MEDICAL DEVICE INSPECTION EVALUATION

Medical Device Industry Initiatives Task Force

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INTRODUCTION

This report presents an analysis of the 559 surveys returned from the beginning of March 1999 through the end of April 2000. The report consists of (1) this introduction, (2) the tabulated responses to each survey question and a few comparisons between questions, (3) a comparison of responses across FDA Regions, (4) a comparison of responses between firms with shorter versus longer inspections, (5) a comparison of responses between larger and smaller firms, and (6) a comparison of responses according to inspection outcome – NAI, VAI, or OAI. The questionnaire and cover letter are in the appendices.

Survey Goals

The Medical Device Industry Initiatives Grassroots Taskforce, composed of representatives from the FDA and medical device industry organizations, sponsored this survey. The survey's purpose was to determine how satisfied medical device firms are with the current FDA inspection process, discover if and where there are any problems with the process, and to foster communication between industry and the FDA.

Survey Procedure

At the close of all pre-market and QS/GMP inspections that began between March 1, 1999 and February 29, 2000, the FDA investigator gave a survey packet to a company representative. The survey packet included a questionnaire, a cover letter to the company, signed by FDA officials, industry representatives, and myself, that explained the questionnaire's purpose, and a postage-paid return envelope (foreign companies received reply envelopes without postage). The boxed portion on the first page of the questionnaire was to have been completed by the investigator before giving the packet to the firm. This area asked the name, address, and phone number of the firm, the product(s) inspected, the inspection's start and end dates, the investigator(s) name(s), which district performed the inspection, whether or not an FDA 483 was issued, and the reason for the inspection.

The firms mailed their completed questionnaires directly to me at the UC Irvine Center for Statistical Consulting. I oversaw the data entry and analyzed the results. I also fielded questions from companies concerned about confidentiality. The cover letters to the companies and the outer and reply envelopes were all on UCI stationary.

Response Rate

I estimate the response rate for both domestic and foreign inspections to be at about 40%. Complete FDA inspection records were not available so this figure cannot be calculated more precisely.

About the Respondents

This section shows the percentage of respondents from each district and the firm sizes of the respondents.

Table 1 shows the number and percentage of responses by district. Foreign inspections were always classified as foreign rather than as from the district that performed the inspection. Investigators did not always complete the top portion of the questionnaire, the area inside the blue box. Some questionnaires arrived with this area blank, and sometimes the companies completed it themselves. When the FDA district was blank, the address of the company was used to determine which district most likely performed the inspection. In cases where there was also no address, the envelope's postmark was used to determine the location.

Table 1. FDA District Office of Responding Firm

	Number	Percent
Atlanta	23	4.1
Baltimore	12	2.2
Chicago	13	2.3
Cincinnati	18	3.2
Dallas	20	3.6
Denver	7	1.3
Detroit	12	2.2
Florida	32	5.7
Kansas City	13	2.3
Los Angeles	54	9.7
Minneapolis	63	11.3
New Orleans*	8	1.4
New England	66	11.8
New Jersey	22	3.9
New York*	16	2.9
Philadelphia	6	1.1
San Francisco	20	3.6
Seattle	17	3.0
San Juan	10	1.8
Foreign Insp.	126	22.6
SUBTOTAL	558	100.0
Unidentifiable	1	
TOTAL	559	

*Nashville respondents are included in the New Orleans district and Buffalo respondents are included in New York.

Table 1 shows that foreign inspections comprise about 23% of the returned surveys and domestic inspections comprise the other 77%.

The questionnaire asked the number of people the firm employs in the medical device division (question 20). The median firm size was 100 medical device employees meaning that half the responding firms had 100 or fewer such employees and half had 100 or more. Table 2 shows the distribution of firm size for all responding companies.

Table 2. Total Number of Employees in the Firm's Medical Device Division, Worldwide (Q-20)

	Number	Percent
1 to 10	93	17.1
11 to 25	51	9.4
26 to 30	14	2.6
31 to 50	53	9.7
51 to 100	66	12.1
101 to 300	86	15.8
301 to 1000	68	12.5
1001 to 5000	60	11.0
More than 5000	54	9.9
SUBTOTAL	545	100.0
No Response	14	
TOTAL	559	

I. ALL RESPONDENTS COMBINED

Reason for the Inspection

Inspections were classified as preapproval, QS/GMP, or other. The reason for inspection was not known for the nine companies with blank FDA boxes and no identifying information on the back of the questionnaire where a telephone number was requested. For the remaining 550 companies, 12% were inspected for preapproval, 83% for QS/GMP, and 16% for other. The reason the total for these figures exceeds 100% is because some inspections were for multiple purposes.

Table 3 breaks down the reason for inspection, whether a single reason or multiple.

Table 3. Combined Reasons for the Inspection

	Number	Percent
Preapproval Only	38	6.9
QS/GMP Only	399	72.5
Other Only	57	10.4
Preapproval and QS/GMP	28	5.1
Preapproval and Other	1	.2
QS/GMP and Other	26	4.7
Preapproval, QS/GMP & Other	1	.2
SUBTOTAL	550	100.0
No Response	9	
TOTAL	559	

Table 3 shows that the overwhelming majority of the respondents (73%) were inspected for QS/GMP only and just 10% were inspected for multiple reasons.

Before the Inspection Began

This section covers responses to questions 1 through 3 and relates to events that occurred before the inspection began.

Responses to question 1 show that 85% of the domestic firms and over 99% of the foreign firms (all but one foreign firm) reported receiving at least some advance notification of the inspection.

Of those who said they did receive advance notice, a follow-up question asked the number of days' notice they received. Table 4 shows the descriptive statistics for the number of days of preannouncement for both domestic and foreign inspections. It shows that the preannounced domestic inspections received an average of a week's notice and the preannounced foreign inspections averaged about eight weeks' notice.

Table 4. Number of Days Advance Notice: Descriptive Statistics (Q-1a)
(for Firms that Received Advance Notice)

	Median	Mean	Range	Standard Deviation	Number of Firms
Domestic Inspections	5	7.2	1 - 92	8.0	355
Foreign Inspections	50	55.5	6 - 144	27.5	119

Table 5 presents the frequency distribution of the number of days' advance notice received for all who received advance notice.

