Formulations, Routes, and Dosage Design

The perfect drug would be along the lines of Paul Eurlich's "magic bullet": As illustrated in Figure 1, a drug molecule is readily administered, completely absorbed, moves to the desired therapeutic target site, does what it is supposed to, and is completely eliminated. The most pressing (and rewarding) area for current drug development is optimizing the therapeutic target delivery part of this process. One of the key steps in the nonclinical and clinical formulation of the drug is the choice of the inactive ingredients (excipients). Excipients are essential components of drug products in the United States, and one must adequately address the safety of the proposed exposure to the excipients in those products. The specific safety data that may be needed will vary depending upon the clinical situation, including such factors as the duration, level, and route of exposure (i.e., means of patient drug administration).

Many guidances exist to aid in the development of pharmaceutical drugs, but very few guidances exist to aid in the safety evaluation of pharmaceutical excipients. The U.S. Food and Drug Administration (FDA)/Center for Drug Evaluation and Research (CDER) adopted, in 2005, the guidance for industry "Nonclinical Studies for Development of Pharmaceutical Excipients," which focuses on the development of safety profiles to support use of new excipients as components of drug or biological products.

A similar guidance was published by the International Pharmaceutical Excipients Council (IPEC), "Excipient Safety Evaluation Guidance," in 1995

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