

PROFILING A FIRM'S CGMP/QS COMPLIANCE STATUS

| | | | |
|---------------|---|------------------|--|
| Table 5-14.1 | Quick Reference Guide | 5-14.3.11 | Remark Status Field |
| Table 5-14.2 | Example of a Maintain Profiles Screen | 5-14.3.12 | Remarks Field |
| 5-14.1 | Introduction | 5-14.3.13 | Change in Operational Status |
| 5-14.2 | Purpose | 5-14.3.14 | Firm Merge |
| 5-14.3 | Instructions | 5-14.3.15 | Troubleshooting |
| 5-14.3.1 | Pre-Inspection Preparation | 5-14.4 | Contact Information |
| 5-14.3.2 | Firm's Operations | 5-14.5 | Data Quality Assurance Projects |
| 5-14.3.3 | Maintain Profiles Screen | 5-14.6 | Establishment Profile Criteria |
| 5-14.3.4 | Previous Inspection Profile | Table 5-14.6.1 | Device, Biologic, and Drug Establishments TO Profile |
| 5-14.3.5 | Firm information | Table 5-14.6.2 | Establishment and Operations NOT to Profile. |
| 5-14.3.6 | Inspection Coverage of Profile Class Codes | 5-14.6.3 | Pre-Approval Inspection |
| 5-14.3.7 | Discontinue and Delete Buttons | 5-14.7 | Profile Classes and Codes |
| 5-14.3.8 | CGMP Inspection and Other Toggle Buttons | 5-14.7.1 | Profile Class Codes |
| 5-14.3.9 | Initial, In Review, and Final | Table 5-14.7.1.1 | Biologics |
| 5-14.3.10 | Final Profile Status | Table 5-14.7.1.2 | Devices |
| 5-14.3.10.1 | Other Status | Table 5-14.7.1.3 | Drugs |
| 5-14.3.10.2 | Acceptable Status | Table 5-14.7.1.4 | Miscellaneous |
| 5-14.3.10.3 | Unacceptable Status | Table 5-14.7.1.5 | Special Veterinary |
| 5-14.3.10.3.1 | Continuation of Unacceptable Status | Table 5.14.8 | Abbreviations And Definitions |
| 5-14.3.10.3.2 | Changing from Unacceptable to Acceptable Status | | |

Table 5-14.1 Quick Reference Guide

| Review Status | Profile Status | Data Entry Role | Remarks Field | Remarks Status Field | Purpose |
|---------------|--------------------------|-----------------|--|---|---|
| Initial | Further Action Indicated | IB | Review and date Ex: "Referred to CB mm/dd/yy" | | EI is potentially OAI |
| | Acceptable | IB | Usually no Remarks required. | | EI is NAI or VAI. |
| In Review | Pending | CB | Recommended enforcement or alternative action; with date as well as review and date. Ex: "Recommend WL; Under review by [CB/Center]" | | Enforcement or alternative action recommended. |
| Final | Other | IB/CB | Enter the action firm is operating under Ex: "Consent Decree (CD) for CGMP (Current Good Manufacturing Practices)/QS (Quality Systems) violations signed on mm/dd/yy." If the CD includes a sunset clause/date, add to Remarks. or "AIP invoked on mm/dd/yy." | When the firm is operating under CD/Injunction/AIP (Application Integrity Policy) and the CGMP/QS EI is: NAI or VAI, then "Acceptable (AC)"; or the inspection is OAI and further enforcement action* is taken, then the Remarks Status is "Unacceptable (UN)." | Firm is operating under a CD or AIP, and a subsequent CGMP EI has occurred. Enforcement Action* may involve medically necessary products or be process or product specific. In this case, such conditions should be reflected in Remarks field (see 3.10 & 3.11(2)). |
| | Acceptable | IB/CB | <ul style="list-style-type: none"> No outstanding OAI inspections No compliance actions | | NAI and VAI inspections; or OAI inspections where no enforcement action was taken and/or was downgraded to VAI. |
| | Unacceptable | CB | Outstanding OAI Inspections | | Only after an enforcement action* occurred as a result of a CGMP/QSIT EI. |

*NOTE: A final profile status of *unacceptable* must be supported with regulatory action as recognized in the Field Management Directive sec 86 (FMD 86). This would include a Warning Letter, seizure, injunction, or prosecution based on CGMP deficiencies. A regulatory meeting or an untitled letter for CGMP deficiencies are not considered enforcement actions for purposes of an unacceptable profile status.

