BioBoston Consulting

Your Pathway from the Lab Bench to Commercial

BIOBOSTON CONSULTING

Why Choose BioBoston Consulting?

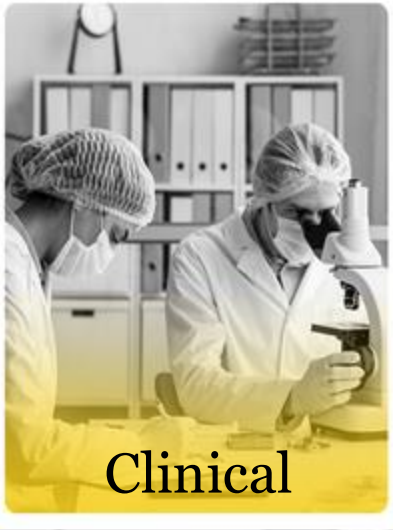
- ✓ **Industry Expertise:** With a team of over 350 global industry experts, each with a proven track record of success, we offer unparalleled expertise to guide you through every stage of your journey.

- ✓ **Cost-Effective Support:** Our lean organizational structure allows us to offer cost-effective solutions without compromising on quality. You'll receive top-notch support at a fraction of the cost.

- ✓ **One-Stop Consulting Firm:** From preclinical planning to commercialization, we're your one-stop shop for all your consulting needs. Our comprehensive range of services ensures that you have everything you need to succeed under one roof.

- ✓ **Client-Centric Approach:** Your satisfaction is at the heart of everything we do. We believe in building long-term relationships based on trust and mutual success. We are committed to understanding your unique needs and goals delivering tailored solutions that exceed your expectations.

Expertise to Drive Your Success



Pre-Clinical

BioBoston Consulting

Funding and Investment Strategies

BioBoston Consulting can help in creating compelling business plans, financial models, and pitching strategies to attract investors or secure grants.

Research and Development (R&D)

Offering advice on experimental design, data interpretation, and optimization of pre-clinical studies.

Recruitment

We're here to support your recruitment needs in the Pharma, Biotech, Medical Device, Diagnostics, and Healthcare industries. Our goal is to find the best talent for you quickly, easily, and within your budget.

Biostatistics and Data Analysis

Services involving statistical analysis, data management, and interpretation of clinical and non-clinical trial data to derive meaningful insights and support decision-making.

Lab Operations and Efficiency

Efficiency in lab operations is critical. BioBoston Consulting can advice on optimizing lab processes, implementing quality management systems, or improving R&D productivity.

Regulatory Strategy Guidance

Offering assistance in understanding early regulatory requirements, guidance on initial compliance, and navigating the regulatory landscape as they move toward clinical phases.

Pre-Clinical

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Clinical Trial Design and Strategy

BioBoston Consulting offers expertise in designing clinical trials, determining trial endpoints, protocol development, and overall strategy to optimize trial success

Clinical Trial Management

We can help manage various aspects of clinical trials, including site selection, patient recruitment, data management, monitoring, and ensuring adherence to protocols

IND/IDE Submission

We have a proven track record of preparing high-quality regulatory submissions that meet the requirements of regulatory agencies, maximizing the chances of approval.

CRO Selection & Qualification

Selecting the right Contract Research Organization (CRO) is critical to successfully complete your clinical trials. A dependable CRO will guarantee good data quality, regulatory compliance, and efficient work.

CDMO Vendor Selection, Qualification & Oversight

A well-chosen Contract Development and Manufacturing Organization (CDMO) can simplify your own work processes, reduce risks, and prevent non- compliance with regulations all through the entire product lifecycle.

CTO Selection & Qualification

It is of vital importance that all aspects in accordance with what you choose will meet stringent requirements for quality and safety. A seasoned CTO would be able to give you the testing support you need across each phase of development, and then ensure that your products meet all standards of compliance and regulation.

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Talk with an Expert

Pre-Clinical

BioBoston Consulting

Vendor Selection & Qualification

Choosing and qualifying suitable vendors is an essential function in the life sciences space to ensure good quality, regulatory compliance, and efficient operations.

Regulatory CMC Support

Alignment of Chemistry, Manufacturing, and Controls (CMC) with regulatory expectations is essential to successfully develop new therapies in a highly-regulated industry such as life sciences.

Technology Transfer Assistance

Facilitating the transfer of technology to different production sites or partners (CDMO).

Project & Risk Management

In the fast-paced and highly dynamic world of the life science industry, good project management and good risk management are essential for success.

Medical Writing

Life sciences, where accuracy and clarity can be the difference between a successful clinical trial or approval process versus months or years of additional work

Strategic Advising

Moving through the maze of the life sciences industry calls for more than brilliant thinking; it requires a strategy that is well-formulated and dynamic in execution, offering sustainable growth, regulatory victories and market leadership.

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Pre-Clinical

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Gap Assessment and Remediation

Ongoing evaluations to identify evolving gaps in capabilities, resources, or compliance standards across all stages of development, ensuring adaptability and readiness for The next phase.

Quality Management Systems (QMS)

In life sciences, QMS is crucial. It makes compliance with regulatory standards achievable, improves operational efficiency and pushes for continuous improvement. In the realm of the life sciences, we provide expert consulting services on quality management systems (QMS).

