Meet Our Team

DARK HORSE CONSULTING GROUP

DHC DARK HORSE CONSULTING | BIOTECH LOGIC A DIVISION OF DARK HORSE CONSULTING GROUP | CONVERGE CONSULTING A DIVISION OF DARK HORSE CONSULTING GROUP

DARK HORSE CONSULTING GROUP

Dark Horse Consulting Group, 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 now 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 of DHC as of early 2026.

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OUR SERVICE DOMAINS

MANAGING PARTNERS / EXECUTIVE LEADERSHIP TEAM

Anthony Davies, Ph.D.
FOUNDER & CEO

Anthony founded Dark Horse Consulting in 2014, bringing his decades of leadership experience in product, process, and manufacturing development to CGT companies in need of guidance. His extensive network within the biotechnology industry allowed him the privilege of hand-picking the exceptional team of consultants working at Dark Horse, chosen for their top-notch performance, broad abilities, and unique expertise.

Anthony's responsibilities as CEO and MP include defining the strategic growth and focus of the practice, team building, liaising with key clients, and developing business for the company. He is a highly sought-after keynote speaker and chair of national and international conferences and seminars, known for his provocative, thoughtful, and sometimes contrarian presentations. Dr. Davies also holds a position as Chair of the DHC Board of Directors.

Prior to the founding of Dark Horse Consulting, Anthony served as a senior executive for multiple publicly traded and privately held companies, building a reputation for innovation, dedication, and competency. A certified Six Sigma Champion, Anthony's industry roles included:

Chief Technology Officer at Capricor Therapeutics: development and expansion of the company's cardiovascular tx portfolio

VP of Product Dev at Geron: leading process dev, tech operations, pilot plant, analytical dev, and cGMP mfg functions…responsible for CMC-related regulatory filings, including the first-ever IND to secure FDA clearance for initiation of clinical testing of an hESC-derived product.

Onyx Pharmaceuticals: critical contributions to the development of Nexavar® and Ibrance®, building mfg teams for the adenovirus gene tx ONYX-015, running a multi-thousand liter, pre-commercial process for this first-in-class product.

anthony@darkhorseconsultinggroup.com

Katy Spink, Ph.D.
PRESIDENT & COO,
MANAGING PARTNER

As President, COO, and MP, Katy leads a variety of operational functions, including BD, HR, communications, and administration. Her work on behalf of DHC clients currently focuses primarily on cross-functional strategic projects such as due diligence, regulatory, cross-functional programs, and business strategies. When Dr. Spink joined DHC, she brought more than a decade of deep experience as a corporate officer of two publicly-traded cell tx companies and provided strategic and operational guidance: leading practice operations and BD.

Katy started her career at strategic management consulting firm McKinsey & Co, where she consulted for an array of biotechnology, medical device, and pharma companies. She then moved on to:

Geron Corp. (first in a BD role, then as Sr. VP of Cell Tx Program Ops and Alliance Management): Katy led the team to FDA clearance to initiate the first-ever clinical trial of a pluripotent stem cell-derived therapy.

Independent consultant: interim COO for an ophthalmology cell tx company, negotiation between biotech companies, successful translational medicine grant applications, project workplan and investment stage-gating plan for a complex multiparty research project

Asterias Biotherapeutics (Exec VP and COO): corporate strategy, BD, IP, investor relations, process dev, research, program mgmt, mfg, quality, and facilities.

katy@darkhorseconsultinggroup.com

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

Rob joined DHC in early 2019 as a Principal on what was then a much smaller consulting team. His expertise ranges from manufacturing to process dev to regulatory, as well as P&PM, market research, and due diligence/business strategy. During his tenure, the UK-based team grew rapidly and in 2021, Rob became GM of DHC Europe, Ltd. He is one of three MPs who run the practice.

Earlier in his career at Asterias Biotherapeutics (Sr Dir of Immunotherapy), Rob oversaw overall dev strategy, cross functional team leadership and clinical trial initiation of the company's allogeneic cancer immunotherapy platform therapy. He delivered substantial progress of the cancer immunotherapy pipeline asset and represented Asterias to investors and at conferences.

Before that, Rob's focus was on clinical research and clinical trial management. Site selection and monitoring, patient recruitment, trial negotiation, and data collection were early responsibilities at ICON and Parexel. Moving into managerial roles at J&J and Amgen, Rob led clinical studies from Phase I to IV. He led teams of clinical research associates, CROs and suppliers, while reporting on recruitment, study milestones, data collection, and more. At Amgen, he was responsible for management of international dev, medical, and branding teams for marketed and pipeline development assets. He used integrated PM best practices in global programs to ensure project delivery and alignment with regional and global commercialization strategies. At Circassia, Rob's responsibilities shifted to a heavy focus on international reg submissions, dev planning, and resolution of manufacturing deficiencies.

rob@darkhorseconsultinggroup.com

EXECUTIVE LEADERSHIP TEAM

John Ng, MBA
GENERAL MANAGER
DHC ASIA PACIFIC

Before joining DHC, John served as CTO of Tessa Therapeutics, where he grew the company from 30 people to more than 200 people. In 2021, he was asked by the Board of Directors to become the Acting CEO and completed a USD $126M fundraising round.

He led the design, build, and validation of their multi-product integrated commercial cGMP facility (134,000 sq ft). The facility obtained the GMP certificate from the Health Authority of Singapore (HSA) to manufacture cell therapy products in early 2023.

As the CTO, John was responsible for the Operations organization, which includes Manufacturing, Process Development, Quality, Program Management, Engineering, and Global Supply Chain. Under his leadership, Tessa Therapeutics completed a phase 3 pivotal autologous cell therapy trial supplied by in-house manufacturing. He also led the translation of multiple programs with Tessa's academic partners, executing successful tech transfers and comparability runs.

Before Tessa Therapeutics, John served in various leadership roles in Technical Operations in publicly listed companies. He spent ten years in China, responsible for Procurement, Global Supply Chain, and Program management.

jng@darkhorseconsultinggroup.com

Sanjin Zvonić, Ph.D.
SVP,
BUSINESS DEVELOPMENT

Dr. Zvonić is a cell and molecular biologist with a strong technical/scientific background in physiology, stem cell biology, and cell therapy CMC. In his current role at DHC, Sanjin is focused on strategic growth and development of the BD function, client engagement, and pipeline growth, while continuing to leverage his technical background as a Practice Expert on select projects.

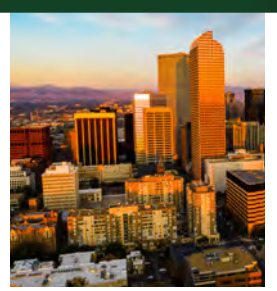
After earning his Doctorate in Cell and Molecular Biology, Sanjin continued on to a post-doctoral position at the Pennington Biomedical Research Center where he contributed to the development of methodologies for the isolation and culture of human adipose stem cells (ASC) from several sources and later utilized ASCs to develop a human *in vitro* model for circadian biology studies. He then transitioned onto a second post-doctoral role at Tulane University, where he directed the technology transfer and development of bone marrow-derived MSC manufacturing and analytical methods in the in-house GMP production facility.

Dr. Zvonic´ has worked at PCT (first focusing on client engagement and technology transfer; later, driving the growth and development of PCT's clinical and commercial manufacturing business lines while integrating into Hitachi Chemical), Novartis Cell and Gene Therapy Unit (developing and commercializing Novartis' CGT pipeline products), and at WindMIL Therapeutics (leading the CMC development of core technologies and pipeline products while contributing to the organizational growth and development).

szvonic@darkhorseconsultinggroup.com

OUR OFFICES, WORLDWIDE

DHC BAY AREA
The San Francisco Bay Area remains our global headquarters and the home base of President, COO, and MP Katy Spink, Ph.D. This office is located at 1255 Treat Blvd, Suite 230; Walnut Creek, CA 94597.



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 now the home office for our CEO, Anthony Davies, Ph.D.

DHC EUROPE
DHC Europe is located at The ClubHouse St. James; 8 St. James's Square; London SW1Y 4JU, and is run by CBO, 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, MBA. This office is located at 9 North Buona Vista Drive; #02-01, The Metropolis Tower One; Singapore 138588.

ORGANIZATIONAL LEADERSHIP

ORGANIZATIONAL LEADERSHIP

Todd Applebaum
CO-FOUNDER, CONVERGE
MANAGING DIRECTOR
DHC BTL CC

Todd Applebaum, MBA, is the Managing Director of Converge Consulting and has expertise in business strategy, operations, manufacturing, and supply chain management, working throughout the Life Sciences spectrum, including the pharmaceutical, biologics, and medical device sectors.

Prior to founding Converge, Applebaum served as VP, Technical Operations at Ovascience, leading Manufacturing, Quality, Supply Chain, and Technical Services as the company transitioned to commercial operations. As VP of Research, Healthcare, and Life Science at Gartner, Applebaum provided strategic insights to executives, analyzed best practices, and authored research reports on industry trends.

Earlier in his career, he co-founded Maxiom Consulting Group, where he led an award-winning management consulting practice, providing Life Science companies with operations strategies, commercialization and launch planning, and operational excellence services.

He holds a MBA from Carnegie Mellon University and a BS in Industrial Engineering from General Motors Institute.

tapplebaum@convergeconsulting.com

Kim Benton, Ph.D.
MASTER PRINCIPAL:
HEAD OF REGULATORY
DHC BTL CC

Dr. Benton specialized in CGT products during her multi-decade career at the US Food and Drug Administration, CBER.

Most recently, she served for as Associate Director for Regulatory Management in the Office of Tissues and Advanced Therapies (OTAT). In this role, she directed the regulatory review program for the broad portfolio of products under OTAT's purview. For the majority of her career at FDA, she directed and managed CMC review.

In her cumulative experience at CBER, Kim participated in all aspects of the regulatory review and oversight of CGT products, from pre-submission meetings (pre-INDs), IND review, BLA review, Ad Comm meetings for scientific topics and for license applications, device review [510(k), PMA, HDE], guidance and policy development, and regulation writing, revision, and interpretation.

Dr. Benton's work with DHC clients often focuses on interpretation of communications from regulatory authorities, and development of strategies to achieve the client's regulatory goal(s) by ensuring that information presented to the regulatory authority in meetings or regulatory submissions is clear and effective.

kbenton@darkhorseconsultinggroup.com

Ralph Brandenberger, Ph.D.
MASTER PRINCIPAL:
HEAD OF CMC
DHC BTL CC

Ralph is a resourceful Tech Ops leader with experience in cell therapy and biologics in both startup environments and established organizations. He brings to DHC his 24 years of experience in development and manufacturing of clinical stage cellular therapeutics & biologics, cGMP master and working cell banks, and biologics process aids used in commercial API manufacturing.

Prior to joining DHC in July 2025, Ralph was CTO at Nkarta Inc. Ralph joined Nkarta to lead the process & analytical development, Quality, manufacturing, and supply chain strategy of Nkarta's allogeneic NK cell platform leading to successful INDs for Nkarta's two product candidates. He built and developed the internal Technical Operations organization and oversaw an external manufacturing and supply chain network for drug product, viral vector, starting materials and raw materials with production of 100+ GMP lots internally and externally. His work included supporting the design, construction and startup of a clinical manufacturing facility and design and construction of a commercial manufacturing facility. Prior to Nkarta, Ralph led process development for two early-stage cell therapy companies, Neurona Therapeutics and Geron Corporation.

In addition to his cell therapy expertise, Ralph has technical operations experience in biologics and cGMP cell banking.

rbrandenberger@darkhorseconsultinggroup.com

ORGANIZATIONAL LEADERSHIP

Scott Bruder, M.D., Ph.D.
MASTER PRINCIPAL:
GM REGENERATIVE MEDICINE

DHC BTL CC

Scott founded BCVG in 2015 after 25 years in the industrial sector, in which he served as the CSO & CMO for Stryker Corporation, and as the CTO at Becton, Dickinson & Company. At Johnson & Johnson, his team built a portfolio of musculoskeletal tissue repair products for the DePuy franchise before establishing J&J Regenerative Tx. Dr. Bruder's inventions, technologies, and teams have launched dozens of products, earning billions of dollars for his employers and patent licensors. He has published 125+ original articles, book chapters, and abstracts, and lectured extensively around the world.

