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Regulatory framework and requirements for orphan drug designation and development programs

Jessica Elizabeth Foley

Gaia Regulatory Sciences, LLC, USA

The US Food and Drug Administration (FDA), European Medicines Agency (EMA), and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) can grant orphan drug designation to a drug or biologic that is designed to treat rare conditions as defined in the regulations. The designation enables each agency to offer certain benefits to manufactures that facilitates rare disease product development. A robust regulatory strategy can help companies to take advantage of the incentives provided by obtaining the designation. The regulatory framework and requirements for orphan drug designation and development programs will be shared during this session, along with strategies and guidance for preparing an application or request for designation to the agencies.

jfoley@gaiareg.com