

Webinar hosted by the American College of Toxicology (ACT):

***A Regulatory and Industry Perspective on the Introduction and Application of
GLP Regulations:***

What They Are, Why They Matter, and How They Apply to Toxicology Studies

11:00am ET, Wednesday, May 29, 2019

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&
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The purpose of this webinar is to provide early career professionals with a general understanding of the Good Laboratory Practices (GLP) involved in conducting nonclinical toxicology studies for pharmaceuticals. This webinar will introduce what GLPs are, who must comply, and why they are important for conducting nonclinical toxicology studies. Our experienced speakers will provide a perspective on their engagement with GLPs and how GLPs are applied in their work. Pedro Del Valle will present an overview of the US Food and Drug Administration (FDA) regulations, explain when and why GLPs are important from a regulatory perspective, and address differences in FDA and international regulations. He will introduce the 3R's of the GLP (Ratify, Review, and Report) approach and briefly discuss how the agency reviewers look at compliance in the study reports they receive. Michael Dorato will provide an industry perspective on the introduction and impact of GLP, the initial response, as well as an overview of GLPs and the responsibilities of study directors, management, and quality assurance units (QAU) in the pharmaceutical environment.

The Code of Federal Regulations (CFR) set forth Title 21, Part 58 outlines the Good Laboratory Practices (GLP) for conducting nonclinical laboratory studies that are intended to support regulatory submissions for an Investigational New Drug (IND) application, a New Drug Application (NDA), or a Biological License Application (BLA) for the initial studies in humans and the final registration or marketing application of a potential therapeutic agent. The webinar will end with a Q&A session for all attendees.

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