MODEL-INDEPENDENT AND MODEL-BASED METHODS TO ASSESS DRUG–DRUG INTERACTIONS FOR THERAPEUTIC PROTEINS

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4.1 INTRODUCTION

Therapeutic proteins (TPs) are playing a greater role in pharmacotherapy due to their high potency and mechanism of action. The main therapeutic protein classes include monoclonal antibodies, interferons, interleukins, hormones such as growth hormone and insulin, colony-stimulating factors, and blood clotting factors. TP therapies have been applied in a variety of disease areas, such as oncology, autoimmune disorders, infectious diseases, and hormone deficiencies.

The value of the global market for TPs was estimated at $93 billion in 2010, with a compound annual growth rate (CAGR) of 16.4% between 2002 and 2010. The market is forecasted to grow at a CAGR of 6.2% between 2010 and 2017, to reach $141.5 billion in 2017.[1] Therefore, TPs are expected to occupy a significant portion of the commercial portfolios of many large pharmaceutical companies. Likewise, their presence on drug formularies and in the marketplace in general necessitates a greater understanding for both the lay and the scientific communities.

By the year 2050, 34.6% of the world population will be aged more than 65 years.[2] Polypharmacy is frequently encountered when treating senior patients, resulting in a high drug–drug interaction (DDI) potential. Unexpected DDIs can lead to reduced efficacy or toxicity. Because the approval of human recombinant insulin as the first biologic by the FDA in 1982,[3] TPs have been used clinically. With the increasing use of TPs, TP-drug interactions (TP-DIs) are more prevalent, and public awareness has increased.

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