

**Online Appendices A and B**  
**“Do Plant Inspections Predict Future Quality? The Role of Investigator Experience”**

**Table A1. Inspection Descriptive Statistics**

Year	2000	2001	2002	2003	2004	2005	2006
# Investigators	238	244	226	277	239	227	244
# Inspections	426	629	639	776	759	748	790
# Plants inspected	457	654	695	831	814	799	859
Mean, inspections per investigator	1.79	2.58	2.83	2.8	3.18	3.3	3.24
Min, inspections per investigator	1	1	1	1	1	1	1
Max, inspections per investigator	19	18	25	19	21	18	16

**Table A2. Site-Specific Inspection Counts**

Site Experience	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	5 <sup>th</sup>	6 <sup>th</sup>	7 <sup>th</sup>	8 <sup>th</sup>	9 <sup>th</sup>	10 <sup>th</sup>	11 <sup>th</sup>	12 <sup>th</sup>	13 <sup>th</sup>	14 <sup>th</sup>	15 <sup>th</sup>	16 <sup>th</sup>	Total	Repeat Visits <sup>a</sup>	Percent of Repeat Visits <sup>b</sup>
Count	3197	1285	171	58	23	10	6	5	3	3	1	1	1	1	1	1	4767	1570	
Back-to-Back		914	143	45	18	7	6	3	2	3	1	1	1	1	1	1	1147		73%
Non Back-to-Back		371	28	13	5	3	0	2	1	0	0	0	0	0	0	0	423		27%

<sup>a</sup>Repeat visits are the sum of all visits after 1st inspection. This equates to 1570 inspections. Repeat visits are either Back-to-Back or Non Back-to-Back (1147+423=1570).

Back-to-Back inspections occur when the investigator was the previous investigator to inspect the plant, while Non-Back-to-Back inspections occur when the investigator did not perform the previous inspection.

