IJBPAS, December, 2025, 14(12): 6759-6769

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

IMPORTANCE OF CRITICAL THINKING IN REGULATORY INTELLIGENCE

DARSHAN GOUDA V G[1*], ABHISHEK B V[2], GOUDANAVAR PS[3] AND AMAR S[4]

1: M Pharm, Department of Pharmaceutics & Regulatory Affairs, Sri Adichunchanagiri College of Pharmacy, ACU, B G Nagar, Karnataka, India

2: Assistant Professor, Department of Pharmaceutics & Regulatory Affairs, Sri Adichunchanagiri College of Pharmacy, ACU, B G Nagar, Karnataka, India

3: Professor & Head, Department of Pharmaceutics & Regulatory Affairs, Sri Adichunchanagiri College of Pharmacy, ACU, B G Nagar, Karnataka, India

4: Assistant Professor, Department of Pharmaceutics & Regulatory Affairs, Sri Adichunchanagiri College of Pharmacy, ACU, B G Nagar, Karnataka, India

***Corresponding Author: Mr. Darshan Gouda V G: E Mail: darshanvgd@gmail.com**

Received 24th Aug. 2024; Revised 15th Oct. 2024; Accepted 19th Dec. 2024; Available online 1st Dec. 2025

https://doi.org/10.31032/IJBPAS/2025/14.12.9687

ABSTRACT

Critical thinking, deriving from an educational psychology perspective is a complex process of reflection that helps individuals become more analytical in their thinking and professional development. Concerns about product development, clinical trials, and filings to get market access in crucial sectors have expanded internationally along with the rising significance of regulatory data. The increasing demands of several agencies led to a shift in regulatory intelligence. Its primary responsibility is to provide strategic advice to guarantee regulatory compliance. The term "regulation intelligence" refers to the challenge of encouraging a greater understanding of regulations. Critical thinking skills are vital for everyone involved in regulatory intelligence. In the ever-changing biopharmaceutical industry, staying informed about the many regulatory changes is essential to ensuring compliance, upholding quality, and lowering risks. The regulatory professionals who apply critical thinking techniques can enhance public health, patient safety, and their ability to successfully navigate the intricate regulatory landscape. It comprises applying what is previously known to improve outcomes in addition to just knowing what is already known.

Keywords: Critical Thinking, Psychology, Product Development, Clinical Trials, Regulatory Intelligence, Biopharmaceutical

INTRODUCTION

Critical thinking is an evidence-based process of actively and skillfully conceptualizing, applying, synthesizing, and evaluating information to reach a conclusion.

Monitoring and evaluating data that is supported by evidence is necessary for regulatory intelligence, in order to distinguish fact from conjecture. In this field, regulatory professionals use critical thinking to obtain and evaluate data, solve issues, and make judgments based on industry trends.

Therefore, we need to develop critical thinking skills, such as reading for comprehension, analysing arguments, streamlining our thoughts, and creating "habits of mind". **[1]**

The importance of critical thinking abilities was further highlighted by an influential 1941 study on the subject conducted by educator Edward Glaser. He stated, "Critical thinking generally requires ability to:

- Acknowledge issues
- Determine practical solutions to address such issues.
- assemble and compile relevant data
- Identify implicit presumptions and principles
- Understand and employ language with precision, lucidity, and discernment.
- Evaluate information
- Determine the validity of arguments and evidence.
- Acknowledge the presence (or absence) of logical connections among statements
- Make reasonable inferences and generalizations.
- Examine the inferences and conclusions that one reaches and
- recreate one's thought habits based on a broader understanding".

