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Regulatory affairs–pharmacovigilance: Collaborative channel

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Interface between the regulatory affairs and the pharmacovigilance divisions is a key to a successful and efficient processing of regulatory submission and in recent times this collaboration has become increasingly important. The success of regulatory strategy is less dependent on the regulations than on how they are interpreted, applied, and communicated within companies and to outside constituents. The drug development process is a lengthy, complex and extremely costly process and regulatory affairs are involved in all stages of drug development and also after drug approval in post-marketing phase. Pharmaceutical companies accumulate the data throughout the discovery and development process in order to get approval for release a drug in the market and they have to abide by an array of strict rules and guidelines in order to ensure safety and efficacy of the drug in humans. Starting from product authorization, the pharmacovigilance department as well as the regulatory affairs department is closely involved in the strategy and planning of a marketing authorization. During the pre-authorization phase, the marketing authorization application phase and during the post-authorization period, the pharmacovigilance life cycle is complementary to the regulatory life cycle. Risk Management Plan and pharmacovigilance system master file play a vital role from the beginning of the marketing authorization of the product and require a good timing as well as an effective interaction. A close collaboration and a proactive planning are necessary for the submission of the periodic safety update reports/periodic benefit-risk evaluation reports. Company core safety information and company core data sheets are essential for the preparation of all published texts like summary of product characteristics and patient information leaflet.

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