

# Building resilience: Navigating challenges and thriving among the demands of regulatory writing

Phani Ayalavajjala<sup>1</sup>, Roy D'Souza<sup>2</sup>

<sup>1</sup> AstraZeneca, Gothenburg, Sweden

<sup>2</sup> AstraZeneca, Cambridge, UK

doi: 10.56012/bhpo9967

## Correspondence to:

Phani Ayalavajjala

phani.ayala@astrazeneca.com

## Abstract

Regulatory writing is a demanding yet rewarding profession in which writers help pave the way for groundbreaking healthcare innovations that improve the lives of patients. However, as critical as our work is, regulatory writing is full of challenges that can feel insurmountable at times, even for the most experienced writers. Through real-life scenarios, we explore the transformative power of resilience, a trait critical in enabling regulatory writers to overcome adversity and obstacles we may face in our daily work. We look at strategies that can help regulatory writers cultivate resilience thus allowing us to thrive in the demands of regulatory writing.



## Background

**P**icture this:

*You are a dedicated regulatory writer, and as your day unfolds, your to-do list seems to expand endlessly. You are tasked with the intricate art of transforming complex scientific terminology into easily understandable prose, interpreting data accurately and transparently, and distilling it all into coherent key messages for your regulatory documents. Your responsibilities include meticulously navigating the ever-changing regulatory landscape and addressing a multitude of comments on your drafts – some helpful, others seemingly bewildering. On top of it all, you provide project management, clarify the roles and responsibilities in the document development process, and often unintentionally are a point of contact for your cross-functional team's general queries. All of this occurs while racing against the relentless ticking of the clock of your document deadline.*

Does this scenario resonate with you? For those in the world of regulatory writing, this scenario is not hypothetical; it is a daily reality. We are the unsung heroes behind the scenes. We bridge complex data interpretation with compliance and global regulatory requirements, ensuring that every document meets stringent standards, paving the way for groundbreaking healthcare innovations to improve the lives of patients. But as indispensable as our work is, it comes with a set of challenges that can sometimes feel insurmountable. The journey of a regulatory writer is a constant push-and-pull between large volumes of data and tight schedules, demanding both technical precision and creative finesse. The question arises: “How do we not just survive but thrive in this demanding landscape?”

In this article, we will embark on a journey, exploring the vital role of resilience in the world of regulatory writing. We will delve into the common

obstacles regulatory writers face, examine the impact on our writing process and well-being, and equip ourselves with strategies to not only weather the storm, but emerge stronger and more resilient.

So, fellow regulatory writers, let's dive into the heart of the matter and discover how resilience can be our trusted companion on this challenging yet rewarding path.

### Understanding the psychological journey through challenges faced by regulatory writers

When regulatory writers find themselves facing a barrage of challenges, they embark on a psychological journey that is all too human. This journey can be broken down into three distinct phases, each with its own emotional and cognitive characteristics.

#### Peaks of worry



Firstly, let's consider Kimberley, a junior regulatory writer who recently embarked on her career in the field. Kimberley finds herself in a challenging situation as she is tasked with creating her first comprehensive summary document. However, the reality of the job hits her hard when her document receives extensive feedback and revisions from various stakeholders, including senior experts in the field.

In this phase, Kimberley experiences what we commonly refer to as "peaks of worry." It is a situation that many of us in the regulatory writing profession can relate to. Initially, when confronted with a daunting challenge such as addressing numerous comments, some contradictory to each other and a number which provide no clear guidance on what changes should be made, individuals tend to reach these "peaks of worry." The mind races with anxiety, and it becomes tempting to either give in to the

overwhelming stress or to burden oneself with excessive worry when trying to progress the work to the next milestone. The weight of the situation can indeed feel insurmountable.

#### Philosophical contemplation



Meet John, an experienced regulatory writer, who planned a streamlined presentation of key data in his Clinical Overview for an upcoming submission. He convened a kick-off meeting where the team approved his proposal to refer to the pivotal Clinical Study Report (CSR) for additional data, emphasising the critical assessment of clinical data within his document. However, after the data readout, the team unexpectedly changed course, demanding inclusion of text, tables, and figures from the CSR in John's document, citing the need for their presence in the Clinical Overview. John now faces the challenge of persuading his team that his original presentation met regulatory requirements and effectively conveyed the necessary information. He warns that adding redundant data could dilute the document's key messages and potentially prompt requests for supplementary information.

In the face of these relentless challenges, John enters a phase we call "philosophical contemplation." This phase is not unique to John; it is part of the psychological journey many regulatory writers go through. During this period, John finds himself pondering what value he brings to a team who do not appear to take onboard his advice from years of experience in writing documents such as this.

Regulatory writers may often find themselves grappling with similar questions regarding the purpose and ultimate significance of their value and work in light of teams seemingly underestimating their advice.