Dr. Bruder is the recipient of numerous international honors and is the only industry scientist to receive the Kappa Delta Award from the AAOS, the Marshall R. Urist Award for Tissue Regeneration Research from the ORS and the Pierre Galletti Award from AIMBE. Dr. Bruder has also maintained an active academic presence. Scott received both his M.D. and Ph.D. from Case, working in the laboratory of Prof. Arnold Caplan, after earning an Honors Sc.B. at Brown University working in the laboratory of Dr. Roy Aaron. An avid skier, jazz pianist, devoted husband and dedicated father, Scott's core beliefs are based on the principles of passion, commitment, and discipline.

scott@bruderconsulting.com

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

DHC BTL CC

Heath Coats has over 35 years of industry and consulting experience, seven of which were as a Biologist with the Division of Manufacturing and Product Quality (DMPQ) in U.S. FDA's CBER. There, he gained extensive knowledge of administrative and regulatory review procedures for INDs and CMC sections of biologics license applications. During his time at the Agency, Heath reviewed applications and supplements for cell therapy products, HPC cord blood, plasma fractionated products, vaccines, allergenics, aseptic processing, and *in vitro* diagnostics.

Heath would also routinely participate in pre-submission meetings with sponsors in order to evaluate facility design, operation, manufacturing and testing procedures, and compliance with GMP.

For DHC clients, Heath's experience has enabled him to provide support by performing audits and mock audits to support due diligence, vendor qualification, and preparation for regulatory inspection. His extensive inspections history makes him a natural fit for clients either preparing for inspections or working to remediate processes for future rounds of inspection.

hcoats@darkhorseconsultinggroup.com

Patrick Giljum
BTL CO-FOUNDER;
HEAD OF OPERATIONS

DHC BTL CC

Patrick Giljum co-founded BioTechLogic in 2004 as the Head of Operations. He has over 27 years of experience in biopharmaceutical process development and cGMP manufacturing of clinical and commercial supplies, supporting multiple Drug Substance and Drug Product technologies. Most recently, he supported the process validation, registration, and commercialization of an adjuvanted vaccine filed in both the US and Europe.

Prior to joining BioTechLogic, Mr. Giljum directed the manufacturing operations for clinical supply, registration, and ongoing commercial supply of biopharmaceutical products within Pfizer (and the former Pharmacia Corporation), including the process validation, registration, and commercialization of Somavert®.

From 1993-1999, Mr. Giljum was involved in the development of multiple Cytokine protein products for G.D. Searle, a division of Monsanto, including molecular biology, synthesis and purification, technology relocation, process validation, and the production of clinical and launch supplies.

Mr. Giljum received his B.A. in Biology/Microbiology and completed graduate studies in Medical Physiology and Molecular Biology at St. Louis University.

pgiljum@biotechlogic.com

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

DHC BTL CC

Nate joined Dark Horse Consulting in 2019, bringing his expertise in stem cell biology, neurobiology, and preclinical modeling. Dr. Manley helps clients build an operational plan for FIH from a CMC and nonclinical perspective, complete with building out program timelines and budget analyses. For a brand new academic spinout that may involve building a plan *de novo*, whereas for other clients it may be a case of evaluating existing development plans to identify operational gaps and recommended remediation strategies. Along all stages of these paths, he assists clients with regulatory strategy and execution: determining the right type of meeting (and optimal timing of that meeting) and helping clients identify must-have vs. nice-to-have data sets to enable successful regulatory engagement. He can also lead authorship of the regulatory submission, from meeting requests to briefing books.

Nate supports a wide range of product types within the CGT field but predominantly focuses on cell and gene-modified cell therapies. Nate works often with pluripotent-based and gene-edited products, and has also worked across the entire spectrum of immunotherapy-based products. Nate routinely helps clients build out nonclinical development plans from a high level but he also drills down to specific study design or protocols, analyses data, and helps draft study reports for future regulatory submission.

nate@darkhorseconsultinggroup.com

ORGANIZATIONAL LEADERSHIP

Scott Rosenberry
CONVERGE CO-FOUNDER;
VP, BD

DHC BTL CC

Scott helps life sciences organizations bridge the gap between strategy and execution to achieve critical business objectives. With deep experience across biotechnology, pharmaceuticals, and regulated industries, Scott partners with clients to address complex challenges in operations, supply chain, information management, and commercialization.

Scott has spent more than two decades in business development and enterprise sales roles supporting life sciences and technology-driven organizations. Prior to Converge, he founded and serves as Principal of Ops2data, a life science consulting ecosystem focused on operational and information management. Earlier in his career, Scott held senior roles at Oracle, where he led enterprise life sciences technology sales, as well as business development and regional sales leadership positions at Maxiom Group and Digital Island.

Scott holds a Bachelor of Science in Finance from the University of Connecticut and is based in the Greater Boston area. He is known for his consultative approach, industry expertise, and long-standing commitment to helping life sciences companies scale successfully.

srosenberry@convergeconsulting.com

Matt Spear, M.D.
CHIEF MEDICAL OFFICER

DHC BTL CC

Throughout his past 30+ years of experience in oncology and gene therapy research and development, Matt has combined deep scientific expertise with functional leadership across both academic and industry roles. He served previously as an Associate Professor at USC Keck School of Medicine and UCSD Medical School / UCSD Cancer Center, where he managed a clinical practice and led drug discovery, gene therapy research and oncology clinical trial programs.

In addition to his industry and academic leadership roles, Matt has contributed extensively to the scientific and medical communities, serving as a CIRM CAR-T Principal Investigator, member of NIH / NCI study sections, as a CPRIT grant reviewer, on biotechnology and pharmaceutical company Advisory Boards, and on IRB/SRC committees and scientific journal editorial review committees related to cancer and gene therapy, as well as in authoring numerous scientific manuscripts and patent applications.

Matt received his BA from Johns Hopkins University and MD from Stanford University, followed by postgraduate training at Massachusetts General Hospital / Harvard University.

mspear@darkhorseconsultinggroup.com

Tracy TreDenick
BTL CO-FOUNDER;
HEAD OF REGULATORY & QUALITY

DHC BTL CC

Tracy co-founded BioTechLogic in 2004 as the Head of Quality and Regulatory. She has over 28 years of experience in Pharmaceutical Quality, Manufacturing and Regulatory.

Most recently she has performed multi-product facility audits with additional pre and post-viral clearance requirements, global commercialization and submission readiness assessments, and prepared several U.S. and Europe CMC sections in the CTD format for an adjuvanted vaccine, combination product, and biosimilar, including the preparation of documents that spanned the course of process development, clinical and commercial-scale manufacturing for both the Drug Substance and Drug Product. This experience enabled a full understanding of the expectations for development, manufacturing, and analytical characterization of the product to obtain global product approval.

Prior to joining BioTechLogic, Ms. TreDenick directed the validation and pre-approval readiness programs for biopharmaceutical products within Pfizer (formerly Pharmacia Corporation), including the process validation, registration, and commercialization of Somavert®, a well-characterized recombinant protein product.

ttredenick@biotechlogic.com

PROJECT LEADERSHIP

Robert Cantow, MBA
PRACTICE DIRECTOR, SUPPLY CHAIN
DHC BTL CC

A Supply Chain executive with over 30 years of experience designing, transforming, and managing complex global supply chains in the medical devices, pharmaceutical, and biotech industries, Bob has deep expertise in global strategy, planning, logistics, manufacturing, and sourcing. Cantow brings a focus on supply chain transformation, which provides a competitive advantage resulting in increased revenue and profit.

Previously, Cantow served as the Senior Director of Supply Chain Operations & Effectiveness for Biogen. He was responsible for managing the Supply Chain Center of Excellence, supporting over $10B in annual sales. Cantow designed and led the execution of a three-year supply chain transformation roadmap.

As the VP of Supply Chain at Boston Scientific, he was responsible for managing 42 global fulfillment centers supporting over $8B in annual sales. Earlier, Cantow managed four manufacturing plants and 11 distribution centers as the Director of Materials Management at W.R. Grace.

Cantow earned his MBA in General Management, as well as his B.S. in Chemical Engineering, from the University of Connecticut. He has also received training from the American Production and Inventory Control Society (APICS).

rcantow@convergeconsulting.com

Liz Cauldwell
PRINCIPAL
DHC BTL CC

Liz joined Dark Horse Consulting in 2021. Liz's consistent emphasis is to get clients to a place of efficiency and operational excellence; she supports a range of DHC clients across developmental stages and modalities for whom those goals align. She works with academic, biotech and contract development and manufacturing organizations, focusing on the manufacturing of allogeneic and autologous cell therapy products.

Her career began at U. Penn., Clinical Vaccine Production Facility with a primary focus on early phases allogeneic and autologous cell therapy production. While at Penn, Liz expanded her working knowledge of cGMP cell therapy production and early phase regulatory submission and management.

In 2016, Liz joined WuXi Advanced Therapies where she managed multiple manufacturing facilities and developed a plethora of experience on capacity and forecast planning, budget and strategy plans for labor utilization, and internal and external technology transfers for both early and late/commercial phase cell therapy products. Liz has a proven track record of establishing and partnering within a cross-functional setting to continually drive progress and quality production of cell therapy products.

ecauldwell@darkhorseconsultinggroup.com

Eileen Choi, Ph.D.
VP, MANUFACTURING SCIENCE & TECHNOLOGY
DHC BTL CC

Eileen joined BioTechLogic in 2019 with more than 20 years of experience working in the biopharmaceutical and chemical engineering fields. Her role at BioTechLogic includes providing consulting services in all areas of technical operations including process and analytical method development and validation. She also provides project management and manufacturing support, process validation expertise, and support for the development, qualification and validation of analytical methods. Additionally, she supports validation activities for biologics clients, such as in-process/media/buffer/solution hold time studies, chromatography and TFF membrane re-use studies, shipping validation, filter validation, and leachables/extractables risk assessments for both in-process product contact material and container closure systems. Her role also includes leading remediation projects to enhance compliance for manufacturing processes and analytical methods in support of manufacturing and quality control of various products.

echoi@biotechlogic.com

Samantha Conner
PRINCIPAL
DHC BTL CC

Samantha Conner is a seasoned project management professional, leading cross-functional initiatives supporting cutting-edge CGT programs. With over a decade of experience spanning CDMO environments and pharmaceutical startups, she brings a unique blend of technical insight, strategic execution, and client-focused leadership to every engagement.

