epsilon
life sciences

CLIENT ALERT

Preserving Trust and Empowering Change: The Vital Considerations when Selecting an Independent Monitor

As part of government settlement agreements, such as Consent Decrees, Deferred Prosecution Agreements, Compliance Addendums, and Corporate Integrity Agreements, life sciences companies are required to engage an independent third-party as an auditor, Monitor, or Independent Review Organization and/ or Compliance Expert to the Board (Monitor). This role can be fulfilled by either an individual or a firm, depending on the requirements of the settlement agreement. The Monitor role is usually a long-term role for multiple years, so it is crucial that your company select a Monitor that is the right fit for your organization. When selecting this Monitor, there are several items to consider:

Independence and Objectivity

Ensure the Monitor is truly independent and has no conflicts of interest that could bias their ability to provide an independent assessment of your company's compliance program. Learn and discuss the details of any past projects that the Monitor performed for your company to ensure the Monitor is truly independent and objective. The Monitor should have no financial ties or relationships that could influence or compromise their ability to perform an objective assessment.

Expertise, Experience, and Qualifications

First and foremost, the Monitor should have deep expertise in the life sciences industry and an understanding of the challenges companies face when bringing products to market and maintaining products on market. The Monitor should have knowledge about the specific compliance issues and risks associated with your business. Ensuring the Monitor has a deep understanding of the relevant laws, regulations and industry standards related to the life sciences industry is essential in their ability to adequately and accurately assess your company's compliance program.

It is also essential that the Monitor have experience serving as the Pre-Monitor or Monitor for companies under similar settlement agreements. Research the Monitor's reputation in the life sciences industry as well as record of accomplishments or case studies on similar monitorship projects.

Better yet, having a Monitor that also has worked in the industry and understands the nuances of commercial and medical/ clinical functions and the cross-functional and siloed nature of the industry can bring an informed approach that supports ongoing maturation of the compliance program.

Communication and Collaboration

Open lines of communication are crucial to ensuring a productive working relationship between your company and the Monitor. Set the expectations related to communication with the Monitor from the beginning and ask for examples of how they have done this with past clients.

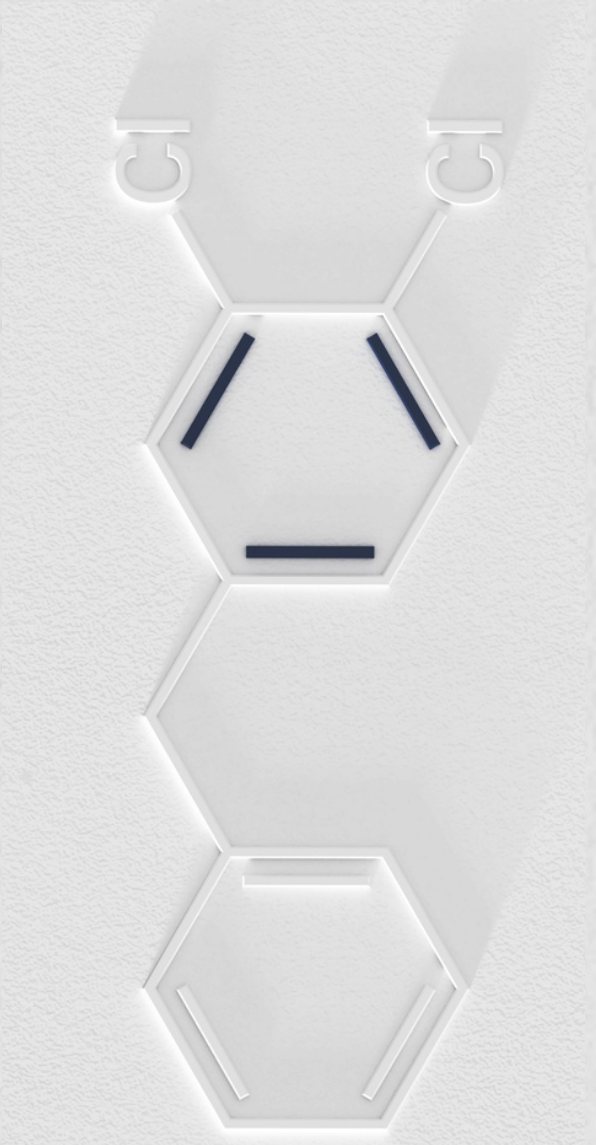
The Monitor should be able to describe their plan for communicating with the government agency and provide examples of past experiences communicating with the government agency that is overseeing the settlement agreement.

Methodology, Timing, and Work Plan

Understand the Monitor's methodology for conducting such assessments and determine if it aligns with life sciences industry standards. The Monitor should also have the appropriate resources to conduct a comprehensive assessment of the compliance program as outlined in the settlement agreement and the agreed upon work plan and timetable for completion.

An experienced Monitor should be able to provide details around the anticipated timing and work with your company to ensure their review is conducted in a manner that is not disruptive for your organization.

Taking these factors into consideration, life sciences companies should select a qualified, independent, and competent Monitor to fulfill the requirements of the settlement agreement while adding value and insight to the ongoing evolution of your company's compliance program and how the compliance program supports the company's fundamental business objectives.



About the Authors

The authors, together with others at Epsilon Life Sciences, have provided Independent Review Organization and Independent Compliance Expert services since the inception of this role in the industry. Whether settling a Consent Decree, Corporate Integrity Agreement, Compliance Addendum, or Deferred Prosecution Agreement, our Experts are well versed in the industry and in all applicable federal health care programs and FDA requirements relating to the areas of concern in the settlement. We help companies of all sizes comply with settlement agreement requirements related to Independent Monitors. Our Experts have served as the Pre-Independent Review Organization, Independent Review Organization, and Compliance Expert for over 40 healthcare and life sciences companies. We also provide implementation assistance to help companies implement their settlement agreement, such as Implementation Report support, identifying and developing required in-scope documents and written standards, training support, and risk assessment support.

Johna Carufel, CCEP, RAC
jcarufel@epsilonlifesciences.com
317.514.1177

Christine Longawa, CPA, CFE
clongawa@epsilonlifesciences.com
708.466.1555

Casey J. Horton, CFE
chorton@epsilonlifesciences.com
312.316.9294

Saul B. Helman, MD, MBA, BS
shelman@epsilonlifesciences.com
317.294.1228