Table 5. Number of Days' Advance Notice: Frequency Distribution (Q-1a)
(for Firms that Received Advance Notice)

		Number	Percent	Cumulative Percent
Domestic Inspections	**1 - 2 Days**	35	9.9	9.9
	3 - 4 Days	75	21.1	31.0
	5 Days	97	27.3	58.3
	6 - 9 Days	86	24.2	82.5
	10 - 29 Days	51	14.4	96.9
	30 - 39 Days	6	1.7	98.6
	40 - 49 Days	3	.8	99.4
	50 or more Days	2	.6	100.0
	SUBTOTAL	355	100.0	
	No Response	11		
	TOTAL	366		
Foreign Inspections	**1 - 2 Days**	0	.0	.0
	3 - 4 Days	0	.0	.0
	5 Days	0	.0	.0
	6 - 9 Days	1	.8	.8
	10 - 29 Days	8	6.7	7.6
	30 - 39 Days	28	23.5	31.1
	40 - 49 Days	18	15.1	46.2
	50 or more Days	64	53.8	100.0
	SUBTOTAL	119	100.0	
	No Response	6		
	TOTAL	125		

The table shows that about 10% of the domestic inspection respondents who received advance notice received only one or two days' notice, but 69% received five or more days' notice. No foreign respondents received fewer than six days' notice, and over half received 50 or more days.

Additionally, the percentage of *all* respondents who received five or more days' advance notice was calculated. Of the domestic inspection respondents, 58% reported advance notice of five or more days; the remainder reported either no advance notice *or* advance notice of fewer than five days. All but one of the foreign inspection respondents, thus 99%, reported having received advance notice of five or more days.

For those 494 firms that reported a *single* reason for inspection (38 preapproval, 399 QS/GMP, and 57 other), the responses to question 1 were also examined according to type of

inspection. All firms receiving a preapproval inspection reported receiving at least one day's advance notice of the inspection, 84% of the domestic QS/GMP inspections were with advance notice, and about 82% of the domestic "other" inspections reported receiving advance notice.

Of those 491 firms that reported having advance notice of the inspection, responses to question 2, regarding the clarity of inspection requirements, were also tabulated. Of those who received preannouncement, approximately 78% of the respondents felt clear about the products needed for the inspection, 74% felt clear about the records needed, and 66% felt clear about the personnel needed.

Firms were also asked whether it was necessary to reschedule the start date of their inspections and, if so, how this impacted their business. Twenty-seven percent reported that their start date had been rescheduled (question 3). Of this 27%, 58% said the change was helpful to their firm and only 8% said it was disruptive.

During the Inspection

This section shows summary results about the length of the inspections and various things that may have happened during the inspection process, including interruptions, personnel and records availability, and behaviors of the investigator.

Since the questionnaire does not ask the length of any interruptions during the inspection, just start date, end date, and whether or not any interruptions exceeded two days, the length of the inspections cannot be accurately calculated. For the estimate below, firms that reported a greater than two day interruption are excluded. Thus, inspection length in the table and figures below is (1) overestimated by a *maximum* of two days, and (2) biased a bit toward the shorter inspections because longer inspections more often have long interruptions and thus are more often excluded from all length of inspection calculations and tables. The mean of the 488 inspections for which length can be estimated is 4.1 days, the median is 4 days, and the standard deviation is 3.7 days. The distribution of inspection lengths is shown in Table 6.

Table 6. Length of Inspection
(for Those Not Interrupted by More than Two Days)

	Number	Percent
1 Day	79	16.2
2 - 3 Days	164	33.6
4 - 5 Days	161	33.0
6 - 10 Days	67	13.7
More than 10 Days	17	3.5
SUBTOTAL	488	100.0
No Response	12	
TOTAL	500	

Table 6 shows that 16% of the inspections lasted only a day and only 4% lasted more than ten days.

Responses to question 4 showed that 10% of all inspections were interrupted for more than two working days. For the 130 inspections with start and end dates separated by more than five working days, 35% reported interruptions of more than two days. Of the interrupted inspections, firms reported that 69% of the interruptions were requested by the FDA, 22% by the firms, and 9% by both. When the FDA requested the interruption, firms generally found the interruption either neutral (40%) or disruptive (37%). Not surprisingly, when the firm requested the inspection interruption, they found the interruption either helpful (58%) or neutral (42%).

As for meeting the needs of the investigators, 92% of respondents said they were able to have all the right personnel available (question 5). When the personnel were not available, generally they were out of town (54%), or home for medical reasons (10%). Ninety-one percent of the respondents said they had all the right records available (question 6). Records were most often unavailable because they were stored off the premises (35%) or lost (30%).

The next two questions asked about the communication between the investigator and the firm. Question 7 asked if the firm was always notified daily of the investigator's observations. Since this question only applies to inspections of more than one day, the 79 one-day inspections and 13 inspections without start or end dates were excluded. Of the remaining 465 respondents, 88% said they were notified daily of the investigator's observations. The most frequent comments from those who said they were not notified daily included being notified less often than daily (22%), being notified the last day only (16%), and being notified only upon request (20%).

Ninety-three percent of the respondents said the investigator gave helpful information or suggestions (question 8).

Outcome of the Inspection

The next set of questions asks about the outcome of the inspection, specifically, details about the FDA 483s received.

Fifty-four percent of the firms reported receiving an FDA 483 at the close of the inspection (question 9). Only responses from this 54% (n=303) are included in figures given in the remainder of this section and in all but one of the items in the next section.

With regards to the FDA 483 observations, 95% of the respondents thought all their 483 observations were understandable (question 15). Table 7 summarizes the errors respondents saw in their FDA 483s.

Table 7. Inappropriate or Inaccurate FDA 483 Observations (Q-14, 16)?

