MEDICAL DEVICE INDUSTRY INITIATIVES TASK FORCE

MEDICAL DEVICE INSPECTION EVALUATION

This Section to be Completed by the FDA

Company Information

Company Name:

Company Address:

Telephone: ( ) Fax: ( ) E-mail:

Type of device(s) inspected:

Dates of Inspection: Start date: ____/____/____ (Month Day Year) End date: ____/____/____ (Month Day Year)

FDA Information

Name of lead investigator:

Number of supporting investigators:

FDA District (circle one): 1-NYK 2-NWE 3-PHI 4-BLT 5-NWJ 6-CIN 7-ATL 8-FLA 9-NSH 10-NOL 11-SJN 12-CHI 13-DET 14-MIN 15-DAL 16-KAN 17-DEN 18-SAN 19-LOS 20-SEA

Was a 483 issued?

1 YES
2 NO

Reason(s) for inspection (circle all that apply):

1 Pre-approval
2 QS/GMP
3 Other (please specify): _____

ALL FOLLOWING TO BE COMPLETED BY THE COMPANY

Definitions:

FDA 483 – FDA form issued to establishment management at the close of inspection if any problem(s) found.
EIR – Establishment Inspection Report
QS/GMP – Quality System/Good Manufacturing Practices

The first set of questions asks what happened before the inspection began. Please circle the number associated with the answer you choose. Your responses to all questions will be kept confidential.

Q-1 Did your company receive advance notification of the inspection?

1 YES → (If yes) How many days advance notification did you receive?
2 NO

_____ NUMBER OF DAYS

Q-2 During the pre-announcement phone call, did you have clarity of inspection requirements as to

a. Products 1 YES 2 NO
b. Records 1 YES 2 NO
c. Personnel 1 YES 2 NO

Q-3 Was it necessary to reschedule the proposed start of the inspection?

1 YES
2 NO

(If yes) Was the impact on your business

1 HELPFUL
2 NEUTRAL
3 DISRUPTIVE

The next set of questions asks about things that may have happened during the inspection.

Q-4 Was it necessary to interrupt the inspection for more than two working days?

1 YES
2 NO

(If yes) Was the interruption requested by

1 FDA
2 YOUR COMPANY

Characterize the impact of the interruption on your company

1 HELPFUL
2 NEUTRAL
3 DISRUPTIVE

Q-5 Were you able to have **all** the right personnel available during the inspection?

1 YES
2 NO → PLEASE EXPLAIN:_____

Q-6 Was your company able to meet **all** the needs of the investigator(s) for records availability?

1 YES
2 NO → PLEASE EXPLAIN:_____

Q-7 During the process of the inspection was your firm always notified daily of the investigator(s) observations?

1 YES
2 NO → PLEASE EXPLAIN:_____

Q-8 Did the investigator(s) provide any helpful information or suggestions?

1 YES
2 NO

The following questions pertain to the outcome of the inspection.

Q-9 Was an FDA 483 issued at the close of the inspection?

1 YES
2 NO → SKIP TO Q-18 ON THE BACK PAGE

Q-10 Were there any corrective actions taken or promised by your company during the process of the inspection? (CIRCLE **ALL** THAT APPLY)

1 YES, TAKEN
2 YES, PROMISED
3 NO, NEITHER → SKIP TO Q-14 ON THE NEXT PAGE

Q-11 Were there any corrective actions taken that were not verified by the FDA inspector(s) and you think could have been?

1 YES → Please list the corrective actions taken which you believe could have been verified by the FDA inspector(s) but were not:

_____

2 NO

3 N/A, NO CORRECTIVE ACTIONS TAKEN

Q-12 Have you already, or do you plan to fulfill any promised actions?

1 YES

2 NO → (If no) Have you advised the FDA of any changes in plans or delays?

1 YES

2 NO

3 N/A, NO CORRECTIVE ACTIONS PROMISED

Q-13 Were the promised or taken corrective actions appropriately annotated on the FDA 483?

1 YES, ALL WERE

2 SOME WERE, SOME WERE NOT

3 NO, NONE WERE

→ Please list whatever actions you believe were not appropriately annotated on the FDA 483:

_____

Q-14 Were there any inaccuracies on the FDA 483 **other than** those you may have described in Q-13 above?

1 YES → (If yes) Were these inaccuracies on the FDA 483 corrected?

1 YES

2 NO → Please describe the situation(s): _____

_____

2 NO

The final set of questions asks your evaluation of the inspection and about your company's actions.

Q-15 Were all of the observations on the FDA 483 understandable?

1 YES

2 NO → Please comment on what was not clear: _____

Q-16 Other than inaccuracies (noted in Q-14 above), were any of the observations on the FDA 483 inappropriate?

1 YES → (If yes) Inappropriate items on the 483 were (CIRCLE **ALL** THAT APPLY):

1 INSIGNIFICANT OBSERVATIONS

2 DIFFERENCE OF INTERPRETATION

3 OTHER → Please explain:_____

2 NO

Q-17 Do you plan to respond to the FDA 483 observations in writing?

1 YES
2 NO→ Please Explain: _____

Q-18 How did this inspection process compare with past inspections?

1 THIS WAS BETTER → Please explain:_____
2 SAME
3 THIS WAS WORSE → Please explain:_____
4 NEVER BEEN INSPECTED BEFORE

Q-19 Was the highest level executive in your facility in attendance at the final discussion with management?

1 YES
2 NO

Q-20 Worldwide, what is the total number of people your company employs in its medical device division(s)?

_____ NUMBER OF PEOPLE

Finally, we ask that you provide contact information should we need clarification about any of your responses. This is for the use by The UCI Center for Statistical Consulting *only* and will *not* be released to the FDA, to any industry group, or to anyone else.

Person Completing this Evaluation:

Name:

Title:

Telephone:

Fax:

We Invite Your Comments. We would like your suggestions concerning how the FDA inspection process could be improved. In particular, we would appreciate information concerning specific questions. If your comment pertains to a particular question number, it would be helpful if you would note the question number.

_____

_____

_____

_____

_____

_____

Thank you very much for your help!

Please return completed questionnaire to:

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