



LIFE SCIENCES

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About Navigant

Navigant, Inc. (NYSE: NCI) is a specialized, global professional services firm that helps clients take control of their future. Navigant's team of experts combines deep industry knowledge with technical expertise to help clients to build, manage and protect their business interests. With a focus on industries and clients facing transformational change and significant regulatory and legal issues, the Firm serves clients primarily in the healthcare, energy and financial services sectors. Across our range of consulting, outsourcing, and legal dispute resolution services, Navigant's practitioners bring sharp insight that pinpoints opportunities and delivers powerful results. More information about Navigant can be found at navigant.com.

COMPLIANCE ASSESSMENT AND RISK EVALUATION SERVICES

Navigant has assisted multiple global and U.S.-based pharmaceutical and medical device companies develop and implement risk assessments inside and outside the context of Corporate Integrity Agreements and Deferred Prosecution Agreements.

- Risk assessments are a vital part of any effective Compliance Program and are now being included in Corporate Integrity Agreements, which is an indicator that this process is being considered a “best practice” by the OIG and DOJ. Further, risk assessments create an opportunity to build a stronger tone of compliance in the organization as a whole by including the business in the development of the compliance work plan year over year.
 - Risk assessments and a review of the risk register should occur no less than every 3 years, and best practice includes a risk assessment as part of the annual budgeting cycle for compliance.
- The purpose of a recurring risk assessment is to prioritize various activities identified by the Compliance department associated with various research & development, marketing, sales and promotional activities, as well as other relevant interactions with Healthcare Professionals/Institutions. The risk based rating output will be used (in conjunction with guidance present in any current government agreements like Corporate Integrity Agreements) to develop the upcoming year's auditing and monitoring plan, supporting the mitigation of identified risks
- Potential components of a risk assessment should include (at a minimum) the elements of impact, likelihood and the mitigation of risk through existing controls in the compliance environment. We refer to these in aggregate as the Baseline Activity Risk. The risks scores can be further refined through the use of a series of multipliers that are relevant to your organization, such as those listed below:

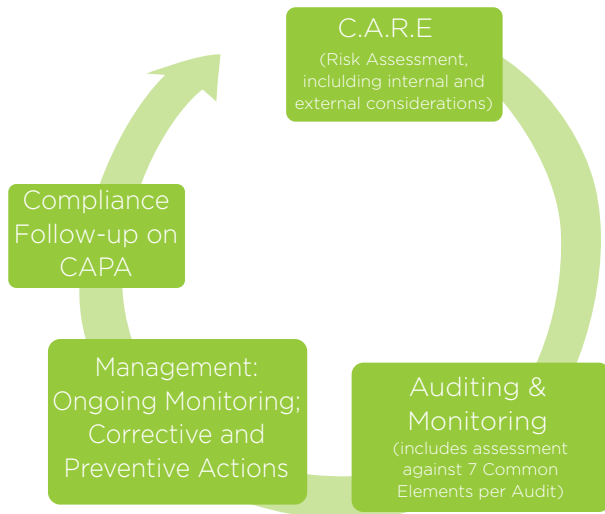
Baseline Activity Risk: Represents the overall industry-wide compliance risk associated with conducting various research & development, marketing, sales and promotional activities, as well as other relevant interactions with Health Care Professionals.

Audit History Risk: Represents the risk to an organization regarding each activity as documented in previous internal auditing and monitoring reviews.

Spend Risk: Represents the risk associated with the relative proportion of promotional spend associated with each particular activity identified.

Product Risk: Represents the risk associated with various factors that might be relevant throughout the life cycle for each product.

Navigant has developed a Compliance Assessment & Risk Evaluation (C.A.R.E) process that provides a focus on risks associated with activities in the organization that implicate certain laws and guidances associated with Interactions with healthcare professionals and institutions (e.g. value, data, etc.) and pricing for products.



Risk assessment is a tool to guide an organization to stronger compliance health and risk sensitization, not a weapon against the business. The exercise of going through the C.A.R.E. process helps socialize the concept of compliance risk and empowers the business to evaluate this risk against current and planned activities that may carry inherent compliance risk. The ability to quantify what has historically been a qualitative measurement will gather new allies to compliance and build one of the foundational aspects of an effective compliance program. Targeted risk mitigation through auditing and monitoring informed through C.A.R.E. strengthens resource allocation.

Our C.A.R.E process results in a heat map which visually demonstrates the top relative Compliance risks for an organization. This heat map is developed as a composite result of interviews, a thorough review of policies and procedures, surveys, and executive insight.

