



**Health Sciences**  
The right people. The right solution. The first time.™



# Corporate Compliance and Integrity Programs

## Our Firm

NSF Health Sciences provides a broad range of practical compliance solutions for clients in the pharmaceutical, medical device and biotechnology industries. Our team of subject matter experts is comprised of seasoned compliance executives and former senior management personnel at the FDA and at pharmaceutical and medical device companies of all demographics. We have nearly a decade of Corporate Integrity Agreement management experience as well as pre- and post- enforcement action compliance program strategies to support large and small initiatives alike.

Our professionals have also worked closely with dedicated federal monitors at the HHS OIG, boards of directors and cross-functional senior leadership, providing a unique perspective to our advisory services. At NSF Health Sciences, we understand that each company has distinctive needs, resources and structure. We work closely with you to develop tailored solutions that satisfy the compliance and business unit objectives of your organization.

## Our Services

NSF Health Sciences provides key support for all facets of compliance programs to accommodate your dynamic business needs. Whether your endeavors are emerging or mature, we have experience creating strategies to help you accomplish your immediate and long-term objectives.

## Consulting Services

At NSF Health Sciences, we draw upon a depth of first-hand experience to create sustainable solutions for the ongoing vitality of your organization. Our consulting services include:

- > Design, implementation and support for continuous improvement efforts of effective compliance programs
- > Compliance program risk assessments and operational enhancements
- > Interim and 'outside' Chief Compliance Officer services
- > Code of Conduct and Ethics development
- > Promotional Review Committee (PRC) materials review and concept review
- > Compliance auditing and monitoring for commercial, clinical and post-market activities
- > Compliance assessments for contracting and interactions with health care professionals
  - Speaker Bureaus
  - Physician consulting services
  - Advisory Boards
  - Clinical trials
  - Research and development
- > Implementation and reporting support for global and domestic transparency programs ('aggregate spend')
- > Development and support for global anti-bribery and anti-corruption programs

## NSF Health Sciences

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# Corporate Compliance and Integrity, continued...

- > Develop and deliver training for employees, boards of directors, consultants and third-party vendors
  - Compliance with US Federal Health Care Programs
  - Voluntary industry Codes of Conduct (PhRMA, AdvaMed, EFPIA, EucoMed, RX&D, MEDEC)
  - Global and Domestic Aggregate Spend (Open Payments, state requirements and EFPIA compliance)
  - Code of Conduct and Ethics
- > Post-CIA compliance program assessment and restructuring

## Remediation Services

NSF Health Sciences Compliance and Integrity Programs experts support our clients through some of the most critical passages in their organizations. Our experience working with federal regulators and executive management furthers the successful navigation and conclusion of comprehensive, multi-year remediation efforts. Our remedial action support services include:

- > Internal investigations of alleged compliance violations
- > Key support for continuity and focus throughout government-led investigations
- > Corporate Integrity Agreement and Deferred Prosecution Agreement compliance support
- > Internal Review Organization and pre-IRO services
- > Board of Directors Compliance Expert services

## About NSF

Founded in 1944, NSF International is committed to protecting and improving human health and the environment on a global scale.

NSF Health Sciences offers training and education, consulting, auditing, GMP and GLP analytical testing, certification, R&D, regulatory guidance and corporate compliance throughout the product lifecycle.

NSF has an established network of laboratories throughout North America, Europe, Latin America and Asia, with a professional staff of engineers, microbiologists, toxicologists, chemists, public health experts and certification specialists.

## Customer Success Story

**Challenge:** A Class II medical device manufacturer entered into a Corporate Integrity Agreement requiring five annual systems reviews by an Internal Review Organization to evaluate its compliance with the agreement.

**Solution:** NSF Health Sciences Medical Devices supported the Corporate Integrity Agreement (CIA) obligations as the Internal Review Organization (IRO) of a medical device company. Through NSF's evaluation and recommendations for improvements to clinical, regulatory and quality systems processes and operations, including labeling, promotion and advertising practices, the company successfully satisfied its obligations under the CIA.



For more information, contact [healthsciences@nsf.org](mailto:healthsciences@nsf.org) or visit [nsf.org/info/healthsciences](https://nsf.org/info/healthsciences)

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