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# Regulatory & Manufacturing Consulting for Life Sciences

## Introduction

The life sciences industry is highly regulated and bringing a new product to market—a drug, biologic, vaccine, gene therapy, or medical device—presents significant challenges. Regulatory and manufacturing consulting is essential for guiding innovators through each stage of product development. Consultants provide expertise to ensure compliance with regulatory standards, streamline timelines, and increase the likelihood of successful product approval.

This document explains consulting costs, provides a step-by-step breakdown of the consulting process, and provides strategic guidance on the best times to engage consultants throughout product development. It emphasizes the importance of strategic engagement and cost management at each stage, ensuring that innovators can make informed decisions to maximize efficiency and success.

## Overview of Consulting Costs

Life science sector consulting costs vary significantly based on product type, project complexity, and development stage. Highly regulated products like gene therapies and biologics are more expensive than less complex products like Class I medical devices.

## General Cost Ranges for Each Product Category

- **Drugs** – Consulting costs for drug development typically range from \$50,000 to over \$500,000. Early-stage strategy development may be less costly, while specialized clinical and regulatory consulting can be more expensive.
- **Biologics** – Due to their complexity, biologics generally require consulting costs between \$100,000 and \$1 million, particularly during stages involving clinical trial design and regulatory submissions.
- **Vaccines** – Vaccine consulting typically costs between \$150,000 and \$600,000, especially for clinical trial design and regulatory interactions.
- **Gene Therapies** – Given the stringent regulatory requirements and specialized science involved, consulting for gene therapies often exceeds \$500,000.
- **Medical Devices** – Consulting costs vary widely by device class. Low-risk Class I devices may incur expenses starting at \$25,000, while Class III devices, which require clinical testing, can have consulting fees that exceed \$500,000. For Class II devices, the cost will be lower the closer

the proposed device is to the predicate device. However, the more novel the device is the higher the costs.

Of note, the lower ends of each of the ranges outlined here assume that innovators do not engage consultants at each of the stages outlined below.

**Consultant Hourly Rate Ranges** – Consultants in regulatory and manufacturing services often bill by the hour, with rates depending on expertise, project demands, and firm size. Here's a breakdown of typical hourly rates:

- **Junior Consultants/Analysts:** \$100 – \$200 per hour. These consultants handle foundational tasks such as data collection, regulatory research, and document support.
- **Mid-level consultants:** \$200 – \$400 per hour. They are often responsible for regulatory pathway assessment, study planning, and early compliance guidance.
- **Senior Consultants/Subject Matter Experts:** \$400 – \$600 per hour. With significant experience, senior consultants handle strategic planning, complex regulatory submissions, and meetings with regulatory authorities.
- **Principal Consultants/Advisors:** \$600 – \$1,000+ per hour. These high-level consultants, industry veterans, or former regulators handle critical strategic planning, advise on complex issues, and provide guidance during essential project phases.

Hourly rates increase with the consultant's expertise and the project's complexity. Due to the specialized nature of these fields, consultants specializing in gene therapy or biologics often command premium rates. Additionally, larger consulting firms may charge higher rates than smaller firms or independent consultants. A good rule of thumb for estimating a baseline for a consultant's experience-appropriate rate is to determine what yearly salary they would command in industry and divide by 2,000 as well as adding 20-30% for their overhead costs. Some consultants also offer fixed-price contracts for specific services, which can help innovators budget more predictably.

**Cost Analysis for Consulting Services** – Consulting services can be costly, but a strategic approach can help innovators optimize spending and focus on areas where consulting provides the most value. Here are some key considerations:

1. **In-house vs. External Consulting:** While in-house teams may save money over time, they require a significant initial investment, and finding specialized expertise can be challenging. External consultants provide targeted expertise when needed without the long-term overhead of hiring full-time staff.
2. **Cost per Stage:** Consulting costs tend to increase as the product advances through the development stages. Early-stage consulting, which focuses on feasibility and strategy, is generally more affordable, while clinical trials, manufacturing, and regulatory submissions are among the most expensive.
3. **Cost-Saving Tips:**
  - **Bundled Services:** Consider engaging one consulting firm for multiple stages, which can sometimes result in cost savings.
  - **Fixed-Price Contracts:** Fixed-price contracts for specific services, such as Investigational New Drug (IND) submission, can offer predictability and help control costs.