Table 5-14.2 Example of a Maintain Profiles screen

| | | | | | | | |
|-------------------------|-------------------------------|---|------------|--|--------|--|--|
| Firm | | FEI: <input type="text" value="1234567890"/> | | Name: <input type="text" value="Cloudy Day, Inc."/> | | | |
| | | Address: <input type="text" value="1234 Sunshine Lane"/> | | City: <input type="text" value="Rockslide"/> | | State: <input type="text" value="WA"/> | |
| | | Province: <input type="text"/> | | Country: <input type="text" value="USA"/> | | Zip Code: <input type="text" value="24567"/> | |
| Profile Classes | | Operation Type | | Last GMP Date | | Last Other Insp Date | |
| Profile Class | | Profile Description | | Last Final Status | | Pending Action Ind | |
| COS | Computer Software | Manufacturer | 11/14/2009 | | Others | <input type="checkbox"/> | |
| ELE | Electronic assembly | Manufacturer | 11/14/2009 | | Others | <input type="checkbox"/> | |
| PRF | Plastic or rubber fabrication | Manufacturer | 11/14/2009 | | Others | <input type="checkbox"/> | |
| Current Profile Status | | Date Type <input checked="" type="checkbox"/> GMP Inspection <input type="checkbox"/> Other | | Date <input type="text" value="10/05/2009"/> | | | |
| Profile Status | | Status Date | | Remarks | | Recommended By | |
| Initial: Further Action | | 10/20/2009 | | Refer to CB 12/14/09 CD signed 04/10/2008 | | Investigator A | |
| In Review: Pending | | 11/29/2009 | | Awaiting final decision or classification | | Compliance Officer B | |
| Final: Others | | 02/11/2010 | | Unacceptable | | Compliance Officer B | |
| | | | | Firm under CD 04/10/2007 Reg. mtg held 02/03/2010 WL issued 02/10/2010 | | SEA-IB-DA | |
| | | | | | | SEA-CB | |
| | | | | | | SEA-CB | |
| | | | | | | District Code | |
| | | | | | | Record Initial | |
| | | | | | | Record In Review | |
| | | | | | | Record Final | |
| | | | | | | Delete Status | |

Example of a firm operating under a Consent Decree where the current CGMP inspection (10/5/09) is OAI.

5-14.1 Introduction

Firm profiles provide a snapshot of the firm's compliance status with CGMP or QS regulations. Profile status is monitored for domestic and foreign firms that manufacture, repack, label/relabel, sterilize, or test drug, medical device, or biological products.

5-14.2 Purpose

Firm profiles provide the compliance status as well as an inventory of product categories covered during a CGMP/QS inspection and are used to support:

- The Government Wide Quality Assurance Program (GWQAP).
- External users such as state and local regulatory authorities and foreign government agencies.
- Other FDA operations such as drug product approvals, export certificates and imports.

5-14.3 Instructions

5-14.3.1 Pre-Inspection Preparation

To obtain a comprehensive history of the firm you are going to inspect go to ORADSS Domestic Reports folder named Establishment History Report and select EHR02_Firm Info and run the report entering the FEI and start and end dates for the period you want reported. Make sure that a final status has been entered for all PCs for the previous inspection. If you find that one or more PCs have an initial status but not a final status, bring this to the attention of your supervisor and finalize prior entering any updates.

5-14.3.2 Firm's Operations

For profile purposes, the firm's operation type can be either as a single entity or in combination with other operations. Look at all the possibilities in the drop down menu before making a selection. Some selections allow for multiple operations. See below for examples:

- a. Specification Developer Only versus Specification Developer Also"

When a firm is a specification developer and they do not manufacture any medical products onsite, select profile class code, SPD, and the Operation Type, "Specification Developer Only."

When a firm is a specification developer and they do onsite manufacturing of medical products which are not the subject of the specifications developed, select SPD with the Operation Type "Specification Developer Also" **and** select the appropriate profile class (PC) of the products they manufacture with Operation Type "Manufacturer."

- b. Control Testing Lab Only versus Control Testing Lab Also

When a firm is a contract control testing laboratory only and does not manufacture medical products, select profile class code, CTL, and Operation Type, "Control Testing Lab Only."

