

Process Improvement Accomplishment

The following information was compiled to inform Center employees on the progress of 5 CDRH Process Improvement Projects. The accomplishments of the 5 groups along with their contacts are listed.

1. 2004 OST (OSEL) Science Prioritization Process

Science Prioritization: Subhas Malghan and Dan Lyle

Science Prioritization was one of Center's 2003 initiatives under the Continuous Process Improvement (CPI) activities. Under the championship of Larry Kessler and Miriam Provost, a team of Center's staff worked with Dan Lyle as the Chair. This team worked throughout the summer of 2003 and developed a process. The process of science prioritization being used by the Office of Science and Technology (OST - - OST was reorganized in March 2004 and renamed as the Office of Science and Engineering Laboratories, OSEL) in 2004 is based on recommendations of this continuous improvement initiative. The implementation of this initiative was led by Subhas Malghan.

The original charge to the CPI Team was to "Develop a new, ongoing standardized, formal process that OST/OSEL uses to identify, evaluate, and prioritize existing and/or proposed research projects which meet high-priority regulatory/review needs of CDRH (both proactive and reactive) with input from OST/OSEL's key customers." One major aspect of the new process is the involvement of all Offices of CDRH in both identifying research projects and evaluating project proposals.

Starting in September 2003, OST/OSEL staff and managers developed more than 70 research project proposals under 14 program areas of interest to the Center. Each Program Area was evaluated by a separate Technical Committee composed of between 4 and 7 members who "have national reputation and/or are leaders in the Center." The function of the Technical Committee is to serve as advisory to the Science Prioritization Oversight Committee (SPOC) of the Center. Specifically, the role of Technical Committees was: 1) review of written project proposals; 2) listen to presentations from advocates of different projects, then ask questions; 3) meeting in closed session to discuss amongst TC members the merits of each project; and 4) independently scoring each project by a set of established criteria."

TC reviews were held in 14 separate but parallel sessions at Twinbrook and White Oak facilities during March 1 to 4, 2004. This was a major effort involving approximately 145 OST/OSEL staff and 90 TC members from CDRH and other parts of the Agency. Following completion of the review by Technical Committees, the scores and comments on all projected were reviewed by SPOC. The TC evaluations and scores served as advisory to the SPOC. The main focus of SPOC was to evaluate and prioritize OST/OSEL project proposals with

emphasis on Center needs. The SPOC completed their review on March 19 and sent the their recommendations to the OST Director on March 25, for funding/resource-allocation decisions.

As a final step in this process, the OST/OSEL is implementing the recommendations of TC and SPOC in the OST/OSEL research projects. This activity is to be completed in April 2004. This is not an end to the Science Prioritization Process that began in September 2003. OST/OSEL scientists and managers will continue to work with the Center staff by keeping them informed of progress and seeking feedback so that the research outcomes become more relevant to the Center needs.

Contact - Subhas Malghan 301-827-4782

2. PMA Close out process:

The PMA close-out CPI team has put together the binder and the PMA staff is distributing them with all incoming original PMAs and panel-track supplements that we receive in FY 04. Over 20 have already been distributed. Also, I discussed this tool in new reviewer training and the documents that are enclosed in the binder are located in the H:drive. So far we have received lots of positive feedback. In order to measure any improvement, we would need to wait a while and 1) survey those reviewers who have received the binders and their managers and 2) look at the numbers for PMAs received in FY 04 and calculate the time between panel and decision letter

Contact- Nicole Wolanski- 301-594-2186 x141

3. After Action Review Process: Mitch Shein- 301-443-8517 x178 and Cherie Wells- 301-594-4589 x144

4. Turbo- 510(k): Contact Sousan Altaie and Elias Mallis Mandate from Senior Staff

Make turbo 510(k) available voluntarily to IVD industry by December 2005 and expand beyond OIVD in FY 05

4a. ODE e510k Team – Updated Project Plan February 2004

Contact- Elias Mallis 301-594-3084 x145

Team Members

Donna-Bea Tillman – Sponsor

Elias Mallis – Team Leader

Nancy Pluhowski – Coach

Heather Rosecrans – 510k Staff

Zimmerman, Barbara C.; Yen, Dwight; Phillips, Robert A; Baxley, John H.; Whipple, David M.; Betz, Bob; Runner, Mary S.; Wentz, Catherine P.; Baker, Karen; Coene, Mike

