Good decision-making practice in the regulatory arena

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Abstract

This article offers insights into decision-making processes and presents some best practices for those working in pharmaceutical regulatory functions. It is beneficial for regulatory professionals to have a fundamental understanding of decision-making as, by the very nature of their role, they are frequently confronted with challenging decisions. Some of these decisions might be multi-dimensional and have far-reaching consequences. Training in the science of decision-making is therefore a worthwhile investment and a topic for possible inclusion in professional development plans.

Decision-making in the drug development arena

Development of a new drug from molecule to market is a complex logistical process that is dependent on multiple and repetitive expert input from a wide range of specialists in various fields. It commonly starts with identifying a therapeutic goal or target disease, screening numerous drug candidates for activity, performing nonclinical tests to assess efficacy and toxicity, assuring quality of manufacturing, and then collecting clinical data on safety and effectiveness from patients in clinical trials. Through this developmental process, there are approximately six recognised "go/no-go" stage gates through the nonclinical and clinical development and three in the pharmaceutical stages. The inherent risks in this drug-development scenario are that decisions often have to be made based on insufficient data, a high degree of uncertainty, time pressure, payer/patient/provider pressures and often in a competitive environment where several stakeholders are competing to be first on the market with their specific drug candidate. Most of these go/no-go decisions are commonly based on judgments by a group of individual experts with varying background knowledge and experience. The regulatory professional can be expected to participate in some aspect of this decision-making group and informed and astute decision-making is imperative for everyone involved.

An important aspect of the regulatory professional's role is to provide input, advice and personal recommendation on regulatory aspects of drug or medical device development. The regulatory professional plays a pivotal role in defining pre-submission strategy and in providing opinion on the adequacy of the submission package to be submitted to regulatory agencies.

What is "decision-making"?

Decision-making, *per se,* can be viewed as being part science and part art, with "art" in this case being the subjective human component within the decision-making process. It can be regarded as the mental or cognitive processes resulting in the selection of a course of action among several alternative scenarios.

This subjective decision-making style reflects the combination of how an individual perceives and comprehends stimuli and the general manner in which he or she chooses to respond to them. It is linked to an individual's knowledge, ability and motivation plus his or her value orientation and tolerance for ambiguity. Decision-making is usually considered to be the result of cognitive processes leading to the selection of a course of action among several alternatives. It represents a reasoning process that may be rational, irrational or emotional based on prior knowledge and experience leading to individual assumptions and preferences. It deals with the logic and rationality of the outcome related to the individual or collective choice made and may be regarded as the result of the problem-solving processes. Decision-making styles include directive, analytical and conceptual approaches. Directive decision-makers take efficient, logical, practical and systematic approaches to solving problems; people with this style are action-oriented and decisive and prefer to focus on facts. Analytical decision-makers use careful, step-wise approaches and typically take longer than others to make decisions. Conceptual decision-makers have a high tolerance for ambiguity and tend to focus on the people or social aspects of a work situation, adopting a long-term perspective and relying on intuition and discussion with others to acquire information; these individuals tend to be willing to take risks and to be good at finding creative solutions to problems.

A decision-making framework

The discipline of regulatory affairs involves a science-based framework based on rules, regulations, directives, guidelines and other legislative requirements. At the level of the individual, adopting a structured approach to decision-making can be of real benefit to the regulatory professional. There is a classical five-step approach to decision making that is helpful in all decision-making situations, particularly more complex questions. This is outlined in Figure 1.

This classical structure provides a useful framework approach that can be easily tailored to better address the needs of the regulatory professional and can help improve the transparency and consistency of decision-making.

It is worthwhile to briefly review some well-documented decision-making traps which should be avoided during decision-making:[1]

- **Anchoring:** Giving disproportionate weight to the first information received. Initial impressions, estimates or data anchor subsequent thoughts and judgments
- **Framing:** The tendency to make inaccurate statements about the decision problem. How a problem is framed can profoundly influence the choices made

Figure 1: Classical five-step approach to decision-making.

