FAST Medical Device Development Training

As anyone who has been in the medical devices business can attest, most device-related projects fail. The process of device development can get stuck at any point for various excuses, but in reality addressing each challenge begins with a common thread: becoming aware of the natural styles and needs of fellow team members.

Having a basic idea of device development still leaves more questions:

- How can a team effectively communicate realistic deadlines?
- How can effective cross-functional / inter-departmental communication take place?
- How does a person go about managing unrealistic expectations?
- How can leaders manage and uphold accountability?
- What tactics can prevent scope creep from late or poorly defined Design Inputs?
- What are the best ways to get timely signoff on Design Controls documents?
- How can a device project team operate more efficiently?

The objectives of this training are to teach people to:

- Describe their own behavioral style and its advantages and challenges
- Assess the behavioral style of another person given reasonable information
- Describe the best approach to interacting with each given behavioral style
- Understand and use the FAST method to approach a medical device project challenge
- Describe the finer points of each step of FAST
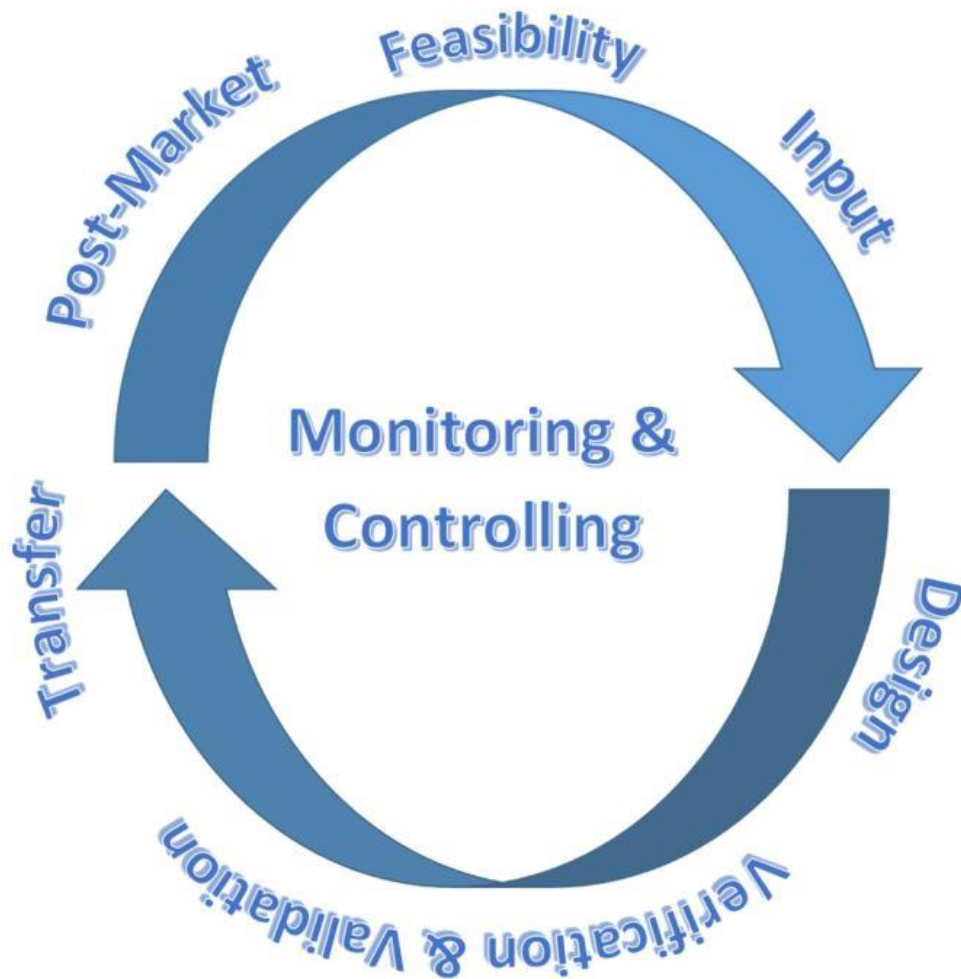- Give examples on how to apply FAST to some common medical device project difficulties

The advantages of this training are:

- It is the only program exclusively focused on medical device development.
- The trainer is a 12-year veteran of the device industry and has worked on over 100 projects in that time
- The trainer is a 25-year user of the DISC model and has deep practical experience with it in the device industry.
- Given the breadth of the trainer's experience, the program can be tailored toward specific device areas and specialties.
- The trainer is familiar with medical device company culture and the deep underlying issues that create challenges in projects.
- It's **FUN**!

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The Medical Device Development Process

A typical medical device development process (see figure below) generally has the same series of steps and milestones. The naming and specifics of each section can vary by company and what system that company is using to manage its portfolio and development. The Stage-Gate® Process (Stage-Gate International) and the Project Management Processes (Project Management Institute) (PMI), for example, name each step differently than in the figure but all of the basic components are present.

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Laying out the process allows insight into some common challenges for each stage. A few examples that many are familiar with are given in the table below, which is far from all-inclusive.

