

MEDICAL DEVICE ACCELERATOR

Tietronix' Medical Device Accelerator (MDA) gives you the ability to navigate and understand the FDA's strict requirements for medical device software development, including adherence to design controls, user requirements capture, risk analysis, and that the design is properly documented. The use of MDA reduces development time, ensures regulatory compliance, and enhances team collaboration, translating to shorter and less expensive development cycles, reduced costs, and quicker time to market.

MDA Features:

- **Process Automation**
MDA is a process-centric product built around a generic rules engine (work flow) that can automate any complex process. This work flow engine, developed by Tietronix (Tie-flow™), is uniquely adept at executing engineering processes in a natural and efficient fashion.
- **Document Management**
MDA provides full document configuration management (CM), from automating document signoff and review (21 CFR part 11 complaint), to highly flexible Change Control Boards (CCB), to user defined document meta data (e.g. draft, pilot, reviewed, etc.), to capturing document change history.
- **Electronic DHF**
MDA electronically captures the DHF (Design History File) and provides tools to easily review past project information.
- **Repeatability**
MDA is process driven so you are assured that each and every project will follow the same process, guaranteeing repeatability of a good design.

MDA Benefits:

- **Easy Adherence to Compliance Standards**
MDA ensures FDA compliance standards are met and followed within the process definition, preventing short-cuts or overlooking important steps in the process.
- **Project Visibility**
MDA provides project managers and team members instant visibility; 24 hours/day, 7 days/week, from anywhere in the world.
- **Clearly Defined Roles and Responsibilities**
MDA allows the project manager to set clearly defined roles, responsibilities, assignments for all team members, preventing team members from 'stepping on' each other.
- **Real-time Change/State Notifications**
MDA provides immediate change/state notifications in a pro-active "push" format, automatically notifying team members assigned to the next step, when a previous step is "closed".



Life Cycle Perform Work Manage Work **Doc. Control** Tools

My Projects: **MTI_Project**

Document Control

Documents Pending Reviews Review Document Manage CCB Category DCR Configuration

Filters

Category: **All** Project: **MTI_Project** Document: Author: **All** Area: **All** **Go**

Category	Core Number	Document	Version	Author	Area
03	0001	schedule.docx	1.0.0.1	Chris DuPont	Published
03	0001	schedule.docx	1.0.0.2	Chris DuPont	Working (In Review)
03	0006	schedule1.docx	1.0.0.0	Chris DuPont	Working (In Review)

Document Information

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Category Project Managemet **Review Status** Approved

Checkout By **Modify By**

[View DCR Information](#) [View Attributes](#)

Figure 1:

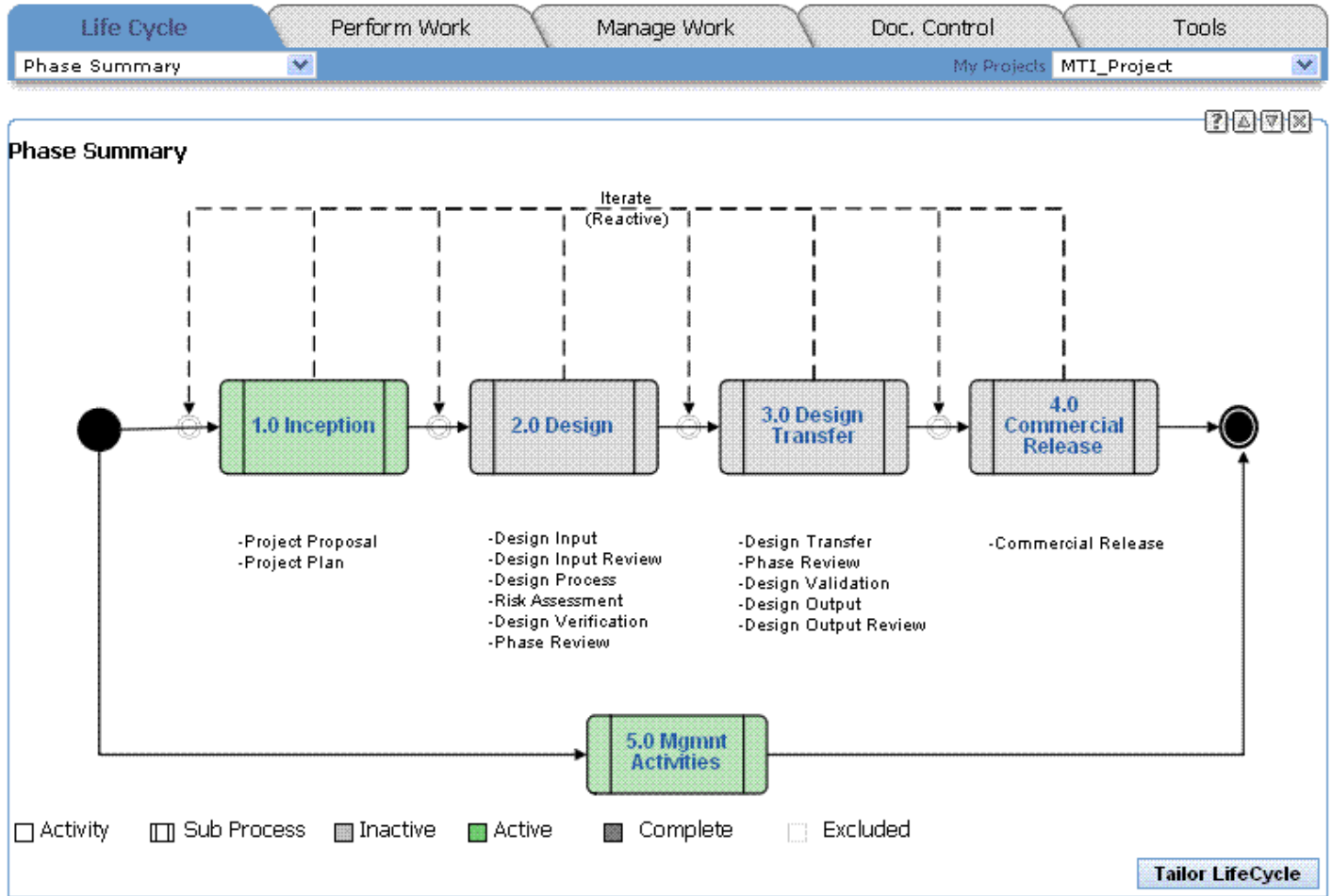


Figure 2: