Pharmaceutical Inspectorate (PI)
Frequently Asked Questions

1. *What are the differences between the Pharmaceutical Inspectorate (PI) and the Product Specialists?*

The Pharmaceutical Inspectorate will be a group of Field Investigators who have specialized experience and specific training in evaluating pharmaceutical manufacturing. The Product Specialists are staff members in the Centers and Field who are experts on the science associated with complex products and technologies. Product Specialists may accompany Investigators during an inspection or will otherwise be available to provide scientific support during the course of an investigation.

2. *Who will the members of the PI report to?*

Members of the PI report directly to the management structure currently in place in the ORA District Offices.

3. *Who will give assignments to the PI?*

Members of the PI will receive assignments from the District Office Management based on the work plan developed by ORA and the Centers.

4. *Is the PI a group of individuals that is separate from the GS-13 Drug Specialists currently in the field?*

Yes, they are separate groups. However, all drug specialists are eligible for nomination by their supervisors to become Level III drug certified and members of the PI.

5. *Will the PI be required to travel both domestically and to foreign countries?*

Yes. Based on the inventory of drug facilities that need to be inspected, members of the PI will conduct both foreign and domestic inspections. The number of inspections conducted outside of the Investigator's District, including foreign inspections, is yet to be determined.

6. *What will be involved with the Level III drug certification program?*

Developed similar to the Level II Drug Certification program, the Level III Drug Certification program will include a variety of training modules on the science, policy, and standards related to FDA's regulation of the pharmaceutical manufacturing process and how evaluations are performed during an inspection. Requirements for the Level III Drug Certification will be developed by a Level III Drug Investigator Certification Board. This Board will be established in August 2003.

7. Who will be eligible to be in the PI?

Investigators who have at least 3 years of experience in inspecting pharmaceutical manufacturing facilities including regulation/inspection of drug facilities and are certified as Level II Drug Investigators (as defined by the ORA certification program) may seek nomination by their district managers to enter the Level III drug certification program. Once they have successfully completed the Level III drug certification program, they will become members of the Pharmaceutical Inspectorate.

8. How will the nomination process?

ORA's Division of Human Resource Development (DHRD) will issue a call for volunteers for the Level III Drug Certification. The Center, District, or Branch manager will create a prioritized list of all volunteer candidates endorsed to be Level III certified and forward that list to DHRD. The Level III Drug Investigator Certification Board will select all candidates for Level III (Pharmaceutical Inspectorate). The Level III Drug Investigator Certification Board will notify those candidates selected for Level III (PI) upon the Board's approval of that candidate's acceptance into the program.

9. Will the PI include analysts, compliance officers, or supervisors?

The PI will include any interested candidate that can fulfill the requirements of the Level III drug certification and maintain the requirements for this certification.

10. Who makes the final selection of an individual to be a part of the PI?

The Level III Drug Investigator Certification Board, consisting of members from CDER, CVM, and ORA, will review nominee packages for Level III certification and membership in the PI and will select applicants based on clearly defined requirements.

11. Who will pay for the training and certification requirements?

The Center for Drug Evaluation and Research will supplement ORA's funding of the training required for Level III drug certification and membership in the PI. In addition, CDER will assist in funding so that the PI is able to maintain their Level III drug certification.

12. How many people will be in the PI and how is this number determined?

The number of Investigator's that will be in the PI will be determined by the inventory of the drug facilities that need to be inspected. This is based on the work plan developed by ORA and the Center. It is anticipated that by the end of the calendar year, 10 Investigator's will be in the PI.

13. Will each district/region be expected to have staff dedicated to the PI?

The location of the members of the PI will be based on the location of the drug facilities that need to be inspected as determined by the work plan developed by ORA and the Center.

14. What types of facilities will the PI inspect and what types of inspections will they perform?

The PI will focus almost exclusively on inspecting pharmaceutical manufacturing facilities that use complex manufacturing technologies.

15. Must you be a member of the PI to conduct inspections of drug facilities?

No. However, as the program evolves, the PI will be expected to perform the more complex and high-risk pharmaceutical manufacturing inspections.

16. Will the PI also perform inspections on other types of facilities (e.g., food and device)?

It is expected that a majority of the PI time will be spent on pharmaceutical inspections. The District Offices will still have the ability to make other assignments, as necessary.

17. Will the PI be expected to be experts in drug manufacturing technologies or simply be knowledgeable of existing technologies as they relate to performing inspections?

The PI will be expected to have a basic understanding of all complex and emerging technologies in manufacturing science and be able to apply their understanding of these technologies to an inspection. If an expert in a specific technology is needed, the Product Specialist should be consulted.

18. What incentives are there for individuals to be a part of the PI?

The Level III Drug Certification will provide PI with the opportunity to be the recognized experts in the latest manufacturing technologies. Members of the PI will have the first opportunity in ORA to be trained on these manufacturing technologies.

19. Is the PI linked to promotion potential?

Not at this time.