Basic Critical Thinking Skills: -

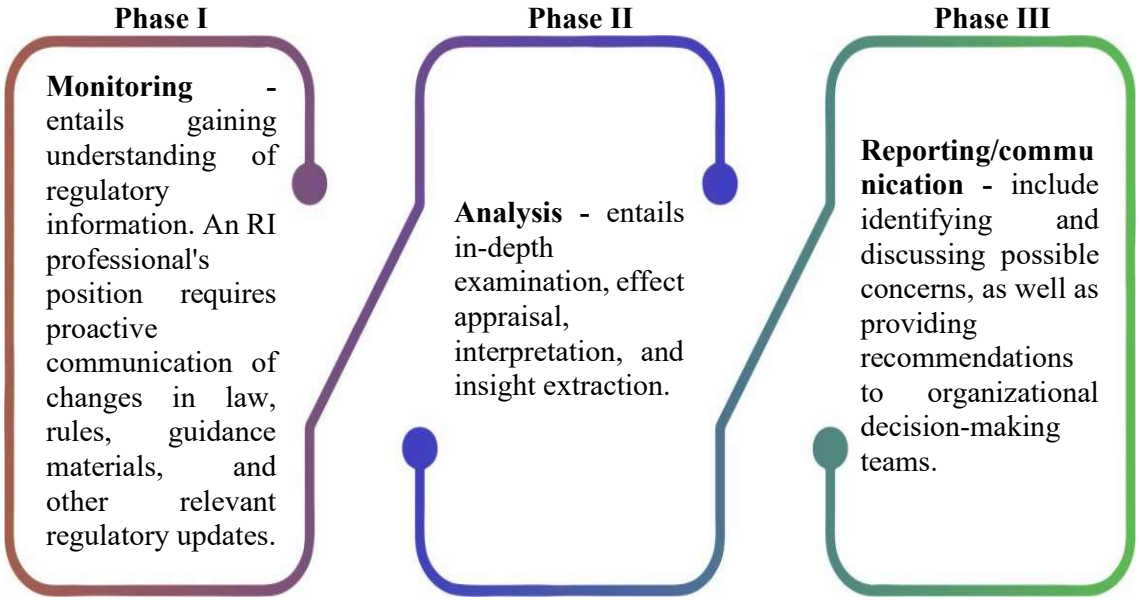
1. Questioning,
2. Interpretation and
3. Communication.

1. Possibly one of the most important aspects of critical thinking is asking questions. Make as many inquiries as you can. Never trust someone who is well-known before you have done independent investigation of your own. The goal of critical thinking is to identify the solution. Use concise, straightforward language and powerful research techniques like the is/is not, the five whys, and other inductive or deductive procedures. Verify the accuracy of the information and the sources' dependability. Asking questions is necessary to comprehend issues and assess their acceptability, application, and resolution.

2. "The ability to evaluate and comprehend the information that is being presented to you, as well as the capacity to convey that information to others, is interpretation." Regulatory workers are regularly required to analyze data, whether it be complicated legislation or abstract medical notions. Throughout your career, it will be crucial to be able to make connections between disparate bits of information in order to draw an accurate conclusion from the data at hand and to communicate this conclusion in a way that the various target audiences can understand.
3. Achieving the first two abilities requires effective communication. Although many educators undervalue them, your interpersonal, presenting, writing, and negotiating skills are essential from the entry level to the executive levels. These are necessary for career advancement and get better with time **[2]**.

Phases of Regulatory Intelligence (RI):

The three major steps of Regulatory Intelligence (RI) are monitoring, analysis, and reporting/communication **[3]**.



OBJECTIVES:

1. To provide in details about the critical thinking and regulatory intelligence.
2. To define in what way to think disparagingly & the importance of critical thinking.

