Revolutionising Regulatory Oversight:

The SFDA's Strategic Shift to Remote Inspections in the Wake of the COVID-19 Pandemic

In 2020 the COVID-19 pandemic disrupted traditional in-person inspections and audits. To adapt to this situation, regulatory agencies turned to remote methods, conducting assessments virtually to ensure oversight, while also prioritising the safety of inspectors. The Saudi Food and Drug Authority (SFDA) has implemented a robust system for remote inspection and auditing, having conducted almost 4000 remote inspections since the start of the pandemic through to the first quarter of 2023. Manufacturers in various categories – including pharmaceuticals, medical devices and food, along with local accreditation offices and establishments such as warehouses and scientific offices – have all undergone remote audits as part of this initiative.

Benefits and Challenges

The adoption of remote inspection methods has brought about several positive outcomes, chiefly in terms of efficiency. Travel time, logistical arrangements and transport costs have all seen notable reductions. The effectiveness of remote audits has been particularly evident in establishments equipped with robust IT infrastructure.

However, remote audits have not been without their challenges. Logistical, financial and technical hurdles can arise during the process. One of the primary technical difficulties encountered is related to internet connectivity, particularly for manufacturers in remote areas. For some companies, sharing critical files can be time-consuming, especially when dealing with physical documents such as design plans for medical devices, as they can take a long time to scan efficiently. Additionally, project managers face a learning curve in navigating the intricacies of the remote audit process. Discrepancies in internet quality may also exist between different areas of a single entity, for example between warehouses and office spaces.

The SFDA understands that different manufacturers pose different levels of risk in terms of compliance and product safety. To optimise resources, the SFDA tailors its approach to allocate greater attention and resources to manufacturers with higher perceived risks. A hybrid approach has been employed in certain cases, with a portion of the audit conducted online and the rest onsite. This approach is implemented selectively and only for situations in which in-person audits are unavoidable.

Overseas Audits

The SFDA's reach extends beyond the Kingdom's borders, as it can conduct audits on companies located overseas. The SFDA can exercise its regulatory authority abroad over international manufacturers whose products are intended for export to Saudi Arabia. This oversight is contingent upon specific criteria tailored to different product categories. Notably, factors like the level of risk associated with a medical device, and the presence or absence of an experienced regulatory authority in the manufacturer's home country play

significant roles in this assessment. The implementation of remote inspections has proven particularly advantageous for international audits, as they eliminate travel expenses.

Data Security

The SFDA places a great deal of importance on maintaining a consistent level of rigour and professionalism in remote inspections through its stringent protocols and skilled personnel. Ensuring the security and confidentiality of sensitive information during remote inspections is of paramount importance. To this end, the SFDA employs reliable software solutions and takes measures to reassure clients about the safety of its data. In order to exert a higher level of control and reduce the reliance on external solutions, the SFDA is working towards the development of its own inspection software. Progress in this regard is already under way and aligned with the SFDA's digitalisation strategy.

Conclusion and Outlook

In the future, the SFDA envisions remote inspections as a pillar of its monitoring framework and is committed to optimising the allocation of resources to this pursuit. It is worth highlighting that despite the benefits of remote inspections, there are certain types of audits whose unique characteristics necessitate an in-person visit.

By maintaining a forward-looking perspective on remote audits, the SFDA aims to enhance the effectiveness of such inspections by establishing precise guidelines and references, leveraging advanced technical tools, and resolving issues pertaining to data security and privacy. This innovative approach underscores the SFDA's dedication to harnessing the full potential of remote inspections, while ensuring robust quality and security standards.