### Recovery and resilience



Lastly, let's turn our attention to Ananya, a seasoned veteran regulatory writer. One day, Ananya receives an urgent request to author a new business critical regulatory document with a tight deadline. To make matters more challenging, the strategy for the content has not been finalised and the team is spread thinly supporting other priority projects simultaneously, and thus are not yet engaged with Ananya. As the clock ticks, Ananya needs to get a draft written in time for the looming review, for which she expects to receive numerous revisions from the various stakeholders.

Ananya's predicament paints a vivid picture of the pressure regulatory writers often face. The sudden and unexpected request to produce a new unplanned document is a scenario that can disrupt even the most meticulously planned schedules. The lack of contribution from subject matter experts because they are spread too thinly across the various projects can add to the anxiety that regulatory writers feel when seeking to progress work to the next key milestone (such as getting a draft ready for an upcoming review).

Initially, when confronted with daunting challenges like no defined strategy, lack of team engagement, potentially complex content, and tight deadlines, it is easy for regulatory writers to become overwhelmed and to be unsure of how to move forward. However, after experiencing the initial "peaks of worry" and a short period of "philosophical contemplation", regulatory writers will enter the transformative phase of "recovery and resilience", the phase where the true essence of resilience shines through.

#### Resilience: a foundation for success

In the dynamic and demanding field of regulatory writing, success is not solely determined by one's technical prowess or knowledge of regulations.

While mastering the intricacies of the profession is undeniably essential, there is another crucial factor that sets exceptional regulatory writers apart – resilience.

### What exactly does resilience mean in the context of regulatory writing?

At its core, resilience is the capacity to bounce back from adversity and adapt positively to challenging situations. In the world of regulatory writing, it is the unwavering resolve to maintain composure when faced with tight deadlines, complex content, managing team dynamics, evolving regulations, and the ever-present possibility of revisions, and many more scenarios that we as regulatory writers encounter daily. Resilience is an unseen force that manifests as the ability to remain focussed and steadfast amidst the storm of demands and uncertainties. It empowers writers to adapt swiftly to shifting requirements and situations while consistently delivering accurate and high-quality documents to their given deadline.

Practically, resilience equips regulatory writers such as Kimberley, John, and Ananya in the above scenarios, to approach difficulties with a problem-solving mindset. Rather than succumbing to worry or over-analysis, resilient writers compartmentalise tasks, leverage available resources, and engage in open communication with peers and stakeholders. They understand that they are not alone in their experiences and that collaboration can lead to innovative solutions.

### Strategies to develop resilience in regulatory writing

Resilience is not an innate trait but a skill that can be nurtured through deliberate efforts. In the realm of regulatory writing, a profession characterised by high demands, uncompromising standards to meet stringent regulations, and substantial responsibilities, building resilience is not merely a choice; it is imperative. To assist empowering regulatory writers on their journey toward cultivating greater resilience, we offer a structured roadmap comprising practical steps and valuable resources.

#### Self-care practices

By nurturing your physical, emotional, and mental well-being, regulatory writers can cultivate resilience and fortify themselves against the rigors of the field, ensuring they remain adaptable, focussed, and capable of thriving amidst the challenges they face.



- **Setting boundaries and taking breaks:** Establish clear work boundaries and prioritise regular breaks away from your computer. When tackling tasks like addressing review comments, short breaks can help you refocus, provide clarity, and prevent misunderstandings. Learning to decline non-essential meetings/tasks also safeguards against burnout.
- **Digital detox:** Set aside dedicated time each day before bedtime to disconnect from electronic devices and screens. This break from technology can help reduce mental clutter and promote relaxation.
- **Mindfulness meditation:** Incorporate mindfulness meditation into your daily routine using apps like Headspace and Calm. These guided sessions can quiet a racing mind, reduce anxiety and rumination, and help you focus on the tasks ahead.
- **Gratitude practice:** Cultivate a sense of gratitude by taking time each day to acknowledge and appreciate the things you are thankful for. This practice can help shift your focus from challenges to positive aspects of your life, fostering resilience and a greater sense of well-being.

#### Mindset shift

In the fast-paced and demanding field of regulatory writing, the ability to embrace challenges is paramount to help regulatory writers grow and build resilience.

- **Prepare for the unexpected:** Instead of fixating on potential problems, create both a primary plan and backup plans. This approach ensures readiness to pivot if unforeseen challenges arise.
- **Break tasks down:** When faced with complex issues, divide them into smaller tasks for

easier resolution. This prevents procrastination and facilitates quicker problem-solving.

- **Embrace positivity:** Foster a constructive mindset by practicing positive self-talk and affirmations using tools like ThinkUp. This habit strengthens resilience and bolsters mental well-being.

#### Effective management techniques

By implementing targeted effective management strategies, regulatory writers can develop their resilience, optimise their performance, and thrive in the demanding and dynamic environment of regulatory writing.

