

Case Study: Global CAPA Implementation at a Major Medical Device Firm

I. Objectives

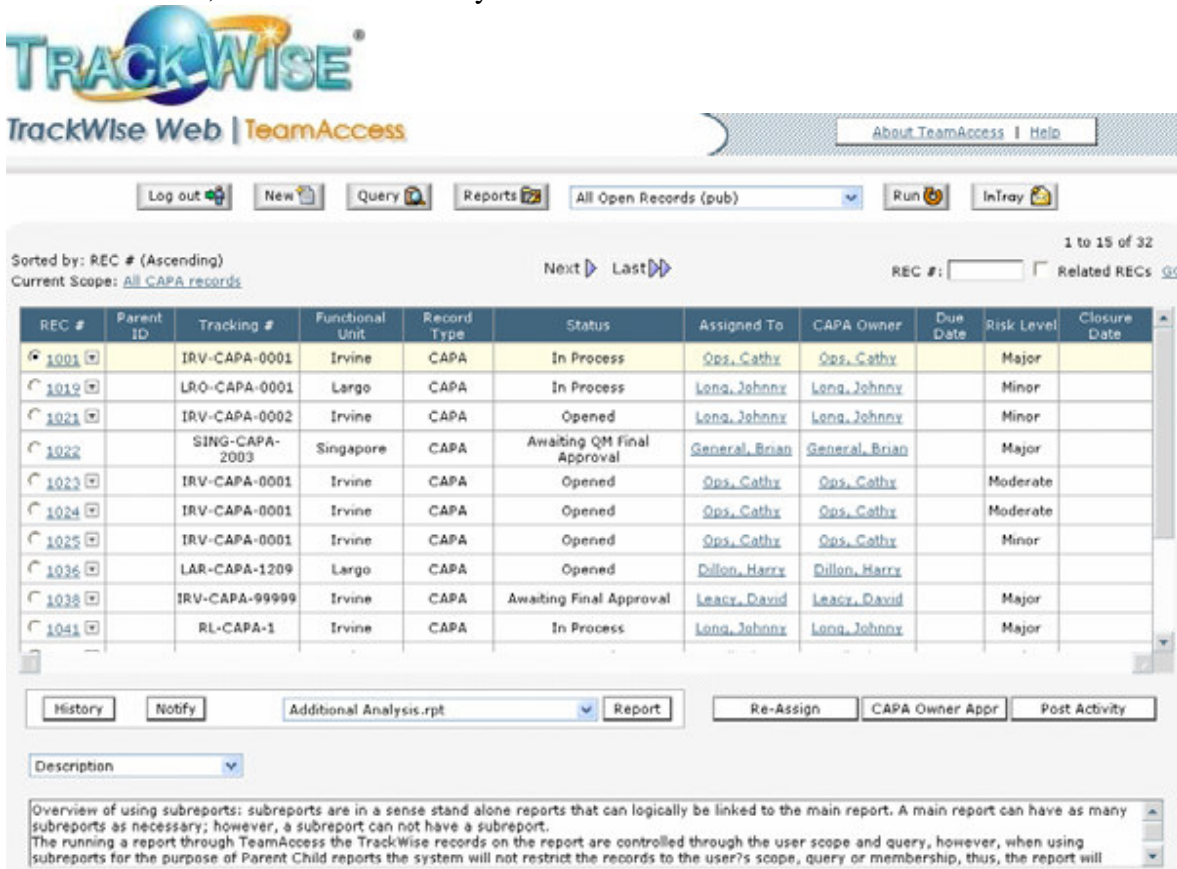
- Implementation was triggered by MD's 483 procedures.
- Implement a robust, standardized process across all functional units in all four divisions

II. Methodology

- Gap analysis & process re-engineering
- Consolidation of general office & manufacturing facility practices
- Developed & trained out an interim Access based, web CAPA system
- TrackWise implementation Project Management
- Quality sub-systems non-conformity processes evaluation
- Development of escalation processes to management review
- Overall project management for FDA commitment tracking

III. Achieved Results

- Standardization, implementation and global roll-out across 40 sites of a single instance, web-based CAPA system



TrackWise Web | TeamAccess

Log out | New | Query | Reports | All Open Records (pub) | Run | InTray

Sorted by: REC # (Ascending) | Current Scope: All CAPA records | 1 to 15 of 32 | REC #: | Related RECs

REC #	Parent ID	Tracking #	Functional Unit	Record Type	Status	Assigned To	CAPA Owner	Due Date	Risk Level	Closure Date
1001		IRV-CAPA-0001	Irvine	CAPA	In Process	Ops, Cathy	Ops, Cathy		Major	
1019		LR0-CAPA-0001	Largo	CAPA	In Process	Long, Johnny	Long, Johnny		Minor	
1021		IRV-CAPA-0002	Irvine	CAPA	Opened	Long, Johnny	Long, Johnny		Minor	
1022		SING-CAPA-2003	Singapore	CAPA	Awaiting QM Final Approval	General, Brian	General, Brian		Major	
1023		IRV-CAPA-0001	Irvine	CAPA	Opened	Ops, Cathy	Ops, Cathy		Moderate	
1024		IRV-CAPA-0001	Irvine	CAPA	Opened	Ops, Cathy	Ops, Cathy		Moderate	
1025		IRV-CAPA-0001	Irvine	CAPA	Opened	Ops, Cathy	Ops, Cathy		Minor	
1036		LAR-CAPA-1209	Largo	CAPA	Opened	Dillon, Harry	Dillon, Harry			
1038		IRV-CAPA-99999	Irvine	CAPA	Awaiting Final Approval	Leacy, David	Leacy, David		Major	
1041		RL-CAPA-1	Irvine	CAPA	In Process	Long, Johnny	Long, Johnny		Major	

History | Notify | Additional Analysis.rpt | Report | Re-Assign | CAPA Owner Appr | Post Activity

Description

Overview of using subreports: subreports are in a sense stand alone reports that can logically be linked to the main report. A main report can have as many subreports as necessary; however, a subreport can not have a subreport. The running a report through TeamAccess the TrackWise records on the report are controlled through the user scope and query, however, when using subreports for the purpose of Parent Child reports the system will not restrict the records to the user's scope, query or membership, thus, the report will