

Code of Ethics

for Regulatory Professionals



REGULATORY AFFAIRS
PROFESSIONALS SOCIETY

Making better healthcare products possiblesm

Fundamental Principles

Regulatory professionals shall:

- Have a primary duty to ensure our employer's activities are conducted in compliance with the laws and regulations of the authorities under which we operate, consistent with advancing, preserving and protecting public health.
- Be competent to perform the services we have been hired or retained to perform. As regulatory professionals we must commit ourselves to continual learning while being able to acknowledge areas that are outside of our expertise.
- Act in an objective manner. As regulatory professionals we must base decisions on factual information. We must not be unduly influenced by competing or conflicting interests.
- Have integrity. As regulatory professionals we must be principled and consistent in applying our views. We must live up to our commitments, and be trustworthy and scrupulous at all times.
- Be honest in all dealings with our employers and others with whom we interact. As regulatory professionals we must ensure that information and communications, whether oral or written, are accurate and complete. We acknowledge that personal and institutional credibility are crucial to our success.
- Have the courage to make difficult decisions and present all relevant information to our organizations to promote wise decisions. As regulatory professionals we must be able to withstand challenges to our views, while at the same time be accountable for our mistakes.
- Be fair in our dealings with all parties. As regulatory professionals we must apply legal and regulatory standards equitably. We must be just in considering the interests of all parties in decision processes.
- Be respectful of others, whether it is our peers, subordinates or external parties with whom we interact. We must treat all individuals with dignity and courtesy.

Duty

Our role as regulatory professionals is defined by our duty to advise individuals and organizations regarding the appropriate regulatory context for actions they may want to take.

Our roles are further defined by our obligations as employees of companies that make important medical products for patients, as members of teams that conduct nonclinical and clinical studies, as regulators, and as members of our profession.

Regulatory professionals:

- Have a primary duty to the unbiased dissemination and interpretation of relevant governmental regulations, industry standards and good practice guidelines.
- Have a duty to our employers to ensure products are safe and beneficial to patients, while maintaining the long-term interests of our employers.
- Have a duty to those who participate in clinical studies and who use regulated products to ensure that, to the extent possible, the benefits justify the risks.
- Have a duty to provide physicians and other healthcare professionals with accurate and complete information about the safety and effectiveness of products.
- Have a duty to our peers to maintain the long-term integrity of our profession and to strive to deserve the public's confidence and respect.

Competence

Competence means that a regulatory professional has the knowledge, abilities and skills necessary to effectively identify, analyze and solve or recommend solutions to regulatory challenges.

Competent regulatory professionals lend credibility to the profession by demonstrating they have the knowledge, experience, dedication and flexibility to adapt to the ever-changing realm of the regulatory profession.

The diversity of individuals and organizational contexts within the regulatory profession necessitates commitment to a standard level of knowledge. This standard may be achieved through a variety of means: education, work experience, and professional training and certifications.

Just as the regulatory profession continues to evolve, maintaining competence within the field is a continual learning process.

Regulatory professionals:

- Seek to remain informed and knowledgeable about current and future trends.
- Avoid claims of competence in any area in which they do not have a thorough understanding.
- Encourage and support opportunities for professional growth and development among peers and subordinates so that all who work in the field can gain and demonstrate competence in the profession.

Objectivity

Objectivity is treating or dealing with facts without distortion by personal feelings or biases.

Regulatory professionals must be objective. Although the regulatory professional must evaluate information from several points of view, he/she must rely on a basic understanding of facts.

The interests of a number of parties may be affected by decisions made by regulatory professionals. These include the company, regulators, healthcare professionals, patients and shareholders, all of whose interests may be served differently and, in some cases, in a contrary fashion. Regulatory professionals need to be cognizant of these interests without letting them unduly influence their final actions.

Regulatory professionals:

- Respond carefully to an opinion issue, recognizing that there is rarely a single right or wrong answer. Opinions can often take on a partisan perspective. Caution must prevail and guide the professional to offer an unbiased expression of facts.
- Present all reasonable regulatory options and associated risks when developing regulatory strategies.
- Clearly differentiate among regulatory requirements, internal requirements and personal preferences.
- Disclose new information appropriately with the proper context.

Integrity

Integrity is a commitment to a set of values. Individuals with integrity are principled, scrupulous and trustworthy. Having integrity suggests that one is “whole,” that one’s beliefs, words and actions are congruent and consistent.

Regulatory professionals with integrity will not compromise their values or trustworthiness for personal gain or professional enhancement.

