

8<sup>th</sup> International Conference and Exhibition on  
**Pharmaceutical Regulatory Affairs and IPR**  
&  
8<sup>th</sup> International Conference and Exhibition on  
**Pharma Audit, GMP, GCP & Quality Control**  
June 08-09, 2018 | Philadelphia, USA

---

## **An overview of expedited drug regulatory pathways**

**Jessica Elizabeth Foley**  
Gaia Regulatory Sciences, LLC, USA

In recent years, the world's leading public health agencies, including the US Food and Drug Administration (FDA), European Medicines Agency (EMA), and Japan's Pharmaceuticals and Medical Devices Agency (PMDA), have implemented regulatory pathways to expedite drug development, review, and approval for promising new therapies. Although, the key features and qualifying criteria for these programs vary significantly, each were designed to accelerate access for patients to innovative treatments for serious and unmet medical needs, by avoiding delays and roadblocks in the regulatory process. The purpose of this session is to provide an overview of the pathways available for accelerating drug development, and to identify their associated evidentiary requirements. Furthermore, the benefits and tradeoffs of each regulatory pathway will be explored, along with the optimal timing and process for pursuing them during drug development.

jfoley@gaiareg.com