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New paper spotlights impact of COVID-19 on regulatory & quality compliance activities for life science companies

Maetrics' new whitepaper provides guidance on re-assessing compliance strategies and requirements

August 2020 – A new white paper from leading regulatory and compliance consultancy, Maetrics, highlights how the COVID-19 pandemic is affecting the key business function that safe-guards patient safety: regulatory and quality compliance in the life science sector.

This new paper offers critical insights to an industry under pressure to meet current global healthcare needs, analyzing specific quality and regulatory issues that have arisen since the start of the pandemic, such as greater supply chain scrutiny. It includes a high level discussion of the strategic approach needed to provide effective regulatory and quality support across the entire organization, as well as a comprehensive checklist for RA & QA professionals which can be used to assess internal readiness for existing and upcoming regulatory changes.

COVID-19 has introduced significant new compliance pressures. Many businesses were already struggling to meet the current set of regulatory deadlines in the US and Europe. The coronavirus health crisis has introduced additional priorities and concerns, including further regulatory changes, product shortages, and supply chain disruption. To respond to these challenges efficiently, companies must take a fresh look at their compliance activities and rethink their strategic approach.

With this in mind, Maetrics has put together a framework for evaluating resource needs both in the short and long-term. When making a strategic review of processes, regulatory compliance resources and responsibilities, and whether they should be outsourced, senior executives can use this checklist to make sure the main bases are covered. Astute planning and allocation of resources will help businesses to achieve greater levels of agility and economy in coping with the rapidly changing requirements.

Steve Cottrell, President at Maetrics, comments: “Though this has undoubtedly been a challenging time for the industry, the need to re-assess operations may also reveal opportunities for increased business efficiency and streamlined processes. We wanted to share this framework as it is based on Maetrics’ collective experience supporting organizations to manage their regulatory requirements during this time.”

“What we have learnt is that the more robust organizations are able to drive a flexible inhouse:outsource resource balance; any rapid changes in their circumstances means that they have support across a variety of product, geographic and specialist regulatory knowledge bases, to deploy when it is most needed, reducing risk for your organization. Scalability and flexibility is the key to regulatory and quality compliance in the new normal. We have included a checklist to assess how

well companies are positioned to meet current and future regulatory obligations and hope this will provide value in the re-evaluation process.”

The full whitepaper is available to download here: <https://bit.ly/30Tjddx>.

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About Maetrics

Founded in 1984, Maetrics is a global life sciences consulting firm focused exclusively on regulatory, quality, and compliance solutions for Medical Device, Diagnostic, Pharmaceutical and Biotechnology companies. With offices throughout Europe and North America, Maetrics can assist with local, regional, or global compliance needs. www.maetrics.com