



BaysMartin Consulting, LLC.

Biotech LifeScience Professionals

+1 866-672-3280

Regulatory@baysMartinConsulting.com

www.baysmartinconsulting.com

READY TO TAKE YOUR PRODUCTS TO THE NEXT LEVEL?

Capabilities Statement

ABOUT US:

BaysMartin Consulting, LLC. (BMC) is a regulatory scientific consulting firm dedicated to providing expertise in regulatory, quality, and clinical compliance to support research and development in the healthcare and life sciences industries. Founded by a seasoned healthcare and regulatory leader with over 20 years of industry experience, BMC has supported diagnostics, therapeutics, and MedTech innovators worldwide. BMC helps innovators navigate US and global pathways. BMC's mission is to empower large and small businesses to bring compliant, impactful solutions to market where equitable access and regulatory clarity fuel innovation across every corner of the life sciences industry.

OUR SERVICES:

- **Regulatory Research and Development Planning & Regulatory Body Submissions**
 - Educate on Federal, State, Local regulatory requirements
 - Create comprehensive technical dossiers for FDA and global submissions (IDE, BLAs, NDAs, 510(k), De Novo, Q-Submissions, IVDR, MDR, Canada, Technical Writing, Digital Health & SaMD)
- **Quality & Compliance Auditing**
 - GxP/GCP audit readiness, FDA warning letters, ISO certification support, and QMS development
- **Research & Development Support**
 - Risk Management, guides and reviews R&D V&V reports
 - Advises on scientific protocols and test reports per required standards
 - FDA premarket pathways for software-driven products.
- **Equity-Centered Clinical & Laboratory Consulting**
 - CLIA/CMS compliance, laboratory setup, and clinical trial regulatory support
 - Empowering underrepresented innovators to design inclusive clinical trials, user studies, and regulatory strategies that reflect diverse patient populations and drive equitable healthcare outcomes.

CLIENTS:

BMC serves clients and tailored to the unique needs of Pharma, Biotech, MedTech, Health Innovators, Universities, Hospital Systems, Start-Ups

COMPANY INFORMATION:

Year Established - 2019 - Registered in State of Minnesota

UEI: U5UFHK2UK2L6

CAGE: 982Q5

NAICS: Primary- 541690- Other Scientific and Technical Consulting Services / Secondary: 541999, 541519, 541714, 541715, 541990, 621511

CERTIFICATIONS:

BMC currently holds the following certifications:

- SAM Registered - Federal Verified Vendor
- SBA certified as Woman-Owned Small Business (WOSB)
- Minnesota Central Certification Program (CERT) and
- MN Targeted Group and Economically Disadvantaged(TG/ED)

