QSIT

- **QUALITY SYSTEM INSPECTION TECHNIQUE**
  - Robert L. Turocy May 6, 2002

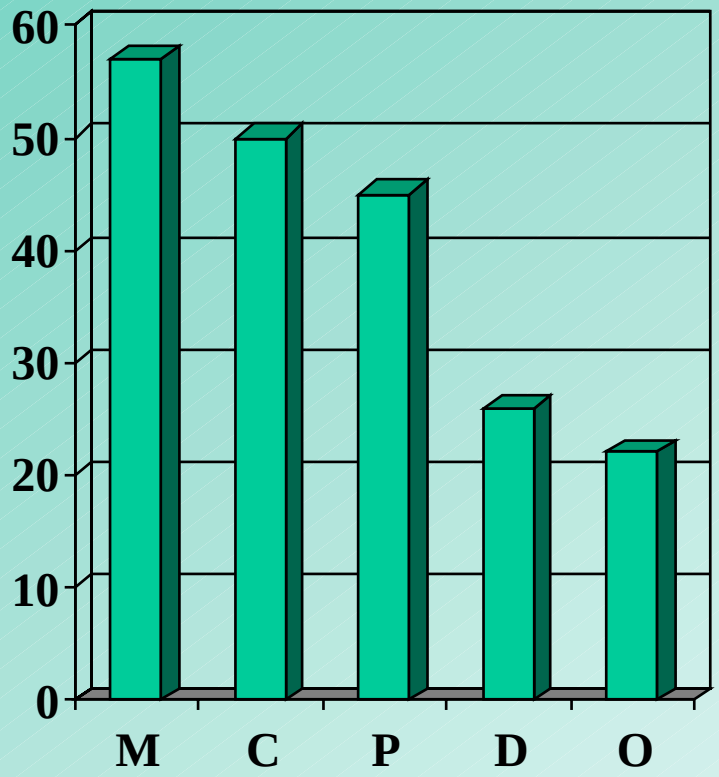
WHAT SPECIFICALLY DO YOU WANT OR NEED TO KNOW ABOUT QSIT??

- 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?

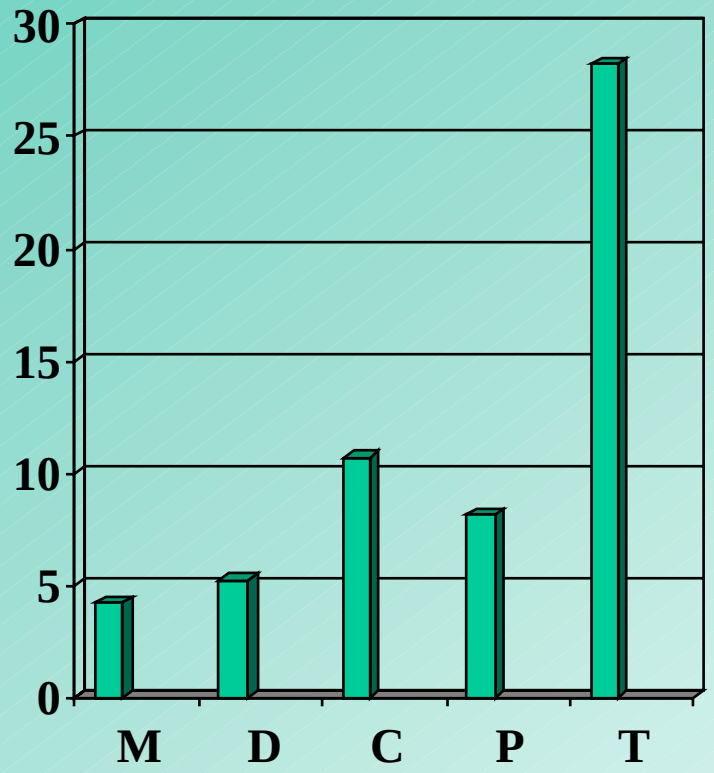
- MANUFACTURER'S COMPLIANCE HISTORY IS THE MAJOR FACTOR

- 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
- SUITABLITY & 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 CRETERIA
- 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

		O 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 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
- ✓INSP. DEVICE MFGRS. CP 7382.845

GHTF

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