

approval by the QA function, (see 5.1.6).

- 5.1.2** The transportation of the returned goods shall be handled according to company's transportation guidelines, including temperature monitoring.
- 5.1.3** If returned goods suffer from quality defects or non-conformities complaints procedures shall be applied and the returned product shall not be placed back into stock. Following the investigation all materials shall be destroyed.
- 5.1.4** If the frequency of returned goods becomes high, an investigation should be made in order to identify the technical or administrative causes and to take necessary corrective action.
- 5.1.5** Returned goods shall be clearly labeled as such, on receipt at the site and segregated from other stock. If a validated computerized storage system is used this segregation does not need to be physical, unless the returned goods falls under section 5.1.3. Where stock is returned from multiple sources, the stock from each source should be independently stored, i.e. the stocks should not be combined to form a batch.
- 5.1.6** Returned goods should only be considered for redistribution, reworking or repackaging after they have been critically assessed by the responsible Quality Assurance Department according to a written procedure.
- 5.1.7** Where a Product Lead Site is nominated, samples should be sent to the Product Lead Site for analysis if appropriate as part for the assessment described in clause 5.1.9.
- 5.1.8** If the material has been released under EU QP-release. The QP responsible for the original release shall approve the assessment according to 5.1.9.
- 5.1.9** Dependent upon the nature of the return the assessment should include the following points:
- The name and strength (potency) of the product;
  - The date of return and the reason for the return;
  - The source of the returned goods;
  - The nature of the returned goods and specific storage and transportation conditions it requires;
  - The condition and history of the returned goods. The primary seal and packaging should be intact. If the primary seal is broken or has been resealed the returned goods should be destroyed;
  - The time elapsed since the material originally left the site and its subsequent storage, transportation and handling;
  - The available shelf life of the returned goods;
  - An assessment of damage or external contamination;
  - A review of the quantities of product originally released and subsequently returned to determine any abnormalities in reconciliation;
  - Review of batch protocol for previous returns.

The assessment should include the following points when appropriate: