Good regulatory practice and the role(s) of a regulatory affairs professional

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Abstract

Good Regulatory Practice is a regulatory affairs quality standard that is based on trained people who understand their professional role and work in an environment that follows standards and processes. This article illustrates the diversity of roles represented by a regulatory affairs professional and explains the importance of focused training of personnel, and of generating departmental regulatory intelligence. Good Regulatory Practice is a prerequisite for achieving an optimal balance between regulatory requirements, anticipated target profile, and time to market.

Keywords: Good regulatory practice, Regulatory intelligence

If you are a (Drug) regulatory affairs (RA) professional, you would certainly be familiar with standards such as Good Manufacturing Practice, Good Laboratory Practice, or Good Clinical Practice. And as a person interested in medical writing, you probably consider the principles of Good Writing Practice in your daily work. But what about a quality standard within RA itself? How about establishing a Good Regulatory Practice (GRP)?

There is no officially published or legally binding GRP standard. Therefore, it is up to the individual RA department or RA professional to define what GRP means in their particular environment. My understanding from the point of view of a global pharmaceutical company is that GRP is:

- To comply with legislation, internal and external standards and policies, as well as the scientific, ethical, and administrative requirements.[1,2]
- To fulfil the responsibilities of an RA professional.

Legislation, standards, and policies are usually well-defined and easily accessible, but the responsibilities of an RA professional need to be correctly understood for the proper implementation of GRP.

Role of an RA professional

One of the responsibilities of an RA professional, at least in a large R&D company, is to provide strategic and technical guidance throughout the life cycle of a product (Fig. 1), right from the discovery of new molecules, via proposals for new development projects, to full product development and obtaining marketing authorisation for a new product.[3] In addition, maintaining existing licences and developing existing products further is crucial to ensure the company's sales over many years until a product is eventually phased out and replaced by a newly discovered one.

One of the core activities of an RA professional is to monitor trends and changes in the regulatory environment and to keep track of the ever-changing legislation with a view on its implications on product development and maintenance.[2] During the development of a new product, a lot of studies are performed and heaps of data and information are generated. However, even the most scientifically complete study and the best results do not guarantee the granting of a marketing authorisation of a product if the regulatory authority is unwilling to accept the way the data are presented. The RA professional compiles all the relevant technical documents during product development and at the time of submission ensures an appropriate presentation of registration documents to the regulatory agencies. The RA professional also ensures that submission timelines are met and that questions from the regulatory agencies are addressed within the given deadlines. Thereby, the RA professional seeks an optimal partnership with the regulatory agencies to guarantee a smooth running of all registration procedures – allowing for a timely launch.

RA is increasingly becoming an important interface with almost every discipline within a

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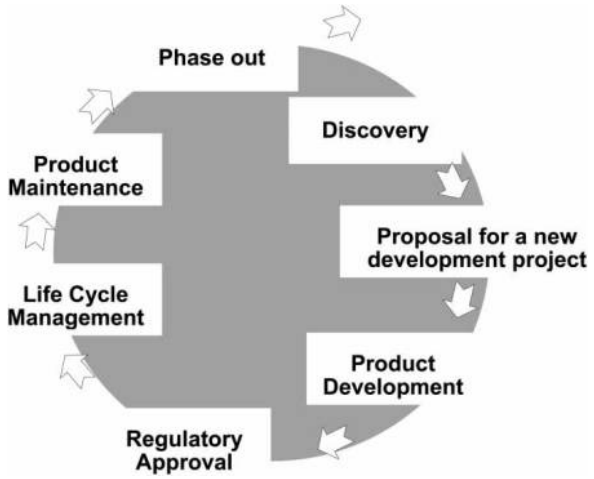

Figure 1: Product life cycle in the pharmaceutical industry.

company. It is also becoming important in external functions. The RA professionals are responsible for:

- Reviewing study protocols and final reports generated by the R&D department of the organisation, and maybe for archiving such documents.
- Accompanying the development of the active ingredient, the formulation and the analytics, as well as the preclinical and clinical development, and the finished product manufacturing.
- Being in contact with the marketing department for the life-cycle management of existing products and development of new ones.
- Being an active member of relevant industry associations.