3. To describe how critical thinking skills can be used in regulatory intelligence.

RESULTS AND DISCUSSION

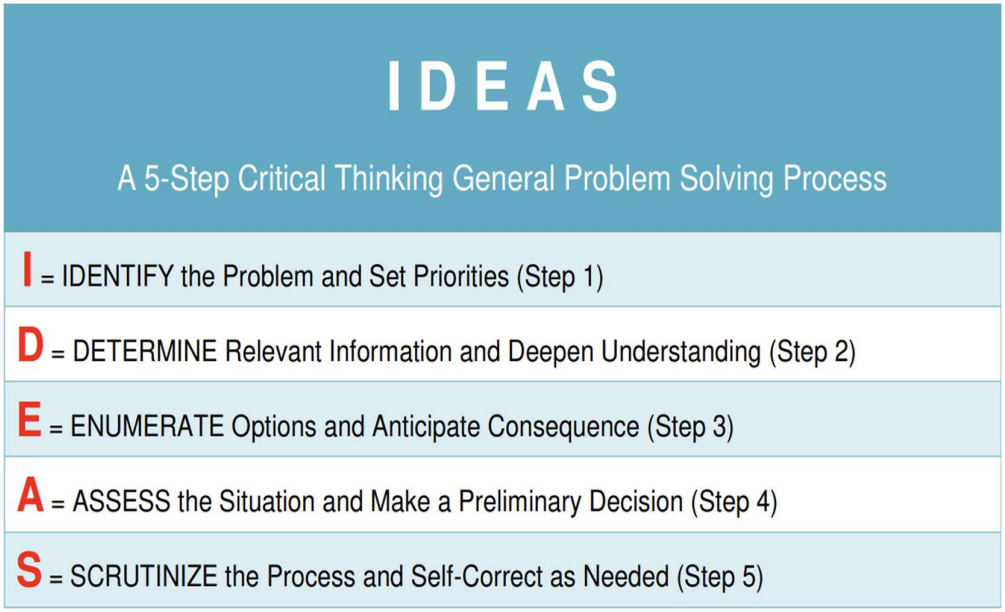


Figure 1: A 5-Step Critical Thinking General Problem-Solving Process

We describe critical thinking as conscious, self-regulatory judgment that leads to interpretation, analysis, evaluation, and inference, as well as an explanation of the evidential, conceptual, methodological, criteriological, or contextual elements that support that conclusion. CT is an excellent investigative method. As a result, CT is a liberating force in education and an invaluable resource in both the private and public sectors. While CT does not imply improved cognition, it is a common and self-correcting human phenomenon. The perfect critical thinker is someone who is always curious, well-informed, trustworthy of reason, open-minded, flexible, fair-minded in evaluation, honest in facing personal biases, cautious in making decisions, willing to change their mind, clear about issues, orderly in complex matters, careful in gathering pertinent information, reasonable in choosing criteria, focused in inquiry, and persistent in seeking answers that are as precise as the subject and the circumstances of the inquiry allow. In order to develop strong critical thinkers, we must strive toward this goal. It blends the cultivation of attitudes that regularly provide insightful information and serve as the cornerstone of a logical, democratic society with the development of CT skills **[4]**.

Regulatory Intelligence Procedure:

Figure 2: Regulatory Intelligence Procedure

Regulatory intelligence is the process of providing strategic information to support successful and efficient decision-making about the business's regulatory requirements. The process comprises identifying pertinent publically accessible data sources, conducting an analysis of the data, and generating essential data for the development of the analysis-based regulatory strategy.

Three Things to Know About Procedures for Regulatory Intelligence:

1. Gather Data.
2. Analyze Information.
3. Regulatory Strategy.

1. **Gathering Data:** Previously, regulatory experts would sometimes limit RI efforts to one particular issue. But discrepancies between the input and the output were discovered, and it became clear that some crucial information was absent from the shelves. RI professionals first do comprehensive research on

regionally unique regulatory criteria for a certain product. When it comes to gathering pertinent regulatory data for their study, RI specialists use a variety of sources.

A few of these resources include:

- Regulatory Information on Websites, Blogs and Social Groups
- Professional Newsletters
- Competitor Product Analysis
- Seminars and Training Sessions
- Literature
- FOI Requests
- Regulatory E-mails
- Professional Networking
- Guidance Documents
- Warning Letters.