Regulatory professionals:

- Live up to commitments.
- Give credit for the work of others.
- Maintain the confidentiality of information, and never disclose information concerning the business or technical affairs of employers or clients without their consent.
- Seek advice from another individual or group whose opinion they respect when uncertain.
- When asked to compromise integrity for the sake of one party over another, reconsider their obligations and the long-term consequences of their actions.
- Avoid being placed in situations that put their integrity at risk.
- Hold strong to beliefs, recognizing that what they believe may be the best course of action may not be in the short-term interest of their employer.
- Never accept compensation that is not earned.
- Avoid conflicts of interest relating to employers or clients, or make them known when they are unavoidable.

Honesty

Honesty is understood as truthfulness, candor and sincerity. It requires a person to act in ways free from deceit or deception, including dishonesty by omission—failing to say something. Honesty requires one to be candid and forthcoming, not simply to refrain from false statements.

Regulatory professionals, in fulfilling their duty to patients, to their employer and to the profession, must exhibit honesty in all of their activities. Honesty builds trust, essential to fostering effective working relationships among regulatory authorities, the regulated industry, individual corporations and individual regulatory professionals.

Regulatory professionals:

- Ensure any information provided to subjects, patients, healthcare providers, employers, regulatory authorities and consumers is accurate and complete.
- Ensure there have not been significant omissions of information or false impressions implied.
- Resist pressures to relax standards of honesty; for example, to achieve expediency.
- Ensure that submissions represent a complete profile of the product under review.

Courage

Courage is the act of choosing what one believes to be the right thing even when doing so is difficult.

Regulatory professionals must have the courage to evaluate, conclude, and provide consistent and accurate regulatory advice. They must have the courage to demand access to information that is required to do their job, and they must do their job as completely as possible, including advising stakeholders of potential risks. Regulatory professionals must have the courage to give bad news when necessary and to accept the consequences of their decisions.

There will be situations where regulatory advice needs to be retracted or corrected. The regulatory professional must have the courage to bring forth the error and accept accountability, where appropriate.

Regulatory professionals:

- Review and reiterate their advice and strategy when necessary or when challenged, and change it when appropriate.
- Ask for help when needed.
- Encourage an open exchange of views that challenge regulatory advice.
- Admit mistakes and take appropriate measures to promptly correct them.
- Deliver bad news quickly to management.
- Provide information about risks and consequences if regulatory advice is overruled or ignored.

Fairness

Fairness means that all persons are being treated equitably. In particular, it includes the principle of treating all persons equally in accordance with the law and holding all those with common responsibilities to a common standard.

Regulatory professionals must consider the rights and needs of all parties affected by outcomes to which they contribute. This includes the wise consideration of laws, science and appropriate societal norms.

Regulatory professionals:

- Respect the letter and spirit of governmental laws and regulations.
- Apply the appropriate legal and regulatory standards to all cases, taking into account cultural and regional differences and local requirements.
- Present the facts and analysis of scientific information using sound statistical interpretation that strives to minimize bias even while giving results that may contain some element of uncertainty.
- Strive to ensure that the interests of all parties, public and private, are appropriately considered in decision processes.

Respect

Respect is the regard for or appreciation of the worth or value of someone or something.

First and foremost, regulatory professionals will respect the role of their colleagues. As regulatory professionals we must also be prepared to recognize and acknowledge the worth of all parties. This recognition demonstrates the belief that everyone has value.

Regulatory professionals:

- Listen to what others have to say in a fair and objective way.
- Refrain from embarrassing, ridiculing or hurting others in their actions or omission of actions.
- Treat all parties, regardless of level or position, with dignity, civility and courtesy.
- Accept that personal differences will occur, but work diligently toward finding a position that accommodates those differences.
- Create a positive environment that encourages and promotes respect.
- Share what they know in a non-intimidating way and are tolerant of those who do not initially understand.
- Avoid conflict where possible. If not possible, find creative ways to resolve conflict in an effort to preserve a positive business relationship.
- Are patient and forgiving when others make mistakes and work to prevent the mistakes from recurring rather than assigning blame.

Statement of Personal Responsibility

It is the professional and ethical responsibility of everyone who practices in the regulatory field to uphold the highest standards of professional conduct in the exercise of their professional duties.

Our profession has a responsibility to uphold the laws and regulations of the authorities under which we operate. In doing so, we hope to make a positive contribution to public health. We aspire to the core values articulated in this code of ethics, and we acknowledge our commitment to adhering to these ideals in our profession.

While the creation of this code of ethics demonstrates the commitment on the part of RAPS to enhance the ethics of regulatory professionals, it should not be construed in any manner as a guarantee or certification of the competency and/or professional qualities of the members of RAPS.



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