CDRH Reviewer Certification Program (RCP)

The Center for Devices and Radiological Health (CDRH)'s Reviewer Certification Program (RCP) is intended for all new Office of Device Evaluation (ODE) and Office of In Vitro Diagnostics and Radiological Health (OIR) pre-market reviewers and began in September 2011.

The professional development of new employees is vital to CDRH's mission; this program serves as an investment in our staff.

Objective: To provide comprehensive new reviewer training.

Purpose: To provide a structured program to address basic core competencies for pre-market reviewers in the Office of Device Evaluation (ODE) and the Office of In Vitro Diagnostics and Radiological Health (OIR). The program provides education and learning to develop the baseline knowledge, skills, and abilities for pre-market reviewers in CDRH from all scientific and engineering disciplines.

Key Elements: A certified reviewer will have successfully completed or have participated in all of the following within the first ten months of employment at CDRH:

- Requisite course work: Course topics are designed to cover all core competencies
- Practical activities: Hands-on activities provide new reviewers with learning opportunities to apply competencies learned in class
- Knowledge Assessment: A comprehensive assessment will be administered near the end of the program
- Audit: An audit of reviewers main work product(s) (ex: 510(k)) will be reviewed by a Master Reviewer near the end of the program.

Benefits: To provide consistent training, basic knowledge and skills necessary for pre-market reviewers to evaluate pre-market medical device submissions in CDRH. This program will enhance pre-market workforce performance, consistency, and review quality.

Certification Program Duration: Basic Certification (Level I): 0-10 months
Intermediate (Level II): 10-18 months