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The IQ Green Chemistry Working Group

The Green Chemistry Working Group seeks to drive innovation and the awareness of green chemistry in pharmaceutical development through the establishment and adoption of best practices, sharing of information within peer networks, and collaboration with regulatory agencies and other key stakeholders.

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Inspiring Sustainable Drug Manufacturing with a Smart Goal Metric

THE CHALLENGE

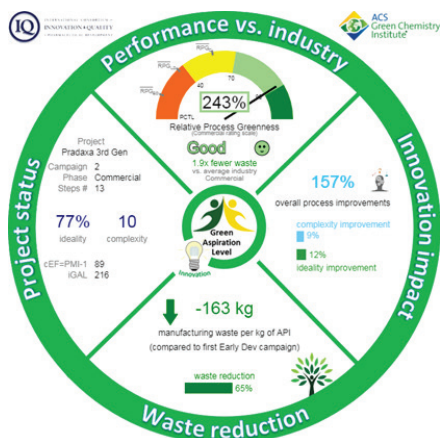
Green and sustainable chemistry is critical for balancing the long-term sustainability of business, society, and the environment. It stimulates scientific innovation, reduces environmental footprint, lowers development and manufacturing costs, and can therefore contribute to the greater affordability of drugs for patients. However, the full potential of sustainable drug manufacturing has been inhibited by the absence of harmonized green chemistry metrics, inconsistent starting points for analysis, and the neglected complexities of the structurally diverse drugs and their manufacturing processes.

OBJECTIVES & APPROACH

Recognizing the need for a harmonized green chemistry metric that will not only enable better measurement of "greenness" but also encourage adoption of greener processes, ten pharmaceutical firms from the IQ Consortium's Green Chemistry Working Group and the ACS Green Chemistry Institute Pharmaceutical Roundtable, together with Professor Roger Sheldon (the inventor of the E factor), joined efforts to create a green chemistry metric that could catalyze innovative green process chemistry, and create a platform to reward the greenest manufacturing process. Over a period of more than a year, the Working Group formulated the critically needed, unified and innovative green manufacturing measure, Green Aspiration Level (GAL). To identify elements critical to evaluating "greenness" and encouraging greener processes, the Working Group conducted research that substantially advanced and expanded on earlier methodology (Green Chem. 2015, 17, 752-768), and completed a detailed analysis of a standardized data set of 46 drug manufacturing processes – including the oft-neglected outsourced production and early supply chain segments. The Working Group then translated the knowledge that it gained through this research into the GAL, which it sought to make meaningful and easy to use.

RESULTS

By creating the GAL, the Working Group accomplished its objective of creating a new green chemistry metric that exceeds conventional approaches to green chemistry metrics for industry (Green Chem. 2017, 19, 281-285). The GAL is easy to use, with calculations requiring mere minutes to develop once the process E factors or process mass intensities (PMIs) have been determined, and has been validated by the Working Group to ensure that it enables consistent and meaningful green manufacturing analyses in the pharmaceutical industry. In addition, the Working Group introduced the Green Scorecard, a novel reporting tool that captures key information for executive leadership, thereby facilitating the tool's intended widespread industrial adoption. Its application is showcased, for example, in the commercial Dabigatran manufacturing process (see Figure). The Scorecard calculator, along with detailed instruction, is freely available on the IQ website.¹



The Green Scorecard was developed by the IQ Green Chemistry Working Group to communicate the value-added impact of green chemistry improvements in a simple and effective way. It shows waste reduction in conjunction with process improvements, along with the current status of process greenness (shown with the "traffic light" gauge).

IMPACT

The Working Group anticipates that broad implementation and utilization of the new goal-driven GAL-based rating system for sustainable drug manufacturing will motivate efforts to significantly lower the environmental footprint of the pharmaceutical industry, in part by influencing the mindset of industry leaders. This will in turn contribute to more economical drug development and manufacture, and thereby contribute to reducing the cost of drugs to patients.

The new insights and ideas can also have widespread application to fine chemical manufacture and beyond. The Working Group is therefore hopeful to influence green thinking and stimulate discussion within broad and diverse scientific and industrial communities to ultimately lead to widespread adoption of the GAL methodology and unification of green chemistry manufacturing metrics to the ultimate benefit of society, environment, and business.

1. <https://iqconsortium.org/initiatives/projects/green-aspiration-level>