Abstract: Juvenile Toxicology

This eLearning module will focus on the principles of juvenile toxicology. The lecture will be offered with two main themes; the first will address whether a juvenile animal study should be conducted, followed by a focus on how it could be conducted. The first section will provide an overview of juvenile toxicology from a regulatory perspective. This will include the ICH S11 guidance for nonclinical juvenile animal testing to support pediatric medicine development (released in 2020) which proposes a weight-of-evidence approach to decide whether a juvenile animal study is warranted. If a study is warranted, this exercise informs on the main objectives of the juvenile animal study including any customized additional endpoints to the 'core' endpoints provided in ICH S11. The second part of the session will focus on study design and delivery approaches to juvenile animal testing for pharmaceutical and nonpharmaceutical industries. Topics addressed will include selection of juvenile toxicology species, age of the animals during treatment, both with strong consideration of comparative organ development. As ADME systems are often immature in juvenile animals, dose range finding approaches will be discussed in detail. Since rodent juvenile animal studies are the most common, study design consideration for treatment of preweaning animals within a litter will be reviewed. Lastly, interpretation considerations unique to juvenile animal studies and application of results to human risk assessment will be discussed with a focus on pharmaceuticals.