



QSIT

- **QUALITY SYSTEM
INSPECTION
TECHNIQUE**

- Robert L. Turocy May 6, 2002



WHAT SPECIFICALLY DO YOU WANT OR NEED TO KNOW ABOUT QSIT??

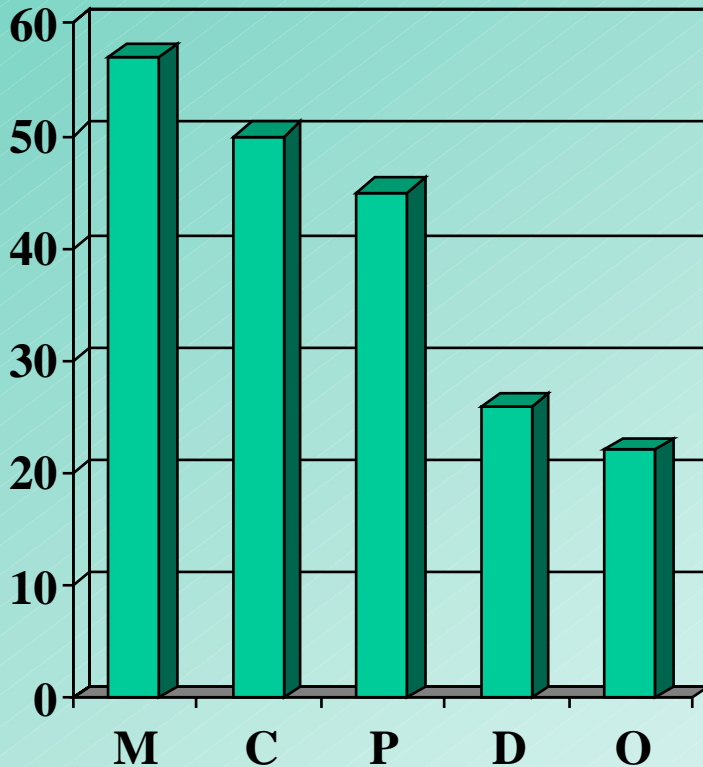
- MANAGEMENT**
- QUALITY & REGULATORY**
- ENGINEERING**
- PRODUCTION, - - - , SERVICE**

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)**



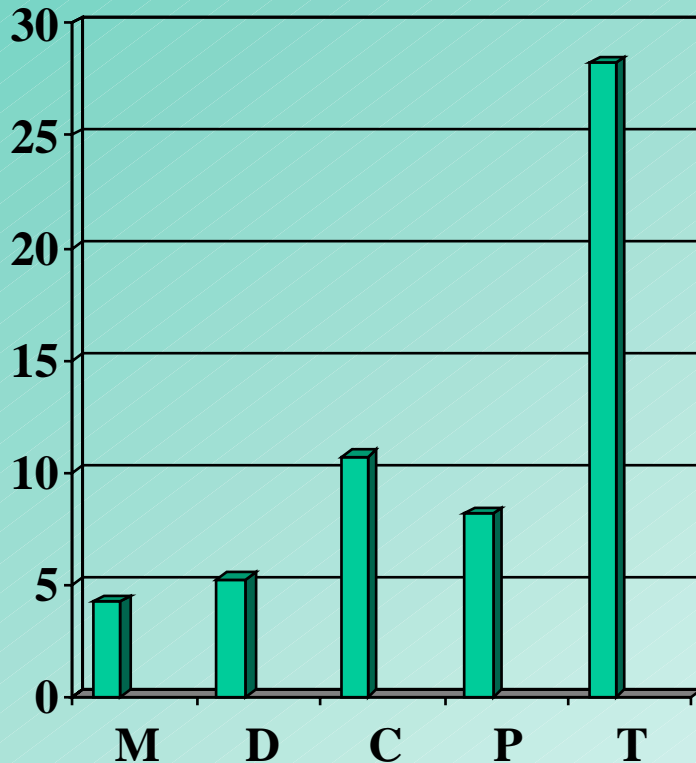
WHEN IS QSIT USED?

- 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**

SAMPLING



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

		0 OUT OF	1 OUT OF	21 OUT OF
E	.10 UCL	51	73	90
F	.05 UCL	107	161	190



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 OUALIFIED & TRAINED**



QSIT REFERENCES

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



XQSIT