SMG 2010.2

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FDA OFFICIAL COUNCILS AND COMMITTEES

FDA BUSINESS PROCESS PLANNING GROUP

Effective Date: 07/01/2004

1. PURPOSE.

The purpose of the FDA Business Process Planning (BPP) function is to ensure that common business processes performed by component organizations are strategically aligned and will be supported by common systems with responsive, reliable and efficient delivery of needed Information Technology (IT) capabilities. This is accomplished through strategically focused and systematic analysis of common business needs, current and planned systems capabilities and identification of options that can provide business synergies. The BPP function operates at the direction of the FDA Management Council and provides timely, accurate and comprehensive analysis to support business process and related IT investment decisions by the Management Council.

2. BACKGROUND.

FDA's strategic plan calls for Agency-wide consolidation of IT systems and support, and calls for the transition of IT from an enabler to a strategic tool for realizing FDA policy goals and objectives, while making reductions in total IT spending. To accomplish this difficult objective, IT investments must be driven by business planning from a corporate Agency-wide perspective. During the same time, the FDA realized the concomitant need to take a quality system approach to achieve, uniformity, transparency and consistency in business process management. Adopting a quality system with repeatable characteristics is expected to result in robust processes and systems, better servicing internal and external customers.

Previously, the Agency has made most system investments at the Center level, including investments for new application development and maintenance. There has been relatively little coordination of these investments across the Agency. In

addition, the value versus cost of these systems has not been fully documented, but this information will be critical to the successful transition to consolidate systems and a well-coordinated approach to investment and management in the next year and beyond.

The FDA Management Council has endorsed the formation of a high-level business planning group, to serve as the principal developer of common Agency business process requirements and associated requirements for system capabilities. This is based on the understanding that, a) many Agency processes cross organizational lines and b) the Agency needs to ensure continuity, standardization and consolidation of common processes which will make it possible to automate them, and c) cross-agency data standards would enable the Agency to decrease duplicative data requests and do cross-system performance analysis. It is anticipated that instituting a business process planning function at the Agency level will enable FDA to build better information system capabilities per dollar of investment; and enable the Agency to eliminate duplication of common systems, allowing for expansion of support for common needs and for special needs, through more efficient allocation of IT funds.

3. SCOPE.

The processes listed in this document are those for operating the Business Process Planning function being implemented in FDA.

The BPP is charged with supporting the Agency mission to protect and promote public health by administering a governance business planning process that results in effective and efficient use of Agency resources.

4. STRUCTURE.

The BPP is an Agency-wide planning group coordinated by the BPP Chair, who reports to the Assistant Commissioner for Planning. The BPP group is comprised of senior business managers from the Agency programs who will lead the efforts of four cross-agency business work groups correspondent to the FDA Business Process Planning Model.

The Cross-cutting Support work group will be comprised of the Agency Executive Officers, representing each of the major programs, and the Agency leads for the Shared Services organization. In addition, the work of the BPP will be closely coordinated where needed with the work of the FDA Data Standards Council (DSC). The FDA DSC is responsible for leading and coordinating development of Agency business data standards (reference FDA DSC Charter).

The FDA Assistant Commissioner for Planning makes recommendations to the Agency Centers and ORA for senior business manager nominees to serve as designated key representatives on the work groups:

a. Improve Health by Access and Availability of New Products

b. Minimize Harm Due to Low Quality Products

c. Maximize Benefits and Minimize Harm for Marketed Products

d. Cross-Cutting Support

Each of the four work groups identified above will have a Chairperson assigned by the BPP. The Work Group Chair will have responsibility for directing the work group and sub-work group activities based on direction from the BPP Chair in accordance to directions set by the FDA Management Council. Additionally the Work Group Chair will be responsible for reporting activity results to the BPP Chair or appointed alternate.

