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Editorial

Genotoxic Impurities

Genotoxic impurities in pharmaceuticals is a hot topic at the moment, and Derek Robinson in his Regulatory Highlights for this journal has kept us all up-to-date with regulatory thinking on this important subject − see this issue for Derek's latest highlights. Also in this issue is a letter from David Snodin, a UK expert in this area, commenting on a paper by Duane Pierson et al. from Lilly (*Org. Process Res. Dev.* **2009**, *13*, 285−291) on the subject of allowable formaldehyde limits, along with Dr. Pierson's response to Dr. Snodin.

For many chemists the wake-up call on genotoxic impurities was when nelfinavir mesylate was temporarily withdrawn from the European market due to contamination by methyl mesylate, formed from methanol and methanesulfonic acid during processing. We should all be concerned about the generation of alkylating agents when forming salts of final product free bases in alcoholic solvents, but the question of whether these agents will reside within the crystals or are removed in the solvent waste may vary from case to case. What is clear is that the process and analytical challenges are quite formidable, since ppm levels will need to be analysed to check whether the "threshold of toxicological concern" limit of not more than 1.5 mcg/day is being breached. A paper recently submitted to *Organic Process Research & Development* (OPRD) addresses many of the issues faced by both large and small companies as well as their outsource partners.

At our editorial advisory board meetings, the topic of genotoxic impurities has been discussed many times, and recently we decided to devote a special issue to this important subject. We are planning this to be published in issue 4 of 2010, and the deadline for submission of manuscripts is December 31, 2009. We hope to attract a wide range of different papers and reviews on the subject, and this editorial therefore serves as a call for papers. I have some good contacts in the industry who have already committed to submitting papers for this special issue in OPRD, and I hope we can attract many more authors. This is a topic which might attract "opinion" papers where a degree of speculation and discussion could take place. Many companies have their own internal guidelines on this subject, and several have their own in-house experts who are potential authors of papers for the special issue. Please bring this to the attention of anyone in your company who is a potential author.

I look forward to receiving your manuscripts.

Trevor Laird
Editor

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