

Editorial

Special Feature Section: Potential Genotoxic Impurities

Recent guidelines from European and American regulatory agencies mandate the control of genotoxic and potentially genotoxic impurities (PGIs) at levels of parts per million (ppm) in drug substances and pose many challenges for development chemists in the manufacture of drug substances and drug products. This PGI special feature section is intended to give an overview of the current situation as it affects process R&D and manufacture. We have been fortunate to receive some excellent articles on this topic, some of which discuss the current guidelines and whether they have scientific merit. Other papers discuss ways in which individual PGIs have been handled at a particular company and the analytical challenges posed by the need to routinely monitor for compounds at ppm levels and below.

Of particular value to readers who are unfamiliar with this topic are review articles which bring the reader up to speed with current thinking. This special feature section begins with three reviews, the first of these being an overview of the subject of PGIs and the history of the regulatory background, from Derek Robinson, who works with me on many projects and also writes the Regulatory Highlights for *Org. Process Res. Dev.* (OPRD). The second review is from David Snodin, now a consultant, who is well-known in the field and has previously commented on a PGI paper in OPRD via a letter to the editor (*Org. Process Res. Dev.* **2009**, *13*, 409, DOI: 10.1021/op900043v). His review focuses on structural alerts and makes fascinating reading for organic chemists. The third review from workers at GlaxoSmithKline focuses on analytical issues and provides several case studies wherein methods for detecting PGIs are outlined.

I thank all authors who contributed to this PGI special feature, their companies for allowing them to publish, and last, but certainly not least, the reviewers who critically commented on and therefore enhanced the papers you see in this special section.

Finally, there is one letter to the editor in this special feature section. As we have previously had letters about PGIs, clearly this topic generates strong views, and I welcome letters commenting on the articles featured here. Only by open discussion can we move forward towards consensus in this challenging area.

Trevor Laird
Editor

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