Her career has been defined by the ability to manage complex, cross-disciplinary projects across diverse therapeutic platforms. Known for her clear communication, organization ability and results-driven mindset, Samantha thrives in collaborative environments that demand both strategic oversight and hands-on problem solving and is recognized for her ability to bridge technical and operational disciplines to deliver successful outcomes

Today, Sam partners with clients to provide expert project management for high-stakes CGT programs: bringing the rare combination of CDMO and Sponsor experience that adds clarity, momentum, and value for early development through delivery.

sconner@darkhorseconsultinggroup.com

Susan Drapeau, Ph.D.
SENIOR PRINCIPAL, REGENERATIVE MEDICINE
DHC BTL CC

Susan has over 24 years of industry experience in cell therapy, biologics, biomaterials, protein therapies and medical device development. Prior to joining BCVG in 2022, Susan led product development, regulatory, preclinical, and program management at Sigilon Therapeutics, a cell therapy company combining biomaterials and cellular engineering to treat rare diseases. Previously, she served as the Senior Director of Business Development and Strategy at Vericel Corporation, and before that, spent 14 years at Medtronic Spine running part of the Biologics product development organization as well as leading due diligence efforts. While at Medtronic, her team launched numerous products, submitted INDs, supported manufacturing and more. Earlier in her career, she worked at Osiris Therapeutics with Dr. Bruder, leading allogeneic cell therapies in orthopedics. Dr. Drapeau serves as an advocate for the biomedical field as part of AIMBE, and sits on the Advisory Board for the Department of Biomedical Engineering at Rice University. Susan is a graduate of Purdue University (BS, Chemical Engineering and BS, Chemistry) and Rice University (PhD, Chemical Engineering).

susan@bruderconsulting.com

David Fetterolf
PARTNER; VP, TECHNICAL OPERATIONS
DHC BTL CC

David has more than 20 years of experience in the biopharmaceutical industry. He has held process development, manufacturing and validation positions at Covance Biotechnology Services, Diosynth (Akzo Nobel), Pharmacia and Pfizer, where he managed API and Drug Product manufacturing technologies, technology relocation and scale-up, validation, and product supply chains at internal and third-party manufacturing sites. He holds a B.S. in Chemical Engineering from Pennsylvania State University and an M.B.A. from Elon University.

dfetterolf@biotechlogic.com

Jennifer Foulkes
PRACTICE DIRECTOR, CLINICAL SUPPLY CHAIN SERVICES
DHC BTL CC

Jennifer Foulkes is an experienced Supply Chain leader with more than 20 years of experience, specializing all areas of clinical supply chain management, from starting up phase 1 first-in-concept studies to managing and closing phase 3 global double-blinded comparator trials. She advises clients on strategies to develop supply chains that expedite FPI and provide long-term reliability to patients. Foulkes performs supply partner selections for packaging and IRT partners, implements and oversees the partnerships, and serves as an SME when day-to-day support is required.

She has implemented Sales and Operations Planning (S&OP) processes at numerous organizations, advising clients on inventory management strategies for all drug stages from raw materials to finished goods, which result in better visibility to supply needs, reduced volume of product expiry, and opportunities for cost reduction.

Foulkes holds a B.S. in Management Engineering and a M.S. in Operations Design & Leadership from Worcester Polytechnic Institute. She is also a certified Lean Six Sigma Black Belt.

jfoulkes@convergeconsulting.com

PROJECT LEADERSHIP

Jeremy Friedler, M.S.
PRACTICE DIRECTOR, SUPPLY CHAIN & OPERATIONS
DHC BTL **CC**

Jeremy Friedler is an experienced biopharmaceutical consultant with 16 years of strategy and operations experience in supply chain and manufacturing operations for life sciences. He brings deep knowledge and analytical expertise in manufacturing and supply chain management, CMC, cGMP quality, and commercial launch planning. Friedler's work with preclinical, clinical and commercial stage pharmaceutical, biotechnology, and cell/gene therapy companies includes addressing a wide range of operations challenges faced by both emerging and established biopharma clients.

Prior to his work with Converge, Friedler spent nearly a decade as a Consultant in the Pharmaceutical & Life Sciences Advisory practice at PricewaterhouseCoopers (PwC) (formerly PRTM), serving large, multinational pharmaceutical companies in addition to mid-sized and emerging biotech companies in supply chain and manufacturing transformation, supply chain and manufacturing operations strategy, and post-merger integration.

Friedler earned his Master's Degree in Supply Chain Management from Northeastern University and his B.A. from Franklin & Marshall College.

jfriedler@convergeconsulting.com

Christina Fuentes, Ph.D.
PRINCIPAL
DHC BTL CC

Christina Fuentes is a Bioengineer with experience in gene and cell therapies. Dr. Fuentes' work with DHC clients has ranged from long-term embedded support to vendor management to technical lead from initial product design stages through to first-in-human/IND approval.

Her past expertise includes synthesis and characterization of hydrogels for scalable, 3D culture of pluripotent stem cells, and in vivo genome editing using adeno-associated virus (AAV) mediated delivery of CRISPR/Cas9. Christina has extensive experience in molecular cloning, viral production and purification, CRISPR/Cas9 design and application, and polymer synthesis. While earning her Ph.D. in Bioengineering at UC Berkeley, Christina's research led to one invited review, two research papers, and one patent.

During her doctoral work, Christina also gained industry experience through a summer internship in the Antibody Engineering Department at Genentech. She conducted and analyzed experiments related to phage display screens of antigen-binding fragments. While interning, Christina was awarded a position in the Genentech Leader Intern Exchange Program (gLINX).

cfuentes@darkhorseconsultinggroup.com

Rachel Houp
EXECUTIVE DIRECTOR, REGULATIONS & QUALITY
DHC **BTL** CC

Rachel has over 20 years of experience in the biopharmaceutical industry. Her responsibilities at BioTechLogic include validation, preparation of CMC regulatory documentation submissions, quality assurance and project management support. Rachel has also gained experience in equipment qualifications. Her specialties include Process Validation over the lifecycle of the process/product, support validations and IND, IMPD, BLA, MAA and PAS CMC submissions in the CTD format. Previously, she held positions in quality assurance, validation, small scale cell culture manufacturing and QC testing at Human Genome Sciences, Diosynth (Akzo Nobel), Covance Biotechnology Services, BioReliance, and Tektagen. As part of the BioTechLogic team, Rachel provides API and Drug Product manufacturing and project support for clients with protein, vaccine, oligonucleotide and synthetic blood products.

rhoup@biotechlogic.com

John Kandl
EXECUTIVE DIRECTOR, TECHNICAL OPERATIONS
DHC **BTL** CC

John joined BioTechLogic in 2008 with a focus on contract manufacturing management, process development, and validation activities. John has over 20 years of experience in the biopharmaceutical industry. He has previously held Quality Assurance positions at Exelixis and Tercica, Inc., where he maintained oversight of the contract manufacturing for numerous APIs and drug products, developed corporate quality systems, validation programs, and regulatory submissions. Prior to this John was a Project Engineer with SAVIS Inc., a consulting firm for the pharmaceutical/biotechnology industry. At SAVIS, John led numerous analytical, equipment, computer, cleaning, and process validation projects.

jkandl@biotechlogic.com

PROJECT LEADERSHIP

Michael Kinzie
PRINCIPAL
DHC BTL CC

Michael has decades of extensive experience in product development of Medical Devices. This requires expertise in Design Controls: 21 CFR 820.30 and ISO 13485; Risk Management ISO14971; Human Factors and Usability Engineering IEC 62366-1; and many other relevant Standards.

With Dark Horse clients, Michael particularly focuses on the degree to which regenerative medicine overlap with high-quality medical device design and manufacturing and bioprocessing manufacturing equipment. Medical device development begins with market research and business strategy (identifying and addressing unmet needs and identifying the competitive landscape), followed by product development (requirements and risk management, etc.), and test validation methods, as well as regulatory elements (including strategy and authorship), and quality. To quote Michael, "Quality is everyone's job," and the ultimate goal in the design and device development of a medical device is to launch a high-quality, safe and effective product, free from defects. It's also important to note that device development is not just the system or related consumable, but any related software as well.

mkinzie@darkhorseconsultinggroup.com

Amanda Mack, Ph.D.
PRINCIPAL
DHC BTL CC

Amanda joined DHC in 2021, bringing expertise in stem cell-derived platforms and products that include process and analytical development, technology transfer, and CMC-related regulatory strategy and submissions.

At DHC, Amanda has enhanced clients' ability to understand their current state of clinical readiness by providing a framework intended to inform the client's development strategy and maximize potential for successful regulatory engagement while balancing considerations linked to business objectives. For early-stage developers, this often includes an assessment of their current program to identify gaps, assess risk, and share mitigation strategies to alleviate potential impact to timeline, budget, and regulatory interactions.

A significant achievement in Amanda's professional career was the opportunity to develop the technology and processes to manufacture induced pluripotent stem cells (iPSCs) for Cellular Dynamics, Intl (CDI) beginning in 2007. This capability advanced internal programs developing iPSC-derived products, catalyzed academic and industrial collaborations, and led to various award grants (NHLBI, CIRM).

amack@darkhorseconsultinggroup.com

Sara Masterson, MBA
PRINCIPAL
DHC BTL CC

Sara focuses primarily on program & alliance management and has a proven record of building and maintaining relationships within a cross functional matrix to continually push the progress and success for production of quality life-saving therapies for patients. She also has extensive knowledge in generation of scopes of work, technological transfer, clinical manufacturing, and lot disposition.

With DHC clients, Sara has found that she can attribute successful managing of the overall progress of client programs to her skills in leading teams and positioning resources to inhabit the most desired project outcomes as they relate to on-time delivery. Sara prioritizes a deep understanding of each clients' needs as well as building trust and successful relationships with those clients.

Analytical Research Laboratories is where she first gained exposure to operating within controlled environments such as ISO 5 and ISO 7 spaces and managing laboratory activities to ensure that clients received documentation to release product for patient use within the agreed-upon timeline.

smasterson@darkhorseconsultinggroup.com

Brent Morse, M.S.
PRINCIPAL

Brent came to DHC with two+ decades in biotech, with experience in process and analytical development, potency assay development, comparability, tech transfers, CRISPR/Cas9 editing, and CMC strategy. At Dark Horse, examples of his work include the following: analytical strategy (potency, genomic safety, and analytical comparability), CMC strategy, including gap analysis, risk assessment, and roadmap to IND, FDA interaction support (e.g., INTERACT, pre-IND, IND, and BLA stage), and interim department head.

Before joining DHC, Brent served as VP of Process and Analytical Dev at Vor Biopharma, where he led the manufacturing processes/analytical strategies and oversaw external GMP manufacturing of Cas9, single guide RNA, and lentiviral vector DP. Brent's team delivered data pkgs to support an IND and CTA for VOR33. Prior to Vor, Brent served as Dir. of Analytical Dev at CRISPR Therapeutics, where he developed an overall analytical strategy plus external gene editing reagent manufacturing. His team supported multiple regulatory filings, including for exa-cel (formerly CTX001), a CRISPR-edited hematopoietic stem cell product that was the first CRISPR edited product evaluated in a company sponsored U.S. clinical trial.

bmorse@darkhorseconsultinggroup.com

PROJECT LEADERSHIP

Barry J. Oliver, Eligible QP, MRSB
SENIOR PRINCIPAL

DHC BTL CC

Barry is a seasoned Executive Global Quality leader in biopharma with broad experience in CGT, biological, sterile injectable and solid dose manufacturing, packaging, and distribution. His 20+ years of experience was gained in the context of the CDMO space, having held multisite, multi-modality corporate quality and compliance responsibilities across UK-, EU-, and US-based facilities supporting customers and partners to produce high quality clinical and commercial medicinal products. Barry's modus operandi is making action happen through tight collaboration and partnership. He also has extensive technical and operational quality experience at site level, having held Site Quality and Production Leadership roles, and is an eligible Qualified Person, Responsible Person, and Controlled Drug Authorized Person. Prior to joining DHC in May 2025, Barry was a member of a hand-picked leadership team that was charged with setting up the Catalent CGT Division. His role as VP Quality, involved forensic due diligence activities as part of worldwide M&A, speedy but robust site integrations and establishing quality teams to support the growth engine of the business.

boliver@darkhorseconsultinggroup.com

James Petricek, MSE, MBA
SENIOR PRINCIPAL, REGENERATIVE MEDICINE

DHC BTL CC

Jim is a seasoned medical device/biotechnology executive with strategy and tactical experience spanning both the device and regenerative medicine platforms, including drug/device combination products, cell-based implants, allografts, and biomaterials. He has extensive experience with early-stage start-ups, emerging companies, Class III medical devices, and PMAs. His expertise spanning product development, marketing and business development, provides clients with extremely valuable cross-functional insights for our client partners. Prior to joining BCVG, Jim was Senior Director at BioMimetic Therapeutics (acquired by Wright Medical) where he had responsibility for product development and commercial strategy for Augment Bone Graft. Jim is a graduate of the University of Michigan (MSE, Biomedical Engineering; BS, Cell and Molecular Biology) and Santa Clara University (MBA, Finance).

jim@bruderconsulting.com

David Phillips
VP, QUALITY

DHC BTL CC

David Phillips has worked in a range of modalities (biologics/recombinant proteins/antibodies, ADCs, peptides, cell therapy, gene therapy programs, small molecules) as well as in both CDMOs and a number of sponsor companies. His experience has ranged from research/pre-IND to the different clinical development stages, and a number of commercial programs. David has been part of numerous inspections from a range of regulatory agencies globally, such as FDA, EMA and various European country agencies, MHRA, PDMA, ANVISA, ANMAT, TGA, Swissmedic, and others.

