QSIT

• QUALITY SYSTEM INSPECTION TECHNIQUE

• Robert L. Turocy May 6, 2002
WHAT SPECIFICALLY DO YOU WANT OR NEED TO KNOW ABOUT QSIT??

- MANAGEMENT
- QUALITY & REGULATORY
- ENGINEERING
- PRODUCTION, - - - , SERVICE
WHAT IS QSIT?

- QSIT IS AN OPTIONAL FDA INSPECTION PROCESS
- QUALITY SYSTEM ORIENTED
- TOP DOWN VERSUS BOTTOM UP
- PRE-INSPECTION ACTIVITIES
- SAMPLING
- FOCUS ON MANAGEMENT
QSIT PILOT INSPECTIONS
FDA 483s

- M = MGMT. 57
- C = CAPA 50
- P = PAPC 45
- D = DESIGN 26
- O = OTHER 22
WHY DOES THE FDA USE QSIT?

- QSIT IS FOCUSED, HARMONIZED, EFFICIENT, INCREASES COMPLIANCE, & MOST IMPORTANT, QSIT ASSISTS IN THE PROTECTING THE PUBLIC FROM UNSAFE MEDICAL DEVICES

- USED TO DETERMINE IF A MANUFACTURER’S QUALITY SYSTEM IS CONFORMING WITH REGULATIONS
WHO DEVELOPED QSIT?

- FDA REENGINEERING EFFORT
- ASSISTED BY INDUSTRY, TRADE ASSOCIATIONS, AND CONSULTANTS
- FDLI FACILITATED MEETINGS, ETC.
HOW IS QSIT IMPLEMENTED?

- **LEVEL 1**, (Abbreviated)
  - CAPA + 1 OTHER SUBSYSTEM

- **LEVEL 2**, (Baseline)
  - MGMT CONTROLS, DESIGN CONTROLS, CAPA, PAPC, AND RETURN TO MGMT CONTROLS

- **LEVEL 3**, (Compliance Follow-up to OFFICIAL ACTION INDICATED)
WHEN IS QSIT USED?

- MANUFACTURER’S COMPLIANCE HISTORY IS THE MAJOR FACTOR
- RISK OF DEVICE
DOES QSIT WORK?

- YES!!! PILOT INSPECTION RESULTS
- QSIT IS HARMONIZED WITH THE EU PROCESS OF INSPECTIONS
- QSIT REDUCED IN-PLANT TIME FROM APPROXIMATELY 67 HOURS TO 28 IN PLANT HOURS
BREAK DOWN OF 28 HOURS

- M = MGMT 4.2
- D = DESIGN 5.2
- C = CAPA 10.7
- P = PAPC 8.1
- T = TOTAL 28.2

6 IN-PLANT HOURS EQUALS 1 DAY
QSIT DOES

✓ REVIEW THE QUALITY SYSTEM

✓ VALIDATE “ESTABLISHED”

✓ REVIEW MANAGEMENT
QSIT DOES NOT

✓ ELIMINATE “FOR CAUSE” INSPECTIONS

✓ FIND AN INFINITE NUMBER OF PRODUCT PROBLEMS
MANAGEMENT CONTROLS

- QUALITY POLICY
- MANAGEMENT REVIEW
- INTERNAL QUALITY AUDIT
- QUALITY PLAN
- QUALITY SYSTEM PROCEDURES
- MANAGEMENT REPRESENTATIVE
- SUITABILITY & EFFECTIVENESS
- ORGANIZATIONAL STRUCTURE, RESPONSIBILITY, AUTHORITY, & RESOURCES
DESIGN CONTROLS

➢ WHEN ARE DESIGN CONTROLS REVIEWED?

- SUBMIT PDP?
- SUBMIT IRB?
- SUBMIT IDE?
- SUBMIT 510(K)?
- SUBMIT PMA?
- MARKET DEVICE?
DESIGN CONTROLS cont.

- DC PROCEDURES
- DESIGN PLAN
- DESIGN INPUTS
- ACCEPTANCE CRITERIA
- DESIGN OUTPUTS
- DESIGN VERIFICATION
- DESIGN VALIDATION
- SW VALIDATION
- RISK ANALYSIS
- PRODUCTION UNIT VALIDATED
- DESIGN CHANGE CONTROL
- DESIGN REVIEWS
- DESIGN TRANSFER
- DESIGN HISTORY FILE
CORRECTIVE & PREVENTATIVE ACTION (CAPA)

- CAPA PROCEDURES
- INFORMATION SOURCES IDENTIFIED
- INFORMATION ANALYZED
- COMPLETE, ACCURATE, & TIMELY INFORMATION
- STATISTICAL METHODS
- FAILURE ANALYSIS VERSUS RISK
- ROOT CAUSE ANALYSIS
- APPROPRIATE CAPA TAKEN & DOCUMENTED
- SHARE INFORMATION – MANAGEMENT REVIEW
PRODUCTION & PROCESS CONTROL (PAPC)

- PAPC PROCEDURES
- CONTROLS & MONITORS
- DEVICE HISTORY RECORDS
- NON-CONFORMING ACTIONS
- EQUIPMENT ADJUSTMENT, CALIBRATION, & MAINTENANCE
- VALIDATION OF PROCESSES
- SW VALIDATION
- PERSONNEL QUALIFICATIONS
LINKAGES TO OTHER SUBSYSTEMS

- MATERIAL CONTROLS
- RECORDS/DOCUMENTS/CHANGE CONTROLS
- FACILITY & EQUIPMENT CONTROLS
MEDICAL DEVICE REPORTING (MDR) A SATELITE TO CAPA

- MDR PROCEDURES
- MDR FILES ESTABLISHED
- MDR INFORMATION COMPLETE
- DEATHS, SI & SI, AND MALFUNCTIONS
CORRECTIONS & REMOVALS (CAR) A SATELITE TO CAPA

- CAR PROCEDURES
- CARs SUBMITTED
- CARs COMPLETED
- CAR FILE ESTABLISHED
MEDICAL DEVICE TRACKING A SATELITE TO CAPA

• FAILURE CAUSES ADVERSE HEALTH CONSEQUENCES

• OBLIGATION FOR TRACEABILITY
CONFIDENCE LIMIT OF (.99) MEANS THAT WE ACCEPT A 99% PROBABILITY THAT NO MORE THAN 10% OF THE REMAINING CASES DO NOT MEET OUR EXPECTATION. THIS IS BASED ON THE FACT THAT WE FIND “O” BAD CASES OUT OF 51 SAMPLES.

### TABLE 2 BINOMIAL SAMPLING

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STERILIZATION PROCESS
CONTROLS A SATELITE TO PAPC

- STERILIZATION PROCEDURES
- PROCESS VALIDATED
- PROCESS CONTROLLED & MONITORED
- APPROPRIATE HANDLING OF NON-CONFORMANCES
- EQUIPMENT ADJUSTMENT, CALIBRATION, & MAINTENANCE
- SW VALIDATION
- PERSONNEL QUALIFIED & TRAINED
QSIT REFERENCES

✓ 21 CFR 820, Preamble & Regulation
✓ ***QSIT HANDBOOK GUIDE
✓ CD ROM COMPUTER BASED TRAINING
✓ http://www.fda.gov/cdrh/dsma/cgmphome.html
✓ INSPI. DEVICE MFGRS. CP 7382.845