Inspections, Compliance, Enforcement, and Criminal Investigations

Foreign Pharmaceutical Manufacturers (5/96)

GUIDE[1] TO INSPECTIONS OF FOREIGN PHARMACEUTICAL MANUFACTURERS

BACKGROUND

There has been a significant increase in the number of foreign inspections of pharmaceutical manufacturing plants in the past few years. This trend is attributable mainly to the increase in the number of pre-approva inspections although the increase has been noted in other areas such as routine GMP inspections and compliance follow-up activities. Considering the resource-intensive nature of the foreign inspection program, it has become clear that effective and efficient inspectional coverage is crucial to the successful management of the program and that can be achieved only through maintenance of consistency and uniformity of inspection and enforcement activities.

Whenever possible, the agency tries to utilize only highly qualified Investigators and Analysts for the foreig inspection program who have extensive experience in conducting drug inspections with demonstrated track records of working effectively in a tight time frame and under considerable pressure. However, it has become increasingly evident that a formal guidance is necessary to address the issues specific to the foreign drug inspection operations as the agency needs to broaden the cadre of personnel to meet the objective of the program. Through this guide, the agency strives to ensure that it continues to realize the consistency and the uniformity in the overall inspectional/enforcement activities and, furthermore, informs the prospective inspection staff of the differences in the foreign vs. domestic drug inspection programs.

This guide was prepared by FDA's Office of Regulatory Affairs (ORA) with the assistance of the Center for Drug Evaluation and Research (CDER) and the Center for Veterinary Medicine (CVM).

PURPOSE

This document is not intended to provide guidance on how to perform an inspection at a foreign drug establishment. Rather, it is intended to address logistical and technical aspects specific to foreign drug inspections. With diminishing resources and increasing responsibilities in this program, efficient utilization of available time and information is a key to affording an adequate inspectional coverage abroad. This means that the investigator or the inspectional team will need to start preparing for the inspections as soon as th inspection itinerary is set.

The guidance provided in this document is intended to establish greater consistency and uniformity in inspectional activities at both domestic and foreign drug manufacturers. Additionally, this document is intended to strengthen the foreign inspection program at all levels through greater utilization of the resources available in the field and the Centers.

This document outlines the types of information and documents that the inspection team is expected to review prior to the foreign inspection trip. It sets forth the roles played by members of the inspection team and the staff in the Office of Regional Operations. It explains the communication process and the flow of work among field offices, the Office of Regional Operations, and respective Centers, namely, Center for Dru Evaluation and Research (CDER) and Center for Veterinary Medicine (CVM) bearing in mind that there are changes taking place in how the program is managed administratively. It sets forth guidance for inspection teams regarding communications with officials of the regulated industry.

For guidance on specific inspectional areas or technical subjects, the investigator should continue to refer to existing inspection guides, appropriate sections of the Compliance Program Guidance Manual, and Compliance Policy Guides.

OVERALL PROGRAM ADMINISTRATION AND MANAGEMENT

The foreign inspection program is under the management and direction of the International and Technical Operations Branch (ITOB) headquarters staff of the Division of Emergency and Investigational Operations/ORO. This branch schedules all foreign inspection trips and provides all the resources necessary for the program activities. ITOB also performs liaison activities with CDER, CVM, field offices, and the regulated industry. In addition, headquarters staff of the branch is responsible for resolving logistical difficulties that may arise during inspection scheduling, in-transit changes, and pre-inspection document support, and other issues.

The field offices evaluate and endorse establishment inspection reports (EIRs) and forward them to ITOB. Inspections performed by the ITOB staff or the Center personnel are evaluated and endorsed by the branch headquarters staff. ITOB forwards EIR packages and any recommendations to the appropriate Center and coordinates all follow-up activities. As mentioned earlier, the policy regarding compliance review and follow-up activities is under review and is subject to change.

Field offices are expected to ensure that assignments are completed on schedule; and to ensure reports and decisions regarding follow-up activities are submitted to ITOB in a timely manner. Field offices are accountable for the work identified in the ORA field workplan covering foreign inspections assigned to their districts and regions.

PROCEDURES AND CONCEPTS

Inspections at foreign drug facilities are expected to be approached in the same manner as domestic inspections. One main difference that poses a significant challenge to the inspection team abroad is the logistics borne by the program itself. The majority of foreign inspections are pre-set and relatively tight time-framed. Unless the inspection is prepared in advance and sharply focused, it is difficult to meet the objectives of the program satisfactorily.

