

## **Allergan EHS Change Management Program**

Allergan has established an overarching methodology for managing EHS impacts and risks resulting from changes made at our facilities. The change management system relies on existing change control processes and inserts EHS assessments and associated actions into that process. Changes can be anything from new product introduction to in-kind replacement of equipment to basic maintenance. At our facilities that are currently using the Allergan Quality Management System (QMS) developed for Allergan by TrackWise, EHS has been included in the change control process. For those facilities not yet on the system, change control is managed through onsite procedures with EHS included.

Examples of change control assessments are EMEA/FDA new product submissions, new product transitions from R&D or acquisition, and modifications local to the facility.

### ***New Product Environmental Assessments***

The US Food and Drug Administration (FDA) and the European Agency for the Evaluation of Medicinal Products (EMA) require Allergan to conduct environmental assessments for new or modified drug products. These assessments estimate the environmental impact of the end use of the product. The assessments are required in order for the drug to be approved for sale.

### ***EHS Product/Process Transition Evaluation Program***

Allergan has implemented a formalized program which requires documented analysis of potential EHS issues and impacts associated with the transition of new products and processes into its manufacturing operations. The evaluation begins in the early stages of new product or new process research and development, and continues into the scale-up and early manufacturing operations. This program complements the Environmental Assessment and Environmental Product Design programs by focusing on EHS issues during end-stage R&D and manufacturing scale-up operations.

The program elements include rigorous assessment of components and finished products, including evaluation of emission potentials, material usage, waste generation, resource utilization, regulatory impacts, product and component toxicology, process safety and employee well-being. It also evaluates secondary issues related to machine and equipment safety, ergonomics, physical hazards, and general health and exposure controls. While the process normally originates at the research and development stage, it includes assessment and participation by personnel at all operational levels affected by the transition of these new technologies.

### ***EHS and Change at Local Facilities***

Each Allergan facility conducts an EHS review of changes to products, processes, and equipment. This will include review of product and process transitions from development phase, research and development, to manufacturing operations phase at each Allergan facility worldwide or through acquisition, third-party manufacture and/or joint venture. Allergan has written procedures and checklists that include the typical EHS parameters that need to be considered when various changes are made. Allergan has also incorporated these EHS parameters into automated tracking systems such as the Quality Management System.