

Code of Ethics for the Pharmaceutical Regulatory Affairs Profession

2022

1. Purpose

The regulatory affairs profession exists to protect public health by monitoring the efficacy and safety of products in a variety of industries, such as pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics, and complementary medicines. Organisations responsible for the development, testing, production, and marketing of these products aim to ensure the provision of safe products that contribute to the health and welfare of the general population.

As pharmaceutical regulatory consultants it is our duty to go beyond the official guidelines and the law to ensure that the healthcare provided is safeguarded and protected. A code of ethics for the pharmaceutical regulatory affairs profession sets the principles, responsibilities and professional values that are fundamental to the profession. These principles reflect and support the profession which is patient-centred and takes into consideration the patients' rights and responsibilities.

The code ensures ethical interactions between companies, healthcare professionals and government entities, providing numerous benefits such as:

- Ensuring that medical decision-making is made in the best interest of the patients
- Enhancing patient access to safe and effective medicinal products
- Increasing public confidence in medicinal products

2. Fundamental Principles

A regulatory expert should:

- Provide all the legal documentation necessary to verify that their operations are carried out in accordance with the rules and laws of the relevant authorities.
- Be capable of carrying out their duties as a regulatory professional.
- Be able to make decisions based on accurate, current information, and whenever required express opposing or contradictory concerns in a clear and concise manner. Judgments should be made consistently and with integrity.
- Be honest in their work to ensure all information and communications are accurate and complete.
- Be able to withstand challenges and be accountable for their errors.
- Be just in all of their interactions with stakeholders and when making decisions, the interest of all parties involved is taken into consideration.
- Respect and courtesy are due to everyone.

3. Duties of the regulatory professional

Regulatory experts are accountable for:

1. Keeping up with the constantly changing laws in every area where a corporation wants to sell its products
2. Disseminating and interpreting applicable laws, regulations, industry standards and Good Practice guidelines without bias.
3. Advising on restrictions and constraints related to law and science
4. Gathering, assembling, and analysing scientific data
5. Submitting registration materials to regulatory organisations and conducting any further talks required to gain or retain marketing authorization for the products in question
6. Providing the highest level of strategic and technical guidance inside their organisations, contributing significantly to the commercial and scientific success of a development program and the organisation as a whole.
7. Helping the business avoid issues brought on by improper scientific thinking, poorly maintained records, or poor data presentation.
8. Participation in the creation of product marketing ideas.
9. Giving their approval before packaging and advertising are employed commercially.

4. Competence

Competence is the ability to recognize, assess, resolve, or suggest solutions to regulatory challenges based on knowledge, experience, ability, and skill sets. To adjust to the requirements that are continuously changing, one must be committed yet adaptable.

A dedication to evolving through a range of choices, including continuing education, job experience, professional training, and certifications, is required due to the diversity of people and organisations within the industry.

Regulator competency maintenance requires ongoing learning. Competence is developed among regulatory professionals by:

- being informed of both present and upcoming trends
- promoting and assisting peers' and colleagues' professional development so that everyone can advance and show proficiencies
- taking advantage of chances for continuous education in regulatory legislation, guidelines, standards, and other updates.

5. Objectivity

Regulatory experts demonstrate objectivity by:

- addressing topics with care, taking into account opposing viewpoints, and making an effort to present the facts objectively
- presenting regulatory options, perspectives, and associated risks when creating regulatory plans
- establishing boundaries between internal requirements, legal requirements, and personal preferences
- properly disclosing new information

6. Integrity and Fairness

Regulatory experts must establish and uphold integrity and fairness by:

- respecting their agreements
- giving credit for other people's work
- maintaining confidentiality
- asking for guidance when unsure
- maintaining integrity
- avoiding circumstances that compromise integrity
- accepting that best choice could not be in their employer's best interests in the near future
- keeping competing interests at bay
- admitting faults, taking responsibility for them, and swiftly fixing any mistakes, misunderstandings, or erroneous perceptions
- educating all stakeholders on the dangers and repercussions of disobeying or disregarding regulatory advice
- respecting both the text and the spirit of the law
- applying the proper regulatory criteria in every situation
- employing sound statistical interpretation to present the facts and objectively analyse scientific data in order to reduce bias and make uncertainty clear
- ensuring that both public and private interests are properly taken into account during the regulatory decision-making process.

7. Honesty

Honesty entails acting without lying or misleading others, even lying by omission or withholding information when doing so would be unethical. Regulatory experts should establish integrity and confidence by:

- ensuring the accuracy and completeness of the data
- the prevention of information omission or the creation of false perceptions.
- resisting the urge to compromise moral values in the name of efficiency
- giving every regulatory submission for a product under consideration a detailed description

8. Respect

Regulatory professionals must acknowledge and respect the roles played by each of their colleagues. Respect is gained by regulatory professionals by:

- listening
- treating everyone with respect and consideration
- recognizing individual uniqueness
- creating a welcoming environment where inclusion, equity, and diversity can flourish
- fostering a culture in which all forms of harassment of others are completely unacceptable
- finding innovative solutions to conflicts
- not placing blame when others make mistakes and being patient and forgiving

9. Overall patient- first approach

It is the regulatory professionals prime objective to protect the well-being, best interest and safety of patients. This is done by regulatory professionals by:

- Respecting and protecting the dignity of individuals, respecting their physical and mental integrity and their rights.
- Safeguarding the patient's access to safe medicinal products which are of good quality and efficacy.