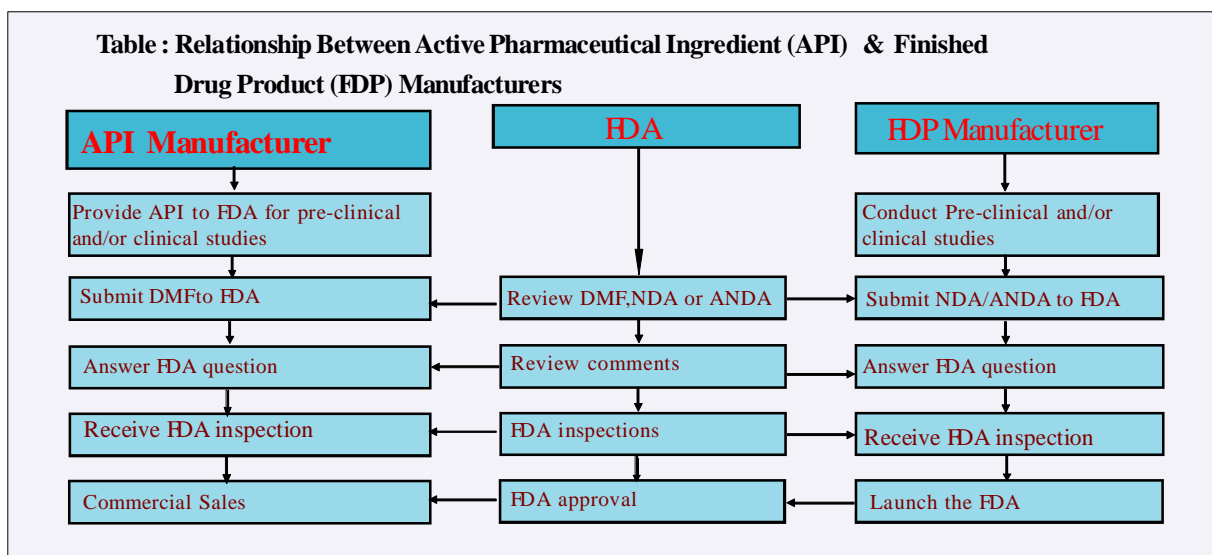


Section12:FDA Inspection Management

ScinoPharm has been audited by US FDA for its GMP compliance. FDA’s acceptance letter is shown on the following page. ScinoPharm’s first FDA Pre-Approval Inspection was triggered when one of our customers filed an ANDA in which they identified ScinoPharm as the supplier of the API and referenced the ScinoPharm DMF in their submission.

Subsequent FDA inspections will be scheduled as seen appropriate by the FDA. Such inspections may be part of their routine GMP inspection or may again be in the form of a PreApproval Inspection triggered by a customer’s NDA or ANDA submission.

The flow chart leading to FDA's inspection of an API manufacturer is shown in the following diagram. The responsibilities and the relationship between the API manufacturer and the drug product manufacturer are also illustrated.



The objective of FDA inspections is to determine whether the methods used in, and the facilities and manufacturing controls used for, the production of APIs are adequate to assure their quality and purity. Therefore, the FDA inspection typically covers equipment, facilities, operations, controls (computer, mechanical or electronic), cleaning procedures, safety, environmental conditions, QC laboratory facility and control procedures, documentation and record keeping, etc. with particular attention to any DMF that has been filed.

In order to prepare for inspections by the FDA, other regulatory agencies (including Taiwan and local), as well as the client's QA/QC professionals, ScinoPharm has developed a comprehensive, company-wide integrated systematic approach to address the following requirements:

- * cGMP Regulations and Guidances.
- * Safety Regulations.
- * Community Requirements.
- * Environmental Regulations.
- * Government and Local Codes.
- * Responsible CARE Program Obligations.