2. **Analyzing and Processing:** It is evident that some of the massive volumes of research data from the first phase need to be sorted in order to locate information that is relevant to the objective. Like the pieces of a jigsaw puzzle, all you have to do is make sure they fit together correctly to provide the necessary data. An effective regulatory plan communicates the optimal course of action and enables adequate preparedness across all organizational disciplines, from production to marketing. This means keeping up with things like the latest trends and patterns in the regulatory industry. We have emphasized that in order for RI to be successful, adherence to the most recent modifications to laws and regulations is required. It may take several adjustments to this procedure before the desired result is obtained.
3. **Regulatory Strategy:** The primary goal of completing the aforementioned tasks is to help a company choose which option is the most suitable and workable. The laws that regulate certain matters vary from country to country. Experts provide a strategy on how to go about passing laws for the specific distribution marketplaces as a result. This course of action is never fully followed, though. Even when the demands of the regulatory environment shift, it progresses gradually **[5]**.

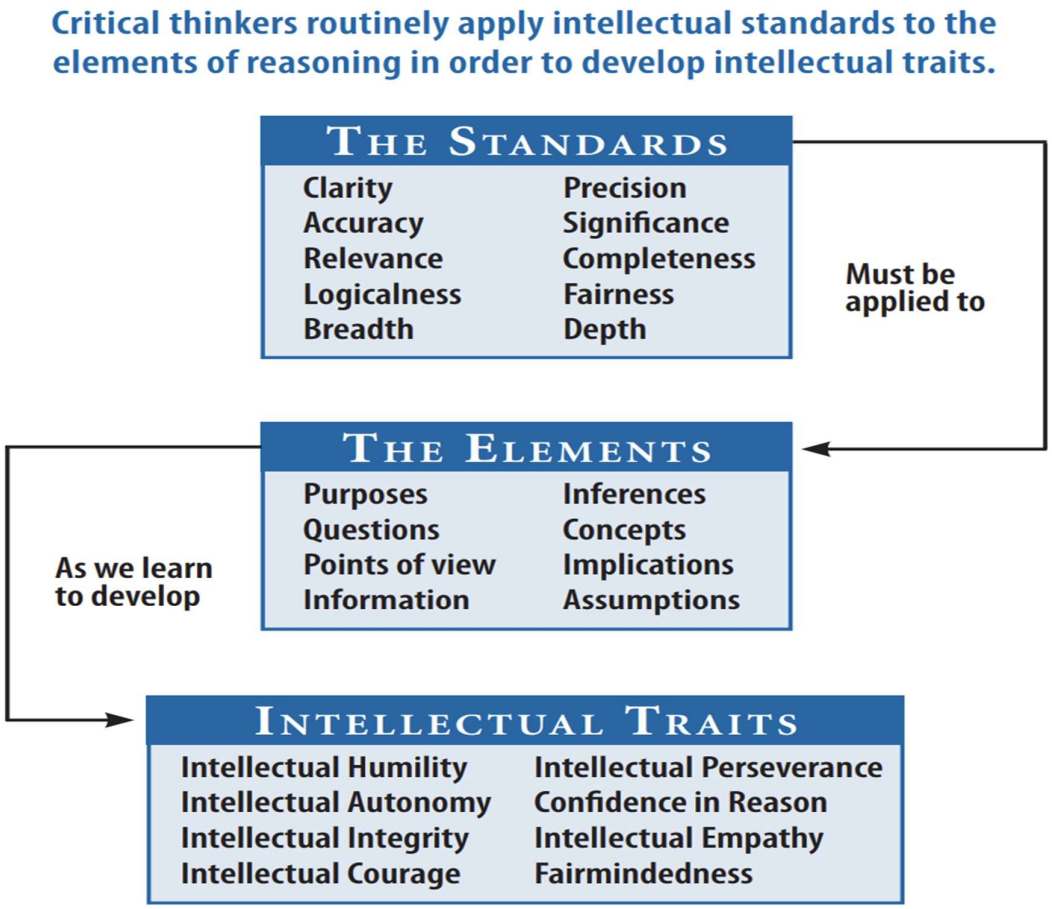


Figure 3: Critical thinkers routinely apply intellectual standards to the elements of reasoning in order to develop intellectual traits [6]

Why Critical Thinking Is Important?

