A Diagram Illustrating the Requirements for the Entrusted Party in the Contract Manufacturing

- Documents related to MAH quality management system
  - Product technology transfer documents
  - Quality risk management
    - Quarterly risk evaluation with MAH
  - Annual product quality review
  - Marketing release management
    - Factory release procedures
    - Decision made by qualified person for marketing release
  - Quality compliant management
  - Return management
    - Deviation classification
  - Recall management
    - Assist in recall
  - Deviation management
  - Change control
    - Change classification principles
  - Specifications and test methods
    - Registration documents, China Pharmacopoeia
    - Raw materials and exceipients, packaging materials, intermediates, finished products
  - Retention samples and stability study
  - OOS/OOT management
  - Production process procedures and blank batch records
  - List of qualified suppliers
    - Material supplier audit and evaluation
  - Incoming materials management
    - Spot check the certificate of analysis of incoming materials by MAH
  - Quality information communication
  - Shared produciton line
  - Self-inspection/internal audit management
    - Plan, protocol, record, report
    - Corrective actions and preventive actions
  - Rejected products handling
  - Corrective actions and preventive actions (CAPA)
  - Discontinued and resumed production
  - Reprocesssing and reworking
  - Warehousing management
  - Main validation activities
  - Documentation management
  - Data management
    - Electronic data management
    - Computerized system
  - Drug traceability system management
- Accept MAH evaluation and assist MAH in issuing an evaluation report on the entrusted party
  - Assessment of production conditions, technical level, quality assurance ability and risk management ability of the entrusted party
    - Production, testing and storage capacities of premises and facilties, utilities, warehouses, production equipment, testing instruments, etc.
    - Risk assesment is performed to ensure the risks are identified and controlled timely
    - Personnel and quality management system meet GMP requirements
    - No bad credit histories
  - Audited by MAH
    - Site audit
    - Spot check
    - Data integrity
    - Corrective actions
- Sign a quality agreeement with MAH
  - Define the responsibilities and obligations of the entrusting party and entrusted party
  - Quality agreement management
    - Preparing, review and approval
    - Long-term archiving, change control
    - Termination management
  - Site personnel
    - Site instruction and supervision during the whole process of production management and quality management
  - Annual report