Hogan Lovells

Justin Yu

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Biography

Justin Yu provides practical regulatory compliance and contracting advice to pharmaceutical and biotechnology companies of all shapes and sizes in order to help them achieve their business goals.

With a background in microbiology, Justin advises various players in the drug and biologics arena on Food and Drug Administration (FDA) regulatory matters in light of their respective business model and products.

As part of his practice, he drafts and negotiates regulatory terms and contracts on behalf of sponsors, applicants, application holders, and others, including clinical trial agreements, investigator-initiated study agreements, contract research organization (CRO) agreements, consulting agreements, quality agreements, safety data exchange/pharmacovigilance agreements, and informed consent forms.

Justin also provides guidance to companies on regulatory issues at various stages of drug development, including issues related to clinical trials, good clinical practice (GCP) requirements and standards, marketing approval, life science mergers and acquisitions, and postmarket compliance programs.

Representative experience

Conducted extensive regulatory diligence and provided

Practices

Pharmaceuticals and Biotechnology Regulatory

Education and admissions

Education

J.D., The University of Chicago Law School, with honors, 2013

B.S., University of California, Los Angeles, with honors, 2008

Bar admissions and qualifications

regulatory advice in connection with LabCorp's US$1.2bn acquisition of Chiltern.

Advised Medicines Development for Global Health in seeking and obtaining a tropical disease priority review voucher and FDA approval of Moxidectin.

Latest thinking and events

- News
  - HHS offers flexibility on human subjects protection regs during COVID-19 pandemic
- News
  - COVID-19's impact on clinical trials prompts FDA to issue guidance to assist with study conduct
- News
  - The global impact of COVID-19 on clinical trials and countermeasure development
- Publications
  - Just One More Day Compliance Deadline for New ClinicalTrials gov Regulations is Tuesday April 18 2017 *Pharma/Biotech Alert*
- Hogan Lovells Publications
  - Ready, Set... Cures Act Expanded Across Policy Deadline Is Almost a Go *Pharmaceutical and Biotechnology Alert*
- Hogan Lovells Publications
  - A "Cure" for Combination Products: 21st Century Cures Act Mandates Greater Transparency of Combination Product Designations *Pharmaceutical and Medical Device Alert*

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