1. INTRODUCTION: THE STRATEGIC PLANNING

Big efforts are necessary to reduce the period of time from the start of development for a new chemical entity, drug substance, or drug product to registration application and finally marketing authorization.

The results of the analytical development and the stability testing fro a NCE form an important part of a registration application.

To reduce the period of time and to provide information to assess variation and changes, a procedure was developed for analytical development and stability testing: the strategic planning.

By a strategic planning it is possible to secure a successful marketing authorization in the shortest period of time and in the most efficient way. The strategy is based on the ICH Harmonized Tripartite Guidelines (1).

Stability Testing of New Substances and Products	Q1A
Photostability Testing of New Substances and Products	Q1B
Text on Validation of Analytical Procedures	Q2A
Extension of the ICH Text "Validation of Analytical Procedures"	Q2B
Impurities in New Drug Substances	Q3A
Impurities in New Drug Products	Q3B
Residual Solvents	Q3C
Specifications, Test Procedures and Acceptance Criteria for New Drug substances and New Drug Products: Chemical Substances	Q6A

It is also based on the Extension of the ICH Tripartite Guideline for worldwide marketing (2,6,7).

Thereby the strategy considers all aspects of analytical development and stability testing for a New Chemical Entity which are necessary for a registration application in the EU, Japan and the USA, and worldwide.

The overall development and stability program for the strategic planning has been divided into six decisive steps (3); see Table 1.

Furthermore, eleven basic principles have been established (4) that are decisive for stability testing and that are applicable to all stages of development, on all dosage forms.

The ICH tripartite stability guideline had taken over these principles and is likewise built upon them.

The 11 principles are as follows:

Selection of batches and samples