When a firm is a (contract) control testing laboratory and manufactures its own medical products onsite, select the appropriate profile class code(s) that

defines its operation, e.g., CTX for drugs, CTD for devices, or CTB for biologics (or a combination) and Operation Type, "Control Testing Laboratory Also." Select also the PCs that define the class of products they manufacture and Operation Type, "Manufacturer."

c. Veterinary Drugs Also versus Veterinary Drugs Only

When a firm manufactures both veterinary and human drugs, select the appropriate profile class codes(s) that defines its operation then select the Operation Type Veterinary Drug Also. When a firm manufactures veterinary drugs only, select the appropriate profile class code(s) that define its operation then select the Operation Type Veterinary Drugs Only.

For other changes in operations, or discontinuing profile required operations of FDA regulated products, update the establishment type industry code information on the MARCS/FACTS Firm Management Services (FMS) screen.

5-14.3.3 Maintain Profiles Screen

When entering profile information, it is important to access the Maintain Profiles screen properly as accessing a profile screen incorrectly will result in data quality errors.

The correct way for Field Offices and Centers to access the Profile screen is to access MARCS (Mission Accomplishments and Regulatory Compliance Services) FACTS (Field Assignments and Compliance Tracking System) database from Inside.FDA's ORA Applications, FACTS web link – clicking on Go takes you to the FDA MARCS Application Production screen. From the menu toolbar, choose Navigate, scroll down to Investigative Operations, move over and click on Inspections. Enter the FEI and click ExecQry to bring up the Maintain Inspection Results screen. From the toolbar, click the profile icon or click Options and scroll down to Profiles. You are now ready to enter/update the Maintain Profile record.

If there is a need to search for a firm through the FACTS Firms Detail screen, select the Inspection button. This will take you to the Maintain Inspection Results screen and from there use Options to reach Profiles. Do not enter profile information via this screen.

NOTE: Information entered/updated through this screen will not be linked to an inspection. Entering and/or updating profile information from this screen is the cause of many profile data errors and problems, such as duplications and/or non-finalized profiles which cause problems with future updates of inspectional information.

5-14.3.4 Previous Inspection Profile

It is important that the profile for the previous inspection be complete with a final profile status for each PC before updating the profile for the current inspection. If this is not done, a banner will appear saying "Initial data already exists," and it will not be possible to close the current inspection in FACTS on the Maintain Inspection Results screen.

5-14.3.5 Firm Information

The Maintain Firm, Maintain Inspection Results, and Maintain Profiles screens should agree in firm name, address, and FEI number. If not, or if the firm has a name or address change, the change must be made on the Maintain Firm screen. For questions, contact your District FACTS Profile Monitor. For foreign firms, contact your trip planner concerning discrepancies. See IOM Directory, ORA Field Program Monitors for contact information.

5-14.3.6 Inspection Coverage of Profile Class Codes

When a CGMP/QS systems based inspection is performed, coverage should reflect the overall state of control for the firm's operations. For this reason, the PCs should reflect all product classes produced by the firm and covered during the inspection, even if they are not directly covered. For example, if a firm is a drug manufacturer and a CGMP/QS systems based inspection is performed, then all PCs should be updated for all products produced by the firm.

When a firm manufactures more than one commodity, e.g., drugs and devices, and the inspection covers only the drug systems, then only update the PCs that represent the drug commodity. See 5-14.7 for more information about profile classes and codes.

5-14.3.7 Discontinue and Delete Buttons

Proper use of the Discontinue and the Delete buttons:
 Discontinue button – The PCs should be discontinued if a firm goes out-of-business or no longer manufactures a drug, device, or biologic product.
 Delete button - PCs and data entered in error can and should be deleted **prior** to clicking the save button and exiting the screen.

NOTE: If you save incorrect data before realizing it and you cannot delete it, contact the GWQAP Team for assistance. See 5-14.4 for Contact Information.

5-14.3.8 CGMP Inspection and Other Toggle Buttons

The CGMP Inspection toggle button is automatically activated when the Profile Required field is checked on the Maintain Inspection Results screen. The *Other* radio button should not be used for profiling purposes.

5-14.3.9 Initial, In Review, and Final

As reflected in Table 5-14.1 above, profile status should be entered as follows:

Initial: Normally entered by the Investigator. Potentially OAI inspections should be immediately entered as FI and NAI/VAI as AC.

In Review: Pending should be entered by the Compliance Officer as soon as the record is received for review.