This central function of RA is nicely illustrated in an article called 'The Hub of the Wheel' by Peter Lassoff.[4] He compares RA with the hub of a big wheel, meaning that RA is not the group to say 'No' to new ideas as it might have been perceived in the past, but one to 'make things happen', to keep the wheel turning.

Regulatory intelligence

A prerequisite to be able to handle the different hats that an RA professional needs to wear is continuous training, and building up what is called regulatory intelligence. An often used definition of intelligence is 'the transformation of information into knowledge'. Information is everywhere but knowledge is very specific to a certain task or role.[5] This specific knowledge can be gained, for example, by a focused training of the RA professional and a targeted development of specific skills such as those in medical writing, sensitive cross-cultural communications, or negotiations.[2] Such skills cannot be gained simply by attending training courses. It is crucial for junior RA staff to actively participate, ideally together with an experienced colleague, in negotiations, teleconferences, industry associations, etc. This hands-on approach is the only way to practice communication skills, to get to know people (e.g. regulators) in person, and to learn from mistakes.

Continuous communication is also very important, not only within the team but also with colleagues from the industry or directly with regulators. The RA department needs to build up experience of new staff and effectively collect know-how of experienced colleagues. There should be a system to retrospectively capture the lessons learned from past experiences – from good and bad experiences, and from the right and wrong decisions.

Good regulatory practice

On the basis of the foregoing discussion, GRP can be described as a quality system of the RA department wherein RA professionals understand their professional role and work in an environment that allows capturing of regulatory intelligence.

The fundamental aspects of any quality system are usually standardised work processes, detailed instructions, and a customised infrastructure. As GRP is not a legal prerequisite, it can be dealt with in a much more relaxed manner and tailored to suit the needs of an RA department, and the company size. The head of the RA department can define, maybe together with the whole team in case of certain issues, the details of GRP as applicable to their functions. In any case, processes should be agreed upon and documented, and should be adapted to the workflows and the organisational structure. Interfaces between functions should be identified and communication pathways at these interfaces should be organised. Furthermore, it should be verified that all systems support the processes. Systems and processes should be reviewed periodically, and where necessary, amended.

As mentioned before, all personnel in the department need to understand their role as RA professionals and to commit themselves to their functions. And, last but not least, in a department that follows GRP, all regulatory activities should support the company strategy.

Summary

To summarise, GRP is a quality standard defined by and for the RA department of a company. Its

implementation requires continuous training of RA professionals, establishment of standardised processes, and generating regulatory intelligence. GRP aims at supporting the development and licensing of safe and effective drugs that are of high quality, while keeping an optimal balance between regulatory requirements, anticipated target profile and time to market.

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Combating impact factor misuse: The San Francisco Declaration on Research Assessment

As a measure of journal quality, the journal impact factor should not be used to assess an individual article or its authors. Indeed, the IF's creator, Eugene Garfield, strongly advises against its misuse in this way.[1] In spite of this, it is routinely used to decide who should get faculty positions at research institutions and who should be awarded research funding.

Concerned by this continuing problem, a group of journal editors and publishers met at the Annual Meeting of The American Society for Cell Biology in San Francisco in December 2012 and developed the San Francisco Declaration on Research Assessment,[2] a set of recommendations on the appropriate evaluation of research, including the use of impact factors.

As well as specific recommendations for funding bodies, research institutions, researchers, and publishers, the declaration includes the following general recommendation:

> *Do not use journal-based metrics, such as Journal Impact Factors, as a surrogate measure of the quality of individual research articles, to assess an individual scientist's contributions, or in hiring, promotion, or funding decisions.*

Launched with the backing of 82 stakeholder organisations, the declaration had at the time of writing been signed by 9305 individuals and 381 organisations. I for one am hoping it has the kind of impact its architects are presumably keen to see.

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