Data Integrity and Software Implementation

Today's data-driven life sciences industry, data integrity is necessary for both regulatory compliance and operational success.

Health Authority Meeting Support

Health Authority Meeting Support involves coordinating regulatory submissions, preparing briefing documents, managing timelines, and conducting mock meetings with pharmaceutical clients. It ensures seamless interactions with bodies like the FDA or EMA, focusing on strategic planning, stakeholder coordination, documentation, and follow-ups to align products with regulatory requirements and accelerate market access.

Clinical

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Technology Transfer Assistance

To guarantee smooth transitions from development to manufacturing processes in the life science industry, effective technology transfer is critical. Our Technology Transfer services at BioBoston Consulting are designed to facilitate smooth and effective transfer, minimizing risks, and maximizing efficiency for our clients.

Clinical Operations

The success of a clinical trial depends on whether it is conducted smoothly, on budget and in compliance with regulations. BioBoston Consulting can help life sciences companies in planning, managing, and executing clinical trials that deliver high-quality, reliable data while minimizing risks and delays.

Clinical Trial Monitoring

When clinical trial monitoring is done well, it is essential that studies comply with regulatory standards and patient safety is given the highest priority.

Clinical Data Management

To success of a Clinical Trails depends on whether it has conducted smooth Data management

Biostatistics and Statistical Analysis

Data is key to product development, clinical trials and regulatory submissions in the life sciences industry.

Regulatory Strategy & Submissions

Navigating the regulatory landscape is a vital component of getting products to market in the life science industry.

Clinical

BioBoston Consulting

Project & Risk Management

In the fast-paced and highly dynamic world of the life science industry, good project management and good risk management are essential for success.

Quality Assurance and Regulatory Compliance

High Quality and Compliance Standards are the pillars of success in the life science industry.

Medical Writing

Life sciences, where accuracy and clarity can be the difference between a successful clinical trial or approval process versus months or years of additional work

Gap Assessment and Remediation

Ongoing evaluations to identify evolving gaps in capabilities, resources, or compliance standards across all stages of development, ensuring adaptability and readiness for The next phase.

FDA Inspection Readiness

Preparation for regulatory inspections is the most effective way to avoid delay and be compliant. BioBoston Consulting through its Inspection Readiness services assist clients in preparing and navigating regulatory inspections with confidence.

GxP Training

Success in the fast-paced and highly regulated life science industry depends on the continuous quest for knowledge and skills

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Clinical

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Qualification & Validation

Perform various forms of validation, including Process Validation, Equipment Qualification, Computer System Validation (CSV), and Analytical Method Validation.

Data Integrity and Software Implementation

Today's data-driven life sciences industry, data integrity is necessary for both regulatory compliance and operational success.

Regulatory CMC Support

Alignment of Chemistry, Manufacturing, and Controls (CMC) with regulatory expectations is essential to successfully develop new therapies in a highly-regulated industry such as life sciences.

Health Authority Meeting Support

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Strategic Advising

Moving through the maze of the life sciences industry calls for more than brilliant thinking; it requires a strategy that is well-formulated and dynamic in execution, offering sustainable growth, regulatory victories and market leadership.

Clinical

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Computer System Validation (CSV)

For Life Science companies, computerized systems are crucial to data control, process automation, and regulatory compliance. Computer-system validation (CSV) is needed to ensure that these programs run as intended in full adherence with industry guidelines.

Internal and Supplier Audits

To ensure proper compliance, process improvements and quality delivery of the internal processes and appropriate supplier interactions, internal and supplier audits should be performed regularly.

Quality Management Systems (QMS)

In life sciences, QMS is crucial. It makes compliance with regulatory standards achievable, improves operational efficiency and pushes for continuous improvement. In the realm of the life sciences, we provide expert consulting services on quality management systems (QMS).

Commercial

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Quality Management Systems Compliance

Ensuring compliance with FDA and domestic and International standards. Provide documentation support, including update and development of Standard Operating Procedures (SOPs), batch records, and validation protocols.

Recruitment

We're here to support your recruitment needs in the Pharma, Biotech, Medical Device, Diagnostics, and Healthcare industries. Our goal is to find the best talent for you quickly, easily, and within your budget.

Quality Assurance and Regulatory Compliance

High Quality and Compliance Standards are the pillars of success in the life science industry. Quality and Compliance throughout the entire life cycle of a product is very critical for success

Project & Risk Management

In the fast-paced and highly dynamic world of the life science industry, good project management and good risk management are essential for success.

Gap Assessment and Remediation

Ongoing evaluations to identify evolving gaps in capabilities, resources, or compliance standards across all stages of development, ensuring adaptability and readiness for
The next phase.

FDA Inspection Readiness

Conduct mock inspections to prepare for regulatory inspections. Provide training to ensure readiness and identify gaps that may need attention.

Commercial

BioBoston Consulting

Internal and Supplier Audits

To ensure proper compliance, process improvements and quality delivery of the internal processes and appropriate supplier interactions, internal and supplier audits should be performed regularly.

Process Optimization

In the life sciences industry efficient processes are essential to drive efficiency and reduce costs while safeguarding that high quality products can be delivered constantly

Qualification & Validation

Perform various forms of validation, including Process Validation, Equipment Qualification, Computer System Validation (CSV), and Analytical Method Validation.

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Supporting Life Sciences from Pre-Clinical to Commercial

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