5. RESPONSIBILITY.

The FDA Business Process Planning Group is responsible for directing the review and analysis of current and expected FDA business process requirements, and for planning and specifying the capabilities needed in the Agency information system which are developed, modified or maintained to meet those requirements in the most effective and cost-effective manner. To accomplish its mission, the BPP group will:

a. Provide leadership in implementing a corporate approach to enterprise-wide perspective in analyzing and identifying solutions to common business problems.

b. Provide vision for a more transparent, consistent and efficient business process and reliable and responsive supporting systems, to energize and assist component organizations in overcoming any perceived organizational barriers.

c. Provide oversight and guidance to work groups formed to develop the analysis of current and future-needed business process requirements and supporting information systems, and a first level of review and ratification of plans, options and any recommendations made by the subgroup.

d. Provide assurance, appropriate communication and early input from Agency customers who participate in the business process, and will interface with and be affected by contemplated changes to Agency approaches and information systems.

e. Identify and analyze potential opportunities, to inform Management Council prioritization of specific business processes for BPP group review and analysis.

f. Provide timely follow-through to perform studies of specific business processes identified by Management Council as 'high priority', including:

    1. Ensuring the formation of sub-work groups with the most knowledgeable process experts from relevant programs,

    2. Effective direction and management of the analysis work of those subgroups to assure timely and complete analysis of business process requirements, current system(s) capabilities, options for future Agency capabilities and approaches to obtaining those capabilities,

    3. Using a quality system approach to identify and apply "best-in-class" business practices and performance measures. This affects and informs the analysis of potential cost-effectiveness of planned or potential IT investments.

g. Applying review and analysis, both starting from business processes to requirements for system support, and starting from legacy, new or contemplated systems developed to support a business process that is common to more than one component. Examples of such systems include but are not limited to:

    1. Existing [different] systems used by different organizational components to support common business process,

    2. New systems recently implemented to support a common business process used by multiple components,

    3. New systems being planned or under development but not yet implemented, that will - or could/should - support a common business process used by multiple components.

h. Identifying essential programs that correlate with the FDA Business Process Model (Appendix A - Figure A) and separate information technology investments supporting these programs from those IT investments that are redundant, discretionary, unnecessary or counterproductive.

i. Providing effective and accurate flow of information between FDA Management Council and four Business Process work groups:

    1. Improve Health by Access and Availability of New Products

    2. Minimize Harm Due to Low Quality Products

    3. Maximize Benefits and Minimize Harm for Marketed Products

4. Cross-Cutting Support

j. Based on analysis of business processes and involvement of key business expertise, ensure alignment of IT investments to evolving Agency business requirements.

k. Supporting and pursuing policies and programs that provide for the efficient and sustainable use of IT investments, and working to revise or eliminate those that do not, in coordination with Agency Enterprise Architecture processes.

6. PROCEDURES.

1. Functional -

The Business Process Planning group reports to the FDA Management Council. The BPP planning process will include the following elements of a quality system approach as described in brief herein:

a. Identify candidate processes and/or systems for further study. Include estimates of the priority and level of effort/time frame required for study.

b. Prepare annual work plan for review, prioritization and approval by the FDA Management Council. The work plan will consist of "high-yield" opportunities from the business process perspective and also from the systems capabilities perspective, as described above [reference Section 5 Responsibilities].

c. Based on priority order of work plan, and business area of prioritization, convene a meeting of related business work group to discuss, identify/formulate subgroup, and develop more detailed work plans. This shall include formulating tasks for the FDA Data Council to conduct market research, gain community or industry usability consensus and develop data standards for emerging business processes.

d. For a given study, analyze current process and business needs, and systems to support them, current versus projected.

1. Identify a set of alternatives to address business need, including 'best' solution if one option dominates others.

2. Assess impact on current business process and systems; what changes would be needed to current business process? Data Standards? Systems?

3. Assess system efficiency gains and cost savings; identifying where opportunities exist and can be realized.

4. Questions considered in the analysis of a business process or existing/candidate system will include:

    - What are the objectives of the process?
    - What are the products/services of the process?
    - Who are the customers? And what are their needs?
    - Who is involved? And what are their roles and responsibilities?
    - What data and information is used?
    - What is the source of data and/or information?
    - Are there other resources required?
    - Is the process statutory or mandated?