David's experience working and living outside of the United States (a global role at Shire, with Lonza Biologics in Singapore, and at VaxGen, Inc./Celltrion in South Korea) provides him with a valuable global perspective. While at Lonza, he helped establish the country's first biologics manufacturing park and collaborated with leading biopharmaceutical companies on large-scale biologics programs, as well as supported the cell therapy build for Lonza's Singapore facility. David was also on the core startup and tech transfer team in establishing the first biologics facility in South Korea (Celltrion). David held numerous quality roles at VaxGen Inc., and Diosynth Biotechnology.

dphillips@biotechlogic.com

Patrick Reischling, MBS
ENGAGEMENT PARTNER, CLINICAL AFFAIRS & STRATEGY

DHC BTL CC

Patrick is a seasoned analytical and innovative business leader with broad experience developing clinical research strategies to ensure robust evidence generation for global market access and market development. Patrick brings over 17 years of experience in the design and execution of clinical trials for medical devices, biologics, human tissue, and blood-based products. He has experience negotiating clinical trial design with the FDA, working with KOLs to design studies, and presenting results. Gathering input from regulatory, health economic, product development, scientific, and marketing stakeholders, Patrick designs clinical evidence plans with the goal of gaining maximum value for the investment. Patrick also has extensive experience building and managing clinical teams to ensure the timely execution of clinical projects while complying with GCP and regulatory requirements. Patrick earned a BA in Biology and MBS in Exercise Science from the University of Colorado in Colorado Springs.

patrick@bruderconsulting.com

PROJECT LEADERSHIP

Julie Spyrison
PARTNER; VP, REGULATORY OPERATIONS

DHC BTL CC

Julie joined BioTechLogic in 2004 with a focus on CMC Regulatory and Project Management activities. As part of the BTL team, Julie is responsible for managing CMC Regulatory submission projects/CMC documentation. As part of the dossier preparation and its lifecycle management, Julie performs source document gap analyses, prepares Agency briefing packages, prepares Module 2.3 and Module 3 CTD sections, authors responses to Agency questions, facilitates the electronic publishing process, and evaluates change control requests post-dossier submission for Regulatory impact.

Julie also provides clients with project management support for multiple Drug Substance and Drug Product technologies. Responsibilities include management of activities associated with contract manufacturing sites, process scale-up and technology transfer, process validation, regulatory submission packages, and global regulatory inspection readiness. She holds a B.S. in Chemical Engineering from Northwestern University.

jspyrison@biotechlogic.com

Jacob Staudhammer
SENIOR PRINCIPAL

DHC BTL CC

Jacob joined Dark Horse Consulting in January of 2021, bringing expertise and training in Viral Vectors, Biochemical Engineering, and Molecular Biology. Jacob's prior work in industry focused on process and analytical development of gene therapy viral vectors, spanning from pre-clinical development through clinical manufacturing and process validation for over 7 clinical-stage programs.

Jacob held increasing roles at Adverum Biotechnologies in Process Development, focusing primarily on Upstream and Downstream development of an SF9-Baculovirus AAV process. Jacob also developed several novel methods for advanced AAV analytics using NGS, which led to the invention of a patent-pending analytical method. While at Orchard Therapeutics, Jacob focused on the Process Validation and Process Characterization of late-phase Lentiviral Vectors (LVV) for Orchard's rare disease portfolio. He oversaw the Process Characterization and PPQ strategy of a late-phase program using a QbD approach, resulting in an effective PPQ strategy.

Jacob holds a Six Sigma Green Belt certification, and has completed certificates from ISPE in Process Validation, and ASQ in Design of Experiments.

jstaudhammer@darkhorseconsultinggroup.com

Madeline St. Onge, MBA
PRINCIPAL

DHC BTL CC

Madeline same to DHC from International Society for Cell & Gene Therapy (ISCT), the global professional organization focused on the clinical translation of cell and gene therapies. At Dark Horse, Madeline supports clients with market research, competitive landscaping, diligence and commercial strategy projects.

Previously, Madeline was responsible for leading corporate revenue generation at ISCT, including conference sponsorships and corporate memberships. In this role, she acted as the voice of industry to ISCT leadership and worked closely with senior industry executives to develop programs that serve the diverse needs of companies across the cell and gene therapy industry. She became intimately familiar with the challenges facing the commercialization of CGT and the importance of cross-sector collaboration to advance the availability of cell and gene therapies for patients. Prior to focusing on industry activities at ISCT, Madeline managed the educational programs for ISCT Annual Meetings, working with key opinion leaders to curate peer reviewed programs serving the needs of all professionals involved in the clinical translation of cell and gene therapies.

mstonge@darkhorseconsultinggroup.com

Mary Swartz
SENIOR DIRECTOR, QUALITY

DHC BTL CC

With more than 20 years of experience in pharmaceutical quality operations, Mary brings deep expertise across cell therapy, biologics, small molecules, gene therapies, and viral vectors. Over the course of their career, she has successfully led greenfield and brownfield laboratory builds, managed complex global product launches, and driven quality excellence across multiple organizations. Her work has spanned the U.S., Europe, and Asia, with extensive collaboration alongside regulatory agencies such as the FDA, EMA, Health Canada, and PMDA.

As Senior Director of Quality at Vor Bio, Mary's leadership ensured that product development and operations consistently aligned with regulatory expectations while supporting innovation and efficiency. In addition to technical and regulatory expertise, Mary has overseen international teams, guided large-scale system implementations, and developed quality strategies that scale with organizational growth. Her ability to balance scientific rigor with business priorities has made her a trusted partner to both executive leadership and external collaborators.

mswartz@biotechlogic.com

Eric Vanderploeg, Ph.D.
ENGAGEMENT PARTNER, PRECLINICAL DEVELOPMENT AND STRATEGY

DHC BTL CC

Eric is an experienced R&D leader with over 15 years working in the biotech, pharma, and medical device industries. He has led cross-functional teams and advanced multiple therapeutic programs from discovery through late-stage preclinical development, bringing deep expertise in regenerative medicine, with a particular focus on cell therapy, biologics, and combination products. Most recently, Eric served as VP, Head of Preclinical at Satellite Biosciences, guiding development of a novel cell therapy for liver disease. Prior to that, he held senior roles at Sigilon Therapeutics leading the preclinical development of stem cell-derived therapies for diabetes and at Bioventus directing biomaterials and combination product development for multiple orthopeadic indications. Eric began his industry career with Pfizer working on research programs for biomaterial mediated drug delivery, advanced wound healing, and fibrosis. Eric holds a Ph.D. in Mechanical Engineering from Georgia Tech and completed postdoctoral research at MIT in the area of cartilage tissue engineering. He is an inventor on multiple patents and a published author in the fields of biomaterials and tissue engineering.

eric@bruderconsulting.com

SUBJECT MATTER EXPERTS

Kristen D. Allen, RAC, CQA
SENIOR CONSULTANT, REGENERATIVE MEDICINE

DHC BTL CC

Kristen Allen is a regulatory affairs and quality professional with more than 15 years of experience supporting medical device companies across the full product lifecycle. She brings deep expertise in Class I instruments and Class II/III implantable device submissions, working extensively with the FDA and European regulatory authorities. Kristen is well versed in FDA Guidance Documents and is known for navigating complex regulatory expectations with both precision and creative insight. Her background includes managing post-market compliance activities, supporting safety and recall decisions, overseeing establishment registrations, and ensuring adherence to Quality System requirements, including Design Controls, CAPA, and healthcare professional contracting. Kristen combines technical rigor with practical problem solving to help organizations meet compliance objectives efficiently and effectively. She holds a Bachelor of Science degree from the University of North Carolina at Wilmington.

kristen@bruderconsulting.com

Spencer C. Bailey, MBA, CPC
ENGAGEMENT PARTNER, REIMBURSEMENT & HEALTH ECONOMICS

DHC BTL CC

Spencer is a talented and insightful professional with significant experience in strategic reimbursement for medical devices and Biologics. An expert in navigating the landscape related to coding, coverage and payment, he brings a wealth of experience from both the payer perspective and that of product development firms requiring long-range planning to ensure maximal reimbursement. His finance training and applied acumen provides a solid foundation for thoughtful analytics and strategic guidance. Spencer is responsible for leading BCVG's reimbursement practice, including assembly of payer-facing clinical dossiers, sales training materials, hospital-facing analysis presentations and budget impact models. Spencer is a graduate of the University of Vermont (BS, MBA).

spencer@bruderconsulting.com

Kristin Baird, M.D.
MASTER PRACTICE EXPERT

DHC BTL CC

Dr. Kristin Baird is board-certified in Pediatric Hematology/Oncology and an SME in hematopoietic stem cell transplantation and CGT regulatory affairs. Dr. Baird has over 18 years of clinical research experience in pediatric oncology at the National Cancer Institute (NCI) in Bethesda Maryland and 8 years of regulatory experience the in U.S. FDA in the role of Medical Officer/Clinical Reviewer.

During her time at the NCI, Dr. Baird served as the Principal Investigator on several clinical trials and was an Associate Investigator on over 30 clinical trials. Additionally, she served on the NCI Safety Monitoring Committee and has over 50 peer-reviewed publications, several book chapters, and multiple national and international presentations to her name.

While at the FDA, Dr. Baird served as a Medical Officer, expert reviewer, and one of the principal advisors to the Division Director and other Center senior staff for evaluating the safety and effectiveness of novel biologic CGT, as well as Phase 1-3 clinical trial designs for oncology and hematology applications. Dr. Baird is adept at evaluating the vast body of clinical data submitted by the nation's pharma industry and academic investigators to support BLAs, INDs, IDEs, and associated applications.

kbaird@darkhorseconsultinggroup.com

SUBJECT MATTER EXPERTS

Joe Balleydier, M.A.
SENIOR PRACTICE EXPERT

DHC BTL CC

Joe joined DHC after 30 years in the biopharmaceutical industry with both large pharma and startup biotech companies. He has broad expertise across multiple biologic modalities including AAVs, recombinant proteins, vaccines, plasmid DNA, and antibodies.

For the past several years, Joe's primary focus has been with process development and manufacturing of AAV derived gene therapy products. He has held multiple roles across process development, MSAT, and manufacturing at startup gene therapy companies at stages from pre-clinical through commercial operations. Joe's main contribution to these organizations has been the establishment of robust, scalable, and well-controlled manufacturing processes.

During his time at AveXis, Joe held roles in process development, MSAT and manufacturing as the company matured into commercial operations. Joe was a key contributor to the BLA CMC efforts for Zolgensma® including the development of the upstream process, process validation, and ownership of several Module 3 sections.

jballeydier@darkhorseconsultinggroup.com

Joshua Beckett
SENIOR CONSULTANT

DHC BTL CC

Joshua brings to Dark Horse his years of expertise in analytical method development, tech transfer and validation. He is also well versed in several methods used to support quality control of gene therapy products. Josh's analytical background has also informed his authorship of regulatory filings. His DHC client projects include a variety of CMC/manufacturing regulatory projects, from pre-IND and INDs to IMPDs and CTAs.

In 2015, Josh joined Florida Biologix/Brammer Bio, now a part of Thermo Fisher Scientific's Viral Vector Services, in Assay Development and Analytics. Here he helped develop qPCR- and ELISA- based methods for several clients.