Final: AC should be entered by the Supervisor for NAI/VAI inspections; UN should be entered by the Compliance Officer for OAI inspections when a regulatory action has been taken.

NOTE: The Status Date automatically records the date that the information is entered or updated in Initial, In Review, and Final Profile Status. It is important to maintain the integrity of the profile information by not changing this date.

Foreign firms: The districts enter the initial status only and the appropriate center enters the final profile class.

5-14.3.10 Final Profile Status

It is important for the Field and Centers to understand that final profile status should be promptly entered when a final agency decision has been made. Profiles should not be held in Pending status if the District or Center decides that the course of action is to not take enforcement action as defined by FMD-86, and, instead, re-inspect.

NOTE: This represents a change in procedure. Previously, an In Review "Pending" status was permitted until a re-inspection was made. Now, unless the District or Center plans to accelerate the re-inspection on an elevated priority basis to reach a final decision, the District or Center should close out the profile status. A final status of UN must be supported with a regulatory action. See 5-14.3.10.3. Please contact GWQAP Team with any concerns. For contact information, see 5-14.4.

5-14.3.10.1 Other Status

Other should be entered as the final profile status for all profile class codes when a firm is operating under a CD or AIP. See Tables 5-14.1 & 5-14.2 above for more information.

5-14.3.10.2 Acceptable Status

AC should be entered as the final profile status when an inspection is classified as NAI or VAI and the firm is not operating under a CD or AIP. See Table 5-14.1 above for more information. If an OAI is not supported by an enforcement action, it is entered as AC as defined in Field Management Directive (FMD)-86.

5-14.3.10.3 Unacceptable Status

UN should be entered as the final profile status when there is an outstanding OAI inspection. Refer to FMD-86 for final classification instructions.

5-14.3.10.3.1 Continuation of Unacceptable Status

A UN status along with the regulatory action taken may be carried forward from one inspection to the next when the follow-up inspection reveals the firm had not addressed the violations identified in the original OAI inspection or an enforcement action. In this case, it is important the Remarks field note this condition. See 5-14.3.11 Remarks field for more information.

5-14.3.10.3.2 Changing from Unacceptable to Acceptable Status

A UN status may be changed to AC when the agency's review of the firm's response to a warning letter reveals the firm's corrective actions adequately address the violations identified, a re-inspection for verification may or may not be warranted. The Remarks field must note the reason for the change.

5-14.3.11 Remarks Status Field

The Remarks Status field is used mainly to indicate the compliance status of a current inspection while the firm operates under a CD or AIP. See Tables 5-14.1 & 5-14.2 for more information and examples.

It may also be used to indicate an exception to the general compliance status. The profile status when under a CD will be "Others." The Remarks Status Field will show the current compliance inspection status (AC/UN). The Remarks Field will note that the firm is operating under a CD (include date and any information required concerning the current inspection).

5-14.3.12 Remarks Field

The Remarks field is a narrative field to be used as often as needed to:

1. Track the status of any potential or completed enforcement or alternative action with dates. This may include an explanation for a continuation of an UN final profile status from one inspection to the next when the follow up inspection reveals the firm's corrective actions were found inadequate. See Table 5-14.1 above or 5-14.4 below for more information and accessing the ORA/OEIO/DCS intranet site, respectively.
2. Indicate when a firm is operating under a CD or AIP with date. Note when there are specific conditions such as product(s) subject to the CD or AIP. This information must remain in Remarks for each PC until the CD/AIP is vacated or revoked.
3. Identify product(s) covered when using the catch all PCs MIS for devices, BMI for biologics and NEC for drugs; and
4. Indicate where a sterilization process(es) takes place such as onsite at the manufacturer, or offsite by a contract sterilizer. If offsite, include the name, address, and FEI of the contract sterilizer.

NOTE: After entering the information once, a copy and paste method can be used to update the Remarks field for each profile class involved as follows:

- a. Highlight the narrative text by clicking in the Remarks field.

- b. Select CTRL C to copy.
- c. Select CTRL V to paste.