<sup>b</sup>1147 ÷ 1570 = 0.73

**Table A3. Descriptive Statistics and Correlation Matrix**

	Mean	Min	Max	SD	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
1	Time <sup>a</sup>	886.9	0	2555	2.15	1.00													
2	Recalls <sup>b</sup>	1.28	0	92	20.10	-0.41*	1.00												
3	Public	0.38	0	1	0.49	-0.26*	0.32*	1.00											
4	% Coll Deg	36.95	0	88.70	17.14	-0.02	0.07*	0.00	1.00										
5	Time recall <sup>c</sup>	290.3	1	2395	424.8	0.06*	-0.15*	-0.13*	-0.16*	1.00									
6	Recall 3yrs <sup>d</sup>	9.02	0	115	18.50	-0.42*	0.56*	0.52*	0.04*	-0.17*	1.00								
7	Scope	25.72	1	1110	32.63	0.16*	-0.18*	-0.15*	-0.03*	0.01	-0.26*	1.00							
8	# Prod	50.30	1	3124	1.64	-0.30*	0.35*	0.30*	0.07*	-0.10*	0.43*	-0.27*	1.00						
9	#New 510k	2.20	0	172	8.80	-0.21*	0.24*	0.28*	-0.02	-0.05*	0.40*	-0.08*	0.42*	1.00					
10	#New PMA	0.11	0	4.2	0.82	-0.11*	0.10*	0.12*	-0.00	-0.01	0.22*	0.03*	0.14*	0.33*	1.00				
11	High CI 3	0.32	0	1	0.47	-0.28*	0.15*	0.24*	0.08*	-0.02*	0.24*	-0.12*	0.36*	0.18*	0.16*	1.00			
12	High CI 2	0.58	0	1	0.49	0.17*	-0.08*	-0.17*	-0.03*	0.01	-0.14*	0.08*	-0.07*	-0.08*	-0.12*	-0.80*	1.00		
13	High CI 1	0.10	0	1	0.24	0.13*	-0.10*	-0.07*	-0.10*	-0.01	-0.12*	0.06*	-0.31*	-0.07*	-0.02	-0.18*	-0.30*	1.00	
14	Sub PMA	0.24	0	1	0.42	-0.27*	0.08*	0.19*	0.03*	-0.01	0.18*	-0.09*	0.27*	0.16*	0.18*	0.81*	-0.65*	-0.14*	1.00
15	Sub 510K	0.63	0	1	0.48	0.09*	0.02	-0.08*	0.04*	-0.01	-0.03*	0.03*	0.11*	-0.02*	-0.12*	-0.53*	0.78*	-0.31*	-0.73*
16	Sub 510Ke	0.13	0	1	0.29	0.17*	-0.13*	-0.11*	-0.11*	-0.01	-0.16*	0.08*	-0.34*	-0.11*	-0.04*	-0.21*	-0.14*	0.76*	-0.18*
17	Surveill.	0.70	0	1	0.46	0.24*	-0.13*	-0.07*	0.07*	0.05*	-0.13*	0.04*	-0.01	-0.03*	-0.02	-0.08*	0.08*	0.00	-0.07*
18	Compliance	0.29	0	1	0.45	-0.24*	0.13*	0.07*	-0.06*	-0.05*	0.12*	-0.03*	0.00	0.02	0.02	0.08*	-0.09*	0.01	0.07*
19	Complaint	0.01	0	1	0.13	-0.05*	0.00	0.01	-0.01	0.01	0.03*	-0.01	0.04*	0.03*	0.00	-0.01	0.03*	-0.02	0.00
20	Official Act	0.16	0	1	0.37	-0.11*	0.09*	0.01	-0.03*	-0.04*	0.09*	-0.03*	0.03*	-0.00	0.00	-0.04*	0.04*	0.00	-0.06*
21	Volun Act	0.39	0	1	0.49	0.05*	0.03*	0.00	0.03*	-0.02	0.00	0.03*	-0.03*	-0.03*	-0.06*	-0.02*	0.04*	-0.03*	-0.05*
22	No Act	0.45	0	1	0.50	0.03*	-0.09*	-0.01	-0.01	0.05*	-0.07*	-0.01	0.01	0.03*	0.05*	0.06*	-0.07*	0.03*	0.09*
23	Site Exp	1.41	0	16	1.03	-0.30*	0.10*	0.10*	-0.41*	-0.01	0.17*	-0.07*	0.13*	0.08*	0.09*	0.16*	-0.11*	-0.06*	0.20*
24	Other Exp	22.63	0	147	23.40	-0.02	-0.05*	0.06*	0.07*	0.06*	0.03*	-0.04*	0.03*	0.06*	0.06*	0.07*	0.04*	-0.04*	0.06*

  

	15	16	17	18	19	20	21	22	23	24	
15	Sub 510K	1.00									
16	Sub 510Ke	-0.42*	1.00								
17	Surveill.	0.07*	-0.01	1.00							
18	Compliance	-0.07*	0.01	-0.96*	1.00						
19	Complaint	0.00	0.00	-0.20*	-0.08*	1.00					
20	Official Act	0.04*	0.01	-0.23*	0.23*	0.01	1.00				
21	Volun Act	0.05*	-0.02	0.02	-0.01	-0.02	-0.35*	1.00			
22	No Act	-0.08*	0.01	0.16*	-0.16*	0.01	-0.39*	-0.72*	1.00		
23	Site Exp	-0.11*	-0.06*	-0.12*	0.12*	0.00	-0.02	-0.02	0.04*	1.00	
24	Other Exp	-0.02	-0.03*	0.11*	-0.12*	0.02	-0.09*	-0.04*	0.11*	0.27*	1.00

<sup>a</sup>Time in days from last inspection to recall. <sup>b</sup> Total recall counts, <sup>c</sup> Time in days since last recall, <sup>d</sup> Recalls at plant last 3 years  
\*p<0.05.