In 2018, Josh moved to Boston to help set up the Quality Control labs at Thermo Fisher Scientific's new Cambridge manufacturing site where he became part of the Analytical Method/Instrument Validation department, writing protocols, training analysts, and compiling data for final summary reports to support the validation of several different types of analytical methods.

jbeckett@darkhorseconsultinggroup.com

Blake Bergam
SENIOR CONSULTANT

DHC BTL CC

Blake joined DHC in 2021, bringing expertise in gene-modified cell tx process as well as technology development, technology transfer and GMP operations. His client projects most frequently consist of initiation of GMP manufacturing, process instrument and single use systems development, CMC regulatory authorship of briefing books, INDs and BLAs, and deep dives into raw material suitability risk assessments.

At Seattle Genetics, responsibilities included execution of bioburden assays, authoring SOPs and ensuring GDP compliance. At Juno Therapeutics in the Quality Assurance Operations department during the startup of Juno's GMP cell therapy manufacturing facility, he oversaw cGMP operations included leukapheresis receipt, raw material and patient lot disposition, batch record review, deviation investigations, SOP and batch record revisions, and training.

Blake's Six Sigma Green Belt enables him to facilitate root cause analysis, failure mode and effects analysis, and continuous improvement initiatives. Achieving his Pharma GMP Professional certification gave him an in-depth understanding of the global regulations and requirements for all things GMP.

bbergam@darkhorseconsultinggroup.com

Sam Blackford, Ph.D.
SENIOR CONSULTANT

DHC BTL CC

Sam is a pluripotent stem cell biologist and tissue engineer with expertise in retinal and hepatic cell therapies. Sam regularly advises clients on nonclinical development and strategy, including interactions with regulators, across all stages of drug product development. He also provides clients with tech writing support in authoring of study reports and regulatory submissions.

Sam began working with pluripotent stem cells as an undergraduate where he successfully derived embryonic stem cell lines from genetic mouse models. This motivated him to undertake a dedicated master's degree in stem cell technologies and to then gain further research experience within Professor Robin Ali's CGT lab at University College London. While at UCL, he gained experience in 3D differentiation within bioreactors, virus production, and cell transplantation. Sam then moved to King's College London to undertake an mRes degree, fabricating natural/synthetic biomaterials, isolation & culture of primary human hepatocytes, and hiPSC-derived organoid culture. During his doctoral studies at King's he established SOPs for the culture and differentiation of cGMP-compliant human pluripotent stem cells into hepatocytes, among other successes.

sblackford@darkhorseconsultinggroup.com

SUBJECT MATTER EXPERTS

Ariel Bornstein
SENIOR CONSULTANT

DHC BTL CC

Ariel joined BioTechLogic in 2020 and has over 15 years of experience in the biopharmaceutical industry. He has held positions in process development, MSAT, commercial manufacturing operations, and technical writing in the recombinant protein, plasma product, and oligonucleotide drug substance and drug product manufacturing fields. His primary consulting responsibilities involve technical and manufacturing operations support, process development and validation activities, process risk assessment, authoring and review of technical reports, batch records, SOPs, and other supporting documents.

Additionally, Ariel supports validation activities for biologics clients, including hold time studies, resin and membrane re-use studies, shipping studies, filter validation, and extractables & leachables assessments.

abornstein@biotechlogic.com

Liam Breen, MChem, MRSC
SENIOR CONSULTANT

DHC BTL CC

Liam is a quality specialist with experience in commercial: biological, sterile injectables, and solid dose manufacture, pkg, and distribution. Liam worked with a wide range of dosage forms, quality systems, and regulatory jurisdictions as a senior quality officer operating and maintaining Pfizer's three major European Mfg and Importation Authorizations (MIAs), through which the company's txs destined for the European market were channeled from all corners of the globe (except Antarctica).

Prior to joining DHC, Liam was working as a senior quality officer supporting the distribution of the BioNTech COVID-19 vaccine. Liam played a hand in the initial setup of the quality apparatus that supported the cutting-edge, 24-7, global, real-time-monitored supply chain for the vaccine; he also led several critical updates for the systems as new challenges presented themselves. During his time operating under these licenses he utilized every facet of the site's QMSs, supported the ongoing batch release activities, and supported multiple competent authority inspections. Before Pfizer, Liam was a high school chemistry teacher and middle school science teacher; this worked wonders on his public speaking and presentation skills.

lbreen@darkhorseconsultinggroup.com

Daniel Bright
PRACTICE EXPERT

DHC BTL CC

Dan is an experienced Program Manager and Manufacturing Operations professional with deep experience and technical expertise in the CGT space. He has worked, built, and managed facilities, people, and portfolios across a variety of organizational types and sizes, including both CDMO and Sponsor-side organizations.

Prior to joining DHC, Dan worked as a Global Program Manager and technical SME at Ferring Pharmaceuticals, taking on roles of increasing scope, accountability, and impact as the company built and commercialized a new portfolio and global footprint in CGT. This included active management of and engagement with a variety of regulatory agencies and geographies across the globe, as well as providing focused SME support to due diligence and investment activities related to advanced therapies. Before Ferring, Dan worked at Cellectis S.A. as Director of Manufacturing. He was responsible for building a team and all related processes and systems for the organization's first directly owned, fully dedicated GMP manufacturing facility.

dbright@darkhorseconsultinggroup.com

Samantha Burton
SENIOR CONSULTANT

DHC BTL CC

Samantha joined BioTechLogic in 2022 with over nine years of intensive startup biotech experience. Samantha consults in drug substance and drug product process development, process optimization, remediation, and facility management. Her role includes preparing and reviewing qualifications, validations, risk assessments, gap assessments, batch records, and other technical documents. She also supports PM associated with contract manufacturing, process scale-up, tech transfer, and commercialization.

Previously, Samantha was a Sr. Engineer/Program Manager at COUR, where she was responsible for process design and management of new and existing drug product mfg. During her tenure at COUR, she coordinated translational activities of five therapies from R&D to GMP production and was the project lead for designing a large-scale pilot manufacturing facility. Before that, Samantha was a Product Dev Engineer, developing innovative solutions for cell culture, tissue repair/regeneration, and offering biologic contract research and mfg services. She has an in-depth understanding of cleanroom design, design control, process validation, and GMP.

sburton@biotechlogic.com

SUBJECT MATTER EXPERTS

Deborah Chen, Ph.D.
SENIOR CONSULTANT

DHC BTL CC

Deb is passionate about bringing new treatments to patients with unmet medical needs. When she joined DHC, she brought more than a decade of experience in biopharma and biotech. Deb was most recently Director, Regulatory CMC at Nuevocor, a gene tx company developing novel treatments for genetic cardiomyopathies. There, she led CDMO selection and oversaw outsourcing of plasmid and viral vector manufacturing for Nuevocor's first GMP batch. She built a cross-disciplinary team to bring in-house expertise in AAV process development as well as analytical capabilities for preclinical, CMC and clinical product-specific assays. She further crafted the strategy for CMC leading to pre-IND and was lead author for the CMC section of the pre-IND.

Prior to this, Deb was a Principal Scientist at Tessa Therapeutics where she collaboratively led the development of bioanalytical methods (including genomic, cell-based, flow cytometry and ELISpot assays) for lot release, characterization, and biomarker studies of clinical-stage cell therapy products.

dchen@darkhorseconsultinggroup.com

Avi Chinthala, M.S.
SENIOR CONSULTANT

DHC BTL CC

Avinash (Avi) Chinthala is a Senior Consultant with BioTechLogic, bringing more than 12 years of experience in analytical development across gene therapy, cell therapy, and gene editing programs. He has deep technical expertise spanning AAV, mRNA, CAR-T modalities, vaccines, and protein-based therapeutics. Avinash has led the design, development, qualification, validation, and transfer of phys-chem, molecular, cell-based, and immunological analytical methods, with extensive experience working within CMC analytical teams under a Quality by Design (QbD) framework. He has supported clients in CRO/CDMO environments and is highly experienced in customer-facing roles. His background includes close collaboration with Process Development, MSAT, and Manufacturing teams, as well as authoring and contributing to deviations, investigations, OOS/OOT reports, and CAPAs within regulated QA systems.

achinthala@biotechlogic.com

Catherine Colandro
SENIOR CONSULTANT

DHC BTL CC

Catherine joined DHC in 2020, bringing experience in process development of cell and gene-modified cell therapy products and optimizing late-stage cell therapy processes for commercial readiness and launch.

Catherine's career started at Biogen, where she was involved in the transfer and monitoring of new molecules from clinical to commercial stages. She developed technical knowledge of upstream laboratory operations for several monoclonal antibody therapies and conducted process monitoring and experiments to assess process robustness and optimization. Catherine then joined Juno Therapeutics as a process engineer, where she made large scale process changes to the clinical CAR-T cell manufacturing processes. Her main focus was to optimize the cell therapy processes in order to increase operational efficiency to ensure successful delivery of the life-saving therapies to patients. Among other successes, she designed and executed multi-donor studies to support the processes changes and aided cGMP implementation and regulatory filings.

ccolandro@darkhorseconsultinggroup.com

Allyson Davidson, Ph.D.
SENIOR CONSULTANT

DHC BTL CC

Allyson joined DHC in 2018, bringing expertise and leadership in cryopreservation, cell enrichment, process design, and technology transfer. Allyson has been studying, inventing, and perfecting cryopreservation techniques for more than a decade. In addition, she has led teams and projects in process development, scale-up, validation, and tech transfer of cell therapies and clinical diagnostics.

With DHC clients, Allyson has particularly focused on quant modeling needs. In 2019, Allyson identified and began to address a significant need for a quantitative platform that could reduce risk by future-proofing CGT manufacturing facilities and COGs. She programmed such a platform from the ground up to support client needs; this program became the Pegasi offering DHC has today. Allyson is skilled in streamlining and optimizing process methods using DoE and statistical data analysis. Her expertise also includes the use of magnetic-activated cell sorting (MACS) for cell isolation and enrichment. Allyson's proficiency with cryopreservation techniques started in graduate school where she earned a Ph.D. in Chem E., achieving novel research on the optimization of cryoprotectant addition and removal procedures for vitrification of adherent mammalian cells.

allyson@darkhorseconsultinggroup.com

SUBJECT MATTER EXPERTS

Elizabeth Figueroa, Ph.D.
PRACTICE EXPERT

DHC BTL CC

Dr. Figueroa applies her expertise as it relates to non-viral gene therapy and immunotherapy process development and manufacturing. At DHC, she provides strategic support for clients working with gene-modified cell therapy and gene-editing therapy programs across all stages of development, with an emphasis on early stage programs (Phase I/II). She also brings experience in device development, in vitro diagnostic assay development, and reagent formulation, in addition to CDMO and vendor management, DOE, Risk Management, and root cause investigations.

Elizabeth began work in CGT in 2012 during her Bioengineering Ph.D. thesis project at Rice University. During this time, she worked with Bellicum Pharmaceuticals to apply her novel non-viral gold nanoparticle gene tx vector to gene-modified cell therapy applications such as CAR-T cell therapy and dendritic cell vaccines. She joined Ziopharm Oncology in 2019, where she led the team developing autologous CAR-T and TCR-T cell therapies for Phase I/II clinical trials. She guided tech transfers from R&D to internal and external manufacturing groups, and led the implementation of process improvements resulting in reduction of COGS and process duration, closed system and automation processing improvements, and frozen drug product development.

efigueroa@darkhorseconsultinggroup.com

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

DHC BTL CC

Prior to joining Dark Horse Consulting Group, Don provided 33+ years of uninterrupted service to the United States Federal government, first as a Pharmacology Research Associate Fellow at the National Institutes of Health followed by over 27 years at the FDA Center for Biologics Evaluation and Research (CBER). While at FDA/CBER, Don served as the CMC reviewer for over 100 files submitted by Sponsors that included INDs, IDEs, 510(k)s, BLAs and a PMA for products ranging from recombinant therapeutic proteins, biologic cellular therapies, and cellular combination products.