The ability to think critically is necessary for autonomy. We expose ourselves to manipulation and give others the opportunity to use us as a weapon to further their own objectives when we make fast judgments based on insufficient knowledge. It may sound dramatic, but there's a chance we end up like the haughty puppet master's puppets.

For the same reason, critical thinking is essential to a democracy in operation. People are regularly forced to endorse policies that are at odds with their needs or ideals through trickery and deception. For instance, empirical evidence unequivocally demonstrates that human survival depends on clean air and comfortable temperatures. If we wish to preserve these necessities for next generations, we must act now.

As said earlier, critical thinking also protects us against those who stand to benefit financially by deceiving us. For example, an unregistered or dishonest stock broker may try to convince you that investing in a certain group of companies today would provide a tenfold return on your money, even if their

assertions are well-supported by data and the markets are notoriously unpredictable **[8]**.

Benefits of Regulatory Intelligence:

There are several significant benefits to regulatory intelligence in the biological sciences.

These are only a few of the **main advantages**:

Improved compliance: By keeping them informed about the most recent regulations and recommendations, RI assists life sciences enterprises in meeting all applicable obligations. This safeguards the company's reputation and discourages disobedience.

Faster time-to-market: By using RI, which monitors regulatory requirements and changes, businesses may speed up the regulatory approval process for new items. This might provide you a significant competitive advantage.

Better risk management: Regulatory risk assessment (RI) helps companies identify and assess the regulatory risks associated with their product lines and operational processes. By being aware of these dangers, businesses may develop measures to reduce these risks and the likelihood of regulatory issues.

Increased efficiency: By providing timely and relevant information, RI can help life sciences companies avoid wasting time and resources on activities that are no longer required or add no value.

Improved decision-making: RI can offer insightful information about the regulatory environment, especially with regard to current developments and trends. Companies may use this information to gain a competitive advantage, improve their strategic choices, and keep up with changing regulations **[3]**.

Role of Critical thinking in regulatory intelligence:

Critical thinking plays a major role in **regulatory intelligence** in the pharmaceutical and healthcare sectors.

Evidence-Based Decision Making: Active and thorough information assessment is necessary for **critical thinking** in order to make well-informed decisions. Evidence-based thinking is a crucial skill for **regulatory intelligence** specialists to employ in order to differentiate fact from speculation **[7]**. Regulatory experts carefully assess data in order to make decisions that impact pharmaceutical development, safety, and compliance.

Problem Solving and Trend Analysis: A critical thinker stays abreast of changes in regulations, technological advancements, and market dynamics through trend analysis and industry surveillance. Regulatory experts deal with complex issues related to labeling, post-market surveillance, and prescription authorization. They may simplify complicated problems and offer

workable solutions by using critical thinking.

Risk Assessment and Mitigation: Critical thinkers draw attention to the risks associated with novel drugs, devices, or treatments. When creating risk-reduction strategies, they take patient safety, effectiveness, and compliance into account.

Navigating Ambiguity and Uncertainty: regulatory environment is constantly shifting and usually ambiguous. Critical thinkers evaluate unclear laws, make well-informed judgments, and adapt to changing legal environments. They assess the material by considering both applications in the actual world and recent scientific discoveries.

Quality Assurance and Compliance: When presenting reports to regulatory bodies, critical thinking guarantees strict quality control, preventing mistakes and omissions. Experts assess legal requirements, making sure that norms and regulations are followed.

