

Supplier Approval, Qualification and Certification

- A Technical Quality Agreement is signed.

If all the prerequisites are fulfilled the Quality department will determine the level of testing required.

7.4 Supplier Certification (Step III)

To become a certified supplier the following actions must have been successfully completed:

- Only suppliers that have achieved qualified status before can achieve the certified status.
- A good history of a thorough partnership program of Audit and evaluation must be available.
- The supplier consistently supplies material of a pre-defined Quality level in an on-time manner at the agreed cost.

If all the prerequisites are fulfilled the Quality Unit will determine if further reduction of testing could be applied. The receipt of a batch specific CoA and an identification testing (e.g. by IR where applicable) is the minimum testing which must be conducted for each batch.

7.5 Reduced Testing

Based on the individual suppliers status and assessment reduced testing will be implemented. This will be individually decided and approved by the Quality Assurance on the Supplier Qualification Change Control sheet (Attachment 2) to this SOP. However routine ID tests & periodic full testing if appropriate CoAs are supplied will be conducted as decided and approved by the Quality Assurance on the Supplier Qualification Change Control Sheet (Attachment 2) to this SOP.

8 ATTACHMENTS

8.1 Attachment 1: Supplier Status List

8.2 Attachment 2: Supplier Change Control Sheet

9 SOP DISTRIBUTION

In this paragraph the customer should indicate the persons and department with authorized copies of this SOP

SOP Authorized Copy Number	Department
01	Sample Production
02	
03	



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