

QA Agreements.

### 5.3 Role of QA Managers

The QA manager's role must include:

- (i) Review and Approval of completed agreements
- (ii) Implementation of the agreements
- (iii) Ensuring that local and international Change Control procedures. i.e. Regulatory Implication Assessment Report /Manufacturing Change Management (MCM) are used to ensure the validity of the agreements.

### 5.4 Key Elements of the QA Agreement

The QA Agreement must define the following:

Scope  
Definition of Terms  
Manufacturing (including packing)  
Deviation Reporting  
Inspections and Audits  
Change Control  
Qualification and validation  
Quality Assurance and Control  
Batch Specific Documentation  
Sample retention  
Release procedures  
Product Recall  
Product Quality Complaints  
Stability  
Agreement Review  
Contacts  
Materials covered by agreement  
Delineation of Responsibilities  
Area specific Key elements to be defined:  
Validation Certificate (If required)  
Batch Certificate requirements (If required)  
Periodic confirmation (If required)  
Product Requirements (If required)  
Annual Product Reviews (If required)  
Product Quality Review (If required)

Each page must be labeled so as to be consistent with the title page. The agreement must also include a revision history and a list of changes from the template.

### 5.5 Types of Agreement

The supply and contractual relationships between most manufacturing sites are of two types. When legal ownership of materials passes simply from one