Hogan Lovells

Adverse Event Reporting Vigilance Reporting

It's a reality that medical devices intended to help patients can sometimes cause harm or malfunction. When that happens, how is your company prepared to deal with applicable regulatory requirements?

Hogan Lovells helps companies navigate the complex framework of reporting adverse events to regulatory bodies and governmental agencies related to the use of their devices. Our wealth of experience in this nuanced area allows us to help determine whether an event is reportable and to develop strategies that ensure adverse events are handled effectively, consistently, and in compliance with the law, while in certain instances seeking to develop alternative reporting approaches to streamline regulatory requirements.

We are also able to assist companies in developing remediation strategies and improvement plans where warranted.

Representative experience

We establish regulatory training programs to educate internal units of major medical device and combination product companies about adverse event reporting requirements and procedures.

We have assisted clients in responding to enforcement actions related to inadequate adverse event reporting and helped develop procedures to protect against future enforcement.

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Practices

Medical Device and Technology Regulatory

We regularly speak publicly on medical device reporting requirements and expectations.

Helped clients conduct retrospective reviews of their files to assess their obligations in submitting Medical Device Reports to the FDA and bring their reporting up to date.

Our lawyers have been named Best Lawyers of America, Washington D.C. Super Lawyers, The Legal 500 U.S. Healthcare: Life Sciences, and LMG Life Science's Stars.

Our practice is ranked by Chambers USA as a top Healthcare: Pharmaceutical/Medical Products Regulatory practice.

Latest thinking and events

News
COVID-19: Daily Report for Life Sciences and Health Care Companies

News
COVID-19: Daily Report for Life Sciences and Health Care Companies (29 June - 3 July 2020)

News
MDCG guidance for consultations of authorities on devices incorporating a medicinal product

News
COVID-19: Daily Report for Life Sciences and Health Care Companies (22 - 26 June 2020)

News
USPTO Alert – New fast track for certain COVID-19 trademark applications

News
COVID-19: Daily Report for Life Sciences and Health Care Companies (15 - 19 June 2020)