

The Product Quality Research Institute (PQRI) is a non-profit consortium of organizations working together to generate and share timely, relevant, and impactful information that advances drug product quality and development.

PQRI Webinar on Sulfonate Esters

Background and Objectives for Webinar

Sulfonate Esters, genotoxic impurities potentially formed through reaction between sulfonic acids and alcohols, have been a significant cause of regulatory concern over recent years. This has even threatened the use of sulfonic acids as salt counterions, an outcome that could have a significant impact on the ability of the pharmaceutical industry to develop APIs in an appropriate physical form. This Webinar will outline the key points from an extensive cross-industry study, performed by a PQRI work group, into the reaction between sulfonic acids and alcohols. These studies show that through the application of simple process control measures that the risk of ester formation can be controlled and even eliminated. This ultimately means that sulfonic acids can be used as salt counterions without fear of ester contamination.

The key objectives of this Webinar are thus:

- To present the outcome of the studies carried out by the PQRI work group focused on sulfonate ester formation/decomposition;
- To outline the significance of these result in terms of presenting how they can be used to establish a set of simple rules that can be applied to processes to minimize, and even avoid ester formation; and
- To ultimately establish that there is no reason to avoid the use of sulfonic acids as salt counterions.

Paper Ref; Teasdale et al, *Organic Process Research & Development* **2009**, 13, 429-433.

Presenter's Biography



Andrew Teasdale is a senior QA executive within AstraZeneca's quality assurance function. His primary role is that of chair of the internal genotoxic impurities advisory group. This group is responsible for all matters relating to genotoxic impurities within the business, being responsible for both strategic direction and problem resolution.

As well as his internal responsibilities, Andrew is involved with a number of external activities linked to the genotoxic impurities area including leading a Product Quality Research Institute (PQRI) work group, which focused on detailed studies of sulfonate ester formation/decomposition.