During his time at Dark Horse, Dr. Fink has worked on a myriad of client projects, successfully enabling clients to benefit from early engagement interactions with FDA as well as achieve their product development goals related to First-in-Human IND filings and biologics license application submissions. He finds it particularly gratifying when he can help clients find solutions to what may otherwise seem to be insoluble problems.

dfink@darkhorseconsultinggroup.com

Carrie Fitzgerald, CQA
PRACTICE EXPERT

DHC BTL CC

With DHC clients, Carrie finds that her expertise is in demand for supplier selection and approval, gap analysis, acting head of quality assurance, QMS development, contamination control strategy, GxP training, and nonclinical study site selection.

Carrie's first position after graduating from Cal Poly was at Prismedical Corporation, where she followed their first 510(k) cleared product through its entire lifecycle, from R&D to commercial scale manufacture at a contract manufacturer. During this same time, she received a US patent for a drug delivery device, was a co-author on a peer reviewed publication, assisted in the preparation and hosting functions for the company's first pre-market inspection, and then acted as the primary host for the subsequent FDA re-inspection for which there were no 483 observations issued. She then joined a clinical stage biotechnology company, XOMA Corporation, where she was responsible for ensuring GMP/GLP compliance throughout the company by effectively managing systems, projects and teams. From XOMA Carrie moved to Genentech, Inc., after which she came full circle and joined another medical device company, Cerus Corp.

cfitzgerald@darkhorseconsultinggroup.com

Ulpiano Flores
CONSULTANT

DHC BTL CC

Ulpiano Flores is a Consultant at Converge Consulting, where he brings expertise in pharmaceutical serialization, supply chain readiness, and quality systems, helping clients navigate complex regulatory compliance such as the Drug Supply Chain Security Act (DSCSA) and traceability initiatives. Ulpiano also supports cross-functional efforts including facility/process risk assessments, quality documentation, vendor management, tech transfer, and clinical supply chain systems. His background in chemical engineering enhances his ability to guide operational improvement and serialization implementation for emerging and established manufacturers. He regularly contributes thought leadership and perspectives on serialization trends and supply chain strategy for Converge Consulting. Prior to his current role, he built technical and analytical experience through diverse industry engagements and education at UCLA.

uflores@convergeconsulting.com

SUBJECT MATTER EXPERTS

Richard Grant
MASTER PRACTICE EXPERT

DHC BTL CC

Richard is a product development engineer and Program Manager with expertise in CGT in design and development of instruments, equipment, and single-use consumables. While consulting for Invetech he worked as a Program Manager, established their San Diego design house, and then became Global VP of Cell Tx. Invetech's client projects involved the specification, design, build, commissioning, testing and V+V of manufacturing systems (equipment and disposables) for both autologous and allogeneic therapies, designed to process a range of cell types to produce therapies for use in clinical trials and future clinical manufacturing. Projects resulted in functionally closed systems intended for the automation of unit process steps as well as complete mfg systems capable of full automation of the entire cell mfg process. Unit process solutions included cell selection, cell wash, volume reduction and recovery, electroporation, counterflow centrifugation, cell mixing/suspension, incubation, closed sampling for QC, formulation, and fill and finish. Systems processed a range of cell types: PBMCs, dendritic cells, pancreatic islet cells, CAR-T, hepatocytes, mesenchymal stem cells, vascular cells, retinal cells, erythrocytes, muscle cells, skin cells, and discogenic cells.

rgrant@darkhorseconsultinggroup.com

Ashley Gucinski, Ph.D.
EXPERT CONSULTANT

DHC BTL CC

Ashley supports clients in a variety of areas, with a focus on analytical, quality, and regulatory considerations. She provides expert advice for the development, qualification, and validation of analytical methods pertaining to biopharma analysis and CMC development under GxP guidelines. She also supports establishing specifications and their associated justifications, the generation of comparability plans and protocols, analytical method transfer and validation, and SOP generation, compliance, and biosimilarity demonstration. She has extensive experience in authoring and performing expert reviews of the Pharmaceutical Quality/CMC sections (Module 3) of the eCTD for regulatory submissions.

Before COUR and BioTechLogic, Ashley was a Research Chemist in the Office of Testing and Research at the US FDA. She has authored 20 peer-reviewed publications.

agucinski@biotechlogic.com

Rashi Gupta, MBA
PRACTICE MANAGER

DHC BTL CC

Rashi Gupta partners with life sciences and biopharmaceutical clients to support strategic operations, Enterprise Resource Planning (ERP) implementation, and supply chain transformation initiatives at Converge Consulting. Since joining Converge in 2021, Rashi has contributed to cross-functional projects that improve operational performance and help organizations scale effectively. She draws on a strong foundation in finance, audit, and management consulting — including prior roles at Deloitte and internship experience in global finance and teaching — to bring analytical rigor and business insight to client engagements. Rashi holds an MBA from Babson College and a Chartered Accountancy qualification from The Institute of Chartered Accountants of India, underpinned by a bachelor's degree in commerce. At Converge, she also contributes thought leadership on ERP and digital transformation topics, helping clients bridge technical implementation with business outcomes.

Rashi partners with life sciences and biopharmaceutical clients to support strategic operations, Enterprise Resource Planning (ERP) implementation, and supply chain transformation initiatives.

rgupta@convergeconsulting.com

Michael Hiles, Ph.D.
ENGAGEMENT PARTNER, PRODUCT DEVELOPMENT & MFG

DHC BTL CC

Mike has more than 30 years of experience discovering, developing, and delivering tissue-engineered medical products to patients worldwide, and his engineering teams developed more than 50 products that were launched in the US and other territories. He has extensive knowledge in preclinical testing and model development, and understands design controls, verifications, and validations quite well. Mike has also been dedicated to continuous improvement, processing efficiency, and design for manufacturing to reduce costs. He is an inventor on more than 50 US patents, and he has a keen sense for what should be patented versus kept as a trade secret. Business Development, partnering, and strategic vision, focusing especially on the patients, round out some of Mike's many strengths. Mike was a founder and long-term builder of Cook Biotech and was its Senior Vice President and CSO when the company was purchased in 2024. Mike is a Purdue Boilermaker through and through by earning his BS and MS in electrical engineering and his PhD in veterinary physiology, pharmacology, and basic medical sciences.

rollingmike@gmail.com

SUBJECT MATTER EXPERTS

Eric Humes, RQAP-GLP
SENIOR PRACTICE EXPERT

DHC BTL CC

Eric Humes is a Quality Assurance executive with more than 32 years of experience spanning biopharmaceutical sponsors, CROs, and independent consulting. His expertise encompasses GLP, GCP, cGMP, and pharmacovigilance systems, with a proven record of establishing and optimizing Quality Management Systems (QMS) that withstand global regulatory scrutiny. He has supported and led inspection readiness and management activities across FDA, EMA, MHRA, PMDA, and ANVISA, and has been directly involved in nine successful marketing applications across oncology, orphan/rare disease, cardiovascular, and biosimilar therapies.

Additionally, Eric has guided organizations through every stage of the product lifecycle. He has held C-suite and senior leadership positions at Agenus, Medpace, ICON, and Bioanalytical Systems, where he built and led Quality organizations that supported biologics, cell and gene therapy, vaccines, and small molecules. His leadership has been instrumental in enabling nine successful marketing applications across diverse therapeutic areas, including oncology and rare diseases.

ehumes@darkhorseconsultinggroup.com

Mile Iliev, MBA
SENIOR CONSULTANT

DHC BTL CC

Mile Iliev is a Senior Consultant at Converge Consulting, where he leads supply chain, logistics, global trade compliance, and strategic advisory services for life sciences and biopharmaceutical clients. With more than a decade of experience in management consulting and operational strategy, Mile helps emerging and established organizations navigate complex supply chain challenges, optimize logistics performance, and build resilient global operations. He provides engagement management for biopharmaceutical supply chain and logistics initiatives, combining data analytics, project management, and financial insights to drive strategic outcomes. Prior to his senior roles at Converge, Mile held positions in business analysis and consulting, and earlier roles spanning business development and strategic market research. He holds an MBA from Babson College and a bachelor's degree in International Economy and Business, and brings cross-cultural communication skills, including proficiency in Spanish, Serbo-Croatian, and Bulgarian.

miliev@convergeconsulting.com

Philip Lavin, Ph.D., FASA, FRAPS
ENGAGEMENT PARTNER, BIOSTATISTICS & REGULATORY, CLINICAL, COMMERCIAL STRATEGY

DHC BTL CC

Phil has 40 years of experience serving as an expert consultant with core expertise in biostatistics (all aspects of study design and analyses inclusive of endpoint construction/validation, sample size calculation, modeling (prognostic, predictive), randomization designs, interim monitoring, bayesian modeling, adaptive designs, meta analyses, survival analyses, longitudinal models, iDMC service), regulatory affairs (21 CFR 312, 21 CFR 812, 505(b)(1-2), PAS, generics, biosimilars), agency representation (FDA, CMS, EMA), strategic consulting (program planning, creative solutions), investor decision making, legal support (research, depositions, testimony); lead biostatistician for 80 NDA, BLA, GRAS, PMA, de novo, and HDE approvals/clearances; served on multiple FDA panels since 1983 as a Special Government Employee through 2015, he was first person to be an elected Fellow of the American Statistical Association and Regulatory Affairs Professional Society. Phil is a graduate of the University of Rochester (AB, Math), and Brown University (PhD, Applied Mathematics).

phil_lavin@hotmail.com

Wendy Liang
SENIOR CONSULTANT

DHC BTL CC

Wendy joined DHC in 2021 with a background in process/platform design and optimization of T-cell therapies for Phase I and pivotal phase manufacturing. In support of DHC clients, Wendy has been particularly focused on regulatory writing, technical gap analyses, CDMO selection, and tech transfers. When supporting regulatory writing for clients, Wendy excels at coming up to speed on their processes, identifying gaps in documentation, and generating polished, concise, and accurate content to support their communications with regulatory bodies.

Wendy's immunology career started at the Louis Picker Lab, supporting HIV vaccine research and their flow cytometry core. Wendy joined Juno Therapeutics (now Bristol Myers Squibb) in 2016. She spent her time there focusing on process development of CAR-T and TCR-based cell therapies, most recently leading process development for a TCR-based cell tx. She was responsible for delivering a novel and robust platform process that incorporated new technologies, reagents, and process targets through the design and execution of statistically-powered multi-donor studies. Wendy also has extensive experience authoring process development plans, batch records, and reports in support of process transfer to cGMP manufacturing.

wliang@darkhorseconsultinggroup.com

Daniel Lourenco, MRes.
SENIOR CONSULTANT
DHC BTL CC

Daniel joined DHC in 2025, bringing CMC expertise in early- and late-stage gene therapy. His experience spans process & analytical development, tech transfer, comparability, regulatory authorship, and project leadership.

Before joining DHC, Daniel spent several years at AviadoBio, where he primarily led the CMC strategy for the company's lead AAV program, AVB-101. Over increasing positions, he executed broad CMC development, comparability planning, clinical trial supply, COGs modeling, and commercialization readiness activities. During his time there, he also led the development of a novel medical device designed for spinal delivery of gene therapies.

In 2019, Daniel joined the CMC-MSAT team at MeiraGTx and was pivotal in establishing the initial downscale manufacturing process and subsequent tech transfer of their AAV assets into GMP. To support an expanding pipeline, Daniel's focus then turned to process intensification, COGs optimization and improving operational efficiencies.