- Efficient Engagement: Engaging consultants at the correct times—such as before critical submissions or when developing regulatory strategies—ensures that resources are used effectively.

## The Consulting Process- A Step-by-Step Guide

Below are high-level stages of development a product undergoing regulatory approval is likely to go through with their associated cost implications, time, and key steps.

A running total range is included which tracks through each stage the lower and upper ends of each range, respectively added together.

### Stage 1 – Strategic Planning

Strategic planning is foundational, defining the new product's goals, market potential, and target product profile. In this stage, consultants help innovators assess the feasibility of their product and outline a preliminary development plan.

- Cost Implications: Strategic planning and initial feasibility studies typically range from \$10,000 to \$50,000.
- When to Engage: It's best to engage consultants early in the research stage for foundational planning and feasibility assessments.
- Key Steps
  - Market Assessment: Consultants assess market demand, competition, and pricing expectations.
  - Target Product Profile (TPP) Development: Defining the intended indications, target population, and primary product attributes.
  - Preclinical Study Design: This involves planning and designing preliminary studies for drugs and biologics.
  - Feasibility Assessment: Consultants assess device feasibility through design and prototyping for medical devices.

*Running total: \$10,000 – \$50,000*

## Stage 2 – Regulatory Pathway Assessment

The regulatory pathway assessment stage is critical to identifying the optimal approval path. Consultants evaluate the most suitable regulatory strategy based on the product type and target markets.

- **Cost Implications:** Regulatory pathway assessment consulting generally costs between \$20,000 and \$100,000.
- **When to Engage:** Ideally, engage consultants after completing preclinical studies or initial design stages.
- **Key Steps**
  - **Pathway Selection** – Based on product specifics, consultants identify appropriate pathways (e.g., 510(k), PMA, IND, and BLA).
  - **Region-Specific Requirements** – Consultants assess regulatory requirements for the target market (FDA, EMA, PMDA, etc.).
  - **Submission Planning** – A clear, tailored submission plan is developed.
  - **Pre-Submission Meetings** - Early engagement with regulatory authorities can be highly beneficial for feedback.

*Running total: \$30,000 – \$150,000*

## Stage 3 – Preclinical/Non-Clinical Consulting

Preclinical and non-clinical consulting focuses on preparing studies to meet regulatory standards and build a case for the product's safety and efficacy.

- **Cost Implications:** Preclinical consulting and study monitoring typically cost between \$30,000 and \$150,000.
- **When to Hire:** Engage consultants after initial development, before beginning clinical trials.
- **Key Steps:**
  - **Study Planning & Compliance** – Consultants help design studies compliant with Good Laboratory Practice (GLP).
  - **GLP Compliance** – Ensuring all studies meet GLP standards is critical for data integrity.
  - **Toxicology, Pharmacology, and Safety** – Key safety assessments are conducted, especially for drugs, biologics, and gene therapies.
  - **Biocompatibility Testing** – Biocompatibility testing assesses safety and potential adverse effects for medical devices.

*Running total: \$60,000 – \$300,000*

## Stage 4 – Clinical Development & Trial Consulting (if applicable)

This stage may not be applicable if your product's regulatory submission does not need an independent clinical trial (e.g., some 510(k) device submissions).

If applicable, in this stage, consultants assist with clinical trial design, protocol development, and compliance to ensure trials meet regulatory expectations.

- Cost Implications: Clinical trial consulting costs typically range from \$50,000 to \$300,000.
- When to Engage: Engage consultants before the IND, IDE application, or pre-submission.
- Key Steps:
  - Clinical Trial Design – Consultants develop trial protocols, including endpoints and study populations.
  - Site Selection & Recruitment – Selecting clinical sites and designing recruitment strategies is critical for trial success.
  - Data Management – Establishing a robust plan for data collection, storage, and analysis is essential.
  - Adverse Event Reporting – Consultants help develop safety monitoring, risk management, and reporting protocols.

*Running total: \$110,000 – \$600,000*

## Stage 5 – Manufacturing & Scale-Up Consulting

As the product progresses through trials, scaling up manufacturing and ensuring compliance with Good Manufacturing Practice (GMP) standards becomes a priority.

- Cost Implications: Manufacturing scale-up consulting ranges from \$50,000 to \$200,000.
- When to Engage: Engage consultants during Phase II or Phase III trials. If no trials are needed, before final regulatory submission.
- Key Steps:
  - CMO Selection – Choosing between contract manufacturing organizations (CMO) or in-house production.
  - Process Validation – Validating the manufacturing process to ensure quality and consistency.
  - GMP Compliance – Ensuring compliance with GMP standards is essential for regulatory approval.
  - Cost Analysis – Consultants project costs for scaling up manufacturing to meet commercial demands.

*Running total: \$160,000 – \$800,000*

## Stage 6 – Submission & Regulatory Filing Consulting

This stage is focused on preparing and submitting applications to regulatory authorities, a complex process that requires attention to detail.

- Cost Implications: Regulatory submission consulting costs range between \$20,000 and \$250,000.
- When to Engage: After completing pivotal studies and gathering data.
- Key Steps:
  - Regulatory Submission Preparation – Consultants prepare applications, such as NDA, BLA, PMA, or 510(k) submissions.
  - Document Compilation – Preparing submissions in electronic Common Technical Document (eCTD) format.
  - Regulatory Query Responses – Consultants address queries and prepare additional data as needed.
  - Advisory Meeting Support - Consultants support advisory committee meetings if required.

*Running total: \$180,000 – \$1,050,000*

## Stage 7- Post-Marketing & Lifecycle Management

Once a product is on the market, ongoing compliance, risk management, and lifecycle management are critical to sustaining its commercial success.

- Cost Implications – Post-marketing support typically ranges from \$20,000 to \$100,000 annually.
- When to Engage – After product approval.
- Key Steps:
  - Post-Market Surveillance – Monitoring product safety and performance.
  - Labeling Updates & Reporting – Updating product labeling and reporting adverse events.
  - Lifecycle Management – Consultants assist with additional indications, market expansions, and product improvements.
  - International Market Preparation – Preparing to enter new markets by assessing regional regulatory requirements.

*Running total: \$200,000 – \$1,150,000*

## Guidelines for Engaging a Consultant at Each Step

Strategic timing is critical to using consulting services effectively:

- Early Development – Engage consultants to help define regulatory pathways and assess feasibility.
- Preclinical & Clinical – Consultants assist with study design, compliance, and trial management.
- Manufacturing – Consulting is essential during scale-up to ensure GMP compliance.
- Submission – Document preparation and submission are crucial stages for regulatory guidance.
- Post-Marketing – Ongoing consulting is valuable for compliance and lifecycle management.

## Choosing the Right Consultant – Key Criteria

The NIH may recommend criteria to identify and evaluate consultants. For example, you can find life science consultants through various reputable online directories and networks. When selecting a consultant, prioritize those with relevant industry experience, a deep understanding of regulatory agencies, a strong record of successful projects, and transparent, upfront pricing. It is also important for consultants to report and detail their hours when submitting invoices for accountability and future auditing purposes. Choose firms or individuals with a proven track record in your specific product area to ensure your consulting investment directly supports your objectives and enhances your project's success potential. Consultants most familiar with your product type (e.g., drug, biologic, device) and specific clinical application are most likely to be good matches for your company – though they may be less available due to non-conflict agreements with current clients.

## Conclusion

As with all consultants, innovators will need to balance short term and generally higher consultation fees with their time or potential long term expected needs that might require identifying a more permanent salaried individual. As shown in the running total ranges, if an innovator engaged consultants at each stage, costs accumulate significantly. With each step, the more that is done ahead of time or in-house, the more value a consultant's time can add by focusing on their specialized skills.

Engaging consultants at the proper stages of development can help innovators navigate the regulatory landscape more effectively, making consulting costs an investment in long-term success. By understanding costs, timing, and the stages where consulting has the most impact, innovators can maximize efficiency and improve the likelihood of regulatory approval for their products.