

Environmental sustainability assessment of batch versus continuous manufacturing: Lessons learned in primary and secondary pharmaceutical manufacturing

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The formulation and scale-up of batch processes is one of the major challenges in the development of pharmaceutical dosage forms. At the same time it is a significant resource demanding process which is generally overlooked in environmental sustainability assessments. Moreover, there is an emerging trend in process intensification from batch to continuous manufacturing, reducing e.g. the time to file commissioning documents for full scale manufacturing. This will be highlighted during the poster presentation with a case study on the manufacturing of TRAMACET®, where a clear reduction in cumulative resource consumption (both energetic and material resources) was to be found in shifting from batch to continuous manufacturing (see figure). Often, one can relate multidisciplinary aspects such as aforementioned business case of Johnson and Johnson and GEA Pharma Systems in reducing production lead times to a significant decrease in environmental burden. For this, a life cycle assessment approach was used (cradle-to-gate). The presentation will cover forecasting models as well, since there is an emerging need coming from fine chemical and pharmaceutical companies in using eco-indicators in early phase R&D decision trees. This would be helpful in filing new generation drugs & technologies (e.g. for lyophilization) to the FDA (Food and Drug Administration) and in anticipating full scale manufacturing burdens. This research has put a huge step forward in integrating operational management and sustainability assessments from a life cycle perspective for small molecules. Future research outlook aims at expanding this methodology for large molecule production technologies from a sustainable supply chain point of view. In the end, no matter how much effort was done in-house, one can only be as lean or as sustainable as the weakest actor in the chain.

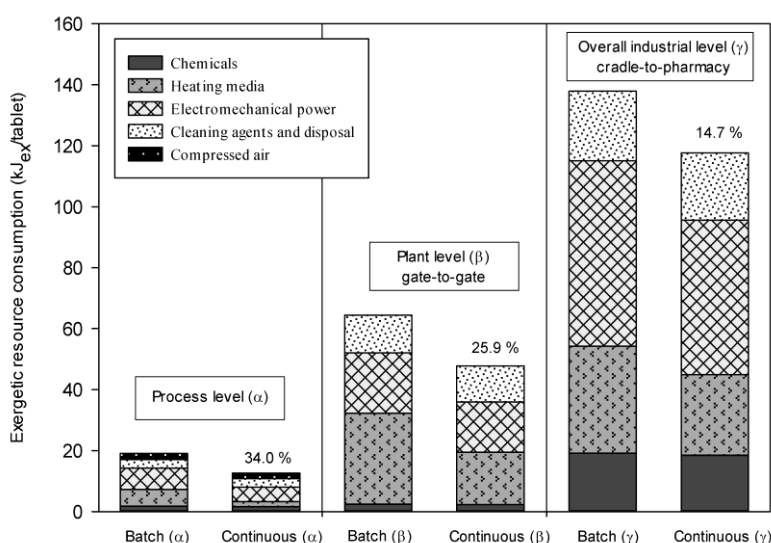


Figure: (De Soete et al., Journal of Green Chemistry, 2013)

Keywords: LCA, Process Intensification, Continuous Manufacturing, Forecasting Sustainability, Experience curves, Emerging Technologies