Change Management

Product group: MCC, Starch, Lactose, Inhalation, Superdisintegrants and Biopharma

All products supplied by DFE Pharma GmbH & Co. KG

Dear Customer,

DFE Pharma GmbH & Co. KG has implemented a procedure for change control in order to ensure that every intended change in products, processes, specifications, test methods, packaging, equipment or locations is carefully judged on the possible impact on quality and safety of the product.

As part of this procedure a classification is made of significant changes which require customers to be informed of the intended change or require customer approval before implementation. The classification is based on the IPEC Significant Change Guide for Pharmaceutical Excipients.

All change requests are judged by a committee (Change Control Board) consisting of representatives of all involved departments.

The change control procedure as implemented by DFE Pharma ensures that all intended changes are judged by a team of experts and are approved by QA. In this way DFE Pharma safeguards that all products consistently remain compliant with all quality and safety requirements and customer expectations.

This statement substitutes all previous versions issued for the brand names mentioned above.
We trust this information, which is made up to the best of our knowledge, will be helpful to you.

With kindest regards,

Name : MAJ Nijman
Job title : Global Quality Director
Signature :

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.