

Pharmaceuticals - Case Studies

Residue assessment

Following a change to packaging, an OTC analgesic was found to have a number of known impurities and one previously unknown impurity exceeding shelf life specification. ToxMinds, working closely with the analytical department of the client, performed a safety assessment of the impurities using a combination of approaches including Quantitative Structure Activity Relationship (QSAR), comparative pharmacokinetic analysis based on the parent product and quantitative risk assessment. The client was able to use the safety assessment to demonstrate to the concerned authorities that there was no risk to consumer safety, no change in efficacy of the product and that stock could remain in the marketplace with continued distribution of product remaining in the client's distribution centres.

IND for Novel Use

Prior to commencement of pivotal clinical trials, our client required the preparation of the nonclinical portion of the IND application to the FDA in full eCTD format. The need for clinical trials to coincide with the cold and flu season in the United States required very tight timings for dossier preparation, particularly in view of the client's limited experience with the eCTD format. ToxMinds was able to complete the nonclinical section of the dossier within the time available and the format required allowing the client to complete a successful application and commence clinical trials as planned.