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Chapter 1 : CIRS - The Centre for Innovation in Regulatory Science

But regulatory innovation is possible everywhere right now, and New York and California offer just two potential models, according to a new white paper from PA Consulting Group.

In fact, the professionals I know in these roles can and do think outside of the proverbial box to support their business colleagues and achieve critical company objectives that help increase the top and bottom line. This topic generated much interest from within the industry and there was an overwhelming response from professionals and their commercial colleagues both here and abroad to comment. Therefore, I will be writing several articles on the subject. In this article, industry veterans share best practices on how regulatory professionals can be more innovative: Regulatory professionals with cognitive flexibility can simultaneously consider two aspects of an idea or situation at one point in time. For example, even if FDA guidance is still gray regarding the use of social media, these individuals are able to examine all possibilities for executing a digital tactic in a compliant manner. They understand and are aware of options and alternatives simultaneously within any given situation. It is only then that we can begin to think not just about risks, but about opportunities and how we can achieve them. We become integrated in the strategic planning and vision of a project â€" and thus, become part of the solution, thinking broader, bigger, and creatively, while also navigating the risk. However, for me, the best results come when my regulatory compliance and legal colleagues deeply understand what we are doing and why we are doing it. When regulatory partners enhance the creative process and provide solutions, our output is quick and effective. To be effective and add real value in a regulatory role, the professional needs to partner with the other functions and get to know the business profoundly. Having the ability to come up with new ideas or options in advance of review committee meetings, or better yet in the meetings, is invaluable from a resource perspective as the team struggles to swiftly find a path forward. Being creative can also mean appropriately challenging current thinking on marketing practices or easily connecting to and leveraging previous experiences on other brands. Regulatory professionals need to be passionate, very good listeners and communicators, assertive, pragmatic, solution-oriented and always explain the rationale behind their recommendations. Successful teams understand that creativity thrives in environments that are grounded in mutual respect and trust. Go on field rides with sales reps. Learn as much as you can about what members of the commercial team face every day. Address their business objectives and strategies. Demonstrate your commitment to understanding the business.

Chapter 2 : Welcome to Compliance Key, US

Regulatory Innovation offers the first detailed study of regulatory innovation in a multiplicity of countries and domains. This book draws on in-depth studies of innovation in regulatory instruments and practices across high- and low-technology sectors, across different countries and from the early to the late 20th century.

In Europe, approximately 25, companies specialize in medical technologies, including more than 1, in France. Among these, 94 percent are small companies those employing fewer than people 1. Despite the strong growth of these startups, which has been facilitated by exchanges with science companies and manufacturers, these businesses continue to face many obstacles in the highly competitive global market. French and European LifeScience startups are growing fast but also face many Regulatory barriers, including Compliance and Funding. Find out how to successfully navigate these hurdles, says MCMasterControl http: Life science companies and notably those in the field of medical devices must be nimble and be able to transition on the fly. The current transitional period for its implementation defines the critical path for CE mark approval. Innovative startups must be fully aware of the changes that compliance will require and must evaluate the return on investment ROI of their product. Many startups worry about being able to meet every requirement. So how can startups overcome these most common hurdles? Tackling regulatory challenges will entail a multidisciplinary approach. Below are three key recommendations on how to overcome some of these regulatory barriers: Before starting the development of a new product, it is important to identify the type and classification of the medical device product. This status will determine which regulations the product will have to comply with. The classification is determined based on the risk it constitutes to the patient. You can use the FDA webpage search function to find the corresponding classification of your device. Medical device classification depends on the intended use of the device e. You can find out more about the definition of intended use within the k Program: Therefore, implementing a quality system is often minimized in favor of activities that are perceived as added values, such as patents, licenses and technological partnerships. But neglecting such a system until the development is completed and the product is launched can be risky. To succeed in this endeavor, an individual within the startup must dedicated to and in charge of regulatory strategy. In addition, for the regulatory strategy to be effective, the company must integrate a culture of documentation from the beginning because 60 percent of product development is about its documentation. For financial reasons, companies often take the shortcut of bouncing between different software and web applications, or they continue to work on paper systems to manage quality. A fully integrated and automated QMS will allow the business to minimize risks in the development phase, reduce time to market and ensure the safety of drugs and medical devices. Rather than using multiple or paper-based systems, LifeScience manufacturers can benefit from a QMS that integrates documentation and results in fewer compliance snags, says MasterControl http: Below are some of the benefits of data access provided by regulatory compliance and the use of a QMS: For example, MasterControl, a U. To conclude, regulatory barriers could potentially prevent European startups from accessing the market. You can avoid this by implementing a relevant regulatory strategy that includes the implementation of QMS to bypass these obstacles. Innovative startups can rely on expert regulatory and compliance partners that specialize in life science manufacturing compliance. A powerful and proven quality system that evolves with current standards is a must-have to provide your startup with the confidence to safely and effectively market the product globally. But regulatory compliance is not the same as quality. Adopted at all levels of the company, a quality approach demonstrates the value of the company, in addition to reducing costs and saving time.

Chapter 3 : Rethinking the Role of Regulatory in Innovation â€“ Part 1 - Pharmaceutical Compliance Monito

The Financial Conduct Authority announces a collaboration with 11 other global regulators and government entities called the Global Financial Innovation Network an important next step in.

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Chapter 4 : Innovation in medicines | European Medicines Agency

time, regulatory reform is a powerful stimulus to further innovation. Competition-enhancing reforms in both the manufacturing and service sectors have been essential to the development and diffusion of new technologies, such.

Chapter 5 : Consultation on the New Reg process | Australian Energy Regulator

I've written several articles about the need to eliminate the misperception that regulatory, legal and compliance professionals are sales suppressors and policemen.

Chapter 6 : Governor's Office for Regulatory Innovation and Assistance

The Governor's Office for Regulatory Innovation and Assistance (ORIA) helps people navigate Washington's environment and business regulatory systems and works with our partners to improve those systems through innovative solutions.

Chapter 7 : Regulatory Barriers to Innovation for Startups

FDA's Centers of Excellence in Regulatory Science and Innovation (CERSIs) are collaborations between FDA and academic institutions to advance regulatory science through innovative research.

Chapter 8 : Regulatory innovation | Lygature

Rather the regulatory process should be publicly accessible, allowing sufficient time for public input. Scientific Integrity The science used to inform regulatory decision-making should be reproducible, objective, and untainted by government influence.

Chapter 9 : Coalition for Regulatory Innovation

innovation allows the firms to escape the regulatory constraints. For example, the regulation of a financial product, such as checks, may cause a bank to develop new financial products, such as.