MALCOM ASSOCIATES
OPTIMIZING DOCUMENTATION AND QUALITY SYSTEMS

# *Medical Device (IVD) Manufacturer* *Framework for Efficient 510(k) Process*

## Client Situation

- Increase of new product launches over next 2-3 years in the U.S. for products manufactured by sister facility in Asia.
- Need to reduce errors and improve efficiencies with the 510(k) process.
- Internal framework or flow for the 510(k) process not clearly defined.
- Individual and departmental understanding and experience with 510(k) process inconsistent.
- Review process identifying missing clinical data prior to 510(k).
- No defined process to monitor post clearance activities.

## Client Strategic Objectives

- Identify potential compliance, systemic, procedural, and inter-relational gaps.
- Improve and better define the overall work flow for the product launch process.
- Define the roles and responsibilities for new and existing personnel within the 510(k) process.
- Improve communication to executive management and regulatory agencies.
- Reduce the amount of redundant and missing information in clinical study documents and clinical reports.

## Key Issues and Internal Barriers

- Speed to market submission process needs to be defined more efficiently.
- Define process to better expedite product launches.
- Departmental roles and responsibilities not clearly defined.
- Responding to organizational needs for new products and changes to existing products.

## Key Program Components

- Review and process flow current 510(k) submission process.
- Identify existing and potential systemic gaps, key inputs/outputs, documentation and data requirements, etc.
- Validate accuracy and sequencing of activities within the process flow(s) with users.

## Results:

- A flow diagram of the entire 510(k) process with proposed improvements identified. (see flow below)
- Breakout flows were created from the overview for departmental use - i.e., Analytical Development, Clinical, Submission Prep, and After Clearance Activities.
- Detailed *'swim lane'* responsibility flows were created, reviewed, modified, and finalized for the most complex activities - i.e., Sample Inventory, Sample Control, and Study Data Results for the Clinical processes and the After Clearance-To-Market process before and after product launch.
- Several Input/Output flows detailing coordination with FDA from MDUFA Fee Payment through submission of the Application were created. Theses flows included links to the required FDA Forms to assist Regulatory Staff with preparation of the Application.

Example process flows: