Life Sciences

Maneuvering through the federal regulatory review and approval process can be daunting, and years of research and investment can hang in the balance. Medical device, pharmaceutical, biotechnology, and other life sciences companies look to EBG Advisors to craft comprehensive, practical, and innovative solutions tailored to their particular needs and goals. We are adept at guiding clients (ranging from startup life sciences companies to many of the largest medical device manufacturers) through the maze of regulatory requirements and keeping them abreast of industry developments and trends.

Our consultants have real-world experience working inside federal regulatory agencies and within the life sciences industry. And many of our consultants have backgrounds that combine scientific, technical, industry, and legal knowledge and experience. Our clients benefit, in terms of the quality and efficiency of advice, when the learning from these disciplines is integrated into the options presented within a legal and regulatory framework.

In addition, our consultants have in-depth knowledge of the medical device environment. Medical device clients value our ability to anticipate change, optimize Food and Drug Administration (FDA) submissions, lessen costs spent during the submission process, maximize product revenue and profits, and strengthen their competitive advantage.

FDA Regulatory Clearance and Approval

Clients rely on EBG Advisors to support them through the FDA clearance and remediation process as well as other federal and state agency requirements. Using our vast experience in this area, we help clients successfully navigate the regulatory

Team

Michael Zagorski

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quagmire. Drug and medical device manufacturers also turn to us to assist them in bringing new products and innovations to market more quickly and efficiently.

EBG Advisors steers clients through many other facets of the regulatory clearance and remediation process, from determining the best way to collect the scientific and clinical evidence needed by regulators to building an appropriate health economics case for reimbursement.

Our FDA regulatory support services also include:

- Guiding early product development and investigational phases
- Assisting with FDA regulatory clearance and approval
- Helping with quality system remediation
- Helping with business planning and reimbursement
- Counseling on post-approval compliance and enforcement
- Advising on regulatory opportunities and other issues
- Assisting with licensing and technology transfer, supply chain and distribution, and clinical trials

Projects

Medicare Compliance for DMEPOS Supplier
December 31, 2021

Media

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Direct Access Laboratory Testing: Navigating the Regulatory Landscape

Unpacking FDA's Final Clinical Decision Support Guidance

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Contact

EBG Advisors is prepared to assist you with undertakings ranging from launching products to obtaining regulatory approval and legal representation. Please provide us with an overview of how we may be of service, or, if you have any questions, let us know and we'll direct them to the right consultant.

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