		Number	Percent
Anything on the FDA 483 Inappropriate (Q-16)?	**Yes**	58	19.5
	No	239	80.5
	SUBTOTAL	297	100.0
	No Response	6	
	TOTAL	303	
Any Inaccuracies on the FDA 483, Other than Annotation (Q-14)?	**Yes**	34	11.3
	No	266	88.7
	SUBTOTAL	300	100.0
	No Response	3	
	TOTAL	303	
One or More FDA 483 Inaccuracies or Inappropriate Observations (Q-14, 16)?	**Yes**	76	25.7
	No	220	74.3
	SUBTOTAL	296	100.0
	No Response	7	
	TOTAL	303	

As shown above, 80.5% of the firms said there were no inappropriate (as opposed to inaccurate) observations on their 483s (question 16). Those who felt that there were inappropriate observations on their 483s were asked a follow-up question about why they believed the observations were inappropriate. Seventy-nine percent cited difference of interpretation, 39% cited "insignificant observation", and 16% cited "other". These figures sum to more than 100% because respondents were allowed to select more than one response to this

question. As for other problems with the 483s, 11% of respondents reported that they had at least one non-annotation related inaccuracy (question 14). The table also shows that 26% of the respondents felt that there was at least one error on their FDA 483: either an inappropriate observation (question 16), or a non-annotation related inaccuracy (question 14), or both. Only 5% reported both non-annotation related inaccuracies and inappropriate observations.

Regarding corrective actions in response to the FDA 483 observations, 11% of the firms took, 34% promised, and 48% both took and promised corrective actions (question 10). Of the firms that took corrective actions, 90% said that all corrective actions which could have been verified by the investigator had been. Of the firms that promised corrective actions, over 99% either had already or planned to fulfill these promises (question 12). Of the companies that took and/or promised corrective actions in response to an FDA 483, 87% reported that all of their actions were annotated on the 483, 5% believed that some of their actions were omitted, and 8% reported that none of their actions were annotated (question 13). All but one firm either had already or planned to fulfill their promised actions (question 12).

After the Inspection

The information in this section pertains to the closeout meeting and the firm's planned responses to their FDA 483 observations.

At the final discussion between the investigator and the firm's management, the firm's highest level executive was present 76% of the time. (This question, number 19, pertained to all respondents.)

Ninety-three percent of the firms that received 483s planned to respond to them in writing (question 17). Most of those who did not plan a written response said it was not necessary (question 17a).

Overall Evaluation of Inspection

When asked how this inspection compared with previous inspections, slightly more than half (52%) of those who had experienced inspections previously thought this inspection was better, 40% thought it was about the same, and only 8% thought this inspection was worse than previous inspections (question 18).

Respondents who said this inspection was better or worse were asked to explain why. Table 8 shows the tabulated responses from those who said this inspection was better. The most often cited reason was the investigator's attitude, approach, or personality. The QSIT method of

inspection and good communication between the investigator and the firm were also frequently mentioned.

Table 8. Why This Inspection Was Better (Q-18)

Why This Inspection Was Better	Number	Percent
Investigator's Attitude/Approach/Personality	61	25.7
Good Communication	30	12.7
Investigator's Knowledge/Experience	16	6.8
Investigator's Organization	15	6.3
Scope of Inspection: General or Global	4	1.7
Scope of Inspection: Detailed or Thorough	16	6.8
Scope of Inspection: Focused, Narrow or Short	17	7.2
Firm More Experienced/Prepared	13	5.5
QSIT	37	15.6
Prenotification	16	6.8
Liked End Result	4	1.7
Other/Vague	8	3.4
TOTAL – 223 Respondents*	237*	100.00%

*Some respondents gave multiple reasons

Those who said this inspection was worse than previous inspections gave a variety of reasons as shown in Table 9. Two explanations were given slightly more often than others: the inspection was too long and the investigator was not knowledgeable.

Table 9. Why This Inspection Was Worse (Q-18)

Why This Inspection Was Worse	Number	Percent
Investigator's Attitude/Approach/Personality	4	10.8
Bad Communication	4	10.8
Investigator's Lack of Knowledge	7	18.9
Investigator's Lack of Organization	3	8.1
Investigator's Lack of Preparation	1	2.7
Length of Inspection/Time	8	21.6
Scope of Inspection (Too Broad, Too Detailed)	4	10.8
Firm Not Prepared	1	2.7
Other/Vague	5	13.5
TOTAL – 32 Respondents*	37*	100.00%

*Some respondents gave multiple reasons.

Additionally, about 33% of respondents wrote comments in the lined section at the end of the questionnaire. The vast majority of these comments pertained to the evaluated inspection as well. About 29% of the end comments were positive about the evaluated inspection; most of these mentioned aspects of the investigator's knowledge and attitude (23%), preannouncement (3%), and QSIT (2%). About 22% of the end comments were negative about the evaluated inspection. Here most respondents mentioned the length of the inspection, its efficiency, focus, or scope (8%), the investigator's attitude or lack of knowledge (4%), that advance notice would have allowed them to adequately prepare for the inspection (2%), or confusion over QSIT (2%). Other negative comments were widely varied and could not be classified. Another 14% of the comments were specific suggestions for the FDA: help the firms prepare by providing an agenda and checklist; try to consolidate inspections or at least understand the requirements of other inspections; suggestions on how to shorten the inspection time and minimize disruption to firms; and other ways the FDA can be more helpful to the firms. Most of the remaining end comments were elaborations of the firm's responses to specific questionnaire items. All of the comments from *all* sections of the questionnaire have been stripped of any specifics that might possibly allow company identification, and have been forwarded to the FDA for their consideration. See section V of this report for more details.

II. BREAKDOWN BY REGION

In this section many of the results from Section I are compared across the five FDA regions. The original plan was to examine responses by district, but many of the districts had few respondents *and* low response rates, both of which make results very unstable. One more respondent with very different answers could have considerably changed that district's breakdown.

Note that all foreign inspections are listed in this section as foreign rather than as from the region that inspected them.

