

Change Order

DOCUMENT NUMBER (Include the Subversion draft revision no. from the Draft QS Documents folder.)	REV. ID
Q-0002 Document Control (Revision 356)	A
Q-0002 Form A Document Template (Revision 332)	Α
Q-0002 Form B Change Order Template (Revision 357)	Α
Q-0005 Document Naming Conventions (Revision TBD)	A
Q-0003 Control of Records (Revision 355)	Α
R-0001 Competence, Awareness, and Training (Revision 359)	A
R-0001 Form A (Revision 360)	A

APPROVED			
NAME	SIGNATURE	TITLE	DATE
Adrian Gropper, MD		Manager	
Susan Belanich		Quality/Regulatory Reviewer	12/17/2004
Not Applicable		Subject Expert	

JUSTIFICATION FOR CHANGE

Documentation and Training form the core of a documented quality system. Implementation of these core procedures will allow MedCommons to begin to implement the remainder of the quality system.

IMPLEMENTATION TASKS ^{1,2}			
OWNER (By Name)	TASK	TARGET DATE	
Susan Belanich	Implement the Documentation database.		
Susan Belanich	Train MedCommons personnel		
Susan Belanich	Validate use of Adobe signatures for electronic signatures.		

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¹ Examples of implementation tasks: Minimum training requirements, acquisition of supplies, installation of equipment, validation, effective date, or obsolescence of an SOP.

 $^{^2}$ Examples of minimum training requirements: "We want [75%] of [Software Testers] trained by [date] or when the [validation date] occurs."