- **Time management tools:** Utilise time management tools and techniques, such as the Pomodoro Technique or time tracking apps, to improve productivity and focus. These tools help you manage your time more effectively and avoid procrastination.
- **Time blocking:** Organise your workday into dedicated time blocks for different tasks, such as drafting, reviewing, and responding to comments. This helps prevent being overwhelmed and ensures focussed attention on each activity.
- **Priority setting:** Identify the most critical tasks and prioritise them based on deadlines and importance. Breaking down larger projects into smaller, manageable tasks can make them feel less daunting and more achievable. It is OK to say “no” to meetings/tasks that are non-essential and distract you from your priorities.
- **Task delegation:** Delegate non-essential tasks to team members or colleagues where possible to lighten your workload and free up time for high-priority responsibilities. Effective delegation requires trust and clear instructions.

- **Effective communication:** Maintain open and transparent communication with project teams and stakeholders to clarify expectations, address concerns, and prevent misunderstandings. Clear communication can reduce stress and improve collaboration.
- **Conflict resolution skills:** Approach conflicts with empathy and professionalism and actively listen to all views. This will help to understand the issue and may lead to a swifter resolution.

### Learning from experiences, mistakes, and collaboration

By leveraging past encounters, refining approaches, and fostering collaborative endeavours, regulatory writers fortify their resilience, adaptability and problem-solving skills, essential elements in navigating the dynamic challenges of their profession.

- **Embrace lessons learned:** Utilise solutions that have proven effective in previous experiences, while remaining open to adapting and improving upon them for continuous enhancement.
- **Adaptability and continuous improvement:** Don't hesitate to modify strategies or solutions that did not yield optimal results previously, as resilience entails learning from mistakes and refining approaches.
- **Share best practices:** Facilitate knowledge sharing among team members by highlighting successful approaches and techniques, promoting a culture of continuous learning and improvement.
- **Cultivate transparency and collaboration:** Foster an environment of openness and teamwork within project teams, emphasising trust-building and effective communication.
- **Engage in collaborative problem-solving:** Actively involve your team members in problem-solving processes, leveraging diverse perspectives and expertise to find innovative solutions.

- **Understand team dynamics:** Draw upon past collaborations with team members to tailor your approach to future interactions, adapting to specific needs and preferences where possible.
- **Advocate for strategic content review:** Encourage reviewers to focus on strategic content evaluation rather than duplicating efforts on editorial aspects, fostering efficiency, effectiveness and improving the quality of the document. This will also reduce the "peaks of worry" that regulatory writers may experience when evaluating the (potentially numerous) review comments.

### Continuous professional development, peer networking and mentorship

In the dynamic field of regulatory writing, where regulations and guidelines evolve, and expectations escalate, continuous professional development emerges as a vital tool for fostering resilience. By investing in ongoing learning and skill enhancement, regulatory writers bolster their capacity to thrive amidst uncertainty, ensuring they remain agile, competent, and resilient in the face of adversity.

- **Stay updated:** Continuous learning and staying informed about technology advancements (e.g., natural language generation [NLG], machine learning [ML], artificial intelligence [AI]) and guidelines are crucial for regulatory writers. Participate in webinars and workshops offered by professional organisations such as the EMWA to keep abreast of the latest developments in the field.
- **Online learning platforms:** Accessing courses on medical writing and related skills through platforms like LinkedIn Learning and Coursera can enhance your knowledge and expertise. These platforms offer a wide range of courses that you can complete at your own pace, allowing for continuous professional development.

- **Peer networks:** Engage with fellow regulatory writers externally through forums, discussion groups, and platforms like LinkedIn. Internally, collaborate with colleagues to exchange experiences and seek advice. It is essential to tap into the knowledge and experience of peers within or outside your organisation who have faced similar situations.
- **Mentorship programmes:** Seek mentorship opportunities within your organisation or industry to gain valuable insights from experienced professionals. Mentorship can provide guidance, support, and encouragement, helping you navigate challenges and develop professionally as a regulatory writer.

### Conclusion

In conclusion, resilience is not a vague or intangible concept, it is the cornerstone of success in regulatory writing. While technical expertise is crucial, it is resilience that empowers writers to harness their skills effectively. By nurturing resilience, regulatory writers can not only survive but thrive in the ever-evolving world of regulatory documentation. It is a reminder that, in the face of overcoming what sometimes may feel like insurmountable obstacles or challenges, a resilient mindset is an opportunity for growth and the key to unlocking one's full potential and achieving lasting success in this demanding profession.

### Disclaimers

The opinions expressed in this article are the authors' own and are not necessarily shared by their employers or EMWA.

### Disclosures and conflicts of interest

The authors declare no conflicts of interest. The images in this article were created with the assistance of the DALL-E 2 AI tool.

### Author information

**Phani Ayalavajjala**, MSc and PhD in Biochemistry, has more than 15 years of experience in regulatory scientific writing including leading global medical writing teams. Currently he is working as a Director and Line Manager at AstraZeneca, Sweden. He has extensive experience in authoring clinical and regulatory deliverables.



**Roy D'Souza**, BSc (Hons) in Biochemistry, has over 23 years of experience in industry including regulatory writing where he has led medical writing submission teams. Currently he is working as a Director and Program Lead at AstraZeneca, UK. He has extensive experience in authoring clinical and regulatory deliverables.