Before the Inspection Began

All but one of the foreign companies reported receiving advance notice (preannouncement; question 1). As for domestic inspection preannouncement, those firms that reported at least one day of advance notice were: 90% of both the Southwest and Central Regions' inspections; 85% of the Pacific and Southeast Regions' inspections; and 72% of the

Additionally, the percentage of respondents who received five or more days' advance notice was calculated. Sixty-six percent of the Southeast Region's respondents; 65% of the Pacific Region's respondents; 60% for the Central Region; 47% for the Southwest Region; 45% for the Northeast Region; and 99% of foreign inspection respondents reported preannouncement of at least five days. The remaining respondents reported either no advance notice *or* advance notice of fewer than five days. Again, the reason for inspection may be a factor in these regional differences.

Those respondents who received advance notice of the inspection were asked whether they felt clear about the products, records, and personnel inspection requirements (question 2). The following figures include only firms that reported receiving at least one day's advance notice. The Pacific and Southeast's firms most often expressed clarity about product inspection requirements, 87% and 83% of the time, respectively. For both the Southwest and Central Regions' firms, 78% reported clarity. Clarity was least often found with the Northeast Region's firms, 70%, and the foreign firms, 74%.

For record inspection requirements, question 2b, the Southeast Region's inspections again reported a high percentage of clarity; 83% of their firms reported that they understood what the record inspection requirements were. Most of the other regions had nearly as high a percentage of their respondents report clarity: in the Central Region, 82% were clear; in the Pacific Region, 80% were clear; and in the Southwest Region, 78% were clear. Again the Northeast (57%) and

foreign (64%) inspections showed the smallest percentages of clarity from the preannouncement phone call.

As for the clarity of personnel inspection requirements, again the Pacific and Southeast Regions' respondents very often reported clear requirements, 75% and 74% respectively. Sixty-seven percent of the firms in the Central Region reported clarity of personnel inspection requirements, as did 65% of the Southwest Region's respondents. Again, the Northeast and foreign respondents reported the least clarity, with 55% and 62% respectively.

Respondents were asked in question 3 if it was necessary to reschedule the start of the inspection. Foreign inspection start dates were rescheduled the most often, at 33% of the time. For domestic inspections, the Pacific Region rescheduled start dates nearly as often, 29% of the time, followed by the Central Region, 27%, the Northeast, 25%, the Southeast, 21%, and, finally, the Southwest with only 15% of their inspection start dates rescheduled.

During the Inspection

The next table shows the number of working days the inspections lasted, broken down by region. As explained in Section I, the length of the inspection for those firms that had their inspections interrupted by more than two working days cannot be estimated. Those firms are therefore excluded from the table below.

Table 10. Length of Inspection

		Length of Inspection (If Not Interrupted by More than Two Days)				
		1 - 3 Days	4 - 5 Days	6 - 10 Days	More than 10 Days	Row Total
Pacific	**Number**	34	24	11		69
	Row %	49.3%	34.8%	15.9%		100.0%
Southwest	**Number**	16	9	6	2	33
	Row %	48.5%	27.3%	18.2%	6.1%	100.0%
Southeast	**Number**	23	21	19	6	69
	Row %	33.3%	30.4%	27.5%	8.7%	100.0%
Northeast	**Number**	51	13	3	4	71
	Row %	71.8%	18.3%	4.2%	5.6%	100.0%
Central	**Number**	69	25	28	5	127
	Row %	54.3%	19.7%	22.0%	3.9%	100.0%
Foreign	**Number**	50	69			119
	Row %	42.0%	58.0%			100.0%
TOTAL	**Number**	243	161	67	17	488
	Row %	49.8%	33.0%	13.7%	3.5%	100.0%

Table 10 shows that, of the uninterrupted inspections, the Northeast had the highest percentage of inspections that ran fewer than four days (72%). Although more of the longer inspections were omitted from the table because they were more often interrupted, the Southeast Region's inspections seem to have run longer than average: 36% lasted more than a week and only a third lasted fewer than four days. Note that none of the foreign inspections lasted longer than a week.

The percentage of inspections with interruptions of longer than two working days ranged from none with the foreign inspections to 23% with the Pacific Region's inspections. Fifteen percent of the Southwest Region's respondents reported that their inspections were interrupted; 12% of both the Northeast and Central Regions' inspections were interrupted for longer than two days. The domestic region with the smallest percentage of respondents reporting two or more day interruptions was the Southeast Region, with only 6% of its inspections interrupted.

The above mentioned interruptions resulted from FDA request (as opposed to firm request or both) roughly two-thirds of the time (60% to 77%) in each district (question 4a). More specific percentages are not provided because the numbers are small and thus the percentages are unstable.

Respondents were asked in question 5 whether they were able to have all the right personnel available during inspection. Responses were virtually constant across districts with the Northeast at 94%, Central and Southwest at 93%, foreign at 91%, Southeast at 90%, and Pacific at 89%.

Whether or not all necessary records were available to the investigators (question 6) varied a bit across regions. The Southeast Region's respondents reported that they were able to provide all the records needed for the inspection in 97% of the cases. Other regions' respondents were able to provide all the records a bit less often: 93% for the Northeast; 91% for Central and foreign; 86% for the Pacific; and 85% for the Southwest. Clearly, the vast majority of all regions' respondents were in agreement that they were able to meet the investigators' needs.

Daily notification of the investigator's observations (question 7) was also tabulated by region and is shown in Table 11. Since this question only applies to inspections of more than one day, only such inspections are included in the table below.

Table 11. Was the Firm Always Notified Daily of the Investigator's Observations (Q-7)?
(for Inspections Longer than One Day)

		Firm Always Notified Daily of Investigator's Observations? Yes	No	Row Total
Pacific	**Number**	71	8	79
	Row %	89.9%	10.1%	100.0%
Southwest	**Number**	27	7	34
	Row %	79.4%	20.6%	100.0%
Southeast	**Number**	50	16	66
	Row %	75.8%	24.2%	100.0%
Northeast	**Number**	51	5	56
	Row %	91.1%	8.9%	100.0%
Central	**Number**	100	13	113
	Row %	88.5%	11.5%	100.0%
Foreign	**Number**	109	8	117
	Row %	93.2%	6.8%	100.0%
TOTAL	**Number**	408	57	465
	Row %	87.7%	12.3%	100.0%

The foreign firms reported most often that they were always notified daily of the inspector's observations. Three regions, the Northeast, Pacific, and Central, each had about 90% of their responding firms with inspections of more than a day report that they were notified daily of observations. The smallest percentage of reported daily notifications was for the Southeast where 76% reported having been notified daily. Note that since the numbers in Table 11 are a bit smaller than in other tables, the percentages are a bit less stable.

