



Certification of Substances Division

New policy for mentioning manufacturing sites on the CEPs

The policy concerning the manufacturing sites mentioned on the CEPs was changed during 2007.

The new policy is that all sites involved in the synthesis of the substance starting from the declared starting material are included on the CEPs. In comparison with the former policy the main difference is that when the manufacturer of a substance purchases the 'crude substance' or a late intermediate and performs only a final purification or salification, the site(s) of manufacture of these purchased materials is mentioned on the CEP.

The European GMP requirements for active substances apply to the manufacture from the declared starting material onwards. The manufacturer of the crude substance/last intermediate is a site directly involved in the manufacturing process described in the dossier, and therefore GMP apply for this manufacturer.

Consequently the companies manufacturing a late intermediate and/or a crude substance are asked to submit the declarations on manufacture according to GMP and willingness to be inspected.

This policy applies also to post-production operations such as micronisation or sterilisation steps, when these are claimed and approved, which can be identified by the subtitle of the substance on the CEP. For these sites declarations on manufacture according to GMP and willingness to be inspected are also requested, and they are mentioned on the CEPs.

On the other hand the sites involved in final handling such as sieving, packaging, milling, or analytical control are no longer mentioned on the CEPs.

For TSE certificate, the sites mentioned on the CEP are those in which the steps of the production are carried out from the declared starting material. Neither the suppliers of animal material nor the sites responsible for the post-production steps (e.g. irradiation for sera) are mentioned on the CEPs.

This policy was implemented in May 2007, and has been applied for both new and revised CEPs, independently of the kind of revision.