Project Description

The purpose of this project is to explore ways in which the use of templates can improve the 510k review process. The team believed that the biggest payoff would be achieved by developing recommended formats for both Traditional and Special 510ks. Because ODE reviews a wide variety of device types, the team envisioned a standardized high-level template for Traditional 510ks that could be supplemented by device-specific sections where needed. A similar approach of a standard high-level template with device-specific sections is also envisioned for review memos. The long-term goal is to implement electronic submissions that can be used to populate an electronic review memo with administrative and descriptive data elements, freeing the reviewer to focus on analysis and recommendations.

Project Goals

Reduce the time needed to review 510ks submissions by implementing standardized submission and review templates.

Objectives

1. Improve the quality of 510ks submissions by developing voluntary templates for Traditional and Special 510ks
2. Reduce the time required to prepare Traditional 510ks review memos by developing a standardized format
3. Pilot the use of template-based electronic submissions

Tentative project schedule

Item	Date	Status
Complete review of existing 510k review templates, and determine feasibility of developing a single review template for traditional 510ks: end of January 2004	end of January 2004	Complete
Complete team draft of a high level submission template for Traditional 510ks	end of March 2004	In progress
Complete GGP sign-off on Traditional 510k template guidance	April 15, 2004	
Complete team draft of submission template for Special 510ks	May 1, 2004	
Complete GGP sign-off on Special 510k template guidance	June 15, 2004	
Develop pilot for electronic submission of Traditional 510ks		
Obtain input from reviewers, branch chiefs, Division, and other stakeholders on key elements for a Traditional 510k review memo		
Complete first draft of Traditional 510k review memo – circulate internally for comments		
Complete final version of Traditional 510k review memo – roll out to staff		
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Evaluation plan

Evaluation factors could include 510k review times, 510k quality assessment, and surveys of industry and reviewer satisfaction.

4B. implementation

OIVD Turbo 510(k) Project- an update on

February 27, 2004

Contact- Sousan Altaie- 301-594-3084 x145

Description of the Project:

Develop an electronic 510(k) submission and make it available voluntarily to the IVD industry by December 2004.

Team Members:

Sponsor- Steve Gutman

Team Leader- Sousan Altaie

Team Members- Sally Selepak, Kathleen Simon; Angel Torres-Cabassa, Arleen Pinkos, Avis Danishefsky, Michael Coene, Brianna Broderick

Time lines for implementation:

Milestone	Projected Completion Date	Status
Develop a paper version 510(k) submission template	January, 2004	Completed December 2003
Develop instruction for use and directions for preparing the 510(k) submission template	January, 2004	Completed December 2003
Pilot the paper version submission template using 9 volunteers solicited by AdvaMed	June,2004	Paper version recieved by volunteers in January, dialog are going on between FDA and volunteers
Develop eSub-Submitter modula	March, 2004	On time
Develop eSub-Loader	March, 2004	On time
Develop eSub-Reviewer -Phase one, eSub-View -Phase two, eSub-Review	July, 2004 Not Scheduled	On time N/A

5. Risk-Based Inspection Workplan Process:

Contact: Frances A. Benedict 301-594-4586 x153

Champion: Tim Ulatowski

Team Leader: Chet Reynolds

In 2003, the Inspection Workplan Process was chosen as one of the Center's first three Continuous Process Improvement (CPI) initiatives. The purpose of the team was "to evaluate and recommend improvements to the CDRH Medical

Device and Radiological Health workplan inspection process.” Based on the recommendations of the Inspection Workplan Process CPI team, a second cross-office Risk-Based Inspection Workplan CPI team was established. The purpose of the second team was to “recommend a process that facilitates Center wide involvement of customers in the development of a risk-based inspection workplan for CDRH.” In September 2003, the Risk-Based Inspection Workplan Team presented the following recommendations to CDRH Senior Staff:

- Develop a Center-wide Risk Definition
- Develop Center-wide Risk Assessment Criteria
- Implement an Inclusive Risk-Based Inspection Workplan Process
- Develop/Implement a Risk-Based Inspection Workplan Training Program

Based on the above recommendations, two new teams have been established. OHIP has the lead role for the team that has been charged with the development of both the Center-Wide Risk Definition and Risk Assessment Criteria. OC has the lead for the team that has been charged with the implementation of the Risk-Based Inspection Criteria. In addition to cross-office representation, the Office of Regulatory Affairs has provided a representative/consultant.

