

Safety Assessment and Risk Management of Pharmaceutical Products

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Abstract

Protecting patient safety and maximizing benefit/risk balance of pharmaceutical products are critically important to the development and commercialization of valued medicines. Activities to effectuate these endeavors occur throughout the life cycle of a pharmaceutical product, beginning with preclinical assessment and continuing in the post-marketing pharmacovigilance phase. In this presentation, we will look at approaches that are commonly used by product developers to fulfill these sacred obligations.

Keywords: Benefit/risk; Pharmacovigilance; Safety assessment; Risk management.

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