5-14.3.13 Change in Operational Status

When the MARCS/FACTS “operational status” of a profiled firm changes, an assessment must be made to determine if the firm is still required to be profiled. If for example, the firm goes out of business the profile and registration fields must be discontinued and cancelled respectively prior to setting the operational status to Out-of-Business (OOB). Remember to uncheck the Profiled Required box from the List of Values (LOV) under Operational Status and select Out-of-Business (OOB) or Not Official Establishment Inventory (NOE). For profile changes other than OOB or not OEI firms refer to IOM Exhibit 5-14.3.7. Also select the Maintain Profiles screen and discontinue each profile class as follows:

1. If appropriate, verify that the registration is cancelled by the registration monitor.
2. Access the Firm Details screen by entering the FEI in Search Firm screen.
3. Navigate to the “Enter Additional Firm Details” screen in Firm Management Services (FMS).
4. Click the Edit link under Status.
5. Select the appropriate operational status from the LOV. For example, select OOB for an out of business firm.
6. Verify the Workload Obligation is appropriately set. For example, for OOB it should be set to N.
7. For OOB and NOE firms, uncheck Profile Required.
8. Select the Profile tab at the top of the “Firm Details” screen.
9. In MARCS/FACTS, select update button in the “Maintain Profile” screen and edit each PC.
10. Save changes and close window.

5-14.3.14 Firm Merge

Before attempting to merge two or more firm records, always check to ensure all profile class codes have been finalized. Do not attempt to merge if the profile status is left in Initial or In Review. Merging firms where the profile classes are not finalized will cause problems that can only be resolved through FDA’s information technology service department and consumes Agency resources. For questions, contact the GWQAP Team. See 5-14.4 below for contact information.

5-14.3.15 Troubleshooting

Troubleshooting information may be found at DCIQA’s intranet site. See 5-14.4 for intranet site location.

5-14.4 Contact Information

Go to [ORA/OEIO/Division of Compliance](#) Systems and select the appropriate Program Area.

NOTE: The COMSTAT Team has been changed to the GWQAP Team. To contact DCS, GWQAP Team Email: GWQAP@FDA.HHS.GOV

5-14.5 Data Quality Assurance Projects

Our GWQAP stakeholders, including the Department of Veterans Affairs (VA), the Department of Defense (DoD) [through the Defense Supply Center Philadelphia (DSCP)], as well as several Local, State, and Foreign Governments, use an external view of FACTS profiles to help them make procurement decisions for medical products. Since these stakeholders can view only the latest acceptable or unacceptable final profile status, profile classes **must** be finalized.

To conduct an audit of non-finalized profiles in your District, the FACTS Profile Monitors are asked to monitor profiles using a program created in the Online Reporting Analysis Decision Support System (ORADSS). The GWQAP Team will remind the District when to conduct this audit, will monitor this audit, and will also communicate with the District Profile Monitor regarding other programs to improve data quality.

Use the active down arrow at the top of the Maintain Inspections Results screen to view the previous inspection and profiles covered. Make sure a final status has been entered for all PCs for the previous inspection. If you find one or more PC has an initial status but not a final status, bring this to the attention of your supervisor.

5-14.6 Establishment Profile Criteria

Table 5-14.6.1 Device, Biologic, Drug, and Veterinary Establishments TO Profile

| | |
|-----------------------------------|--|
| Manufacturer | Makes a new or a changed product from one or more ingredients. |
| Remanufacturer | Processes, conditions, renovates, repackages, restores, or performs any other act to a finished device that significantly changes the device's performance or safety specifications or intended use. |
| Reprocessor | Performs remanufacturing operations on a single use device. |
| Packer/ Repacker | Packs a product or products into different containers without making any changes in the form of the product. |
| Labeler/Relabeler | An establishment which affixes the original labeling to a product or changes in any way the labeling on a product without affecting the product or its container. |
| Contract Sterilizers | Performs sterilization or irradiation of products or components of products regulated by FDA on a contract basis. |
| Control Testing Laboratories | Performs production quality control work related to products regulated by FDA on a contract basis. |
| Assemblers of Medical Device Kits | Responsible for assembling finished devices into medical device kits. |
| Tissue Establishments | Only tissue establishments inspected as device firms under the Quality System regulations. |
| Specification | Initiates or develops specifications for |

| | |
|-----------|---|
| Developer | a device that is distributed under the establishment's own name but is manufactured by a second person. |
|-----------|---|