The final question examined in this section compares opinions of whether the investigator gave any helpful information or suggestions (question 8) across regions. The foreign firms most often found their investigator to be helpful with 98% reporting that the investigator gave helpful information or suggestions. For the five domestic regions, 96% of the Southeast respondents, 93% of the Central, 90% of the Southwest, and 89% of the Pacific and Northeast respondents reported that the investigator gave helpful information or suggestions.

Outcome of the Inspection

This section contains comparisons across regions of corrective actions taken and promised by the firms and possible problems with their 483s. First, Table 12 shows the firms' responses about whether they received an FDA 483 (question 9).

Table 12. Issuance of an FDA 483

		FDA 483 Issued?		Row
		Yes	No	Total
Pacific	**Number**	52	39	91
	Row %	57.1%	42.9%	100.0%
Southwest	**Number**	27	13	40
	Row %	67.5%	32.5%	100.0%
Southeast	**Number**	44	29	73
	Row %	60.3%	39.7%	100.0%
Northeast	**Number**	39	43	82
	Row %	47.6%	52.4%	100.0%
Central	**Number**	70	76	146
	Row %	47.9%	52.1%	100.0%
Foreign	**Number**	71	55	126
	Row %	56.3%	43.7%	100.0%
TOTAL	**Number**	303	255	558
	Row %	54.3%	45.7%	100.0%

As shown, roughly 50 to 70% of each region's inspections received 483s. Proportionately more 483s were given in the Southwest and fewer in the Northeast and Central regions, but the differences were not striking.

Only the 303 respondents who were issued 483s are included in the remainder of this section.

Question 15 asked the firms if all the observations on their FDA 483s were clear. Table 13 shows their responses broken down by region.

Table 13. Clarity of the FDA 483 Observations (Q-15)

		Were All Observations on the 483 Understandable?		Row
		Yes	No	Total
Pacific	**Number**	51	1	52
	Row %	98.1%	1.9%	100.0%
Southwest	**Number**	22	5	27
	Row %	81.5%	18.5%	100.0%
Southeast	**Number**	42	2	44
	Row %	95.5%	4.5%	100.0%
Northeast	**Number**	36	3	39
	Row %	92.3%	7.7%	100.0%
Central	**Number**	67	3	70
	Row %	95.7%	4.3%	100.0%
Foreign	**Number**	70	1	71
	Row %	98.6%	1.4%	100.0%
TOTAL	**Number**	288	15	303
	Row %	95.0%	5.0%	100.0%

The table shows that firms overwhelmingly thought the observations on their 483s were understandable, though the Southwest region's respondents were clear about the observations a bit less often.

Respondents were also asked if they found any FDA 483 observations to be inappropriate, as opposed to inaccurate (question 16). Mostly firms felt the 483 observations were appropriate. Differences between the regions were relatively small – all were in approximately the 70 to 80 percent range for accuracy (a "no" response). Foreign respondents most often felt all their 483 observations were appropriate, as 91% of foreign firms gave a "no" response to the question. Eighty-four percent of the Northeast Region's respondents said that all their FDA 483 observations were appropriate, as did 81% of both the Southwest and Central Regions' respondents, 72% of the Southeast's respondents, and 69% of the Pacific Region's respondents.

Table 14 shows the percentage of respondents with *any* errors on their FDA 483s. As in Table 7, Section I, it summarizes responses to questions 14 and 16 so that any respondent who felt that they had a problem on their 483 with a non-annotation related inaccuracy or an inappropriate observation is classified as a "yes". Corrective action annotation problems (question 13) and lack of clarity (question 15) were again not considered errors.

Table 14. Were there One or More FDA 483 Inaccuracies or Inappropriate Observations (Q-14, 16)?

		One or More FDA 483 Inaccuracies or Inappropriate Observations		Row
		Yes	No	Total
Pacific	**Number**	17	34	51
	Row %	33.3%	66.7%	100.0%
Southwest	**Number**	7	19	26
	Row %	26.9%	73.1%	100.0%
Southeast	**Number**	14	29	43
	Row %	32.6%	67.4%	100.0%
Northeast	**Number**	7	30	37
	Row %	18.9%	81.1%	100.0%
Central	**Number**	19	49	68
	Row %	27.9%	72.1%	100.0%
Foreign	**Number**	12	59	71
	Row %	16.9%	83.1%	100.0%
TOTAL	**Number**	76	220	296
	Row %	25.7%	74.3%	100.0%

The most satisfied respondents were from the Foreign and Northeast Region's inspections. The Pacific and Southeast Regions' respondents were the least satisfied, with about a third of their respondents reporting at least one non-annotation inaccuracy or inappropriate observation on their 483s.

Next we turn to problems with the firms' promised and/or taken corrective actions. The vast majority of firms (85% to 98%) in all regions either promised or took corrective actions. Question 11 asked the firms if any of the corrective actions they took could have been verified by the inspector but were not. Again, the vast majority from all regions reported that their investigator had acted appropriately. Ninety-five percent of the foreign respondents whose firms took corrective actions said that the investigator had verified all their corrective actions. For the domestic respondents, 94% of the Northeast Region's respondents who took corrective actions said that all that could have been verified were verified. This figure was 92% for the Southwest Region, 90% for the Southeast Region, 87% for the Pacific Region, and 86% for the Central Region. In other words, there are slightly fewer complaints about investigators not verifying corrective actions in the Northeast, and slightly more complaints in the Central and Pacific regions. However, since this question only pertained to those who responded "yes" to having taken corrective actions in question 10, the numbers are small and therefore less stable than most of the other percentages given in this report.