    To answer these questions the BPP will use and implement a quality business planning model, comprised of seven (7) components, as described below, that interacts with a cross-section of committees and work groups:

    1.0 - DEFINE: Provide resource for the FDA Management Council to define business objectives; propose management strategies options to be followed in identifying, standardizing or establishing business processes; through Agency work groups establish the process, data, and information system baselines from which to begin Agency cross-cutting process development and/or improvement.

    Goal: To provide the FDA Management Council with "high-yielding" study candidates for further analysis. This includes potential missed opportunities for new development, as well as "pain points" for areas identified at Center level through capabilities assessments.

    2.0 - ANALYZE: Provide guidance to work groups to analyze Agency business processes for redundant, discretionary, unnecessary or counter-productive processes, to investigate methods to simplify and streamline limited value added processes, and examine all processes to identify more effective and efficient alternatives to the process, data, and system baselines. Additionally provide guidance to the work groups to evaluate business alternatives; coordinate resources

to baseline processes through a preliminary business and functional economic analysis to select a preferred course of action.

Goal: To gather business process details, including objectives, cost, involved stakeholders, requirements, dependencies, capabilities, and interoperability.

3.0 - REVIEW: Provide feedback to FDA Management Council with analysis information and current viable strategies and/or options needed to assess contemporary thinking regarding direction of the BPP and work groups.

Goal: To provide the FDA Management Council an opportunity to assess, challenge and implement change to course, scope and schedule to BPP activities. This represents a decision point for senior management.

4.0 - PLAN: Plan implementation of the preferred course of action by developing detailed statements of business requirements, baseline impacts, costs, benefits, and schedule through work groups.

Goal: To originate a plan that articulates, in executive summary form, proposed actions (e.g., IT Investment) for Management Council consideration.

5.0 - APPROVE: Oversee extraction from the planning data information (reference 4 - Plan) needed to finalize the business and functional economic analysis, which will be used by the FDA Management Council to approve proceeding with the proposed process development or improvement and any associated data or system change.

Goal: To gain FDA Management Council consensus to execute options or direction from plans formulated in component " 4 - Plan".

6.0 - EXECUTE: Govern the execution of approved process and data changes, and provide functional management oversight of any associated information system changes through coordination with Business Process Planning four work groups and/or FDA DSC.

Goal: To have the Business Process Planning Group set in motion activities towards achieving the objectives approved by the FDA Management Council.

7.0 - EVALUATE: Regular program review and assessment of inherent processes as well as emerging business requirements.

Goal: 1) To assess the effectiveness of the BPP for each implemented change by evaluating performance for each of the above components (#'s 1-6); and 2) to provide continuous review and assessment of business processes and systems supporting those processes.

2. Meetings –

   a. The BPP will make arrangements for regular meetings with the four work groups and the FDA DSC to communicate and provide guidance on FDA Management Council directions.

   b. The BPP Chair or alternate (as requested) will be responsible for setting the agenda, considering submitted agenda modification requests, determine the final agenda, communicate to any individual's request excluded from agenda and communicating the final agenda.

   c. The BPP Chair and Project Manager will meet weekly with the FDA Assistant Commissioner of Planning to provide weekly progress.

   d. The BPP Chair, Project Manager and any appointed Chair of a BPP work group (as necessary) will attend FDA Management Council semi-monthly meetings when requested by the Assistant Commissioner of Planning or the Management Council.

   e. The BPP Chair and/or Project Manager will attend and actively participate (voting members) in FDA Data Standards Council (DSC) meetings.

3. Communication-

   a. The BPP will be responsible for publishing meeting minutes of regular BPP meetings held with the four work groups and FDA DSC.

   b. The BPP will respond to the needs of the FDA Management Council and make information available as required.

   c. The BPP will provide each of the four work groups and the FDA Data Standards Council with FDA Management Council decisions and provide guidance where required or requested.

7. EFFECTIVE DATE.

The effective date of this guide is July 1, 2004.