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PRESS RELEASE

TSG Consulting urges medical device manufacturers to take advantage of FDA's Pre-Sub meeting program

WASHINGTON DC – 12 July, 2019: With the majority of 510(k) submissions having major deficiencies or being rejected the first time, scientific and regulatory experts TSG Consulting recommend that manufacturers schedule a Pre-Submission (Pre-Sub) meeting with the FDA to improve the likelihood of the medical device being approved for sale in the US market.

510(k) submissions allow manufacturers to fast-track approval of their medical device by claiming it is "substantially-equivalent" to a device that has already been cleared and marketed in the US. However, depending on the modifications made to the device, this may begin with multiple setbacks for the applicant, for example the FDA might refuse to accept the submission if it is incomplete, or send a long list of major deficiencies if the submission is technically inaccurate. A formal Pre-Submission meeting with the FDA is an opportunity for applicants to gauge the FDA's current thinking on their device's overall safety and effectiveness, as well as resolve any technical issues prior to the final 510(k) submission.

"Pre-Sub meetings are completely voluntary and give applicants the opportunity to interact with the FDA at no cost," says Dr Om Singh, Senior Scientific Consultant, TSG Consulting, and former Lead Reviewer at the FDA. "The Pre-Sub program is extremely valuable for obtaining the FDA's written feedback on existing technology, as well as helping to identify a path forward for device development and clearance or approval. FDA's feedback is highly desirable in situations where a company may need to provide more information to ensure acceptance of the submission, for example when a device is semi-critical or critical. It is important though that FDA's advice is sought early in order to allow for the quality of data to be improved before it is included in the actual 510(k) submission."

To help companies prepare for a Pre-Submission meeting, TSG Consulting has published a free paper – How to get the most out of 510(k) Pre-Submission meetings with FDA. In addition to outlining the types of scenarios where Pre-Sub meetings are useful, the paper also outlines what needs to be submitted in the Pre-Sub package in order to obtain the most effective feedback. The free paper is available to download at www.tsgconsulting.com/advisory/how-to-guide-pre-submission-meetings-fda/

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About TSG Consulting

TSG provides companies with high-quality regulatory and scientific consulting services. We help clients worldwide address the technical and regulatory issues in taking their products to market in multiple jurisdictions. Our scientific expertise, regulatory knowledge and understanding of local nuances enable our clients to navigate the complex and ever-changing regulatory landscape across the globe.

We serve a number of key markets and industry sectors including agricultural, industrial, consumer, food and beverage, animal health, and medical. Our teams comprise scientists and regulatory experts – many of whom have previously held positions at regulatory agencies, departments and in industry. This combination of science, regulatory expertise and knowledge of how institutions and industry operate provides our clients with superior and well-rounded guidance.

TSG Consulting is a Science Group company. Science Group provides independent advisory and leading-edge product development services focused on science and technology initiatives. It has offices in Europe and North America, two UK-based dedicated R&D innovation centres and more than 400 employees. Other Science Group companies include Sagentia, Oakland Innovation, OTM Consulting & Leatherhead Food Research.

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Science Group plc (AIM:SAG) is an international consulting services group supporting the product innovation lifecycle to enable our clients to deliver on their investments in R&D. Our services fall into four broad categories: Applied Science, Product Development, Technology Advisory and Regulatory. These services are combined with vertical market expertise in Medical, Food & Beverage, Industrial, Chemical, Energy and Consumer sectors. With offices throughout Europe and North America and over 30 languages written and spoken, Science Group supports a global client base.

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