



# **FDA QSIT COMPARED TO EUROPEAN NOTIFIED BODY (NB) AUDIT, AUSTRALIA, CANADA, JAPAN, ETC.**

Robert L. Turocy, May 6, 2002

# FDA VERSUS NB

➤ **FDA  
INSPECTION**

➤ **NB AUDIT OR  
ASSESSMENT**

➤ **FDA NOT  
LIMITED IN  
TIME,  
CONTENT OR  
DEPTH BUT  
GUIDED VIA  
QSIT**

➤ **NB CLEAR  
SCOPE,  
AGENDA, AND  
SCHEDULE**

# FDA VERSUS NB

➤ **FDA's FOCUS IS ON SAFETY OF DEVICE VIA AN EFFECTIVE QUALITY SYSTEM CONFORMING WITH REGULATIONS**

➤ **NB ATTAINS CONFIDENCE IN THE MFG's QUALITY SYSTEM, PLUS DOC**

# FDA VERSUS NB

➤ **FDA's FIVE (5)  
DAY ADVANCE  
NOTICE OF  
INSPECTION  
WITH REQUEST  
FOR UPPER  
LEVEL  
QUALITY  
DOCUMENTS**

➤ **NB AUDITS ARE  
SCHEDULED  
WITH MFG FOR  
A MUTUALLY  
ACCEPTABLE  
DATE**

# FDA VERSUS NB

➤ **FDA  
INSPECTIONS  
SHOW ONLY  
QUALITY  
SYSTEM  
PROBLEMS**

➤ **NB AUDITS  
PROVIDE BOTH  
NEGATIVE &  
POSITIVE  
FINDINGS &  
OBSERVATIONS**

# FDA VERSUS NB

➤ **FDA FOCUS ON  
SUB-SYSTEM  
PROBLEMS  
INTENSIFIES  
THE NEED TO  
DISCOVER  
ADDITIONAL  
PROBLEMS**

➤ **NB AUDIT  
FOCUS IS ON  
CURRENT  
PROBLEMS OR  
FROM ITEMS  
DISCOVERED  
DURING THE  
PREVIOUS  
AUDIT**

# FDA VERSUS NB

➤ **FDA 483 FORM IS SOMETIMES FOLLOWED WITH A WARNING LETTER AND POTENTIAL FOR REGULATORY ACTION**

➤ **NB AUDIT RESULTS IN FINDINGS OR OBSERVATIONS OTHER ACTION IS RARE**

# FDA VERSUS NB

➤ **FDA VIEWS  
MFG'S  
COMMITMENT  
TO CAPA  
WHICH MAY  
LEAD TO  
FUTURE  
COMPLIANCE  
ACTIONS**

➤ **NB VIEWS  
MFG'S  
COMMITMENT  
TO CAPA AS A  
GENUINE  
COMMITMENT  
WITH FOLLOW  
UP DURING  
NEXT AUDIT**

# FDA VERSUS NB

➤ **FDA  
INSPECTIONS  
OCCUR  
BETWEEN 2 TO  
7 YEARS**

➤ **NB AUDITS  
OCCUR  
ANNUALLY  
BASED ON THE  
CHANGES TO  
THE QUALITY  
SYSTEM &  
FOLLOW-UPS  
OF PREVIOUS  
AUDITS**

# FDA VERSUS NB

➤ **FDA NEW OR SIGNIFICANTLY CHANGED DEVICE, MFG MUST SUBMIT PREMARKET NOTIFICATION**

➤ **NB REVIEWS TECHNICAL FILES OF NEW OR SIGNIFICANTLY CHANGED DEVICE**



# **JAPAN, AUSTRALIA, AND CANADA**

- ✓ **ACCEPT DOCUMENTATION, FOR EXAMPLE;  
510(K) SUBSTANTIAL EQUIVALENT LETTERS,  
CERTIFICATE TO FOREIGN GOVERNMENTS, NB  
CERTIFICATES OF QUALITY SYSTEM  
CONFORMANCE, MFG'S DECLARATION OF  
CONFORMITY TO CE MARK REQUIREMENTS,  
PROMOTIONAL LITERATURE, OPERATORS  
MANUAL, ASSEMBLY, INSTALLATION,  
ADJUSTING, AND TESTING INSTRUCTIONS,  
TEST METHODS AND DATA TO  
INTERNATIONAL STANDARDS.**



# CHINA, KOREA

- **THE QUALITY SYSTEM IS AUDITED AND THE PRODUCT IS TESTED TO INTERNATIONAL STANDARDS SUCH AS IEC 60601-1 SAFETY TESTING**



**GLOBAL HARMONIZATION TASK  
FORCE EFFORTS TOWARDS  
REGULATORY CONFORMANCE  
OF MEDICAL DEVICES,  
UTILIZATION OF  
INTERNATIONAL STANDARDS,  
ETC. WILL ENHANCE THE  
MEDICAL DEVICE INDUSTRY TO  
APPROACH THEIR GOAL**



**GOVERNMENT REGULATORS  
AND INDUSTRY ALL HAVE A  
COMMON GOAL: TO  
PROVIDE SAFE, EFFECTIVE,  
& STATE OF THE ART  
DEVICES AT A FAIR &  
REASONABLE COST**