**Table A4. Robustness Checks-Model Exclusions. Cox Regression Analysis-Hazard of a Recall**

	No Exclusions <sup>a</sup>		Class II Recalls only <sup>b</sup>		Surveillance only <sup>c</sup>		Compliance only <sup>d</sup>	
	(1) β	(2) SE	(3) β	(4) SE	(5) β	(6) SE	(7) β	(8) SE
Public	0.18	(0.12)	0.17	(0.12)	0.15	(0.14)	0.18	(0.17)
% College Degree	0.01**	(0.00)	0.01**	(0.00)	0.01*	(0.00)	0.01+	(0.00)
Ln_Time since last recall	-0.06***	(0.02)	-0.07***	(0.02)	-0.08***	(0.02)	-0.03	(0.03)
Recalls (last 3 years)	0.04***	(0.01)	0.04***	(0.01)	0.03***	(0.01)	0.07***	(0.01)
2000	0.33**	(0.12)	0.34**	(0.12)	0.43**	(0.15)	0.19	(0.21)
2001	0.07	(0.12)	0.14	(0.11)	0.09	(0.15)	0.19	(0.19)
2002	0.12	(0.11)	0.17	(0.12)	0.22	(0.14)	-0.02	(0.23)
2003	-0.12	(0.12)	-0.04	(0.13)	-0.09	(0.15)	-0.23	(0.19)
2004	0.00	(0.11)	0.02	(0.12)	-0.01	(0.16)	-0.17	(0.18)
2005	-0.01	(0.08)	-0.01	(0.08)	0.06	(0.11)	-0.26	(0.17)
Ln_Scope	-0.09**	(0.03)	-0.10**	(0.03)	-0.13**	(0.03)	-0.04	(0.05)
Ln_Number of Products	0.19***	(0.04)	0.20***	(0.04)	0.24***	(0.06)	0.13**	(0.05)
Number of New 510K	0.00	(0.00)	0.00	(0.00)	0.00	(0.00)	-0.00	(0.00)
Number of New PMA	-0.02	(0.03)	-0.02	(0.03)	-0.05	(0.04)	0.08+	(0.04)
Highest Class 3	0.03	(0.41)	0.05	(0.40)	0.04	(0.36)	0.19	(0.69)
Highest Class 2	-0.26	(0.39)	-0.31	(0.37)	-0.24	(0.34)	-0.35	(0.62)
Highest Submission PMA	0.23	(0.43)	0.18	(0.40)	0.15	(0.33)	0.13	(0.75)
Highest Submission 510K	0.32	(0.39)	0.31	(0.36)	0.45	(0.28)	0.17	(0.67)
Surveillance	-0.32	(0.20)	-0.27	(0.20)				
Compliance	0.03	(0.20)	0.12	(0.21)				
Voluntary Action	-0.24**	(0.09)	-0.19+	(0.10)	-0.23*	(0.12)	-0.12	(0.13)
No Action	-0.31***	(0.09)	-0.27**	(0.10)	-0.30*	(0.13)	-0.50***	(0.14)
Site-specific experience	0.18***	(0.03)	0.19***	(0.03)	0.23***	(0.04)	0.24***	(0.06)
Other experience	-0.00	(0.00)	-0.00	(0.00)	-0.00	(0.00)	-0.00	(0.00)
Site-specific experience×Vol. Action	0.17*	(0.07)	0.16*	(0.07)	0.30***	(0.07)	0.03	(0.10)
Site-specific experience×No Action	0.16*	(0.06)	0.15*	(0.07)	0.18*	(0.07)	0.29**	(0.11)
Other experience×Vol. Action	-0.00	(0.00)	-0.00	(0.00)	-0.00	(0.01)	0.00	(0.01)
Other experience×No Action	-0.00	(0.00)	-0.00	(0.00)	0.00	(0.01)	-0.00	(0.01)
Observations	7630		6918		5221		2123	
Wald $\chi^2$	3942.91		4557.46		2079.09		837.22	

Standard errors in parentheses \* p<0.1, \*\* p<0.05, \*\*\* p<0.01. <sup>a</sup> All observations in the data. Includes 4,767 inspections and 2,863 recalls. 4,767 + 2,863 = 7,630 inspections and recalls. <sup>b</sup> Excludes class I and class III recalls. 7,630 - [80 class I recalls + 632 class III recalls] = 6,918 inspections and recalls. <sup>c</sup> Excludes 2,409 compliance and complaint inspections and their associated subsequent recalls, 7,630 - 2,409 = 5,221 inspections and recalls. <sup>d</sup> Excludes 5,507 surveillance and complaint inspections and their associated recalls. 7,630 - 5,507 = 2,123. Sales and Firm dummies included but not shown