Question 13 asked if the promised and/or taken corrective actions were properly annotated on the FDA 483. Again, the overwhelming majority of firms reported that they were. For the Northeast Region's respondents, 91% of the firms that took or promised corrective actions reported that all their actions were properly annotated on the 483 and an additional 3% reported that some were properly annotated. For the Southwest Region's respondents, 91% of the firms that took or promised corrective actions reported that all were properly annotated on the 483. No one from the Southwest Region reported partial annotation. Eighty-eight percent of the Central Region's respondents reported full annotation, and an additional 5% reported partial annotation. Similarly, eighty-seven percent of the Pacific Region's respondents reported full annotation, and an additional 6% reported partial annotation. For the Southeast, 79% reported full annotation and another 14% reported partial. Foreign respondents again were among the most content: 88% of those who took or promised corrective actions reported full annotation and 3% reported partial. Although these figures show that respondents criticized the Southeast investigators' use of the annotation process a bit more often than those from other regions regarding failure to fully annotate corrective actions on the FDA 483, this difference was small when the instability of the small numbers is taken into account.

After the Inspection

This section compares responses about things that happened at the close of the inspection and afterwards.

Seventy-six percent of all 559 firms reported that their highest level executive was present at the final discussion between the investigator and the firm's management, the closeout meeting (question 19). The breakdown according to region was: 86% Pacific; 83% foreign; 81% Southeast; 70% Northeast; 69% Central; and 65% Southwest.

Of the 303 firms that received FDA 483s, most regions had over 90% of their responding firms report that they planned to respond to the FDA in writing (question 17): 96% of the Southeast firms; 94% of the Central and Pacific firms; 93% of the foreign and Southwest firms; and 84% of the Northeast firms.

Overall Evaluation of Inspection

Table 15 shows the respondents' opinions about how this inspection compared with previous inspections, for those who had experienced previous inspections.

Table 15. How Did This Inspection Process Compare with Previous Inspections (Q-18)?

		How Did this Inspection Process Compare with Previous Inspections?			
		This was Better	This was Same	This was Worse	Row Total
Pacific	**Number**	39	32	7	78
	Row %	50.0%	41.0%	9.0%	100.0%
Southwest	**Number**	13	14	5	32
	Row %	40.6%	43.8%	15.6%	100.0%
Southeast	**Number**	31	24	6	61
	Row %	50.8%	39.3%	9.8%	100.0%
Northeast	**Number**	20	30	5	55
	Row %	36.4%	54.5%	9.1%	100.0%
Central	**Number**	72	42	10	124
	Row %	58.1%	33.9%	8.1%	100.0%
Foreign	**Number**	60	38	3	101
	Row %	59.4%	37.6%	3.0%	100.0%
TOTAL	**Number**	235	180	36	451
	Row %	52.1%	39.9%	8.0%	100.0%

As shown, the foreign and Central Region respondents were the most positive about this inspection with nearly 60% of each reporting that this inspection was better than previous. The Southwest Region's respondents most often reported that this inspection was worse than previous – about 16% said this inspection was worse as compared with about 8% to 10% of respondents in the other four regions. This may be related to the fact that the Southwest Region firms were issued a slightly higher percentage of 483s (Table 12).

III. LENGTH OF VS. REASON FOR THE INSPECTION

In this section, the number of working days the inspection lasted is compared with the type of inspection.

Recall that the length of inspection is difficult to estimate. The questionnaire does not ask the length of *any* interruptions during the inspection, just whether there was an interruption that exceeded two days. Thus, firms that reported an interruption of more than two working days were excluded from all "length of inspection" calculations and thus from this section of the report. Note that firms with interruptions of only one or two working days *are* included in this section and that their length of inspection is not adjusted downward for the interruption. Thus, (1) the longest inspections are underrepresented in this section and (2) the length of inspection is slightly overestimated.

Length of inspection was broken into five categories based on the number of working days: 1 day, 2 or 3 days, 4 or 5 days, 6 to 10 days, and more than 10 days. Table 16 shows the comparison between purpose of the inspection and the number of days the inspection lasted.

Table 16. Reason for the Inspection by Length of Inspection

Reason for Inspection		Length of Inspection (If Not Interrupted by More than Two Days)					Row Total
		1 Day	2 - 3 Days	4 - 5 Days	6 - 10 Days	More than 10 Days	
Preapproval Only	Number	3	10	20	2		35
	Row %	8.6%	28.6%	57.1%	5.7%		100.0%
QS/GMP Only	Number	59	121	109	50	9	348
	Row %	17.0%	34.8%	31.3%	14.4%	2.6%	100.0%
Other Only	Number	13	21	15	3		52
	Row %	25.0%	40.4%	28.8%	5.8%		100.0%
Preapproval & QS/GMP	Number	1	7	7	6	5	26
	Row %	3.8%	26.9%	26.9%	23.1%	19.2%	100.0%
Preapproval & Other	Number		1				1
	Row %		100.0%				100.0%
QS/GMP & Other	Number	3	4	9	6	3	25
	Row %	12.0%	16.0%	36.0%	24.0%	12.0%	100.0%
TOTAL	Number	79	164	160	67	17	487
	Row %	16.2%	33.7%	32.9%	13.8%	3.5%	100.0%

The table shows that inspections performed solely for preapproval generally lasted 4 to 5 days (the median was 4 days), QS/GMP inspections generally lasted 2 to 5 days (the median was also 4 days), and inspections performed primarily for other reasons were often shorter, generally 2 or 3 days (the median was 3 days).

IV. INSPECTION OUTCOME COMPARISONS

The inspection outcome was provided by the FDA for 306 domestic inspections, about 71% of the domestic inspections covered in this report. Outcomes were classified as NAI, either no FDA 483 or no substantive FDA 483; VAI, substantive FDA 483 but no Warning Letter; or OAI, Warning Letter or worse was received by the firm. Table 17 shows the breakdown of these outcomes for the 306 domestic firms.

