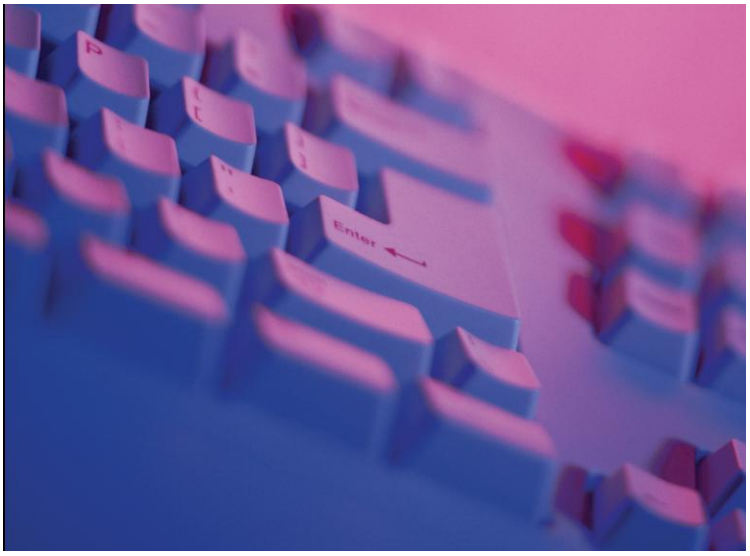
MEDICAL DEVICE ACCELERATOR

The Medical Device Accelerator (MDA) is process automation software built specifically to deliver rapid FDA compliant medical device products. Just as TurboTax™ transforms the ordinary taxpayer into a tax accountant, MDA takes you from innovation to implementation faster, more compliant, and less expensively than any other development path. MDA provides the ability to navigate and understand the FDA's strict requirements for medical device development. MDA provides adherence to design controls, user requirements capture, risk analysis, and company best practices. The use of MDA reduces development time, ensures regulatory compliance, and enhances team collaboration. This translates to shorter and less expensive development cycles, reduced costs, and quicker times to market.



Easy Adherence to Regulations:

MDA orchestrates well-defined workflow processes to achieve FDA compliance. This avoids the omission of critical steps or documentation that results in non-compliance.

Project Visibility:

MDA's dashboard provides real-time project and process status to authorized team members: anytime, anywhere. The project manager can define who has access to information within MDA.

Clearly Defined Roles:

The project manager defines roles, responsibilities, and assignments for all team members ensuring collaboration and eliminating duplicated work.

Real-time Notifications:

MDA automatically notifies team members assigned to specific work of changes to status, alerts, or new assignments. MDA provides immediate notification in a "push" format.

Process Automation:

MDA is a process-centric product using a workflow engine that automates any complex process. This workflow engine, developed by Tietronix, executes complex engineering processes in a flexible fashion.

Document Management:

MDA provides full document configuration management. MDA automates document review and approval (21 CFR part 11 complaint), creates highly flexible Change Control Boards, state-defines user document meta-data (e.g. draft, pilot, reviewed, final) and captures document change histories.

Electronic DHF:

MDA electronically captures the Design History File (DHF) and provides tools to easily review past project information.

Repeatability:

MDA executes the same defined process and best-practices every time. New team members require less training to do their job.

TIETRONIX

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