Medical Device and Technology

Helping companies navigate the COVID-19 pandemic

Our Medical Device and Technology team has been at the forefront of the COVID-19 legal response since the pandemic swept across the globe. In just a few short months, our team has taken on nearly 200 matters, ranging from attaining U.S. Food and Drug Administration (FDA) Emergency Use Authorizations (EUAs) for critical medical devices and testing kits, to advising on legal risks of producing various types of personal protective equipment (PPE) and importing devices – such as ventilators from China – for use in the U.S. and around the world.

The COVID-19 pandemic requires quick-turn, out-of-the-box approaches to mitigating a global health crisis that evolves daily. We are helping our clients navigate the minefield of regulations and work with the relevant government agencies to develop creative approaches that respond to immediate needs, and potentially alter the long-term implications of this disease.

Below are examples of a few key areas in which our team has assisted clients.

Telehealth and remote patient monitoring are here to stay now that COVID-19 has forced us to prove that virtual health technology works, and that patients can make the technology work for them. We have assisted clients in implementing these solutions, whether it be through expedited 510(k) notices or enforcement discretion for products that do not fall under traditional EUAs.

Emergency Use Authorization authority has been granted to FDA to permit the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent SARS-CoV-2 infection and COVID-19 disease. We have helped many clients submit COVID-19 related EUA requests for: molecular and serology diagnostic tests; ventilators, respirators, and their associated parts; remote monitoring devices; surgical masks and other PPE and PPE reprocessing methods; and other treatment devices. We are closely tracking FDA's evolving guidance on EUA's and additional enforcement discretion approaches during the pandemic, and helping manufacturers and laboratories offering COVID-19 tests and test validation – who rely on EUA authority – to remain in compliance with FDA standards.

Disruptions to operations caused by the COVID-19 pandemic are unprecedented, creating the ultimate stress test for global businesses. For manufacturing operations, ability to source components and supplies for medical devices, especially from foreign countries, has been adversely affected by travel and other restrictions. We have assisted companies in dealing with supply chain issues, as well as responding to supply chain issues (e.g., using manufacturing capabilities for different purposes than intended). For clinical studies, insufficient supply of the study product and missed study visits could cause protocol deviations resulting in problems with obtaining data to assess outcomes, measurements, or statistical analyses. Sponsors with ongoing clinical studies, or those deciding whether to proceed with a clinical study, must carefully consider how to handle these challenges, including changes to study protocols and analysis plans, and the associated regulatory implications. Our team has helped clients navigate this crisis, assess risk, and consider pragmatic and tailored solutions. We are closely monitoring FDA and European Union guidance on the issue, which provide significant regulatory flexibility.

Importing medical devices has always presented sizable regulatory challenges. But through our work with clients during the COVID-19 crisis, we have helped speed up that process while ensuring safety standards are retained. We have helped many clients

to understand the European marking requirements applicable to face masks, including FFP2 masks and surgical masks. In the U.S., we have helped clients navigate strict FDA requirements and the sheer logistical complexity involved to move the products across borders. We are also facilitating long-term opportunities, such as seeking marketing authorizations and analyzing supply chain vulnerabilities that will benefit the post-pandemic marketplace.

Requiring reporting of test results has been a key feature of governments' COVID-19 responses. As clients have sought to expand testing beyond "traditional" health care and laboratory settings, and into point-of-care use (e.g., the workplace, public gatherings), compliance with these reporting requirements has become more challenging. Our compliance team helps clients to assess and understand the ever-expanding patchwork of reporting obligations – at the local, state/regional, and national levels – and to comply with emerging regulations.

Remote audits and inspections have become necessary as travel restrictions affect the ability of the FDA, notified bodies, and MDSAP Auditing Organization to perform on-site audits. Further, limitations on personnel and staffing are creating challenges to completing scheduled internal audits or preparing for preapproval or postmarket surveillance inspections. Our team has received ISO 13485 auditor certification, and has developed a plan for conducting remote Quality System Audits of most elements of your Quality Management System. We are able to use numerous platforms, including Web-Ex, Zoom, Skype, Google Meet and others. We also can utilize secure file transfers to ensure confidentiality and data protection.

Representative experience

- Assisting multiple clients regarding EUA submissions for COVID-19 diagnostic tests, treatments, and surgical masks.
- Advising numerous non-traditional life sciences and device companies on the requirements and logistics of producing critical need supplies.
- Advised **Vayu Global Health Innovations** in obtaining an EUA from FDA that allowed its bubble CPAP (bCPAP) device to be immediately distributed to hospitals to help alleviate the ventilator shortage associated with COVID-19.
- Teamed up with regulatory consultant Wanda Henry Co. to advise **Sansure Biotech, Inc.** in its FDA EUA for a molecular diagnostic test kit for COVID-19.
- Advising **Ford Motor Company** in its collaboration with GE Healthcare to help reinforce the Strategic National Stockpile and to support the treatment of coronavirus patients.
- Advised the **Kraft Group/New England Patriots** to obtain the necessary government approvals to pick up 1.3 million N95 masks from Shenzhen, China, and deliver them to the Commonwealth of Massachusetts.

Awards and rankings

Ranked Band 1 for Healthcare: Pharmaceutical/Medical Products Regulatory in the District of Columbia, *Chambers USA*, 2020

Ranked Band 1 for Life Sciences, *Chambers Global,* 2020

Ranked Band 1 for Life Sciences, *Chambers Europe*, 2020

Regulatory Firm of the Year by *LMG Life Sciences*, 2018-2019