**Table A5. Robustness Checks- Cox Regression Analysis-Hazard of a Recall**

	Investigator fixed effects <sup>a</sup>		No inspections by investigator in first five years <sup>b</sup>	
	(1) β	(2) SE	(3) β	(4) SE
Public	0.29***	(0.08)	0.19**	(0.07)
% College Degree	0.01*	(0.00)	0.01**	(0.00)
Ln_Time since last recall	-0.06***	(0.02)	-0.10***	(0.02)
Recalls (last 3 years)	0.02***	(0.00)	0.03***	(0.00)
2000	-0.77***	(0.16)	-0.17	(0.14)
2001	-0.56***	(0.13)	0.03	(0.11)
2002	-0.35**	(0.12)	0.15	(0.09)
2003	-0.45***	(0.11)	-0.11	(0.09)
2004	-0.20+	(0.10)	-0.01	(0.09)
2005	-0.19*	(0.09)	-0.01	(0.08)
Ln_Scope	-0.09**	(0.03)	-0.10**	(0.02)
Ln_Number of Products	0.21***	(0.03)	0.17***	(0.02)
Number of New 510K	-0.00	(0.00)	-0.00	(0.00)
Number of New PMA	0.02	(0.03)	-0.01	(0.02)
Highest Class 3	0.04	(0.28)	0.37	(0.26)
Highest Class 2	-0.31	(0.26)	-0.09	(0.24)
Highest Submission PMA	0.31	(0.26)	0.05	(0.24)
Highest Submission 510K	0.29	(0.22)	0.22	(0.22)
Surveillance	-0.51*	(0.21)	-0.30+	(0.17)
Compliance	-0.09	(0.22)	0.05	(0.18)
Voluntary Action	-0.31***	(0.09)	-0.26***	(0.08)
No Action	-0.44***	(0.10)	-0.29***	(0.08)
Site-specific experience	0.19***	(0.03)	0.15***	(0.02)
Other experience	-0.01***	(0.00)	-0.00	(0.00)
Site-specific experience×Vol.	0.22**	(0.08)	0.16*	(0.07)
Site-specific experience×No Action	0.22***	(0.06)	0.18**	(0.05)
Other experience×Vol. Action	0.00	(0.00)	-0.00	(0.00)
Other experience×No Action	0.00	(0.00)	-0.00	(0.00)
Observations	7630		7232	
Wald $\chi^2$	3988.96		2687.12	

Standard errors in parentheses + p<0.1, \* p<0.05, \*\* p<0.01. Note: Sales and Firm fixed effects included but not shown <sup>a</sup> Inspector fixed effects included not shown.

<sup>b</sup> Excludes 398 observations for inspectors that had inspected a plant in the first 5 years of the experience data (1994 to 1998). 7,630-398=7,232

**Table A6. Robustness Checks-Negative Binomial Regression Results with Site-Specific Experience as Dependent Variable**

	(1)	(2)
	$\beta$	SE
Public	-0.01	(0.04)
% College Degree	-0.01*	(0.01)
Ln_Time since last recall	-0.01	(0.01)
Recalls (last 3 years)	0.01	(0.01)
2000	-0.01	(0.06)
2001	-0.01	(0.05)
2002	0.04	(0.05)
2003	0.01	(0.04)
2004	0.01	(0.04)
2005	0.04	(0.04)
Ln_Scope	-0.02	(0.02)
Ln_Number of Products	-0.00	(0.01)
Number of New 510K	0.01	(0.00)
Number of New PMA	0.00	(0.01)
Highest Class 3	-0.07	(0.08)
Highest Class 2	0.04	(0.05)
Highest Submission PMA	0.29**	(0.08)
Highest Submission 510K	0.05	(0.04)
Surveillance	0.06	(0.11)
Compliance	0.20+	(0.11)
Previous Voluntary Action	-0.01	(0.03)
Previous No Action	-0.02	(0.03)
Other experience	0.01**	(0.01)
Constant	0.44**	(0.16)
Observations	7630	
Wald $\chi^2$	10492	

