

## Excel and Spreadsheet Related Warning Letters

### **Earlham Analytical Laboratories, July 29, 2002**

- There is no provision in the test method procedure for the use of a spreadsheet for entering test parameters and calculation of test results that was used to calculate the results of blend samples of XXXX and XXXXX.
- Our Investigator noted that the laboratory is using an electronic record system for processing and storage of data from the atomic absorption and HPLC instruments that is not set up to control the security and data integrity in that the system is not password controlled, there is no systematic back-up provision, and there is no audit trail of the system capabilities. The system does not appear to be designed and controlled in compliance with the requirements of 21 CFR, Part 11, Electronic Records

### **Cardinal Health, Inc. July 10, 2001**

- Failure to have an adequate validation procedure for computerized spreadsheets used for in-process and finished product analytical calculations. The current validation procedure uses only the values that result in within specification findings, aberrant high findings, and aberrant low findings [21 CFR 211.165(e)]. For example, SOP 644.00, QA/QC Spreadsheet Validation, is deficient in that only a small range of values are being used to challenge computerized spreadsheet mathematical calculations.
- Failure to use fully validated computer spreadsheets to calculate analytical results for in-process and finished product testing [21 CFR 211.165(e)]. For example, the computer spreadsheets used to calculate analytical results for... have not been validated.

### **Medical Industrial Equipment Ltd. June 8, 2000**

- Failure to validate computer software used as part of the quality system for its intended use according to an established protocol as required by 21 CFR 820.70(i). For example: Software such as Excel, Access, and Word used to create and maintain data bases (rejects, complaints, and concessions) and electronic documents, is not validated.

### **Apheresis Technologies, Inc, Nov 12 1999.**

- There is no documentation covering Excel application software, or any procedures instituted covering the protection of electronic records or an established back-up system

### **Drager Medizintechnik GmbH, Aug 6, 1999**

- Failure to validate computer software used as part of the quality system for its intended use according to an established protocol as required by 21 CFR 820.70(i). For example, the data in the Excel spreadsheet identified as a "Hit List" of top non-conforming components contains 16 record counts for part number 8601618 DC converter failures compared to 18 record counts for part number 860168 DC converter failures in the dbase database. The spreadsheet is used for management review of component suppliers for all components.

### **B. Braun Medical Inc, April 29, 1999**

- Your response indicated that Braun is currently changing the complaint handling system from tracking complaint information on an ... spreadsheet to using an off-the-shelf database system, ... Tracker. As required by 21 CFR 820.70(i), Automated Processes, this off-the-shelf software shall be validated for its intended use if Braun has not already done so.

### **Willis Eye Associates. July 7, 1998**

- You failed to investigate the failure of the ... when operating in MS Access. The system locks up at random and it is unknown whether the software which controls the .... during off of MS Excel, could be similarly affected.