Table 5-14.6.2 Establishment and Operations NOT to Profile

| |
|---|
| Blood Banks |
| Methadone Clinics |
| Manufacturers of "Research Use Only" Products |
| Pharmacies (including pharmacy compounders) and Retail firms |
| Distributors |
| Plasmapheresis Centers |
| Custom Device Manufacturers |
| Veterinary Medical Device Firms |
| X-ray Assemblers |
| Mammography Clinics |
| Manufacturers of General Purpose Articles (Devices) |
| Physicians' Offices, Hospitals and Clinics |
| Laser Light Shows/Television and Microwave Oven Manufacturers |
| Sun tanning Establishments |
| Device Component Manufacturers |
| Clinical Investigators/Bioresearch Monitoring |
| Tissue firms inspected under Good Tissue Practices |
| Any Non-GMP Inspection |

5-14.6.3 Pre-Approval Inspections

Pre-Approval inspections that cover the firm's systems (*Quality Control + 1*) should be treated like any other CGMP or QSIT inspection and should be profiled. When a pre-approval inspection is the initial inspection of firm and results in the firm not being approved to market within the U.S., the firm should not be profiled. The investigator should uncheck the profile required box on the Maintain Inspection Results screen.

NOTE: If the decision not to find the firm acceptable is reversed by the Center review, the Center is responsible for contacting the District to have the firm profiled. The District will inform the Center when the update is complete so the Center can then enter the Final classification.

When a pre-approval inspection finds problems affecting the product approval, but they do not affect the overall CGMP/QSR compliance status of the firm, the Profile Status should be entered as acceptable.

Information regarding withholding the approval of the product should be annotated on the Maintain Inspection Results screen in the Remarks field under District Decisions.

5-14.7 Profile Classes and Codes

The profile system is based upon product categories or classes, and is not product specific. Select the most appropriate profile class(es) to describe the product(s) the firm manufactures or otherwise processes.

When describing devices, often more than one class is needed to describe the operations/assembly involved in

the device. A rule of thumb is to think of the composition of the device and then select the profile classes that define the make-up of that device and its assembly. For example a catheter and needle unit is profiled as MTL (metal fabrication and assembly) and PRF (plastic or rubber fabrication and assembly). A Cutter, orthopedic cast, 110 volt AC-DC, is profiled as MTL, PRF and ELE (electrical). For devices that have software and are operated by computer, codes COS (software) and COH (computer hardware) should be added.

SPD (specification developer) should be used if a firm only develops the design and specifications and has the device manufactured by someone else. In this case use only SPD, do not include other profile classes unless the firm also manufactures other medical products on-site.

Catch-all codes: MIS for devices, NEC and CRU for drugs, and BMI for biologics can be used when product does not fit into any product class identified by the list of PCs. When using these codes, identify the type of product in the Remarks field for that code. If the product is a sterile product, don't forget to include the appropriate sterilization PC and identify if onsite or offsite.

When a product or products have been transferred from one Center to another, discontinue the profile class from the former Center representing that product if that profile class is no longer needed for any remaining products, and add a profile class which represents the new Center.

NOTE: Some Drug definitions have been updated.

5-14.7.1 Profile Class Codes

For more information, contact your District Profile Monitor or DCIQA. See 5-14.4 for contact information.

Table 5-14.7.1.1 Biologics

| BIOLOGICS | |
|--------------------|--|
| Profile Class Code | Definitions |
| AEV | ANTITOXINS AND ANTIVENINS |
| AFP | ANIMAL DERIVED FRACTIONATION PRODUCTS |
| ALP | ALLERGENIC PRODUCTS |
| BGR | BLOOD GROUPING REAGENTS |
| BMI | BIOLOGICAL PRODUCTS NOT ELSEWHERE CLASSIFIED (Blood collection bags with anti-coagulant, plasma volume expanders, Limulus Amebocyte Lysate (LAL) test kit, etc.; Note specific products(s) in Remarks field) |
| CBS | COMPUTER BIOLOGICAL SOFTWARE |
| CGT | CELL AND GENE THERAPY PRODUCTS |
| CTB | CONTROL TESTING LABORATORY "ALSO" |
| HFP | HUMAN DERIVED FRACTIONATION PRODUCTS |
| RBD | RECOMBINANT ANALOGUES OF BLOOD DERIVATIVE PRODUCTS |
| TIS | HUMAN TISSUE REGULATED BY FDA |
| VBP | VACCINE BULK PRODUCT |

| | |
|-----|--------------------------|
| VFP | VACCINE FINISHED PRODUCT |
| VIV | IN VIVO DIAGNOSTICS |
| VTK | VIRAL MARKER TEST KIT |

