Global Expedited Programs for Cell and Gene Therapies

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Join Kimberley as she discusses expedited programs for cell and gene therapies. Limited space is available. Reserve your spot today!

Overview:

Gene and cellular therapies hold tremendous promise for addressing some of the most problematic diseases, including those without treatment options and rare genetic conditions. Developers of these therapies should work with regulators beginning at the earliest stages of development. The interactions with regulators on how to design the development program allows for a facilitation of the approval process and ultimately bringing the treatment to the patients. In the U.S., there are three programs designed to promote product development: fast track, breakthrough therapy, and Regenerative Medicine Advanced Therapy (RMAT) designations. The US (accelerated approval), EU (conditional marketing approval) and Japan (conditional and term-limited approval) also offer conditional approval mechanism for expediting the registration pathway of promising therapies. As regulatory authorities continue to issue new guidelines that assist with the interpretation of the regulations, it is critical for sponsors to stay current with evolving standards and best practices.

Join Us On
October 6, 2022
10 am EDT, 7 am PDT,
16:00 CEST
To Register Click Below
Webinar Registration

Or

October 13, 2022
2 pm EDT, 11 am PDT,
20:00 CEST
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Key Learning Objectives:

- Provide a review of these expedited regulatory pathways
- Review best practices for successful implementation
- Provide a discussion of attendee specific questions

[Click here for more information and to register for this webinar.]