Daniel's career began in 2016 at Pall Corporation where he supported the development of novel bioprocessing technologies, as well as the adaptation of modality-agnostic equipment to the emerging needs of CGT.

dlourenco@darkhorseconsultinggroup.com

Ashley Manfredini
CONSULTANT
DHC BTL CC

Ashley began her career in the flavor industry in 2017, where she built a strong foundation in GMP, GLP, and GDP. In 2021, she joined GxP Quality Services as a QA Specialist, implementing early-phase electronic quality management systems. Ashley then advanced her expertise at Blistex Inc., working within the OTC and cosmetics industry as part of the Quality Assurance and Regulatory Affairs team. With a solid background in cGMP, GDP, and GxP compliance, she specializes in implementing and managing Quality Management Systems (QMS) and document change control processes. Her experience ensures adherence to FDA regulations and industry standards, helping organizations maintain the highest levels of quality and compliance. Ashley holds a Bachelor of Science in Nutrition & Dietetics with a minor in Chemistry.

amanfredini@biotechlogic.com

Rebecca Marshall, M.S., MBA
ENGAGEMENT PARTNER, STRATEGIC PLANNING & MARKET DEVELOPMENT
DHC BTL CC

Rebecca is a well-rounded executive with significant general management experience as well as specific experience identifying business opportunities, developing strategies, managing business relationships, and driving results. She has held leadership roles in start-up companies, high-growth companies, and publicly traded companies in the Orthopaedics and Regenerative Medicine space. Her ability to think strategically and tactically, to solve problems, and to assess the landscape from both a business and a technical perspective, has enabled her to assist clients with a wide range of projects. Rebecca is a graduate of the University of Florida (BS, MS, MBA).

rebecca@bruderconsulting.com

Jake Mason
CONSULTANT
DHC BTL CC

Jake D. Mason is a Consultant at Converge Consulting, where he leverages deep expertise in life sciences clinical systems, technology integration, and operational performance to support biopharmaceutical and biotechnology clients. With a strong foundation in clinical systems management and strategy, Jake partners with cross-functional teams to optimize clinical operations, improve data and technology workflows, and align enterprise systems with business and regulatory needs. He combines technical acumen with practical implementation experience to help clients enhance clinical development processes and system readiness. Jake holds a degree from California State University-Fresno and is based in the Hayward, California area. At Converge, he contributes to engagements that bridge clinical insight and execution, supporting enhanced performance and scalability for life sciences organizations navigating complex clinical systems landscapes.

jmason@convergeconsulting.com

Brittany McConnell
CONSULTANT
DHC BTL CC

Brittany joined BioTechLogic in 2022 after positions at Neurogene and Novartis Gene Therapy Technologies. At Neurogene, she served in a quality and program support position. She worked as a bioprocess engineer for Novartis, focusing on cell expansion and upstream processing, and was extensively involved in QC sample mgmt, compliance doc review, and PM.

For BTL, Brittany provides PM and manufacturing support for clients with CGT products, as well as consulting services in all areas of technical operations, including commercial drug substance and drug product manufacture, process development and validation, preparation of technical reports, batch records, SOPs, and other supporting documents. She will also conduct remediation projects to enhance compliance for manufacturing processes, including gap assessments, risk assessments for manufacturing processes regarding product quality/stability/aggregate generation, and implementation of corresponding corrective and preventive actions. Brittany has numerous areas of training, including 21 CFR Part 11, clean room systems, clinical trial overview, and engineering design best practices.

bmcconnell@biotechlogic.com

Michael Nest, M.S.
PRACTICE MANAGER
DHC BTL CC

Michael Nest is a Senior Clinical Supply Consultant at Converge Consulting, where he brings deep expertise in clinical supply operations and strategic execution for life sciences clients. At Converge, Mike focuses on optimizing clinical supply chain agility, risk management, and end-to-end planning to ensure investigational and clinical therapies reach patients reliably and efficiently. He regularly contributes thought leadership on clinical supply challenges — including agility and digital transformation in supply networks — and has been featured presenting and authoring industry insights on these topics. Prior to Converge, he held senior roles such as global head of clinical supply chain at Blueprint Medicines, where he led cross-functional teams to streamline global clinical operations. In his consulting role, Mike partners with biotech and pharmaceutical organizations to navigate complex clinical supply environments and implement effective, data-driven solutions across programs and therapeutic modalities.

Michael focuses on optimizing clinical supply chain agility, risk management, and end-to-end planning to ensure investigational and clinical therapies reach patients reliably and efficiently.

mnest@convergeconsulting.com

Sean O'Farrell, Ph.D.
SENIOR CONSULTANT
DHC BTL CC

Sean joined DHC in 2021, after working in both R&D and Process Development teams at GammaDelta Therapeutics. His primary areas of expertise include immunobiology, bridging cell therapy production processes from research to CMC, and nonclinical development of CGT. Sean has supported DHC clients on a range of projects areas including nonclinical study design and oversight, comparability strategy, process and analytical development. He has also provided expertise to a number of investment firms during the due diligence process of promising CGT assets. Sean brings experience in training staff on end-to-end cell tx production processes, DoE design, execution and analysis, and scientific presentation cell therapy process research and development, assay development and nonclinical strategy.

Sean started out in the lab of Adrian Hayday, where he undertook his Ph.D. and post-doctoral training. He joined GammaDelta Therapeutics in 2018, where his primary role was to aid the development of a GMP-friendly bioprocesses for a series of γδ T cell drug product candidates. Among other successes, Sean led efforts utilizing design of experiment (DoE) approaches to safeguard product yield and quality.

sofarrell@darkhorseconsultinggroup.com

Zach Ogorzalek, MBA
CONSULTANT
DHC BTL CC

Zach Ogorzalek is a Consultant at Converge Consulting, where he supports strategic supply chain and logistics operations for clients in the life sciences sector. He draws on strong analytical skills and a foundation in supply chain management to help optimize distribution processes, improve operational workflows, and enhance visibility across complex client engagements. Zach is currently completing his academic studies with a focus on supply chain management and marketing analytics, which complements his work in data-driven problem solving and logistics coordination. Prior to joining Converge, he developed practical experience in logistics and business enablement roles that strengthened his ability to work with cross-functional teams and support client deliverables. At Converge, Zach contributes to projects that streamline supply chain performance and drive measurable outcomes for growing biopharmaceutical and healthcare organizations.

zorgorzalek@convergeconsulting.com

SUBJECT MATTER EXPERTS

Ashutosh Pandit, MBA
PRACTICE MANAGER
DHC BTL CC

Ashutosh "Ash" Pandit is a Senior Consultant at Converge Consulting, where he applies strategic and operational expertise to support life sciences and biopharmaceutical organizations. With over a decade of experience spanning management consulting, operations, finance, and CMC advisory, Ash partners with emerging and established biopharma clients to tackle complex challenges and deliver impactful solutions. He has led cross-functional initiatives that improve operational excellence, strengthen quality systems, and bridge gaps between finance, program management, and technical execution. Ash is recognized for his ability to translate data-driven insights into actionable strategies and has contributed thought leadership on critical industry topics through articles and case studies. His broad background includes both global and client-facing roles that enhance business performance and drive growth within the life sciences sector.

apandit@convergeconsulting.com

Madison Pope
ANALYST
DHC BTL CC

A molecular biologist by training, Madison studied mechanisms of genetic recombination, DNA damage repair, and genome engineering in a lab at the University of Miami Miller School of Medicine. Through her research project exploring the genetics of the radiation-resistant bacterium Deinococcus radiodurans, she gained hands-on experience in molecular cloning, plasmid design and application, and bacterial genetics by building a library of recombinant DNA constructs using non-viral mobile genetic elements. Madison immersed herself in the CGT landscape during her 2+ total years as a DHC intern, gaining comprehensive exposure to manufacturing, analytical, and regulatory aspects of viral and non-viral gene therapies before joining as a full-time Analyst in September of 2025.

mpope@darkhorseconsultinggroup.com

Sabtari Sabir
CLINICAL SUPPLY CHAIN CONSULTANT
DHC BTL CC

Sabtari "Sab" Sabir is a Clinical Supply Chain Consultant where she supports strategic supply chain and operations initiatives for clients across biopharma industries. Sab brings a strong foundation in supply chain management, logistics, and data-driven problem solving, built through academic preparation and real-world experience. At Converge, Sab applies analytical skills to help optimize business processes, enhance supply chain visibility, and contribute to client success in consulting engagements. Prior to her current role, she gained practical experience through logistics and business enablement co-ops, further developing capabilities in cross-functional collaboration and operational insight. Sab is passionate about continuous learning and applying innovative solutions to complex supply chain challenges.

ssabir@convergeconsulting.com

Tal Salz, Ph.D.
SENIOR PRACTICE EXPERT
DHC BTL CC

Dr. Salz came to Dark Horse after 6 years working for the FDA, during which she honed her regulatory experience in reviewing the CMC information supporting development of CGT(CBER/OTAT). Before that, she spent 7+ years working in cellular & molecular biology, genomics, epigenetic, immunology, and virology. With DHC clients, Tal has focused primarily on CMC Regulatory authorship and review for FDA as well as other global regulatory bodies.

Tal's doctoral and post-doctoral research was interdisciplinary, with a focus on genomic and epigenetics. Tal began her FDA regulatory career as a Commissioner's Fellow in CBER, where she was a cell therapy product reviewer in the Cell Therapy Branch and led a regulatory project which focused on product comparability. Dr. Salz then joined the Gene Therapy Branch as a gene therapy product reviewer. She has experience with allogeneic and autologous genetically modified cell products such as CAR T cells, CAR NK cells, T cell receptor (TCR)-modified T cells, genetically modified Induced Pluripotent Stem Cells (iPSCs) and CD34 cells, and genome editing products. She also has experience with reviewing and advising on various regulatory submissions including INTERACTs, pre-INDs, INDs, BLAs, supplements, and designation requests.

tsalz@darkhorseconsultinggroup.com

SUBJECT MATTER EXPERTS

Nicola Selley
ENGAGEMENT PARTNER, REGULATORY AFFAIRS STRATEGY & SUBMISSIONS
DHC BTL CC

Nicola draws on a foundation of experience serving 21 years in regulatory affairs leadership roles with Allergan and Johnson & Johnson medical device companies. She has been instrumental in obtaining PMA product approvals and 510(k) clearances for a diverse number of products, including devices used in plastic and reconstructive surgery, dermatology, gastroenterology, cardiology, and ophthalmology. Nicola brings significant expertise in defining regulatory pathways, determining regulatory strategies, and executing successful regulatory submissions to gain product approvals.

nicola@bruderconsulting.com

Uzma Shoukat-Mumtaz, PMP
SENIOR CONSULTANT
DHC BTL CC

Uzma joined DHC in 2019, with expertise in process dev, tech transfer, and GMP manufacturing of CGT products, including pluripotent stem cells. Uzma recently passed the PMP exam and earned her PMP® certification.

Uzma specializes in helping clients in many areas of CMC. She has written regulatory documentation for multiple jurisdictions, performed risk assessments and due diligence activities, and been a primary tech writer for clients requiring support in drafting reports, SOPs, and batch records. She has built a QMS from scratch, conducted VoC surveys and market research analysis, led tech transfers and training activities, been a PiP, and has assisted clients with their CDMO selection. Uzma built and maintains the ever-growing DHC CDMO database.

Uzma's started at Geron, where she was responsible for mfg hESC derived cell therapies in a cGMP setting. She later moved on to research roles at iPierian and Cellogy, where she developed hands-on expertise in cell line dev, stem cell differentiation, and cell banking.

uzma@darkhorseconsultinggroup.com

Steve Sinclair
CONSULTANT
DHC BTL CC

Experienced clinical supply chain professional with a strong track record in managing end-to-end supply, labeling, packaging, and distribution operations for clinical trial materials. Skilled in Interactive Response Technology (IRT), regulatory compliance, and cross-functional collaboration to ensure clinical supplies are delivered accurately and on time across global studies. Adept at forecasting demand, optimizing operational processes, and supporting clinical teams and external partners to advance trial execution. Known for driving efficiencies, maintaining high quality standards, and navigating complex logistics in regulated environments. Passionate about solving supply chain challenges that directly impact patient outcomes and clinical success. Always looking for opportunities to leverage data-driven insights and industry best practices to improve clinical supply strategies and operational performance.

ssinclair@convergeconsulting.com

John Stroncek, Ph.D.
SENIOR CONSULTANT
DHC BTL CC

John is a regulatory and product development leader with over 15 years of experience building and assessing novel implantable devices and surgical systems from concept to clinical use and market entry. Dr. Stroncek's work with DHC clients focuses on bridging the gap between innovative engineering and Agency expectations to help clients anticipate and mitigate regulatory hurdles. John's expertise allows him to incorporate cross-functional insight —spanning R&D, Clinical, Quality, and Regulatory—to ensure the delivery of high-quality, safe, and effective products.