Robust standard errors used. Sales and Firm dummies included not shown.  
Standard errors in parentheses + p<0.1, \* p<0.05, \*\* p<0.01

**Table A7. Cox Regression Analysis-Hazard of a Recall. Back-to-Back vs. Non Back-to-Back Site-Specific Experience**

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
	$\beta$	SE	$\beta$	SE	$\beta$	SE	$\beta$	SE	$\beta$	SE
Public	0.21***	(0.06)	0.21**	(0.07)	0.19**	(0.07)	0.20**	(0.07)	0.20**	(0.07)
% College Degree	0.01*	(0.00)	0.01***	(0.00)	0.01***	(0.00)	0.01***	(0.00)	0.01***	(0.00)
Ln_Time since last recall	-0.11***	(0.01)	-0.11***	(0.01)	-0.11***	(0.01)	-0.10***	(0.01)	-0.10***	(0.01)
Recalls (last 3 years)	0.02***	(0.00)	0.02***	(0.00)	0.02***	(0.00)	0.02***	(0.00)	0.02***	(0.00)
Ln_Scope	-0.11***	(0.02)	-0.10***	(0.02)	-0.11***	(0.02)	-0.11***	(0.02)	-0.11***	(0.02)
Ln_Number of Products	0.16***	(0.02)	0.16***	(0.02)	0.16***	(0.02)	0.16***	(0.02)	0.16***	(0.02)
Number of New 510K	-0.00	(0.00)	-0.00	(0.00)	-0.00	(0.00)	-0.00	(0.00)	-0.00	(0.00)
Number of New PMA	-0.01	(0.02)	-0.03	(0.02)	-0.03	(0.02)	-0.03	(0.03)	-0.03	(0.02)
Highest Class 3	-0.07	(0.23)	-0.05	(0.22)	-0.03	(0.22)	-0.00	(0.23)	-0.01	(0.23)
Highest Class 2	-0.33	(0.21)	-0.33	(0.21)	-0.31	(0.21)	-0.29	(0.21)	-0.30	(0.21)
Highest Submission PMA	0.30	(0.21)	0.19	(0.21)	0.21	(0.21)	0.22	(0.21)	0.23	(0.21)
Highest Submission 510K	0.35+	(0.19)	0.33+	(0.19)	0.34+	(0.19)	0.35+	(0.19)	0.36+	(0.19)
Surveillance	-0.26	(0.17)	-0.27	(0.17)	-0.28+	(0.17)	-0.26	(0.17)	-0.27	(0.17)
Compliance	0.09	(0.17)	0.06	(0.17)	0.04	(0.17)	0.06	(0.17)	0.05	(0.17)
Voluntary Action	-0.27***	(0.07)	-0.25***	(0.07)	-0.25***	(0.07)	-0.29***	(0.07)	-1.30**	(0.49)
No Action	-0.41***	(0.07)	-0.39***	(0.07)	-0.37***	(0.07)	-0.39***	(0.07)	-1.03*	(0.49)
Other experience	-0.00	(0.00)	-0.00**	(0.00)	-0.00*	(0.00)	-0.00**	(0.00)	-0.00*	(0.00)
Other experience×Vol. Action	-0.00	(0.00)	-0.00	(0.00)	-0.00	(0.00)	-0.01	(0.00)	-0.01+	(0.00)
Other experience×No Action	0.00	(0.00)	-0.00	(0.00)	-0.00	(0.00)	-0.00	(0.00)	-0.00	(0.00)
Back-to-Back Site experience			0.19***	(0.02)	0.20***	(0.02)	0.22***	(0.02)	0.22***	(0.02)
Non Back-to-Back Site experience					-0.51***	(0.11)	-0.53***	(0.11)	-1.26**	(0.45)
Back-to-Back exp×Vol. Action							0.22***	(0.06)	0.23***	(0.06)
Back-to-Back exp×No Action							0.15**	(0.05)	0.16**	(0.05)
Non Back-to-Back exp×Vol. Action									0.98*	(0.47)
Non Back-to-Back exp×No Action									0.63	(0.48)
Observations	7630		7630		7630		7630		7630	
Wald $\chi^2$	2703.28		2783.50		2813.23		2828.56		2835.15	

Standard errors in parentheses + p<0.1, \* p<0.05, \*\* p<0.01. Note: Sales, Year, and Firm dummies included but not shown.

