



**To whom it may concern**

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## **Change Control**

MEGGLE Products:

- Lactose Monohydrate (USP-NF / Ph. Eur. / JP): GranuLac® 70 US, GranuLac® 140 US, GranuLac® 200 US
- Anhydrous Lactose (USP-NF / Ph. Eur. / JP): DuraLac® H

Change Control according to IPEC-Americas Significant Change Guide for Bulk Pharmaceutical Excipients is implemented.

The Change Control procedure includes an appropriate evaluation of customers' and authorities' information about the change.

Quality Unit has the responsibility and authority for final approval of changes.

MEGGLE USA is responsible for customer and authority notification.

Best regards

**MEGGLE USA inc.**



Dr. Gabriele Müller