

Regulatory Strategy

Bio Book



At Syner-G, we are committed to helping our partners navigate complexity and move their programs forward with clarity and confidence.

As the life sciences landscape continues to evolve, the path from early development to approval has become increasingly complex. Regulatory strategy is no longer a step in the process. It is the foundation that aligns clinical development, CMC, and commercialization into a cohesive plan that drives progress and reduces risk.

Our team of experienced regulatory, clinical, and CMC leaders works alongside your organization to bring structure to that complexity. We focus on creating clear, actionable strategies that support informed decision making, align stakeholders, and position programs for long-term success. From early-stage planning through late-stage development, our approach ensures that each step is intentional and aligned to your ultimate goals.

We support our clients with integrated regulatory strategy, clinical development planning, and execution support, providing the depth of expertise needed to guide programs from concept through commercialization. This holistic approach enables tailored solutions that are both practical and effective in real-world environments.

In a landscape often shaped by large firms and rigid models, Syner-G brings a flexible, biotech-focused approach grounded in experience across Regulatory, R&D, and CMC. Our team understands the realities our clients face and works to deliver solutions that are aligned, efficient, and built to adapt as programs evolve.

We are proud to serve as a trusted partner to organizations advancing innovative therapies and improving patient outcomes. This team represents the expertise and commitment behind that work.

Thank you for your continued trust.

Sincerely,



Ron Kraus
Chief Executive Officer



Christine Norman-Tiner

SVP, Regulatory Consulting

Christine works closely with executive teams, investors, and cross-functional stakeholders to translate complex data into clear, actionable direction.



Christine brings more than 25 years of experience guiding complex clinical and drug development programs across biologics, small molecules, medical devices, and advanced therapies. She is a trusted regulatory leader known for shaping global strategies that enable organizations to move efficiently from early development through approval.

When organizations are navigating high-stakes regulatory decisions, they turn to Christine for clarity, structure, and forward momentum. Her expertise spans the full development lifecycle, including early-stage strategy, IND-enabling work, global regulatory submissions, and health authority engagement. She has led regulatory strategy across a wide range of pathways, including IND, NDA, BLA, IDE, and expedited programs such as RMAT, Breakthrough Therapy, and Orphan Drug designations.

At Syner-G, Christine partners with life sciences companies to build integrated regulatory strategies that align clinical, nonclinical, and CMC development into a cohesive plan. Her approach ensures that programs are not only scientifically sound, but also positioned for efficient execution and regulatory success. She works closely with executive teams, investors, and cross-functional stakeholders to translate complex data into clear, actionable direction.

Christine has deep experience leading interactions with global health authorities, including the FDA, EMA, and MHRA. She is highly skilled in preparing organizations for critical regulatory milestones, from pre-IND through late-stage submissions, while ensuring alignment across internal teams and external partners. Her ability to interpret complex data packages and guide strategic decision making has made her a valued advisor across a wide range of therapeutic areas, including cell and gene therapy and rare disease.

Prior to joining Syner-G, Christine held senior leadership roles across regulatory strategy and clinical development, where she built and scaled regulatory functions, supported global programs, and led cross-functional teams through critical development milestones. Her experience spans both emerging biotech and established organizations, giving her a practical understanding of how to tailor strategy to each client's stage and goals.

Christine holds a Master of Science in Chemistry from the University of Maryland and a Bachelor of Science in Chemistry and Physics from the University of Houston. She also completed advanced training at Baylor College of Medicine.

25+ years

of experience guiding complex clinical and drug development programs across biologics, small molecules, medical devices, and advanced therapies.

Expertise

in the full development lifecycle, including early-stage strategy, IND-enabling work, global regulatory submissions, and health authority engagement.

Velvizhi Heine, PhD, RAC

VP, Regulatory CMC

Velvizhi's successful project management leadership results in meeting the client's objectives.



Velvizhi Heine, Ph.D., joined Syner-G in 2016 and is a highly accomplished biopharmaceutical professional with over 24 years of experience in technical development and Regulatory CMC across biologics and small-molecule programs. She has extensive expertise spanning product development, analytical method development and validation, quality control, and Regulatory CMC. Her core Regulatory CMC expertise includes regulatory strategy development, change control impact assessments, analytical control strategies, lifecycle CMC maintenance, and global CMC submission planning and execution.

