Jennifer Pfeiffer Abstract

The Therapeutic Products Directorate is responsible for the pre-market review and approval of prescription drugs.

Evaluators in the Directorate assess innovative and generic products for their safety, efficacy, and quality. One of the roles of the Quality scientific evaluator is to ensure that the manufacturing process for the commercial lots reflect the clinical and/or bioequivalence lots to ensure the safety and efficacy are conserved.

In complex products, the excipient can be controlling the critical quality attributes of the drug product. In these cases, changes to the grade or physical properties of the excipient can significantly affect product performance.

In this presentation, some of Health Canada's concerns, review processes, and strategies for changes in excipient properties will be outlined. In order to illustrate some of Health Canada's approaches, case studies from ophthalmic drops, extended-release solution, extended-release tablets, and oral solutions will be discussed.