Prior to joining Dark Horse, John served as a Lead Reviewer at the FDA's Office of Orthopedic Devices. During his tenure at the Agency, he was the primary reviewer and sponsor-facing point of contact for more than 100 regulatory submissions, including pre-submissions, 510(k)s, IDEs, and panel-track PMA supplements. His tenure at the FDA was defined by his ability to coordinate multidisciplinary teams of statisticians, clinicians, veterinarians, and engineers to drive clear regulatory decisions.

jstroncek@darkhorseconsultinggroup.com

SUBJECT MATTER EXPERTS

Gauri Tawde
SENIOR CONSULTANT
DHC BTL CC

Gauri Tawde is a results-oriented management consultant specializing in leading global strategy and business transformation engagements with a focus on supply chain and operations within the Life Sciences domain, adept at leveraging data-driven insights to shape and influence strategic decision-making. At Converge, Gauri partners with cross-functional teams to drive alignment across critical functions, support program delivery, and contribute to high-impact projects across the firm's full service portfolio. She brings a strong analytical mindset and a pragmatic approach to problem solving, helping clients bridge gaps between technical, operational, and financial perspectives in complex environments. Gauri's consulting work emphasizes clear communication, process improvement, and informed decision-making to enhance organizational effectiveness and client outcomes. She is committed to advancing best-in-class practices that support sustainable growth and operational excellence for emerging and established life sciences companies. A certified Lean Six Sigma Black Belt, she is committed to driving operational excellence and enterprise-wide efficiency through continuous improvement and innovation.

gtawde@convergeconsulting.com

Lyndsey Treacher
SENIOR CONSULTANT
DHC BTL CC

Lyndsey joined DHC in 2021, bringing expertise in small- and medium-sized biotech with a focus on QA, computer system validation, and implementation. For DHC clients, Lyndsey has performed not only QA projects but training and PM as well. Her experience with GMP- and GCP-compliant computer systems supports QA and QC projects from the ground up. Her experience has provided particular insight into the challenges that younger companies experience when setting up compliant computer systems and validation.

Lyndsey started at Circassia where she gained important experience in the different GxPs. She was the system owner for the eDMS and involved in the generation and management of many document types, incl. SOPs, Issues, CAPAs, Protocols, and Reports. During this time she gained auditing experience and an IRCA auditing qualification. Lyndsey then moved into a computer system-focused role within the company where she was the implementation lead on an eQMS system consisting of Complaints, CAPA/Non-conformance and Change Control processes that covered pharmaceuticals, medical devices and combination products.

ltreacher@darkhorseconsultinggroup.com

Melissa Triggiano, M.S.
SENIOR CONSULTANT
DHC BTL CC

Melissa's career started in a T cell immunology research lab at Duke, where she developed comprehensive immune profiling assays utilizing polychromatic flow cytometry and cytokine multiplexing to identify signatures in a variety of clinical indications including cancer, pulmonary disease, and solid organ transplants pre- and post-treatment. Additionally, she worked closely with the School of Engineering to design and perform novel single cell immune assays and magnetic labeling for lab-on-chip applications.

Melissa then joined Precision BioSciences where she was responsible for leading a team of researchers within the Cell Tx CMC Analytical group. She served as the technical SME in bioassay and flow cytometry method dev for Precision's ARCUS gene-edited allogeneic CAR-T cell therapy programs, including PBCAR0191, PBCAR20A, PBCAR269A, and PBCAR19B.

At DHC, Melissa has particularly enjoyed providing process and analytical dev guidance and solutions for early and late-stage developers of gene-edited cell tx products.

mtriggiano@darkhorseconsultinggroup.com

Haleigh Wetzel
SENIOR CONSULTANT
DHC BTL CC

Haleigh first joined BioTechLogic as an intern while completing her degree at the University of Rochester. She returned to BTL after acquiring quality and process improvement, protocol management and development, quality control review, and project plan management experience through her positions with Astellas Pharmaceuticals, ECOG-ACRIN, and the TIMI Study Group. Haleigh has completed numerous training areas, including Collaborative Institutional Training Initiative (CITI) GCP course completion and certification in Clinical Trials with Investigational Drugs and Biologics. Additionally, she has completed Introduction to Biologic Drug Development and CMC Regulatory Parts 1 and 2.

As a QA Consultant, Haleigh provides quality assurance and quality systems consultancy for start-up peptide and biologic companies as well as FDA remediation projects, implements and manages electronic Document Management System programs (e.g., ZenQMS and VEEVA), manages personnel training and onboarding, performs traditional document control functions, including SOP drafting, routing in eDMS, approval, and training, manages audits, including reports and observations, manages enrollment forms and ensures qualifications are complete.

hwetzel@biotechlogic.com

SUBJECT MATTER EXPERTS

Malachi Wickman, M.S.
SENIOR CONSULTANT
DHC BTL CC

Malachi joined DHC in 2021, bringing experience in the Biotechnology industry, primarily focused on raw material supply and project management for cell therapy research and clinical trials.

In working on DHC projects, Malachi finds that her project management lens provides utility for a range of CGT manufacturing and development clients. Her commonly requested projects vary from helping clients enhance and streamline their operations to developing regulatory submissions to monitoring manufacturing at a CDMO, and to identifying whether a facility build-out is on track...and if not, how to remediate the situation.

Malachi spent her pre-DHC years as a member of the CGT Solutions team at the American Red Cross. During her time there, she advanced to be a Director of Client Relationship Management, overseeing raw material supply for and management of 10+ clients in the allogeneic cell and gene therapy industry in both research and clinical trial stages. Malachi aided the product development and healthy donor apheresis program growth as a result of both her work with clients and internal collaboration.

mwickman@darkhorseconsultinggroup.com

Conan Young, Ph.D.
ENGAGEMENT PARTNER, PRECLINICAL & PRODUCT DEVELOPMENT
DHC BTL CC

Conan has over 20 years of experience as an R&D leader serving the biopharmaceutical and medical device industry driving the non-clinical, manufacturing and technical development and commercialization of advanced biologics, implantable medical devices and combination products. Prior to supporting BCVG, Conan was Vice President, R&D at Wright Medical (now Stryker) leading recombinant PDGF-BB product development strategy, quality control and drug substance manufacturing to treat orthopedic indications. Previously, he served as Director, Research at MiMedx leading non-clinical development of amniotic tissue allograft for dermal wound, surgical and orthopedic indications. Conan spent 5 years serving as Director, R&D at Shire Pharmaceuticals (previously Advanced BioHealing) leading non-clinical development and manufacturing tech transfer of human allogeneic cell therapies for dermal wound care and vascular repair. He holds a Ph.D.(Microbiology) from the University of British Columbia, a MSc. (Microbial Biotechnology) from the University of Waterloo, and a B.Sc. (Cellular, Molecular and Microbial Biology) from the University of Calgary.

conan@bruderconsulting.com

Amy Zhang, M.S.
SENIOR CONSULTANT
DHC BTL CC

Amy brings over a decade of experience in the biotech and medical device industries, driving strategy and execution across discovery, regulatory submissions, and clinical development. She has led cross-functional teams in advancing cell therapy, combination products, and biologics. Most recently, at Abbott Laboratories, Amy supported global regulatory compliance for vascular devices, translating clinical evidence into regulatory submissions and responses. Prior to Abbott, she managed early-stage programs at biotech startups including Viridian Therapeutics and Sigilon Therapeutics, advancing monoclonal antibody and cell therapy assets for rare and autoimmune diseases. Amy holds a Master's in Medical Sciences from Boston University and a Bachelor's in Biology from Indiana University.

amy@bruderconsulting.com

MEET OUR BUSINESS DEVELOPMENT TEAM

Oliver Ball, MSc.
DIRECTOR,
BUSINESS DEVELOPMENT

Oliver's blend of analytical and operations skills were honed specifically in the advanced therapy sector. Having worked as a consultant and a BD manager, Oliver brings a deep understanding of industry characteristics and dynamics. Oliver's aim is to ensure that all clients have an outstanding experience while maximizing their opportunities to benefit from our value proposition. Oliver has a differentiated educational background and professional profile, having focused on the advanced therapy space since writing his undergraduate thesis on iPSC technology. Following up with a unique Master's degree entitled *Cellular Therapy from Bench to Market* at King's College London, Oliver went on to make an impact as a graduate by authoring the Advanced Therapies Investment Report 2017, which was widely circulated and referenced at the time. Oliver went on to publish several more papers in the space with a range of co-authors, publishing in *Cytotherapy* and *Cell & Gene Therapy Insights*.

oball@darkhorseconsultinggroup.com / 408.326.0303 x221

Eric Edwards, M.S., MBA
DIRECTOR,
MARKETING &
COMMUNICATIONS

Eric is a tenured marketing professional with a strong blend of business acumen and technical expertise, specializing in the CGT space. He has built a career at the intersection of science and strategy, translating complex concepts into clear, compelling narratives that drive engagement in support of commercial objectives. Eric brings a thoughtful, data-driven approach to shaping go-to-market strategies and advancing the missions of companies working to bring transformative therapies to patients. Upon completing a master's in biochemistry and a STEM-focused MBA, Eric began his career at a startup pioneering the development of animal-component-free cell culture media leveraging rice-derived recombinant human blood proteins. He later worked at Thermo Fisher Scientific and Cellares, at which he led the company's marketing efforts.

eedwards@darkhorseconsultinggroup.com / 408.326.0303 Ext. 343

Alex Gibb
DIRECTOR,
BUSINESS DEVELOPMENT

Alex first joined BioTechLogic in 2013 as a Senior Consultant in analytical sciences, having previously held technical positions at Novartis and Amgen. He left to pursue an analytical position at CSL Seqirus before eventually transitioning his career toward business development at KBI Biopharma and Resilience. In 2023, Alex returned to BioTechLogic as the Director of Business Development. He applies his analytical science experience and business development expertise to help biopharmaceutical developers, including gene and cell therapy organizations, advance their therapeutics to market faster. He is dedicated to assisting biotechnology companies in transforming innovative and lifesaving therapies from ideas to marketable products through his expertise in life sciences, bioprocess development, and vaccine manufacturing.

agibb@darkhorseconsultinggroup.com / 303.775.9264

Rachel Luarte
SENIOR MANAGER,
BUSINESS OPERATIONS

Rachel has one of the longest tenures of anyone at Dark Horse Consulting Group, having joined DHC in September 2019 as then Administrative Coordinator in the Office of the CEO. She comes, atypically, from a liberal arts background, with a degree in logic, philosophy, and classics and an emphasis on theoretical math. She joined DHC's then-fledgling BD team in 2022 as Business Operations Specialist and now acts as Manager of Business Operations, managing both DHC's and BTL's book of clients to ensure operational excellence, practice-wide allocation of appropriate resources, and client satisfaction. To quote Rachel on working with the DHC Group, "Everyone is given the opportunity to contribute, applying themselves to the best of their ability and experience. The results of such an environment speak for themselves."

rachel@darkhorseconsultinggroup.com / 408.326.0303 x207

Sanjin Zvonić, Ph.D.
SVP,
BUSINESS DEVELOPMENT

Dr. Zvonić is a cell and molecular biologist with a strong technical/scientific background in physiology, stem cell biology, and cell therapy CMC. In his current role at DHC, Sanjin is focused on strategic growth and development of the BD function, client engagement, and pipeline growth, while continuing to leverage his technical background as a Practice Expert on select projects.

After earning his Doctorate in Cell and Molecular Biology, Sanjin continued on to a post-doctoral position at the Pennington Biomedical Research Center where he contributed to the development of methodologies for the isolation and culture of human adipose stem cells (ASC) from several sources and later utilized ASCs to develop a human *in vitro* model for circadian biology studies.

Turn to page 4 to read more about Sanjin.

szvonic@darkhorseconsultinggroup.com / 408.680.2527