Case Study

Electronic Record Retrieval During FDA Audit

The FDA had just completed an audit of a leading medical OEM. The medical OEM informed their contract manufacturer that the FDA would be arriving the following week for an audit of several high volume class 2 medical devices. In addition to a general audit, the FDA in particular wanted to review DHR's for products built at a certain time and with components from particular lot codes.

The Challenge

During an FDA audit, the ability to produce correct, clear and verifiable quality records in a timely manner is essential. Implemented properly, the right MES/MOM solution can provide the structure for, and ensures compliance with key elements of the FDA QSR (Quality Systems Regulation). A leading OEM of class 2 medical devices had outsourced production of its products to Sanmina, a leading contract manufacturer of medical products. Eight of Sanmina's medical manufacturing facilities use the 42Q cloud solution. The FDA would be at Sanmina in a few days, and Sanmina knew the FDA was expecting to see:

- DHR's for production of high volume medical devices, built within a certain date range.
- DHR's for products built using integrated circuits from specific lot codes.
- Test and parametric data for specific products.
- Training records related to a work instruction ECO (Engineering Change Order).

Why 42Q

Sanmina has been using 42Q as its MES/MOMS core for many years in multiple medical manufacturing facilities producing both high volume medical devices, along with highly complex diagnostic imaging equipment. The implementation has become very mature:

- All electronic DHR's. DHR's are "evergreen", with any product rework or subsequent upgrades or repairs automatically appended to the original electronic DHR.
- The electronic DHR's have automatic linkages to component lot data for complete electronic traceability.
- Integration with training record databases and software. Operators badge scan into their workstations, and if they are not trained to the current work instruction revision, they are locked out.
- Automatic upload of test and parametric data, associated with a specific device serial number.
- Full integration with production equipment via API's (e.g. barcode scanners, label printers, test equipment).
- Multi-plant integration and visibility in the top level DHR: Genealogy, traceability and linkage of sub-assembly DHR's (e.g. PCBA's built in other Sanmina plants) to the top system level DHR.

The FDA Audit

The FDA auditor asked to see DHR's from a specific date range. These DHR's were delivered to the auditor in a matter of minutes, since they were all online in an easily searched database. Training records were produced, and the auditor was impressed to discover that training records were also electronic with linkages to PLM (Product Lifecycle Management) software, and ensured that the operator was trained to the latest revision of the procedure. Next, validation data for the quality system and 42Q were reviewed by the auditor.

The auditor commented that the overall implementation of electronic DHR's, component traceability and operator training was one of the best he had seen.

Results

The speed of producing the requested information, along with the quality and consistency of the records resulted in a successful audit. Comments made by the FDA auditor during the closing meeting were highly complementary regarding the implementation and validation of the quality system. Positive comments were also made about the complete "end to end" integration and electronic records made possible with 42Q, from incoming inspection through production, all the way to the shipping dock.

	RMA Number= RMA-10924					
42	1/5/2006	09:29:37	30814	2 RWR1 RWK Returns	Rmv. Attribute	15
	CEL1100041_Hard Drive: CEL04145057					
43	1/5/2006	09:30:23	30814	2 RWR1 RWK Returns	Rmv. Attribute	22
	Probe: CEL0419754					
44	1/5/2006	09:31:05	30814	2 RWR1 RWK Returns	Rmv. Attribute	19
	CEL2100058_TEMP/o PCB: CEL04097053					
45	1/5/2006	09:31:30	30814	2 RWR1 RWK Returns	Comment	
	REFER TO ECO E29E002669					
46	1/5/2006	09:32:00	30814	2 RWR1 RWK Returns	Add Component	23
	CEL1100041_Hard Drive: CEL05154009					
47	1/5/2006	09:33:37	30814	2 RWR1 RWK Returns	Add Component	24
	CEL2100058_TEMP/o PCB: CEL04097053					
48	1/5/2006	09:33:45	30814	2 RWR1 RWK Returns	Record Defect	#2
	Qty: 1 *Defect:* F001 - Functional Failure					
49	1/5/2006	09:33:45	30814	2 RWR1 RWK Returns	FAIL to	RWK1 Pass :1
50	1/22/2006	12:49:09	39845		Manual MOVE to	XWIP
51	1/22/2006	12:49:10	39845		Comment	
	wip clean per TG					
52	1/27/2006	05:34:47	30814	2 SYS1 SYSTEM TEST 1	Record Defect	#3
	Qty: 1 *Defect:* 0220 - WRONG COMPONENT *Ref.Des:* PUMP HRA					
53	1/27/2006	05:35:28	30814	2 SYS1 SYSTEM TEST 1	Repair Defect	#2
54	1/27/2006	05:35:32	30814	2 SYS1 SYSTEM TEST 1	Repair Defect	#3
55	1/27/2006	05:35:36	30814	2 SYS1 SYSTEM TEST 1	PASS to	FLNI
56	1/27/2006	05:35:36	30814	2 SYS1 SYSTEM TEST 1	FAIL to	SYS1 Pass :3
57	1/27/2006	13:39:04	33552	2 Inspection	PASS to	BURN
58	1/27/2006	13:42:21	30814	2 Burn in	PASS to	SYS2
59	1/27/2006	13:42:26	30814	2 SYS2 SYSTEM TEST 2	PASS to	BXQC
60	1/27/2006	13:43:07	33552	2 BXQC Inspect Final	PASS to	PACK
61	1/30/2006	10:26:30	31008	2 PACK_OUT	Add Component	25
	Probe: CEL0601110					
62	1/30/2006	10:26:59	31008	2 PACK_OUT	Comment	
	RMA#10924					
63	1/30/2006	10:27:03	31008	2 PACK_OUT	PASS to	CMP1

Example of 42Q electronic DHR, with hyperlinks to traceability information for key components.