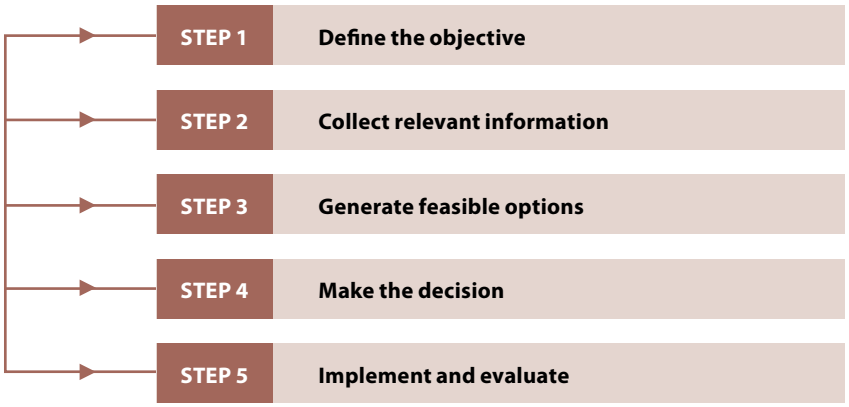
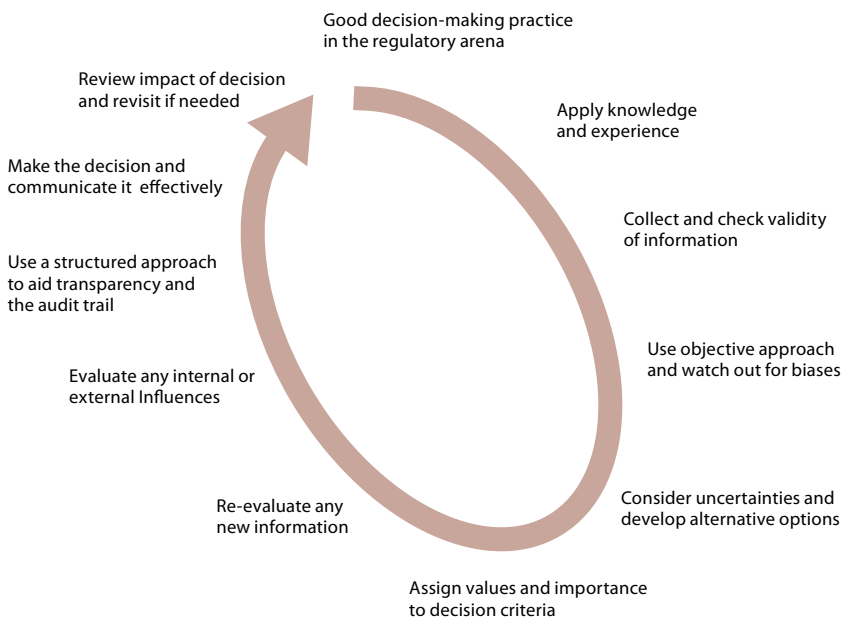


Figure 2: Good decision-making practice approach for the regulatory professional.



- **Prudence:** There is a tendency to be prudent or even over-cautious in adjusting estimates or forecasts, "just to be on the safe side", and such fear can even result in a decision not being made
- **Status quo/perpetuate:** The tendency to maintain an existing position even when a better alternative exists
- **Confirming-evidence**: An approach where the individual seeks out information that supports an existing instinct or point of view, while avoiding information that contradicts it
- **Overconfidence:** A tendency to be overconfident about the ability to judge and make accurate predictions
- **Recallability**: The tendency to give undue weight to recent dramatic events
- **Sunk cost:** This refers to costs that have been incurred and cannot be recovered and may result in a tendency repeat past mistakes.

Best practice decision-making for the regulatory professional

The regulatory professional is asked to provide opinion on scientific information and strategic proposals, and to generate documents such as SWOTs (strengths, weaknesses, opportunities, threats) and position papers in addition to other key regulatory items. Regulatory professionals should aim to apply their scientific knowledge, professional experience, planning and effective communication skills in their decision-making approach.

It is fundamentally important that the decision to be made (decision context) is clearly understood from the outset. Likewise, the objectives and tolerance with obtaining the must-haves ("musts") and the nice-to-haves ("wants") need to be identified. The use of "time-outs" to review or re-evaluate new information received, and monitoring of intrinsic or extrinsic influences such as "time pressure" or formal organisational hierarchy decision-making requirements, need to be managed. Finally, it is imperative that regulatory professionals effectively communicate their decisions. After completion, they should evaluate the impact of their decisions. This structured approach should enable transparency, high quality and assurance in a regulatory professional's decision-making approach.

A schematic example of a best practice decision-making approach for the regulatory professional is outlined in Figure 2.

Effective decision-making is an evolving art/science and an area in which the regulatory professional can develop understanding, effectiveness and differential value within an organisation. Although "decision-making" is a study module on most MBA course curricula, it is not yet a standard part of the training and development plan for most regulatory professionals. An awareness of decision-making tools and techniques such as "decision-conferencing", "the Delphi technique", SWOTs, decision-trees or the more advanced techniques relating to modelling, simulation, multi-criteria decision-analyses (MCDA) is a valuable addition to the armamentarium of today's regulatory professional.

In conclusion, decision-making is a subjective process which can be easily enhanced by the use of simple structured approaches such as those outlined. The ability to make effective decisions is a key requirement and expectation of regulatory professionals. Self-discipline and the adherence to simple best-practice techniques can be expected to benefit both the individual regulatory professional and, in turn, his or her organisation.

References

1 J S Hammond, R L Keeney, H Raiffa. 'Making smart decisions', *Harvard Business Review Press*, 2011.