Another factor to keep in mind is that the authority to inspect foreign drug facilities does not come from Section 704 of the Food, Drug and Cosmetic Act (the Act,) but from the agency's ability to exercise Section 801 of the Act and commitments made by the sponsors of applications, if applicable. For that reason, the agency is not required to provide stringent documentary evidence to establish violations of the Act. However, the inspection team is expected to collect sufficient records to substantiate its findings and to aid in the further review process by the agency.

The inspection team should consult appropriate sections of the Compliance Program Guidance Manual (CPGM) to determine the level and the area of coverage. The team should also refer to pertinent sections of the Compliance Policy Guides (CPGs), Regulatory Procedures Manual (RPM), and various inspection guides when preparing for and conducting foreign inspections.

As a general rule, sample collection is not required during inspections at foreign facilities. However, some compliance programs, such as the drug pre-approval and post-approval programs, may require sample collection as part of the inspection process. Be guided by the respective compliance program. The inspection team leader is responsible for contacting the assigned Center application reviewers and discussing the need for sample collections. When significantly violative conditions are observed during an inspection, the team leader should alert ITOB with its findings either by phone or FAX for timely evaluation of the situation. At the end of each inspection, the inspection team leader is expected to communicate the result of the inspection to ITOB, if possible, by FAX, (301) 443-6919, transmission of the form FDA 483, a brief summary of findings, and a proposed recommendation.

INSPECTION SCHEDULING

ITOB headquarters staff is responsible for scheduling all foreign inspectional activities. When requests for inspection from various components of the agency are received by ITOB, it schedules and assigns inspections to foreign inspection cadre members according to their specialties and availability. Geographical factor also influences the assignment of the inspections; i.e., ITOB tries to assign inspections to the lead investigator of the home district where the sponsor firm is located. This proximity to the sponsor firm will provide the inspection team some advantage in dealing with the US representative at all stages of the inspection.

At the initial stage of inspection planning, ITOB headquarters staff contact the domestic sponsor of an application to obtain any pertinent information necessary for preparation of the inspection scheduling. If any documents or data regarding the facility to be inspected need to be obtained, ITOB will arrange with the sponsor to have them forwarded directly to the inspection team leader in sufficient time prior to the trip departure date.

ITOB will coordinate the collection and the routing of documents and information from various headquarters offices to the team leaders. When deemed appropriate, a briefing may be held at the headquarters office prior to the trip. For those who are travelling abroad on an inspection trip for the first time, they are required to be briefed at the headquarters office.

REVIEWING DOCUMENTS PRIOR TO TRIP AND WHILE AT THE FIRM

Responsibility of the inspection team is to evaluate the foreign facility's compliance with cGMPs and its adherence to application commitments and DMF information, if applicable. The inspection team is expected to review background documents and records whenever possible and prepare for the inspection prior to travelling abroad. This is necessary due to the tight time-frame usually assigned to each inspection; without advance preparation, an adequate inspectional coverage cannot realistically be attained in most cases. At this stage of planning, the inspection team will have to determine tentatively those issues needing attention during the on-site inspection.

DMFs, (A)NDAs, (A)ADAs, and (A)NADAs filed with the agency are accessible to the inspection team through ITOB. Copies of the above are sometimes available at district offices with NDA managers. For an application product, the inspection team should, at least, obtain and review the chemistry, manufacturing

and controls (CMC) section of the application prior to the inspection. This section contains information regarding bio-batches, process and controls, analytical methods, and supporting analytical data. Also worth reviewing are reviewers' comments and correspondence between the sponsor and the agency (deficiency letters and written responses). They usually contain application-specific issues, but occasionally provide indications of GMP concerns to focus on. For an approved application, annual reports should be reviewed to identify any potential problems. For bulk drug substances, most of which are covered by DMFs, the inspection team should review the section describing the final purification steps of the manufacturing process.

Sometimes, it becomes necessary to review the documents that are not part of data filed with the agency prior to the scheduled inspection. Either ITOB or the inspection team may request those data from the domestic sponsor or the foreign facility. They are documents that would be routinely inspected, but may be too bulky or lengthy to cover during the limited on-site inspection. Examples of such documents are manufacturing process validations, cleaning validations, and stability data.