Effective Communication: Critical thinkers are able to communicate complex regulatory concepts to a variety of audiences, such as coworkers, patients, and healthcare providers. Their proof convinces others, influencing decisions on regulations and policy.

Strategic Planning: Critical thinkers predict future obstacles through the combination of legal requirements and business goals. They utilize resources wisely, setting important tasks in order of significance and providing proof for them.

CONCLUSION

Regulatory intelligence is a critical tool for life sciences organizations to succeed in the complex regulatory environment of today while maintaining compliance, global competitiveness, and compliance. RI helps firms to identify issues, examine patterns, and handle compliance proactively.

Utilizing current regulatory information and insights allows businesses to make informed choices, reduce regulatory risks, and take proactive steps to accelerate approvals and grasp new opportunities.

In today's world, leadership abilities and critical thinking may become increasingly crucial. Typically, they are undervalued abilities that need to be acquired and used from the time of employment until retirement. They serve as the cornerstone for the executive abilities that companies look for. At all levels, those who possess these abilities are easily acknowledged and rewarded.

In conclusion, regulatory professionals can successfully negotiate the complex terrain of medical research, safety, and compliance thanks to their critical thinking abilities. It encourages risk management, evidence-based decision making, and clear communication. Critical thinkers continue to guide the expanding regulatory sector in a

way that safeguards both business advancement and patient safety.

I've given a comprehensive summary of the value of critical thinking in regulatory intelligence, highlighting how it supports evidence-based decision making, risk assessment, and issue resolution.

ACKNOWLEDGEMENT

Our thanks to Sri Adichunchanagiri College of Pharmacy, B. G. Nagara for their support.

CONFLICT OF INTEREST

None to declare.

REFERENCES

[1] Importance of critical thinking in regulatory intelligence [Internet]. [cited 2024 May 18]. Available from: https://www.raps.org/events/importance-of-critical-thinking-in-regulatory-intelligence

[2] Yocher RE. Critical thinking and leadership skills for regulatory professionals [Internet]. [cited 2024 May 18]. Available from: https://www.raps.org/News-and-Articles/News-Articles/2019/8/Critical-Thinking-and-Leadership-Skills-for-Regula

[3] Scilife. A game-changing approach: The importance of regulatory intelligence in the pharmaceutical industry [Internet]. 2023 [cited 2024 May 18]. Available from: https://www.linkedin.com/pulse/game-changing-approach-importance-regulatory-intelligence-pharmaceutical/

[4] Facione, P. A. (2011). Critical thinking: What it is and why it counts. Insight assessment, 2007(1), 1-23. Available from: https://www.researchgate.net/publication/251303244_Critical_Thinking_What_It_Is_and_Why_It_Counts

[5] Koli P, Raut S, Mande R, Shelake S, Chougule N, Student U. AN OVERVIEW OF REGULATORY INTELLIGENCE. 2023 [cited 2024 Jun 4];11:953. Available from: http://www.ijcrt.org/papers/IJCRT2304232.pdf

[6] Paul R, Elder L. Critical Thinking. Pearson Education (Us); 2015. Available from: https://home.miracosta.edu/rfrench/documents/MiniGuidetoCT.pdf

[7] Importance of Critical Thinking in Regulatory Intelligence [Internet]. RAPS Regulatory Exchange. [cited 2024 May 30]. Available from: https://connect.raps.org/events/event-description?CalendarEventKey=664e6769-01dd-42c0-b41c-01882d136705

[8] The Importance of Critical Thinking & How to Think Critically [Internet]. www.linkedin.com. [cited

2024 Jun 4]. Available from: https://www.linkedin.com/pulse/importance-critical-thinking-how-think-critically-rupinder-dhillon/

[9] A Comprehensive Review of Regulatory Intelligence and Its Framework [Internet]. Default. 2024. Available from: https://www.pda.org/pda-letter-portal/home/full-article/a-comprehensive-review-of-regulatory-intelligence-and-its-framework