The Risk Definition/Assessment Criteria (RDAC) Implementation Team Leader is Nancy Wynne. In January 2004, the RDAC Team began a review of the material gathered by the RBWP Team including risk models from CDRH Offices, definitions developed by sister Centers, and a review of the Commissioner’s Action plan. In February the team developed a definition of risk which is consistent with the CDER definition and satisfies the Commissioner’s Actions Plan item 1.02.01.28; integration of ISO standard 14971:2000 (Application of Risk Management to Medical Devices) into CDRH workplanning. In March, 2004, the definition recommended by the RDAC team was accepted by the Center:

Risk is a combination of the probability of occurrence of harm and the severity of that harm, Harm is a negative effect on a person or person’s health due to an unsafe or ineffective device; or reduction in a device’s safety/effectiveness, clinical benefit, fitness for use, improper use, or quality.

The Risk-Based Inspection Workplan Implementation Team Leader is Debra Adams. This team is charged with developing written SOP’s and implementing the process proposed by the second CPI team. The new process is consistent with the CDRH Total Product Life Cycle concept and implementation will satisfy the Commissioner’s Action Plan items 1.02.01.04, 1.02.01.09, 1.02.01.14, and 1.02.03.04 (see below).

The first step of the new process is the development of inspection workplan proposals based on risk. In January and February, 2004, CDRH Offices were asked to develop proposals for inclusion into the FY-2005 Workplan Forecast by assessing public health hazards using their internal risk-based models. In March, 2004, OC hosted the first Annual Inspection Workplan Prioritization Meeting. Criteria for evaluating the proposals were developed from feedback supplied by the second CPI team. Representatives from each Office were chosen to serve on a Prioritization Panel. Presentations at the meeting were limited to the top 5 proposals from each Office. The results from the Annual Prioritization Meeting will be used to prepare the CDRH response to the ORA Workplan Forecast Call document. The next step is for OC to negotiate with ORA regarding the CDRH risk-based priorities.

Future steps in the new process include quarterly update meetings. Based on the quarterly feedback, as appropriate, adjustments as to the implementation of the Inspection Workplan will be negotiated by OC. Feedback from the Annual Meeting will also be used by the OHIP led RDAC Implementation team to develop improved assessment criteria. The recommendation for the development of a web site and RBWP Program Representatives training will be addressed at a later date.

The items from the Commissioner's Action Plan addressed by the Risk-Based Inspection Workplan CPI team are as follows:

Item #	Action
1.02.01.04	Workplanning: Improve CDRH's workplanning process so that it includes incorporation of risk based priorities, best practices, and development of a multi-factorial risk model for both domestic and import operations.
1.02.01.09	Inspections: Identify common factors and a system to assist CDRH in prioritizing and choosing sites/systems for inspection, including the establishment of a process for conducting statistically based audits of areas not identified as high risk as a means to ensure that the agency is targeting appropriate sites for inspection and compliance/enforcement activities.
1.02.01.14	Compliance/Enforcement: Establish a process by which CDRH will set compliance priorities by conducting a series of annual assessments that identify the internal and external hazards a regulated firm faces (e.g. those within versus outside of a firm's control); addressing risk estimate & characterization of the hazards(s); and determining the consequences to the public health as a result of agency action vs. inaction.
1.02.01.28	Integrate ISO standard 14971:2000 (Application of Risk Management to Medical Devices) into CDRH workplanning processes.
1.02.03.04	Establish policies and procedures that enhance the use of a tiered approach to foreign device inspections based upon risk for devices so that the amount/type of oversight (e.g., full inspections, abbreviated or focused inspections, evaluations of GMP documents, etc.) is proportional to the degree of risk. Process should be designed to promote development and maintenance of a flexible and risk-based stratified list of foreign facilities requiring inspection to maximize efficient use of foreign inspection resources.

