

Inspectional Findings: Computer Systems

ISCT Liaison Meeting

September 10, 2009

Mary Malarkey, Director OCBQ/CBER/FDA



U.S. Department of Health and Human Services

Food and Drug Administration

Regulations?

- Products regulated solely under section 361 of the Public Health Service Act:
 - 21 CFR 1271.160(d)
- Products also regulated under section 351 of the Public Health Service Act and the Federal Food, Drug and Cosmetic Act:
 - 21 CFR 211.68(a)(b) and (c)

§1271.160(d) FY07 to date

9 observations on 8 inspections

Fiscal year	Frequency of Observations
FY07	4
FY08	4
FY09 (to date)	1

Reasons for Observations

Reason	Frequency
No software validation	4
Inadequate validation records	2
No verification of off-the-shelf software	3

§ 211.68(b) FY07 to date

14 observations on 13 inspections- blood banks

Fiscal Year	Frequency of Observations
FY07	8
FY08	4
FY09 to date	2

Reasons for Observations

Reason	Frequency
No/incomplete/inadequate validation	5
Inadequate validation plan/documentation/approval	4
Change control/security	4
No back-up file	1

Drug Inspections

§ 211.68

- 47 observations for FY07 to date
- Same issues – examples:
 - “During the inspection it was discovered that the Plant/Production Manager and his Assistant were inadvertently given the ability to change the master records within the firm's computer system; a privilege intended solely for Mr. X, the developer of the master record”

Continued

“There (are) no audit trail capabilities in the internal software used to create and store electronic batch records. Changes can be made to the electronic records with no means of determining when the change was made, who made the change, and what the information was prior to the change being made.”

Continued (2)

“The ABC computer systems have not been validated to ensure data accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records”

“The computer system has not been validated by the firm and there is no documentation that the data entered into the computer system was verified against the production records.”

Continued (3)

“There was no validation of the XYZ software version 4.1 installed on ABC instrument for the control and processing of data, which includes the functions, operations and security of the system.”

“You do not have documented validation for your inventory control computer system.”

Special Thanks to:

Tom Adams, Special Assistant to the
Director, OCBO