Table 5-14.7.1.2 Devices

| DEVICES | |
|--------------------|---|
| Profile Class Code | Definitions |
| BBP | BLOOD AND BLOOD PRODUCTS UNLICENSED |
| CCR | CLINICAL CHEMISTRY REAGENTS (including diagnostic tapes, sticks, etc.) |
| COH | COMPUTER HARDWARE |
| COS | COMPUTER SOFTWARE (Devices only) |
| CSP | CHEMICAL STERILIZATION |
| CTD | CONTROL TESTING LABORATORIES "ALSO" (Device manufacturer that is also a contract testing lab.) |
| DKA | DEVICE KIT ASSEMBLER (Ex: lumbar puncture kit, anesthesiology kit, suture removal kit) |
| ELE | ELECTRICAL ASSEMBLY |
| FSP | FILTRATION STERILIZATION |
| GLA | GLASS OR CERAMIC FABRICATION AND ASSEMBLY |
| GSP | GAS (ETO, PROPYLENE OXIDE STERILIZATION) |
| HCP | HEMATOLOGY AND COAGULATION PRODUCTS |
| HSP | DRY HEAT STERILIZATION |
| HTD | HUMAN TISSUE DEVICES |
| IDD | Injectable delivery device (syringes, auto injectors/pens) |
| MED | MEDIA (including microbiological and tissue culture, growth media and accessories, and ingredients) |
| MIS | NOT ELSEWHERE CLASSIFIED (Note specific product(s) in <i>Remarks</i> field) |
| MSO | Metered Spray Other (incl. nasal sprays, sublingual sprays) |
| MTL | METAL FABRICATION AND ASSEMBLY |
| OID | Orally inhaled delivery (incl. MDIs, DPIs, sprays) |
| OPT | OPTIC FABRICATION AND ASSEMBLY (Optical products or parts, e.g., eye glass lenses, intraocular lenses, contact lenses, lens portion of a laser, etc.) |
| PAT | Patch (incl. conventional patches, micro needles) |
| PBM | PROCESSED BIOLOGIC MATERIAL (Only animal or plant material used as a device) |
| PRF | PLASTIC OR RUBBER FABRICATION AND ASSEMBLY |
| RIP | RADIOIMMUNOASSAY PRODUCTS |
| RSP | RADIATION STERILIZATION |
| SIP | SEROLOGICAL AND IMMUNOLOGICAL PRODUCTS (Including bacterial typing, rheumatoid factors, pregnancy kits, IVD other than VIRAL marker test kits, etc.) |
| SOL | DEVICE SOLUTIONS AND GELS (Including contact gels, dialysis solutions, dental pastes, adhesives, etc.) |
| SSP | STEAM STERILIZATION |
| SPD | SPECIFICATION DEVELOPERS (Note in <i>Remarks</i> field where finished product testing is conducted.) |
| TSP | FRACTIONAL TYNDALLIZATION STERILIZATION |
| TXT | TEXTILE FABRICATION AND ASSEMBLY |
| WOD | WOOD FABRICATION AND ASSEMBLY |
| WSP | WATER STERILIZATION |