Table 17. Current Inspection Outcome

	Number	Percent
NAI – No Substantive 483	153	50.0
VAI – Subst. 483, No W/L	115	37.6
OAI - W/L or Worse	38	12.4
Total	306	100.0

In this section, inspection outcome is compared with the number of medical device employees in the firm, preannouncement, length of the inspection, whether the firm's highest level executive attended the closeout meeting, and how this inspection compared with previous.

Table 18 shows that there is little relationship between the firms' number of medical device employees and the three inspection outcomes except that the largest firms were a bit less likely to be OAI.

Table 18. Current Inspection Outcome by Firm's Number of Employees (Q-20)

Current Inspection Outcome		Total Number Employed in Medical Device Worldwide: 1 to 36	37 to 225	More than 225	Row Total
NAI - No Substantive 483	Number	43	54	52	149
	Column %	48.9%	47.0%	54.7%	50.0%
VAI - Subst. 483, No W/L	Number	32	42	37	111
	Column %	36.4%	36.5%	38.9%	37.2%
OAI - W/L or Worse	Number	13	19	6	38
	Column %	14.8%	16.5%	6.3%	12.8%
TOTAL	Number	88	115	95	298
	Column %	100.0%	100.0%	100.0%	100.0%

The majority of the firms inspected, whether they received advance notification or not, were NAI or VAI, as shown in Table 19.

Table 19. Current Inspection Outcome by Preannouncement (Q-1)

Current Inspection Outcome		Did Firm Receive Advance Notification? Yes	No	Row Total
NAI – No Substantive 483	Number	135	18	153
	Column %	52.1%	38.3%	50.0%
VAI – Subst. 483, No W/L	Number	97	18	115
	Column %	37.5%	38.3%	37.6%
OAI – W/L or Worse	Number	27	11	38
	Column %	10.4%	23.4%	12.4%
TOTAL	Number	259	47	306
	Column %	100.0%	100.0%	100.0%

The inspection outcome and length of the inspection were related. Table 20 below shows results consistent with those in Section III of this report: the more serious the problems found the longer the inspection. This table shows the 267 firms for which both outcome results were available and length of inspection could be estimated.

Table 20. Current Inspection Outcome by Length of Inspection (if Not Interrupted by More than 2 Days)

Current Inspection Outcome		Length of Inspection (if Not Interrupted by More than 2 Days) 1 - 3 Days	4 - 5 Days	6 - 10 Days	More Than 10 Days	Row Total
NAI - No Substantive 483	Number	98	32	14	2	146
	Column %	71.0%	47.1%	28.0%	18.2%	54.7%
VAI - Subst. 483, No W/L	Number	35	28	23	6	92
	Column %	25.4%	41.2%	46.0%	54.5%	34.5%
OAI - W/L or Worse	Number	5	8	13	3	29
	Column %	3.6%	11.8%	26.0%	27.3%	10.9%
TOTAL	Number	138	68	50	11	267
	Column %	100.0%	100.0%	100.0%	100.0%	100.0%

Finally, the inspection outcome was compared with whether the respondent felt this inspection was better or worse than previous inspections. Table 21 shows that there is a weak relationship between how much the respondent liked this inspection and how favorable its outcome.

Table 21. Current Inspection Outcome by How Did This Inspection Process Compare with Previous (Q-18)?

Current Inspection Outcome		How Did this Inspection Process Compare with Previous? Better	Same	Worse	Row Total
NAI - No Substantive 483	Number	63	66	2	131
	Column %	50.4%	58.4%	8.7%	50.2%
VAI - Subst. 483, No W/L	Number	50	39	12	101
	Column %	40.0%	34.5%	52.2%	38.7%
OAI - W/L or Worse	Number	12	8	9	29
	Column %	9.6%	7.1%	39.1%	11.1%
TOTAL	Number	125	113	23	261
	Column %	100.0%	100.0%	100.0%	100.0%

It is interesting to note that 12 of the OAI respondents felt this inspection was better than previous and two of the NAI respondents felt this inspection was worse than previous. Neither of those two reported having received an FDA 483. One said that this inspection was worse because it took more time, the other said it was worse because employees had to cancel vacations to accommodate the inspection schedule.

For the 12 respondents with very unfavorable inspection results who were still very positive about the inspection, four cited the positive attitude of their investigator ("understanding," "helpful," "courteous," "flexible," "knowledgeable"), two liked the comprehensive nature of the inspection, one liked that it was shorter and more focused, one mentioned QSIT's predictability, two mentioned good communication and daily wrapups, and one of those two also mentioned preannouncement.

V. FROM THE MEDICAL DEVICE INDUSTRY INITIATIVES GRASSROOTS TASK FORCE

Task Force Subcommittee Members:
Nancy Singer, AdvaMed and Denise Dion, FDA
Lauren Andersen, AdvaMed & Andersen Caledonia Ltd.
Elaine Messa, Quintiles Consulting & Former Director of Los Angeles District Office, FDA
Leif Olsen, AMDM & BioWhittaker
Susan Reilly, ASQ Biomedical Division & Reilly and Associates

Participating FDA Officials:
Ronald G. Chesemore
Former ACRA, ORA
Bruce B. Burlington, M.D.
Former Director, CDRH
Deborah D. Ralston
Director, ORO
Lillian Gill
Director, OC, CDRH
Gary G. Dean
Former Director, DEN-DO
Edward Esparza
Former RFDD, SWR, ORA
Denise Dion
Investigator, ORA

Participating Industry Officials:
Lauren Andersen
AdvaMed & Andersen Caledonia Ltd.
Wayne Barlow
MDMA & Wescor
Thomas Henteleff
CLI & Kleinfeld, Kaplan and Becker
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Thomas Meskan
Medical Alley
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Quintiles Consulting & Former Dir. LOS-DO
Leif Olsen
AMDM & BioWhittaker
Susan Reilly
ASQ Biomedical Div. & Reilly and Assoc.
Nancy Singer
AdvaMed

The Medical Device Industry Initiatives Grassroots Task Force wishes to thank the FDA officials who coordinated the distribution of the Medical Device Inspection Evaluation, and the industry officials who took the time to fill out the questionnaire and return it to the University of California, Irvine, Center for Statistical Consulting.

