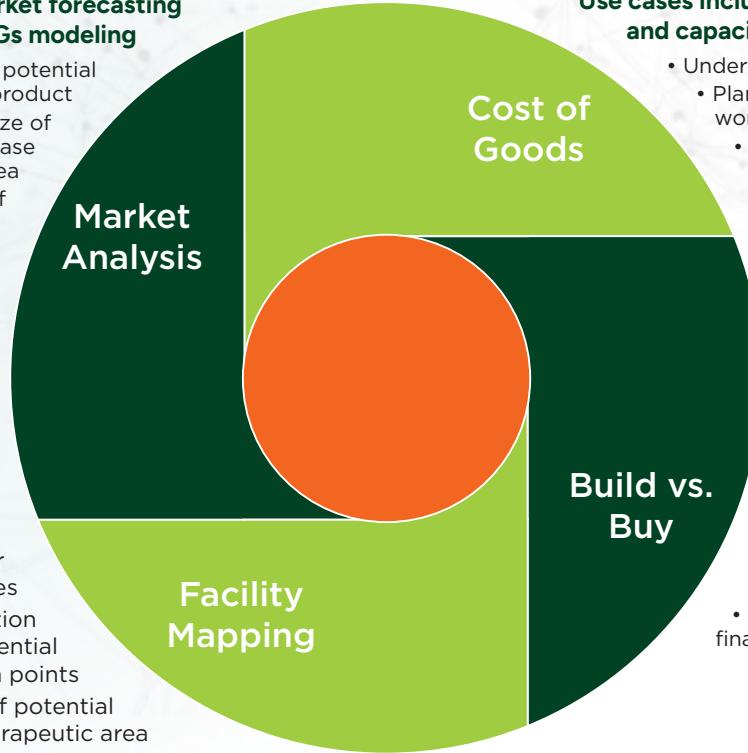
**Use cases include market forecasting, COGs analysis, and capacity planning (internal or external)**

- Understand potential market size for a therapy
- Plan capital allocation strategy based on COGs, workforce, and production requirements
- Assess implications of build vs. buy decisions
- Inform fundraising timelines

### for CDMOs & Service Providers

**Use cases include capacity planning, operating expense, and revenue analysis**

- Optimize facility design for operational and financial efficiencies
- Plan labor and capacity allocation strategies based on potential client mix and inflection points
  - Understand size of potential customer base by therapeutic area



### for Investors

**Use cases include market forecasting and cost timelines for capital projects**

- Understand market opportunity for a potential investment
- Understand size and growth rates of specific CGT market segments
- Optimize facility design for operational and financial efficiencies



**WHITE PAPER**  
**Is CGT Ready for Prime Time?**

Allyson Davidson, Ph.D., DHC SENIOR CONSULTANT  
Madeline St. Onge, MBA., DHC PRINCIPAL  
Sanjin Zvonić, Ph.D., DHCG SVP, BUSINESS DEVELOPMENT



**DARK HORSE  
CONSULTING  
GROUP**

**BIO TECH  
LOGIC**  
A DIVISION OF DARK HORSE CONSULTING GROUP

**DHC**  
DARK HORSE CONSULTING

**CONVERGE  
CONSULTING**  
A DIVISION OF DARK HORSE CONSULTING GROUP



**Visit [darkhorseconsultinggroup.com/consult/](https://darkhorseconsultinggroup.com/consult/)  
or scan this QR code to request  
an initial consultation.**

**US Headquarters:**  
1255 Treat Blvd  
Suite 230  
Walnut Creek, CA 94597

**UK Headquarters:**  
The ClubHouse St. James  
8 St. James's Square  
London SW1Y 4JU

**Asia Pacific Headquarters:**  
9 North Buona Vista Dr #02-01  
The Metropolis Tower One  
Singapore 138588

**Email:**  
[contactus@darkhorseconsultinggroup.com](mailto:contactus@darkhorseconsultinggroup.com)