Table 5-14.7.1.3 Drugs and Veterinary

| DRUGS | |
|--------------------|---|
| Profile Class Code | Definitions |
| ADM | AEROSOL DISPENSED MEDICATION |
| CBI | RECOMBINANT/NON-RECOMBINANT PROTEIN DS OF BIOLOGIC ORIGIN |
| CEX | STARTING/INTERMEDIATE DERIVED FROM PLANT/ANIMAL EXTRACTION |
| CFN | NON-STERILE API BY FERMENTATION |
| CFS | STERILE API BY FERMENTATION |
| CHG | CAPSULES, PROMPT RELEASE |
| CRU | NON-STERILE STARTING/INTERMEDIATE/NEC (not Plant/Animal) |
| CRX | STERILE STARTING/INTERMEDIATE/NEC (not Plant/Animal) |
| CSG | CAPSULES, SOFT GELATIN |
| CSN | NON-STERILE API BY CHEMICAL SYNTHESIS |
| CSS | STERILE API BY CHEMICAL SYNTHESIS |
| CTR | CAPSULES, MODIFIED RELEASE |
| CTX | CONTROL TESTING LABORATORIES ALSO - Drugs |
| CXA | PURIFIED API DERIVED FROM PLANT/ANIMAL EXTRACTION |
| EXC | EXCIPIENT (also referred to as inactive ingredient) |
| GAS | MEDICAL GAS (includes liquid oxygen) |
| HMA | Homeopathic API/drug substance/tinctures |
| HMF | Homeopathic finished drug products |
| LIQ | NON-STERILE LIQUID (other than suspensions & emulsions) |
| LVP | LARGE VOLUME PARENTERALS |
| NEC | NOT ELSEWHERE CLASSIFIED FINISHED DRUG |
| OIN | OINTMENTS, NON-STERILE (including creams, jelly, paste, etc.) |
| PET | POSITRON EMISSION TOMOGRAPHY |
| POW | NON-STERILE POWDERS (Includes oral and topical) |
| SES | SUSPENSIONS AND EMULSIONS (NON PARENTERALS) |
| SLQ | STERILE LIQUID (other than suspensions & emulsions) |
| SON | STERILE OINTMENT |
| SPW | STERILE POWDER |
| SUP | SUPPOSITORIES |
| SVL | SMALL VOLUME PARENTERALS (Lyophilized) |
| SVS | STERILE-FILLED SMALL VOLUME PARENTERAL DRUGS |
| SVT | TERMINALLY STERILIZED SMALL VOLUME PARENTERALS |
| TCM | TABLETS, PROMPT RELEASE |
| TCT | TABLETS, DELAYED RELEASE |
| TDP | TRANSDERMAL PATCHES |
| TTR | TABLETS, EXTENDED RELEASE |

NOTE: API - Active Pharmaceutical Ingredient is sometimes referred to as Drug Substance. SNI profile class has been discontinued and replaced with SLQ, SON, and SPW for Sterile Liquid, Sterile Ointment, and Sterile Powder respectively, whichever is appropriate.

Table 5-14.7.1.4 Miscellaneous

| MISCELLANEOUS | |
|--------------------|--|
| Profile Class Code | Definitions |
| CTL | CONTROL TESTING LABORATORIES "ONLY" No manufacturing done on site. |

Table 5-14.7.1.5 Special Veterinary

| SPECIAL VETERINARY | |
|--------------------|--------------------------|
| Profile Class Code | Definitions |
| IMN | IMPLANT NON-STERILE |
| IMS | IMPLANT STERILE |
| TAM | TYPE A MEDICATED ARTICLE |

5-14.8 Abbreviations and Definitions

| Abbreviation | Definition | Reference |
|--------------|--|------------------------------------|
| AC | Acceptable | Table 5-14.1 Quick Reference Guide |
| AIP | Application Integrity Policy | Table 5-14.1 |
| CB | Compliance Branch | Table 5-14.1 |
| CD | Consent Decree | Table 5-14.1 |
| CGMP | Current Good Manufacturing Practice | Table 5-14.1 |
| CTRL | Control | 5-14.3.11 |
| DCS | Division of Compliance Systems | 5-14.4 |
| DoD | Department of Defense | 5-14.5 |
| EI | Establishment Inspection | Table 5-14.1 |
| FACTS | Field Assignments and Compliance Tracking System | 5-14.3.2 |
| FEI | FDA Establishment Identifier | 5-14.3.2 |
| FI | Further Action Indicated | Table 5-14.1 |
| FMD | Field Management Directive | 5-14.3.9 |
| GWQAP | Government-Wide Quality Assurance Program | 5-14.3.2 |
| IB | Investigations Branch | Table 5-14.1 |
| IOM | Investigations Operations | 5-14.3.4 |

| | Manual | |
|--------|--|--------------|
| LOV | List of Values | 5-14.3.12 |
| MARCS | Mission Accomplishments and Regulatory Compliance Services | 5-14.3.2 |
| NAI | No Action Indicated | Table 5-14.1 |
| OAI | Official Action Indicated | Table 5-14.1 |
| OOB | Out of Business | 5-14.3.12 |
| ORADSS | Online Reporting Analysis Decision Support System | 5-14.5 |
| PC | Profile Class | 5-14.6 |
| QC | Quality Control | 5-14.7.3 |
| QS | Quality Systems | Table 5-14.1 |
| QSIT | Quality Systems Inspection Technique | Table 5-14.1 |
| QSR | Quality Systems Regulations | Table 5-14.1 |
| UN | Unacceptable | Table 5-14.1 |
| VA | Department of Veteran's Affairs | 5-14.5 |
| VAI | Voluntary Action Indicated | Table 5-14.1 |
| WL | Warning Letter | Table 5-14.1 |