Hogan Lovells

Fabien Roy

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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'

Languages

English
French

Practices

Medical Device and Technology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Digital Health

Medical Devices

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

- EU Regulatory: Pharma, Medical Devices and Biotech, Next Generation Partner, *Legal 500 EMEA*, 2020
- EU Regulatory: Pharma, Medical Devices and Biotech, *Legal 500 EMEA*, 2018-2020
- Rising Star, Life Sciences, Belgium, *Expert Guides*, 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

- Webinar
  - AI – A brave new world?
- News
  - Towards a revision of current tissue, blood, and cells legislation in the European Union
- Hogan Lovells Publications
  - Podcast: Talking the cure
- News
  - Regulation of COVID-19 Tests in the EU: when do you need to involve a Notified Body?

Cell, Tissue, and Gene Therapies

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

- News
  - The European Commission has published guidance on the vigilance system for insulin infusion pumps
- Insights
  - UK regulation of medical devices from 1 January 2021