While at the firm the inspection team should evaluate all process failures, product failures, failures in laboratory tests, and process changes. Process failures and process changes are important because they have a significant impact on the adequacy of process validation. Attention should be given to all reports of failure investigations of any batches requiring rework or reprocessing.

For sterile products, the following should be reviewed: microbial test results for all batches; all initial positive sterility test results and reports of investigation; all organisms isolated and source; environmental monitoring results and investigations; monitoring of Water for Injection (WFI) systems for microbial and endotoxin qualities. For aseptic processes, media fills need to be reviewed. Also, keep in mind that dosage forms other than injectables may have microbiological requirements.

Complaint files should be reviewed for all products being covered.

Determine and report all products that the firm manufactures, which products of those are shipped to the United States, and the amounts being shipped to the USA since the last inspection or over the last two years.

TEAM INSPECTION

A large number of foreign inspections today are performed by teams of Investigators and Analysts. There is no question about the importance of close cooperation between the two groups for the success of the program. The lead Investigator is responsible for making the pre-inspection preparation and identifying the areas of focus for each member. The lead Investigator is also responsible for providing the Analyst with any records or data that need to be reviewed prior to the inspection. During the inspection, he or she leads the direction of the investigation and determines the types of records or operations to be examined by the team. However, keep in mind that the ultimate objective is to maximize the inspectional coverage by working together as a team and the role played by each team member should be flexible. In fact, the team members often need to operate independently at different locations.

Investigators and Analysts are expected to communicate inspectional strategies and findings at all times during the inspection. Strategy discussions outside the inspectional hours are encouraged. The team should avoid giving any appearance of discord or disagreement in the presence of the firm's personnel.

INSPECTIONAL GUIDANCE

Foreign drug inspections will generally involve bulk pharmaceutical chemicals (BPCs) or dosage forms. The end product may be sterile or non-sterile. Contract processors or contract laboratories may also be assigned. The Investigators/Analysts will inspect these facilities in the same manner as domestic facilities. The inspection team should be guided by the appropriate Compliance Programs and Compliance Policy Guides. Also, there are several inspectional guides that may be useful to review and understand prior to conducting the inspection. The inspection team may wish to carry copies of pertinent programs and guides to be used as inspectional tools and also to have available for copying by the firms being inspected.

There are numerous sources of information regarding inspectional guides, Compliance Programs, policy guides, etc. These include FDA-on-Disk (FDA personnel have access to this on ORA's CD ROM Gold Disk), FDA's Electronic Bulletin Boards, FDA's Internet Home Page, CDER staff, CVM staff, and staff in the Investigations Branch of the Division of Emergency and Investigations Operations. It is recommended that the inspection team be prepared to provide the appropriate telephone number or Internet addresses to firm to assist them in obtaining the various inspectional guides.

Refer to Attachment A for a listing of pertinent Compliance Programs, Compliance Policy Guides, and inspectional guides.

FDA World Wide Web Home Page address:

http://www.fda.gov

PRE-APPROVAL INSPECTIONS

Pre-approval inspections (PAIs) requested by CDER and CVM for approval of specific NDAs/ANDAs/NADAsA constitute a major segment of FDA's foreign pharmaceutical inspection activities. When a PAI inspection is scheduled at a given facility, ITOB may, at its discretion, request the inspection team also cover other product applications needing priority handling. District NDA program managers should keep track of and advise ITOB headquarters staff of any significant issues pending at the facility that must be resolved before an application can be approved even if CDER or CVM has not completed its review of the application.

Many of the PAI assignments are generated as a result of the Prescription Drug User Fee Act (PDUFA). These assignments are identified as such and bear relatively short deadlines. They must be given the highest priority and handled in a timely manner.

At the earliest time after completion of an inspection, the team leader should notify ITOB headquarters staff of the outcome of the inspection. He or she should transmit to ITOB via FAX the Inspectional Observations, Form FDA 483 (if one is issued), a brief summary of findings, and proposed recommendations. Subsequently, the EIR is expected to list all of the applications covered during the inspection and the status of each application. Be guided by appropriate Compliance Programs and Compliance Policy Guides for making endorsements and recommendations.

CULTURAL ASPECTS

More and more inspections are being performed at places outside of our own cultural boundaries. Even in places that share common cultural traits, we often observe big disparities in regulatory climates in the industry being inspected. How we conduct ourselves abroad may well determine how much information we bring back from the firms we inspect on which to base our regulatory decisions.