We feel that this survey has been valuable in that it (1) provided firms an opportunity to give anonymous feedback to the FDA and to industry about their inspection experience; (2) allowed comparisons across regions of companies' reactions to inspections; and (3) helped

determine if the medical device industry initiatives (pre-announced inspections, annotated 483s, etc.) were being followed.

Feedback to the FDA consisted of (1) a quantitative analysis of the survey results and (2) the many comments which respondents wrote on the questionnaires. The FDA Office of Regulatory Affairs and Center for Devices and Radiological Health management have received a thorough report of the analyses of the questionnaire data. They have also been provided with all the many comments respondents wrote, both short comments written in response to specific questions and longer comments written at the end of the questionnaire. Before forwarding them, comments were stripped of any specifics which might possibly have allowed identification of the company, including FDA district and region, dates of inspection, product being inspected, inspection outcome, and anything unique about the inspection, etc. Comments were typed and categorized according to content by the UC Irvine Center for Statistical Consulting before being forwarded to the FDA.

Regional differences appear to be minimal, but the Office of Regulatory Affairs is continuing its ongoing efforts to assure uniformity and consistency in inspections and enforcement.

In light of the fact that 52% of firms believed the inspection was better than previous inspections, the Committee believes that the medical device industry initiatives of pre-announcing inspections and annotating Form FDA 483s are causing the medical device industry to view the inspection process in a more positive light than it has in the past. The Committee was pleased that most inspections are pre-announced, and 58% of the domestic and 99% of the foreign companies were given five or more days of advance notice before the start of an inspection.

The actual questionnaires have now been shredded by the UC Irvine Center for Statistical Consulting. Only the electronic data file remains, and it has been stripped of all fields that might allow identification of respondents, including region, district, dates of inspection, and all comments.

APPENDIX A:
THE QUESTIONNAIRE COVER LETTER

The FDA investigator gave the questionnaire (Appendix B), a reply envelope addressed to Dr. Anita Iannucci at UC Irvine, and the following cover letter to the firm's representative at the close of inspection. The cover letter was printed on UC Irvine stationary – white paper with blue and black ink. All three items were together in a UC Irvine stationary envelope without any addressee but with a UC Irvine return address.

UNIVERSITY OF CALIFORNIA, IRVINE

BERKELEY • DAVIS • IRVINE • LOS ANGELES • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

The UCI Center for Statistical Consulting

Social Science Plaza B 1296
Irvine, CA 92697-5105
(949) 824-1680
FAX (949) 824-1683

Dear Colleague:

Medical device manufacturers such as yours have raised concerns about the FDA inspection process leading the FDA to institute revisions. These revisions are now under review. A combined FDA and industry task force is studying the effects of the revised inspection procedure and is seeking the industry's opinions about how well the current FDA inspection process is working.

Your company, having just been through a Quality System/Good Manufacturing Practices (QS/GMP) or pre-market inspection, is being asked to give its opinion on these matters. In order that the results will truly represent the thinking of the medical device industry, it is important that each questionnaire be completed and returned.

You may be assured of complete confidentiality in spite of the fact that your name appears on the first page. The identification is so that we may check your name off the mailing list when your questionnaire is returned, and that we may contact you if we have questions about your responses. Your questionnaire should be returned to me at the University of California, Irvine. I will be overseeing the data entry, performing the analyses and writing a report of the results. I will **not** release individual companies' responses to the FDA, to industry associations, nor to anyone else. The final report will present data in such a way that individual responses are not discernable, thus protecting the anonymity of the respondents.

The results of this research will be used exclusively by the FDA and industry taskforce to improve the inspection process as well as to further cooperation between FDA and the medical device industry. A summary of the results will be posted on the FDA (www.fda.gov), HIMA (www.himanet.com), AMDM (www.amdm.org) and MDMA (www.medicaldevices.org) web sites.

We would be most happy to answer any questions you might have. Please contact: Nancy Singer, Special Counsel to Health Industry Manufacturers Association (HIMA), at (202) 434-7222 or e-mail nsinger@himanet.com; Leif Olsen, President, Association of Medical Diagnostics Manufacturers (AMDM), at (301) 898-7025 or e-mail leif@biowhittaker.com; or Denise Dion, Investigator, Division of Emergency and Investigational Operations, FDA, at (301) 827-5645 or e-mail ddion@ora.fda.gov; or Anita Iannucci at the University of California, Irvine, at (949) 824-1682 or e-mail iannucci@uci.edu.

Thank you for your assistance.

Sincerely,

Anita L. Iannucci

Anita L. Iannucci, Ph.D.
UCI Center for Statistical Consulting

FDA Officials:

Gary J. Dykstra, Acting ACRA
Bruce B. Burlington, M.D., Director, CDRH
Edward Esparza, RFDD, Southwest Region
Deborah D. Ralston, Acting Director, ORO
Lillian Gill, Director, OC, CDRH
Elaine Messa, Director, LOS-DO
Gary G. Dean, Director, DEN-DO

Industry Officials:

Nancy Singer, HIMA
Leif Olsen, AMDM
Susan Reilly, ASQ Biomedical Division
Wayne Barlow, MDMA
Thomas Meskan, Medical Alley
Thomas Henteleff, CLI
Ernest S. Malachowski, CMDA
L. Andersen (HIMA Director), Andersen Products

APPENDIX B:
THE QUESTIONNAIRE

The questionnaire was printed in the form of a booklet, two double-sided sheets of blue ink on white paper. The FDA investigator was to have filled out the box at the top of page 1 before giving the questionnaire packet to the firm, but in actual practice this was not always done. When the investigator left the box empty, often the firm filled in the information. When it was returned blank, my assistant telephoned the firm to obtain the information. We did not contact the FDA for the data because the FDA was not to know which firms returned their questionnaires and which did not.

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:

Anita Iannucci, Ph.D.
The UCI Center for Statistical Consulting
Social Science Plaza
University of California
Irvine, CA 92697-**5105**
(949) 824-1682 iannucci@uci.edu