

Fabien Roy

Partner

Brussels

Biography

As partner of our Life Sciences practice, Fabien Roy focuses his practice at Hogan Lovells on advising clients on European Union (EU) and national regulatory matters involving medical devices and pharmaceutical laws and guidelines. Fabien follows the new regulations on medical devices (MDR and IVDR) and the GDPR very closely and regularly advises clients on the requirements applicable to their digital health technologies. With a practice entirely focusing on complex regulatory issues faced by Life Sciences clients, he can quickly address and anticipate complex challenges and propose innovative solutions enabling clients to focus on their business.

Fabien focuses particularly on guiding clients through the regulatory and technical regulatory requirements applicable to the CE marking of medical devices. He assists clients in addressing a range of complex issues during clinical investigation procedures (e.g. authorisation from the EU Member States competent authorities, opinion from Ethics Committee, amendment to the Protocol, informed consent, serious adverse event qualification and notification, handling of personal data), conformity assessment and registration procedures (e.g. preparation and review of Technical Files, preparation and review of responses to the competent authorities' and Notified Bodies'



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Languages

English

French

Practices

Medical Device and Technology
Regulatory

Industries

Life Sciences and Health Care

requests) and post-market activities (e.g. adverse event reporting, Field Safety Corrective Actions and promotional and advertising of medical devices).

Fabien is also a qualified lead auditor for ISO 13485 quality management systems. He consequently has a deep understanding of the range of quality issues encountered by medical device Clients. Fabien also assists Life Sciences Clients in the preparation, drafting and review of numerous agreements including clinical study agreements, sponsor's representative agreements, registry agreements, CRO agreements, European Authorised Representative Agreements and distribution agreements.

Awards and rankings

- Rising Star, Life Sciences, Belgium, *Expert Guides*, 2019
- EU Regulatory: Pharma, Medical Devices and Biotech, *Legal 500 EMEA*, 2018-2019
- Brussels Life Sciences practices awarded Finance Monthly – Law Award 2015 in the category of Life Sciences Law Firm of the Year – Belgium, 2015

Latest thinking and events

- Hogan Lovells Publications
 - Harmonizing cybersecurity for medical devices: International collaboration moves forward *Medical Device Alert*
- Blog Post
 - New MDCG Guidance on Summary of Safety and Clinical Performance under the Medical Devices Regulation (MDR)
- Blog Post
 - The European Commission has published Guidelines concerning the use of phthalates in medical devices
- Blog Post

Areas of focus

Digital Health

Medical Devices

Education and admissions

Education

D.E.S.S. European Law, Université de Rennes 1, with merit, 2007

Memberships

the European Forum for Good Clinical Practice (EFGCP)-MedTech Europe Working Party

Qualified Lead Auditor ISO 13485

Qualified Lead Auditor ISO 13485

Bar admissions and qualifications

Brussels

Accolades

'Particularly knowledgeable about EU regulatory issues concerning medical devices'

Legal 500 Belgium Life Sciences
2017

- Publication of rules on designation of expert panels under the Medical Devices Regulations
- Blog Post
 - European Commission draft implementing regulation on the reprocessing of single-use medical devices: public consultation is open
- Blog Post
 - European commission publishes Additional Guidance regarding the Medical Devices Vigilance System