She has authored and reviewed CMC sections for global regulatory submissions, including INDs, IMPDs, BLAs, MAAs, and post-approval variations, and has supported interactions with health authorities across the United States, Europe, Canada, Japan, China, Latin America, and APAC regions. She has a proven track record of delivering high-quality, on time CMC regulatory submissions for both large biopharmaceutical companies and emerging biotechnology companies.

She is known for fostering strong collaboration and clear, effective communication to drive successful outcomes. She leads a team of Regulatory CMC professionals supporting a broad portfolio of pharmaceutical products from early development through commercialization. Velvizhi has led teams of Regulatory CMC experts to the timely and successful completion of more than 500 regulatory submissions across diverse products. Her project management leadership consistently enables clients to meet critical regulatory and development objectives, supporting the delivery of innovative therapies for the treatment of cancer, infectious diseases, and rare diseases.

Prior to joining Syner-G, Velvizhi held positions at Biogen and Illumina, where she contributed to the development of multiple therapeutic products. She holds a Ph.D. in Biochemistry and Cancer Biology and completed postdoctoral training at the Harvard Institutes of Medicine and Harvard Medical School in Boston. Earlier in her career, she conducted academic research in cancer biology, with her work published in several peer-reviewed scientific journals.

24+ years

of experience supporting early- to late-stage drug development programs through commercialization, with expertise in biologics, including advanced and complex therapies.

Expertise

in Regulatory CMC strategy and global submissions, spanning IND to BLA and post-approval lifecycle management, including technical development and direct engagement with global health authorities to support successful product approvals.

Jeff Golden

VP, Regulatory Operations

Jeff has played a crucial role in the successful filing of drug and biologic applications to the FDA, EMA, Health Canada, and Swissmedic.



Jeff Golden is a regulatory operations leader with more than 20 years of pharmaceutical industry experience in global regulatory information management, eCTD submissions, and electronic publishing systems. He provides strategic and operational guidance for regulatory submissions across Syner-G's pharmaceutical and biotech client base, overseeing the systems, processes, and teams that keep complex programs moving forward.

Under Jeff's leadership, Syner-G's Regulatory Operations function has supported more than 150 sponsors across a broad range of therapeutic areas. He has been instrumental in the successful filing of drug and biologic applications to the FDA, EMA, Health Canada, and Swissmedic, with experience spanning IND, NDA, BLA, CTA, MAA, NDS, and DMF application types across the US, Canada, UK, EU, Switzerland, and Australia. In addition to major marketing applications, Jeff has extensive experience preparing and publishing clinical study reports, briefing packages, and advisory meeting packages.

Jeff works directly with sponsors at all stages of development — from IND-enabling work through approval — helping organizations build submission-ready infrastructure, navigate agency requirements, and establish the internal processes needed to support long-term regulatory success. His client-facing approach combines deep technical knowledge with practical guidance, ensuring that sponsors of all sizes are equipped to execute with confidence.

Jeff's career in Regulatory Operations began at TAP Pharmaceuticals, where he served as a publisher on the company's first NDA submitted in eCTD format — Uloric® (febuxostat) for the treatment of gout. As TAP transitioned to Takeda Pharmaceuticals, Jeff took on expanding

responsibility in publishing and submission management, contributing to the successful approval of several of the company's priority programs, including Uloric®, Dexilant®, and the Alogliptin family of products. During his tenure at Takeda, Jeff's submission work extended well beyond US borders, encompassing new drug applications filed across the Americas, Europe, Asia, and Africa.

Jeff completed the Accelerator Leadership Development Program through Keystone Partners, focused on advancing executive leadership competencies in strategic thinking, organizational development, and cross-functional team performance. He holds a BS in Business Management from Elmhurst University.

20+ years

of experience in global regulatory information management and eCTD submissions

150+ sponsors

supported across a broad range of therapeutic areas

Kevin Swiss, PhD

Principal, Regulatory CMC

Kevin builds strong relationships with internal and external stakeholders focusing on team success and timely project completion.