The inspection team is there to make an assessment of each foreign facility on FDA's terms. Foreign firms are under no obligation to comply with the U.S. regulations except for their commitments in applications filed with the agency and/or for their desire to market their products in the U.S.A. In dealing with a foreign firm, therefore, it is important not to impose our views on it during the inspection. Observe its manufacturing operations and verify them with the filed processes. Review the production records and document any deficiencies and discrepancies. The mission of the inspection team is, as is true in the domestic inspections, to gather as much information as possible to allow the agency to make an informed decision. Avoid a confrontational approach, if at all possible. Yet, be assertive and clear about what information and/or documentation the firm should provide to the team.

Views of the inspection team (or of the agency) and inspectional findings should be discussed with the firm during the exit interview in a constructive manner. Regulatory processes of other countries are usually different from ours, and the inspection team may need to explain to the firm the implication of the findings and ways to remedy the problems, including possible corrective actions.

COMMUNICATIONS

Prior to the inspection trip, the inspection team may contact the domestic sponsor directly by phone or by visit when deemed necessary and expeditious. However, as a rule, contact ITOB first to see if the information may be obtained through the Branch.

The inspection team is encouraged to contact the CDER reviewers at any time to discuss issues or concerns regarding the specific application. As mentioned in the previous section, Center reviewers may provide some information valuable for determining the direction of the inspection.

During the trip, the inspection team is expected to keep in touch with ITOB at all times for technical, administrative, or any other matters. ITOB sometimes needs to keep the team apprised of any additional information or changes while in transit. With regards to technical support during travel, ITOB will try to tap available resources within the Agency, including the National Experts and appropriate Center personnel to respond to the request in a timely manner.

When the inspection team finds significant GMP violations or data integrity problems at the foreign facility that may require additional attention, such findings should be immediately communicated to ITOB either by phone or FAX. On rare occasions, the inspection schedule may have to be amended if the findings warrant extensive evidence documentation. At the conclusion of each inspection, the team leader will notify ITOB with the result of the inspection by FAX including the Inspectional Observations, Form FDA 483 (if one is issued), a brief summary of findings and the team's recommendation.

REVIEW AND ENDORSEMENT OF INSPECTION RESULTS

The District (field) offices are responsible for review of all inspection findings and for proposing appropriate endorsements and recommendations consistent with the current policy applicable to domestic facilities. Follow the time-frames specified in the various Compliance Programs.

Current procedure requires that the District office forward the EIR package to ITOB for its evaluation of the District's endorsement and recommendation for consistency and uniformity. Then, ITOB headquarters staff will route the EIR package to the appropriate Center for their concurrence. The District office should be aware of changes in procedures regarding the routing of inspection reports, recommendations, compliance review, and other post-inspectional activities.

For the inspections performed by the staff of ITOB or headquarter's employees (ORA, CDER, or any other Center) shall continue to be forwarded to ITOB for its review and endorsement. ITOB is considered to be the home district for these employees.

For pre-approval inspections, Investigators and Districts should be guided by the current policy, particularly as it relates to District responsibilities regarding approval or withhold recommendations, compliance activities, and correspondence to the appropriate Center offices and applicants.

Written responses to FDA 483 observations and other correspondence received in ITOB will be copied to members of the inspection team for their review and comment. The inspection team is expected to provide any comment in writing back to ITOB as soon as possible. The inspection team leader is responsible for coordinating the manner in which the comment is provided.

ITOB headquarters staff is responsible for coordinating with the Centers, when applicable, in determining the need for any inspectional follow-up at the foreign facilities. ITOB should always coordinate the follow-up activities with the appropriate Center if the inspection request was initiated by that Center.

VALIDATION POLICY

All drug manufacturing processes are expected to have been validated prior to shipping. (Refer to HFC-133 memo dated November, 1995) This may mean that a manufacturer is not required to have documentation o a validated manufacturing process at the time of the inspection. However, this should not deter the inspection team from making an assessment of the firm's manufacturing process(es). Especially, for a bulk drug substance that has been manufactured for years employing an established process for many years and is not expected to change, the firm should have had sufficient experience with the respective process to have their critical process parameters under control to attain reliable and consistent product quality. During the inspection, the inspection team should attempt to evaluate if there are any significant variations in critical process parameters by examining a series of batch production records. If the process needs to be constantly fine-tuned from batch to batch, that is a sign of an invalidated process.

