

Out of chaos: Past transformed presents future options.

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Prologue: Uncertainty in pharmaceutical manufacturing and real-world utility can lead to anxiety, while predictability—such as meeting targets or passing inspections—instills confidence and ensures quality. A systems approach infused with design thinking is vital for accurately, precisely and consistently achieving the correct targets and evidencing success. This approach must address real-world needs, expectations and unadulterated communication of documented evidence of consistent quality. Cultivating higher consciousness, or qualia, is essential but challenging. As the world appears to spiral into chaos, how we tackle this challenge will determine whether we face a dystopian future or true enlightenment. This article explains why transforming the past is necessary and how to do so in a way that presents new, meaningful options for an enlightened future.

INTRODUCTION

New knowledge, particularly in research and development, arises from the questions we ask, the confidence we seek in our answers and the assumptions—or “accepted” truths—we draw from existing knowledge. A common saying is that knowledge begets more knowledge, but what happens when prior knowledge is shrouded in trade secrets, protected as intellectual property, or fundamentally flawed yet holds an anchor of approval and validity? Chaos ensues.

But what does chaos mean? The meaning of chaos depends on context. Consider the Bloomberg News headline from 30 August 2017: “With U.S. Generic Drug Market in Chaos, Indian Upstarts Rise” (Ari Altstedter, 2017). In this context, chaos suggests a system teetering on instability, where established players face unpredictable supply issues, creating openings for new startups. From a systems perspective, chaos refers to extreme sensitivity to initial or starting conditions, leading to erratic or unpredictable behavior beyond an average.

We live and work in social systems; a corporate or pharmaceutical quality management system is a hybrid socio-technical system. When such a system exhibits unpredictability, what are the unaccounted sensitivities embedded in its inception?

Reflecting on these questions, I authored an industry report 2019 titled “Chaos to Continual Improvement: Path to Harmonization” (Hussain, 2019). An expert opinion is helpful but must also be grounded in knowledge. Building on collaborative research at the National Institute for Pharmaceutical Technology and Education, we proposed a remedy called “Pharmaceutical ‘New Prior Knowledge’: Twenty-First Century Assurance of Therapeutic Equivalence” (Hussain, Gurvich and Morris, 2019).

In 2020, a virus, SARS-CoV-2, whose origins (“initial conditions”) are still debated, changed the world and chaos ensued. Testing to document infections became the basis for declaring and managing the COVID-19 pandemic. History may ultimately judge the scientific rigor and maturity of the public health response. This report, however, focuses on strategies to leapfrog out of chaos.

LEAPFROGGING OUT OF CHAOS

The need for a leapfrog strategy becomes evident with the pandemic experience still fresh in collective memory. Leapfrogging involves bypassing traditional, incremental progress to advance rapidly, avoiding past missteps or irrelevant steps. This strategy prioritizes human potential, leverages technology for humanity’s benefit and strengthens institutional frameworks to harness positive synergies (Otto Schulz and Mauricio Zuazua, 2018).

Technology is often a double-edged sword; it is essential to harness technology while mindful of mitigating its risks, including addiction. My work in the tobacco sector has given me a nuanced understanding of technology’s role in assessing evidence and claims related to modified-risk tobacco products designed for harm reduction (FDA, 2024). Integrating this experience with my pharmaceutical background led me to explore potential leapfrog strategies, including in Thailand’s biotechnology sector, as detailed in an online presentation (Hussain, 2024a).

Although I have not visited Pakistan in person, I have gained valuable insights through virtual engagements and initiatives such as the Culture of Cultivating Knowledge (CCK) and the book “Pharmaceutical Quality for the 21st Century: Feeling the Shadow of the Future” (Obaid, 2021). I hope this article inspires the pharmaceutical community in Pakistan to identify leapfrog opportunities hiding in plain sight and chart a transformative path that generates an enlightening “butterfly effect.”

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A door-opening leapfrog opportunity hiding in plain sight

Sir Muhammad Iqbal's quote, "Be aware of your worth, use all of your power to achieve it. Create an ocean from a dewdrop. Do not beg for light from the moon; obtain it from the spark within you," speaks to self-realization and the transformative potential within individuals. It emphasizes that even a tiny inner spark can ignite profound personal and societal change, embodying the essence of a "butterfly effect."

Self-authorship is a crucial adult development stage (Kegan, 1998). It can help professionals by grounding their language in knowledge, ensuring evidence is accurately represented and preventing false claims. In a post-truth world, this represents a significant opportunity often overlooked. With the rise of large language models and generative AI, we have an unprecedented chance to use these tools to promote self-authorship and encourage informed, reflective practice. Failing to do so may lead to a form of enslavement.

A seed crystal can crystalize a transformation

The world is excited to adopt Generative AI. A former colleague at the FDA recently invited me to participate in a conference on AI-unable drug development and commercialization. I was reluctant to do so, but I am glad I did. I now need to call out urgently regarding the need for due diligence (Hussain, 2024b, Hussain, 2024c).

What should the process be for due diligence in English, Urdu, and the sixty-plus lineages spoken in Pakistan? Should we outline the principles of current good linguistic practice? Perhaps an effort can be undertaken, as in the CCK effort discussed and democratized across the population, to build consensus on ground communication at every level of an organization in [valid] knowledge in the SMART cities and factors we may soon live and work in.

To leapfrog out of chaos, such efforts would focus on identifying and nurturing the following:

Core Strengths: Recognize and utilize local capabilities, such as a well-educated, youthful workforce skilled at adapting to new technologies and methodologies. These foundational elements set the stage for a transformative "butterfly effect" that impacts all levels of society, breaks outdated constraints, challenges deeply held assumptions, and promotes the pursuit of "new prior knowledge." This empowerment helps individuals pose meaningful questions and seek answers with the confidence needed for impactful innovation.

Technological Integration: Utilize digital tools such as AI and data analytics to modernize quality management, enhance predictive capabilities, and improve decision-making. However, do so responsibly to maintain human

accountability and facilitate more timely feedback to support continuous improvement.

Adaptive Learning and Leadership: To navigate and adapt effectively in complex, uncertain situations, fostering continuous professional development is essential. Emphasizing experiential learning and systems thinking equips individuals to become leaders who embody self-authorship and are capable of strategic, empathetic decision-making. Sensemaking or meaning-making supports this by enabling individuals and organizations to interpret ambiguity, identify patterns, and create a coherent understanding. This reflective process integrates higher Orders of Consciousness, where individuals challenge assumptions, synthesize knowledge, and construct new meanings beyond established frameworks, ensuring adaptability and informed action in evolving contexts.

Collaborative Ecosystems: Establish partnerships among academia, industry, and government to foster innovation, knowledge sharing, and regulatory advancement. Specific areas often require attention include rigorous statistics, particularly multivariate analysis, material science, and engineering. The National Institute for Pharmaceutical Technology and Education, a not-for-profit collaboration among several universities in the United States, may be helpful for study (Hussain, Morris and Gurvich, 2021).

CONCLUSION

Pharmaceutical professionals are qualified through their education, training, and experience to take on responsibilities that affirm the validity of their work, which must be documented with integrity. Continuous development and practice improvement are essential for building confidence and internal validation, reducing reliance on external affirmation. Self-authorship, representing the fourth order of consciousness or qualia, is a crucial milestone in adult development. As professionals mature, their choices and language become more deeply rooted in facts and evidence.

In a world increasingly defined by chaos and misinformation, fostering self-authorship as a communication standard is critical to ensuring that messages are rooted in verified knowledge and minimizing the risk of false claims. Cultivating this level of awareness is essential yet challenging.

Generative AI poses both an opportunity and a risk. On the one hand, it could reduce professionals to mere "copying and pasting" automatons with a "carbon footprint" that must be minimized. On the other hand, it holds the potential to enrich professional development, serving as a tool for deeper learning and reflection. Creating a culture that prioritizes factual information and rigorous due diligence is crucial to harnessing AI effectively and

ensuring that linguistic practices support all of Pakistan's diverse languages.

A tiny inner spark can ignite significant personal and societal transformation, embodying the essence of the "butterfly effect" and paving the way for sustainable progress and enlightened development. Might language be a door-opening leapfrog opportunity hiding in plain sight?

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