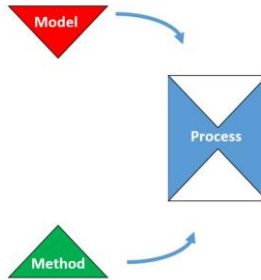**Common Challenges in Medical Device Development Projects**

Process Stage	Other Names	Typical Challenges
Feasibility	Project Initiation	• Disagreements over IP between company and university • Management fails to buy into project • Limited resources especially key stakeholders i.e. Regulatory
Input	Project Planning	• Management demands accurate budget/timeline before project requirements are set • Underestimation of tasks, resources, budgets, schedules by stakeholders not doing the work • Crucial prospective team members unavailable for the project
Design	Project Planning and Definition	• Disagreements over task planning • Meeting poorly set time, cost, and quality requirements in previous phase • Schedule delays from poorly categorized inputs in last phase
Verification & Validation	Project Execution	• Slow clinical trial enrollment delaying project (also pre-market clinical data may not be present) • Resistance to building in project, product, vendor safeguards • Additional scope demands from stakeholders
Transfer	Design Transfer	• Underestimation of tasks, resources, budgets, schedules by project team for manufacturing engineers who will make the product • Poor communication and interfacing with Operations • Misunderstanding purposes of crucial documents (DHF, DMR, DHR, etc.)
Post-Market	Commercial Phase	• Inaccurate estimation of launch budget • Resistance to maximizing publicity through diverse media • Obscure and poorly communicated changes from Medical and Regulatory Affairs
Monitoring & Controlling	Quality Assurance & Quality Control	• Lack of QA resources at critical times • Quality requirements not communicated on time • Poor (or no) systems to define project and personnel performance

The challenges in the table above have two common elements:

- They cannot be solved through superior knowledge of device development or technical expertise.

- Superior experience can help but is unlikely to fully mitigate them.

It thus becomes necessary to apply a method and a model to attack these challenges. Though each associated problem that arises during medical device development is unique and will have its own specifics, the model and method allow for a starting point which should lead to a unique solution when applied:

The DISC Model

The model used to meet these needs comes from the DISC system of behavioral styles which is then applied to teach people how to tackle the device life cycle. DISC is a validated behavioral style model with a long history of application in a business setting. In addition to the standard DISC principles which designate four primary styles along with combinations, modern adjustments to the presentation methodology are incorporated to increase retention by trainees. This is the first time this format of the model has been adapted specifically for medical device companies and their unique unmet needs.

Birds are used as a mnemonic device in place of hard-to-remember terms to describe the major behavioral styles in the DISC system. When participants understand their own behavioral styles which are determined through a pre-course survey, they are then instructed on the differences between them and how to relate to each one. No one style is superior or more beneficial, but styles can be over or under-utilized as well as imposed on fellow coworkers and direct reports. The nature of how this creates difficulties elucidates the pathway to better communication and avoidance of some unnecessary interpersonal conflict.
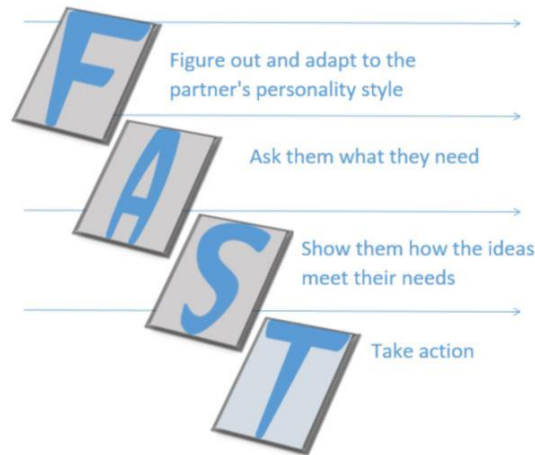
While the DISC Model is extremely enriching for its insights into human behavior and understanding the actions of coworkers, managers, and stakeholders, it does not describe a direct method for use in the workplace. For this, a method of application incorporating DISC is necessary. The method, in conjunction with insights from DISC, allows the team to address the process of medical device development and its associated challenges.

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The FAST Method

The FAST method is an easily remembered and incorporated application of the DISC Model which has been synthesized from the best practices in consultative selling, principled negotiation skillsets, and conflict management. Like the modification to the DISC Model which uses a mnemonic device to make it more accessible, the FAST method streamlines several methods and combines them into something applicable to medical device projects and associated challenges. Teaching this method to the trainees completes their toolbox of model, method, and process and better prepares them to deal with their daily challenges "FASTer".

FAST uses four steps to approach a challenge which involves personality and style differences on a project team.

Figure out and adapt to the partner's personality style

Ask them what they need

Show them how the ideas meet their needs

Take action

The stunning simplicity of the steps hides their deep layers of technique and applicative learning. Training on the DISC Model includes a how-to on the first step of FAST, which is necessary to begin the method. What is not evident, however, is the specific art of asking and uncovering needs via candid connection, concern, and a forthright interview process taught as part of the method. Showing and demonstrating ideas as a next step in the method is also not an innate behavior if done as an honest extension of FAST. It requires principled negotiation and empathy, always with behavioral style in mind. Taking action too can be a more complex process than thought, because as any medical device professional would know, it requires verification and/or validation. Overall, the application of the method takes practice and experience to become better at it, but it can yield preliminary results quite quickly.

Training Participants

Spiral Medical development conducts training for medical device professionals at all levels of proficiency and experience. This particular training material is geared toward the following professionals:

- Medical device project team members of any department with basic knowledge of Design Controls, Regulatory requirements, and QA/QC procedures (3+ years of experience)
- Project Managers that seek to enhance their relational skills
- Functional Managers seeking to improve team communication
- Project teams that wish to increase efficiency and better their relationship with Management and each other
- Organizational change agents that desire clearer organizational communication

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For more information, or to book this training for your team, contact:

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