For the majority of bulk drug processes, the single most important quality attribute is the substance purity. Therefore, particular attention must be paid to the evaluation of final purification processes.

Even in the case of finished dosage form drugs, the inspection team should determine if the product has been already manufactured for the local market. For many applications submitted by foreign sponsors, the products have been marketed outside the U.S.A. for years and their processes usually established. The inspection team should first determine if the product and the process being inspected are new at the time of the inspection. If the application process is substantially similar to the existing process, the inspection team should attempt to find out if the firm has validation data and if other available production data support a validated process.

When and if the inspection team notes on the FDA 483 the lack of a validated process, the observation should be supported by a detailed account of how the inspection team came to that conclusion. The

concept of validated processes and documenting such evidence is not yet a widely accepted one outside the U.S.A. Being specific about what the observation implies will not only help the foreign firm to understand the issue, but also allow the agency to make an appropriate informed compliance decision.

DOCUMENTATION OF VIOLATIONS OF cGMPs

During the inspection of a foreign drug manufacturer, it is not necessary to obtain the same level of documentation expected from a domestic inspection to establish evidence of GMP violations or data integrity problems. The agency has the authority under the FD&C Act to administratively restrict the importation of a product without demonstrating the adulteration of the product. The burden of proof is placed on the importing party. However, the inspection report should contain sufficient information and documentation to support a conclusion by the reviewing office that significant violations of the law exist to warrant restricting importation of the commodity and/or non-approval of affected application(s). Where data integrity problems are suspected, an attempt should be made to establish a pattern of practice. If the inspection team determines that extensive evidence documentation is required and fears that the evidence might be destroyed, ITOB should be contacted at the earliest possible time so as to develop a prompt logistical support plan.

ATTACHMENT A

The following list shows some of the references to be used by travelers. This list is not all inclusive. Travelers should use whatever resources available to them to keep this list updated and adapted for their needs.