**Table A8. Mediation Analysis**  
**Logistic Regression with clustered SE**  
**Dependent Variable is Official Action Outcome (1/0)**

	(1)	(2)
	$\beta$	SE
Public	0.11	(0.18)
% College Degree	0.01	(0.01)
Ln_Time since last recall	-0.01	(0.03)
Recalls (last 3 years)	0.04*	(0.01)
2000	0.88*	(0.36)
2001	0.66*	(0.31)
2002	0.39	(0.25)
2003	0.17	(0.23)
2004	0.36+	(0.20)
2005	0.39*	(0.18)
Ln_Scope	-0.03	(0.08)
Ln_Number of Products	0.07	(0.05)
Number of New 510K	0.02*	(0.01)
Number of New PMA	-0.01	(0.07)
Highest Class 3	0.23	(0.36)
Highest Class 2	0.23	(0.27)
Highest Submission PMA	-1.04**	(0.38)
Highest Submission 510K	-0.33	(0.23)
Surveillance	-1.43***	(0.42)
Compliance	0.02	(0.43)
Site-Specific Experience	0.02	(0.11)
Other experience	0.01	(0.01)
Constant	-17.35***	(1.45)
Observations	7630	
Wald $\chi^2$	2726.71	

Robust standard errors used. Sales, Investigator, and Firm dummies included not shown.  
Standard errors in parentheses + p<0.1, \* p<0.05, \*\* p<0.01

## **Appendix B. Redacted Actual FDA Plant Inspection Findings**

### Redacted FDA Plant Inspection Finding #1. Manufacturing and Quality Processes:

1. Failure to adequately ensure that when the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedure, as required by 21 CFR 820.75(a). For example:

a. The [redacted] test method was not adequately validated as part of the [redacted] process for the [redacted] assembly processes or independently as a test method for process screening and acceptance.

2. Failure to adequately establish procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics have not been adequately established, as required 21 CFR 820.250(a). For example, your statistical tool for CAPA data trending is inadequate for the intended use for identifying problems to assess whether a preventive action or corrective action is indicated.

### Redacted FDA Plant Inspection Report #2. Supplier Processes:

1. Failure to establish and maintain adequate procedures for purchasing controls that ensure the type and extent of control to be exercised over the product, services and suppliers is based on the supplier evaluation process, required by 21 CFR 820.50(a). For example [redacted].

2. Failure to adequately establish procedures for corrective and preventive actions, as required by 21 CFR 820.100(a). Specifically,

a. Your firm failed to follow procedure, “Corrective Action Preventive Action (CAPA) Procedure” in that you failed to open a CAPA when changes were made to your supplier control procedures as part of a continuous improvement project. The procedural changes were made to supplier control procedures, including [redacted], to address the handling of suppliers that do not agree to be audited by your firm and/or sign [redacted] quality agreement. The changes affected approximately [redacted] suppliers.

### Redacted FDA Plant Inspection Report #3. Design Processes:

1. Failure to establish and maintain procedures to verify device design to ensure that the design outputs meets the design input requirements, as required by 21 CFR 820.30(f). For example, design verification of the [redacted] was conducted in [redacted] after changes were made to the device, including a change to the material of the outer [redacted].

2. Failure to establish and maintain adequate design validation procedures to include risk analysis, a requirement of 21 CFR 820.30(g). Specifically: The Risk Management Process [redacted] requires the Risk Management File to be updated as required when issues arise that introduce new hazards or increased residual risk. However, the Safety Update Assessment [redacted] has not been updated to include the information in [redacted].