



AFRiSUMMIT

Grand Nile Tower, Cairo - Egypt

3 - 6 November 2024

Initiative By



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Exclusive Interview with **Satchel Sponsor**



Dr Claudy Raymond

Chairman &
Managing Director



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www.pharmaregafri summit.com

1. How does One Pharma Medics stay updated with the rapidly changing regulatory landscape in the pharmaceutical industry, and what strategies do you implement to ensure compliance?

One Pharma Medics adopts a robust and multifaceted strategy to ensure compliance with evolving regulatory requirements. This can be achieved by:

Continuous Monitoring of updates from key regulatory bodies and using Advanced Business Intelligence Tools which are sophisticated tools to stay informed and compliant. In addition to Internal Compliance Teams which are dedicated teams to uphold standards, besides conducting the Regular Audits and comprehensive employee training programs.

Plans for Proactive Risk Management and implement measures to identify and mitigate potential risks.

Strong Regulatory Relationships and Maintaining close ties with regulatory authorities and Expert Collaboration which facilitates Working with industry experts to navigate complex regulations effectively.

This comprehensive approach ensures that One Pharma Medics remains at the forefront of regulatory compliance.

2. What are the most significant regulatory challenges that have been faced in recent years, and how did you address them?

One Pharma Medics has successfully navigated significant regulatory challenges in Egypt, characterised by rapid changes and stringent deadlines. The company achieved this by quickly adapting and adjusting to new regulations, with the support of Robust Internal Systems to ensure compliance and Streamlined Processes to meet tight deadlines.

In addition, Improving coordination across teams, and all of this led One Pharma Medics to Set a new record in registration filings over the past two years through meticulous planning and robust compliance strategies.

This reflects the underscores of One Pharma Medics' commitment to maintaining regulatory compliance and achieving operational excellence.

3. How is technology, transforming regulatory affairs at One Pharma Medics? Can you provide examples of how these tools have improved your processes?

Technology is significantly transforming regulatory affairs at One Pharma Medics, enhancing efficiency, accuracy, and compliance. Here are some key ways technology is making an impact:

- Automated Submissions which ensures consistency and reduces human error in regulatory document submissions.
- Digital Platforms that facilitate better coordination and communication among teams, streamlining processes and improving
- Digital Transformation by the Egyptian Drug Authority (EDA), where The EDA's shift to digitalization has streamlined the submission & approval processes, reducing timeframes and improving transparency.

- In addition to Online Portals which provide real-time updates and facilitate easier communication between regulatory bodies and pharmaceutical companies.

At One Pharma Medics, we successfully integrated internal technology platforms aligning with governmental platforms to make use to all of these tools, guaranteeing faster approvals and increasing the accuracy of the whole processes

These technological advancements have enabled One Pharma Medics to navigate complex regulatory landscapes more effectively, ensuring compliance and operational excellence.

4. What trends do you foresee shaping the future of regulatory affairs in the pharmaceutical industry, and how is One Pharma Medics preparing to adapt to these changes?

eCTD (Electronic Common Technical Document) implementation can be a strategic advancement shaping the future of pharmaceutical regulatory affairs as this will lead to accelerated & standardized processes.

Also, using the new tools of AI and ML to analyze data, predict risks, and automate tasks and Real-world evidence (RWE) data to support product approvals and post-market surveillance.

Global Harmonization to Aligning practices with global standards to facilitate international operations.

Patient-centric approaches by Integrating patient feedback into regulatory strategies to meet patient needs.

At One Pharma Medics as we already adopt hi-tec integrated systems, we believe that we are well prepared for such advancements with tailored system modules fitting such criteria, where we pro-actively work on our internal system adding features to be aligned with most expected requirements by these platforms.

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