COMPLIANCE PROGRAMS

1. 7356.002 Drug Process Inspections

2. 7356.002A Small Volume Parenterals

3. 7356.002B Drug Repackers and Relabelers

4. 7356.002C Radioactive Drugs

5. 7356.002F Bulk Pharmaceutical Chemicals

6. 7346.832 Pre-Approval Inspections

7. 7346.843 Post-Approval Audits

COMPLIANCE POLICY GUIDES

CHAPTER 4 - HUMAN DRUGS

1. CPG 7132a.06: Finished Dosage Form Drug Products in Bulk Containers - Applications of cGMPRs

2. CPG 7132c.04, CPG 7132.05, & CPG 7132a.01: All related to Compendial/Test Requirements

3. CPG 7132a.17, CPG 7132.a.12, CPG 7132a.15, CPG 7132a.07, & CPG 7132a.08: All related to computers

4. CPG 7132.13: Repacking of Drug Products - Testing/Examination Under cGMPs

5. CPG 7132a.04, CPG 7132b.11, & CPG 7132a.10: All related to Stability/Expiration

6. CPG 7132c.08: Process Validation Requirements for Drug Products Subject to Pre-Market Approval

7. CPG 7150.16: Status and Responsibilities of Contract Sterilizers Engaged in the Sterilization of Drugs and Devices

8. CPG 7151.02: FDA Access to Results of Quality Assurance Program Audits and Inspections

CHAPTER 2 - BIOLOGICS

CHAPTER 3 - DEVICES

CHAPTER 6 - VETERINARY MEDICINE

REGULATORY PROCEDURES MANUAL

CDER GUIDELINES

1. Bulk Pharmaceutical Chemicals, 9/91

2. Preparation of IND Products, 3/91

3. Sterile Drug Products - Aseptic Processing, 6/87

4. General Principles of Process Validation, 5/87

5. Limulus Amebocyte Lysate Test, 10/89

6. The various 13 guides related to NDA/ANDAs

7. Format and Content for the CMC Section, 9/94

8. Stability Testing of New Drug Products, 9/94

9. Validating Laboratory Automation Systems, 10/94

10. Validation of Chromatographic Methods, 11/94

11. Sterilization Process Validation in Applications, 11/94

12. Validation of Computerized Liquid Chromatographic Systems, 8/92

13. Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test, 12/87

14. Sterilization Process Validation: Recommendations for Information to be Submitted to CDER/CVM Applications, 1/93

15. Guidance to Industry on the Packaging of Test Batches, 2/95

16. Various SUPAC Documents

INSPECTION GUIDES

1. Guide to Inspections of Oral Solid Dosage Forms Pre/Post Approval Issues for Development and Validation, 1/94

2. Guide to Inspections of Topical Drug Products, 7/94

3. Guide to Inspections of High Purity Water Systems, 7/93

4. Guide to Inspections of Validation of Cleaning Processes, 7/93

5. Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories, 7/93

6. Guide to Inspections of Lyophilization of Parenterals, 7/93

7. Guide to Inspections of Sterile Drug Substance Manufacturers, 7/94

8. Guide to Inspection of Solid Oral Dosage Form Validation Activities, 3/93

9. Guide to Inspections of Pharmaceutical Quality Control Laboratories, 7/93

10. Guide to Inspections of Oral Solutions and Suspensions, 8/94

11. Guide to Inspection of Computerized Systems in Drug Processing, 2/83

12. Guide to Inspections of Dosage Form Drug Manufacturers - CGMPs, 10/93

13. Preapproval Inspection Guide for Laboratory Analysts, 3/91

14. Software Development Activities Technical Report, 7/87

15. Interim Guide to Inspection of Validation of Filters for Sterilizing Liquids, 1995

16. ORA Stability Guidance for Preapproval Inspections, 3/92

17. Inspection of Bulk Chemical Substances, 3/92

HUMAN DRUG CGMP NOTES

INTERNATIONAL CONFERENCE ON HARMONIZATION GUIDELINES

OTHER

1. Federal Standard 209E

2. ISO 9000 Documents

3. Review of Procedures for the Detection of Residual Penicillins in Drugs

4. Inspection Technical Guide #41: Expiration Dating & Stability Testing for Human Drugs, 10/85

5. Federal Register on ETO Residues, 6/78

6. Drug Stability Guideline for Veterinary Drug Products, 12/90

7. Various Technical Reports and Monographs from the Parenteral Drug Association

a. Validation of Aseptic Drug Powder Filling Processes

b. Validation of Steam Sterilization Cycles

c. Validation of Aseptic Filling for Solution Products

d. Aspects of Container/Closure Integrity

e. Design Concepts for the Validation of a Water for Injection System

f. Validation of Dry Heat Processes Used for Sterilization and Depyrogenation

8. Sterility and Pyrogen Requirements for Injectable Drug Products (CVM)

9. Various AAMI Documents

10. Various trade association publications

TEXTBOOK REFERENCES

There are a number of textbooks available related to pharmaceutical production which serve as valuable reference sources. Consult with the FDA Medical Library, National Experts, DEIO/ Investigations Branch, or other places for these references. The following is a partial list that may prove helpful:

1. Aseptic Pharmaceutical Manufacturing I & II

2. Computer Systems Validation for the Pharmaceutical and Medical Device Industries

3. Design and Operation of Pharmaceutical Bio-Cleanrooms and Aseptic Areas

4. Drug Stability Principles and Practices

5. Failure Mode and Effect Analysis

6. Good Manufacturing Practices for Pharmaceuticals

7. Guidelines for Laboratory Quality Auditing

8. Industrial Sterilization

9. Introduction to Pharmaceutical Dosage Forms

10. Isolator Technology

11. Juran's Quality Control Handbook

12. Parenteral Products

13. Parenteral Quality Control

14. Pharmaceutical Dosage Forms: Parenteral Medications Vols 1,2, & 3

15. Pharmaceutical Dosage Forms: Tablets Vols 1, 2, & 3

16. Pharmaceutical Process Validation, Second Edition

17. Pharmaceutical Statistics Practical and Clinical Applications

18. Pyrogens

19. Remington's Pharmaceutical Sciences, 18th edition

20. Sterile Pharmaceutical Manufacturing Vols 1 & 2

21. Sterilization of Medical Products

22. The Merck Index

23. The Pharmaceutical Quality Control Handbook

24. The Theory and Practice of Industrial Pharmacy

25. Validation of Aseptic Pharmaceutical Processes

26. USP/NF

1. [1] Note: This document is reference materials for Investigators and other FDA personnel. The document does not bind FDA, and does not confer any rights, privileges, benefits, or immunities for or on any person(s).

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