Final Concept Paper
Q3B: Guideline on Impurities in Drug Products
Dated and endorsed by the Steering Committee on 10 March 1994

Problem statement/Objectives

Since it is the Drug Product which is actually consumed and since new impurities can arise in the drug product due to degradation of the active ingredient or interaction of the active ingredient with other components, it is considered essential to review the requirements on impurities . This is felt as a natural and logical extension of the Drug Substance requirements and is needed to ensure consistency of approaches. The objective would be to prepare a consolidated guideline on impurities in new drug substances and dosage forms.

Background/Status quo

The guideline, which represents a consensus view on Impurities in Drug Substances has been released for consultation.

Impact

An international guideline covering impurities in drug substances and dosage forms will meet a critical need for consistency in approach to meet regulatory requirements in the three regions.

Time frame

The initial draft is under review and will be discussed in detail at the October meeting of the EWG.
A Step 2 guideline will be required by March 1995 if Step 4, and an announcement of a consolidated ICH Guideline on Impurities (Drug Substance and Dosage Form) is to be achieved at ICH 3, November 1995.

Expert Group

The same Expert Working Group that dealt with the drug substance guideline would be appropriate.