Kevin Swiss, Ph.D., is an experienced pharmaceutical quality professional with 30 years of progressive experience in CMC regulatory, CMC development, and technical operations including analytical development, drug substance, and drug product manufacturing.

Kevin leads with a team-centric management style and has a strong history of leading small molecule CMC and CMC regulatory development projects from simple dosage form tablets and capsules, solutions and syrups, to complex dosage forms including inhalation, sterile injectables, topicals, and combination drug-devices. He builds strong relationships with internal and external stakeholders focusing on team success and timely project completion.

His expertise is in critical strategic thinking to avoid pitfalls in CMC phase-based development, complete response letter (CRL) mitigation, ICH and FDA guidelines, and CMC development. His main areas of expertise include CMC regulatory strategy in oral, inhalation, sterile injectables, topicals and combination drugs; CMC development of small molecules from idea to IND, including meetings with FDA, and ultimately NDA and approval. Kevin is a nitrosamine expert and has authored several nitrosamine risk-based analyses which includes drug substance manufacturing to drug product stability.

Kevin's previous experience includes US FDA, Kowa Research Institute, Nautilus Pharmaceuticals, Vitruvius Therapeutics, Pharmanet LLC, and Boehringer Ingelheim Pharmaceuticals. His undergraduate degree is from University of North Carolina Greensboro and holds graduate degrees from Princeton University and Emory University.

He has contributed to more than 30 successful IND submissions. He has led approval of several marketing applications (NDA or MAA) including QVAR, Tavist, Clarinex, Marqibo, Cambia, Livalo, and more than 10 ANDAs.

30+ years

of progressive experience in CMC regulatory, CMC development, and technical operations including analytical development, drug substance, and drug product manufacturing.

+30 successful IND submissions

Renee Boerner, PhD

Principal, Regulatory Affairs

Renee has served as a regulatory lead or significant contributor for the approval of four US commercial products.



Renee is a seasoned regulatory strategy consultant with more than 30 years of experience in the pharmaceutical and biotechnology industries. She is a highly regarded expert in Regulatory Affairs, CMC, and Quality, with a strong track record of success supporting investigational and marketing applications for small to mid-sized companies across multiple therapeutic areas, including oncology, central nervous system (CNS) disorders, and infectious diseases. She is particularly recognized for her ability to distill complex scientific and regulatory information into clear, concise, and actionable insights for diverse audiences.

She has served as a regulatory lead, primary FDA contact and key contributor to numerous INDs, IMPDs and marketing applications, including the approval of four U.S. commercial products (i.e., Jynneos® for the prevention of smallpox and Mpox). Renee has extensive experience leading and participating in regulatory agency interactions, including U.S. FDA and European authority meetings, and has collaborated with global partners to secure product approvals in Europe and Asia, including Taiwan and South Korea.

In her consulting role at Syner-G, Renee develops and implements global regulatory strategies across all stages of product development, including IND, CTA/IMPD, NDA, BLA, and MAA submissions. She provides strategic guidance with a particular focus on biologics and advanced therapies, such as vaccines, gene therapies, and cellular-derived products, including extracellular vesicles. Her expertise also includes conducting comprehensive gap assessments to identify risks, labeling strategy and promotional review, ensuring compliance while supporting effective and accurate product communication.

Prior to her current work, Renee held leadership and strategic roles at several biotechnology organizations, where she established and led regulatory teams, developed and executed regulatory strategies, and contributed extensively to regulatory submission modules. Earlier in her career, she led analytical and formulation development efforts supporting the clinical advancement of multiple biopharmaceutical programs.

Renee earned her B.S. in Biochemistry from the University of Wisconsin and a Ph.D. in Biochemistry from the University of Minnesota. She subsequently completed postdoctoral research at Glaxo, further strengthening her scientific foundation in drug development.

30+ years

of experience in the pharmaceutical and biotechnology industries.

Contributed to +40 IND/IMPD submissions

Farhad Amiri, PhD, FAHA

Sr. Consultant, Nonclinical Regulatory

Farhad is known for his ability to lead cross-functional teams and guide organizations through complex regulatory decision-making.



