been notified in accordance with a well-defined reporting system before any product is released.

- Any deviations in manufacturing or quality control have been investigated in accordance with a well-defined system before any product is released.
- Any additional sampling, inspection, tests and checks have been carried out or initiated, as appropriate, to cover planned changes or deviations.
- All necessary Production and QC documentation have been completed and endorsed by Line Management, trained in appropriate disciplines.
- Appropriate audits, self-inspections and spot checks are being carried out by experienced staff.
- All relevant factors have been considered including any observations not specifically associated with the batch under review (e.g. sub-division to output batches from a common input, factors associated with continuous production runs and environmental controls).
- A finished product batch certification register is in place and retrievable.
- Information on batch confirmation when performed is to be retained and retrievable to support the finished product batch certification by the QP.
- The legal requirements regarding imported products have been fully met. (Reference: 2001/83/EC, Article 51). This includes ensuring testing is performed within the EU/EEA to the requirements of the marketing authorization. Unless there is a mutual recognition agreement in place that allows for the acceptance of a manufacturing batch certificate.
- The arrangements in the QA agreement with the supplying site are verified and agreed.

5.2.8 Release for sale activities performed on behalf of the QP must be done in accordance with local procedures that have been reviewed and approved by the QP. Where deemed appropriate the name of the delegate performing the activity should be recorded. For example the generation of a batch certificate.

5.2.9 Each Site will have the responsibility for ensuring the accuracy of the QP register for those individuals who are accredited as a QP.

5.2.10 The receiving warehouse will implement receipt procedures for verifying receipt order versus consignment, verifying transportation conditions and inspection for damage. Released bulk production batches and/or finished product batches will then be accepted without further checks, except those necessary to confirm that local legal requirements have been met.

5.2.11 The receiving warehouse will refer any inconsistency with respect to section 5.2.12 to the QP of the releasing site.

5.2.12 The QA function responsible for the batch release arrangements as described in the Marketing Authorization holder will remain the key contact for the market and will be accountable for utilizing the appropriate systems designated in the relevant compliance Manual and in Quality Assurance Agreements.

5.2.13 Whatever particular arrangements are made for certification and release of batches, it should always be possible to identify and recall without delay all