Farhad brings more than 20 years of experience across clinical drug development and global regulatory affairs, with deep expertise guiding complex programs from early development through marketing authorization. He is a trusted advisor to life sciences organizations navigating the intersection of nonclinical, clinical, and regulatory strategy across global markets.

When organizations are managing complex development pathways, they rely on Farhad for his ability to bring structure, scientific rigor, and strategic clarity. His experience spans a broad range of therapeutic areas, including oncology, CNS, cardiology, infectious disease, and rare disease, as well as modalities such as biologics, small molecules, cell and gene therapies, vaccines, and biosimilars.

At Syner-G, Farhad partners with biotech and pharmaceutical companies to develop and execute integrated regulatory strategies that align nonclinical and clinical development with global regulatory expectations. He has led and supported more than 45 regulatory submissions across major health authorities, including the FDA, EMA, MHRA, Health Canada, and other international agencies. His expertise includes regulatory interactions at every stage of development, from early advisory meetings through IND, CTA, NDA, and BLA submissions.

Farhad is known for his ability to lead cross-functional teams and guide organizations through complex regulatory decision making. He works closely with R&D, clinical, manufacturing, and executive stakeholders to ensure alignment across programs, while identifying risks early and developing strategies to address them. His leadership extends to managing multidisciplinary teams, mentoring scientific experts, and serving as a strategic partner throughout the product lifecycle.

Prior to joining Syner-G, Farhad held senior leadership roles across regulatory strategy, toxicology, and scientific affairs, where he led global development programs, managed large cross-functional teams, and oversaw nonclinical and clinical strategy for a wide range of products. His experience includes leading GLP and non-GLP studies, supporting clinical development programs, and managing regulatory strategy across North America, Europe, and Asia.

Farhad holds a PhD in Biomedical Sciences from Université de Montréal and completed postdoctoral training in vascular biology and cellular signaling. He is a Fellow of the American Heart Association (FAHA) and maintains active expertise in Good Laboratory Practice (GLP) and Good Clinical Practice (GCP).

20+ years

of experience across clinical drug development and global regulatory affairs, with deep expertise guiding complex programs from early development through marketing authorization.

45+ regulatory submissions

Kathrin Copley, PhD, MBA

VP, Nonclinical Regulatory

Organizations rely on Kathrin for her ability to align nonclinical strategy with broader development and regulatory goals.



Kathrin brings more than 25 years of experience across pharmaceutical development, quality, and regulatory affairs, with deep expertise in nonclinical strategy and regulatory execution across small molecules, biologics, and cell and gene therapies. She is a trusted regulatory leader known for guiding complex programs from early development through IND readiness with clarity and precision.

When organizations are navigating critical early-stage decisions, they rely on Kathrin for her ability to align nonclinical strategy with broader development and regulatory goals. Her experience spans IND-enabling programs, regulatory submissions, and health authority interactions, including pre-IND, INTERACT, and other FDA engagements. She has led and contributed to multiple successful IND submissions across a range of therapeutic modalities.

At Syner-G, Kathrin partners with biotech and pharmaceutical companies to develop integrated regulatory strategies that ensure nonclinical, CMC, and clinical components are aligned from the outset. Her approach emphasizes clear, concise regulatory messaging and well-structured development plans that reduce risk and support efficient progression into clinical trials.

Kathrin is highly experienced in regulatory documentation and strategy development, including nonclinical study design, gap assessments, regulatory roadmaps, and briefing packages. She brings a strong foundation in cGMP, GLP, and GCP, along with hands-on experience supporting manufacturing, quality systems, and regulatory compliance across development programs.

Prior to joining Syner-G, Kathrin held senior leadership roles in regulatory and scientific affairs, where she led cross-functional teams, supported global development programs, and advised sponsors on regulatory strategy and execution. Her experience spans both consulting and industry roles, giving her a practical perspective on advancing programs in dynamic and resource-constrained environments.

Kathrin holds a PhD in Biochemistry from the University of Nevada, Reno, an MBA from the Rady School of Management at the University of California, San Diego, and a Bachelor of Science in Biochemistry from the University of California, Davis. She maintains Regulatory Affairs Certification (RAC) in Drugs.

25+ years

of experience across pharmaceutical development, quality, and regulatory affairs

Experience

in both consulting and industry roles