

**1. Which class of device generates the greatest amount of complaint activity for your firm?**

	answered question	237
	skipped question	5
	Response Percent	Response Count
Class I	16.0%	38
Class II	<b>62.9%</b>	<b>149</b>
Class III	21.1%	50

**2. What is the approximate number of US-based employees in your firm?**

	answered question	241
	skipped question	1
	Response Percent	Response Count
0 - 100	26.6%	64
101 - 500	<b>29.9%</b>	<b>72</b>
501 - 1000	14.5%	35
1001 - 10,000	23.7%	57
10,001 - 50,000	5.4%	13
Over 50,000	0.0%	0

**3. How many FTEs (full time equivalents) are directly involved in your firm's complaint handling process? (Note one FTE would work a 40-hour work week. Two part time employees each of whom devotes 20 hours per week to an area together would equal one FTE.)**

	answered question	242
	skipped question	0
	Response Percent	Response Count

3. How many FTEs (full time equivalents) are directly involved in your firm's complaint handling process? (Note one FTE would work a 40-hour work week. Two part time employees each of whom devotes 20 hours per week to an area together would equal one FTE.)

1	21.9%	53
2-5	<b>35.5%</b>	<b>86</b>
6-10	20.2%	49
Other (please specify) <a href="#">Show replies</a>	22.7%	55

4. Of the following, which is the most common method that customers or others, e.g., sales and service personnel, use to communicate complaints about your medical devices?

	answered question		240
	skipped question		2
		<b>Response Percent</b>	<b>Response Count</b>
Call a designated number for complaints		<b>41.7%</b>	<b>100</b>
Call the main number for the firm		25.0%	60
Use the "Contact Us" link on the firm's web site		2.1%	5
Use a specific link for complaints on the firm's web site		0.8%	2
Communicate directly with company field personnel		30.8%	74
Other (please specify) <a href="#">Show replies</a>		10.4%	25

5. If your firm uses a web-based solution to capture complaints via the internet, what is the name of the firm who developed the solution?

	answered question		85
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5. If your firm uses a web-based solution to capture complaints via the internet, what is the name of the firm who developed the solution?

skipped question	157
	<b>Response Count</b>
<a href="#">Show replies</a>	85

6. If your firm uses a web-based solution to capture complaints via the internet, please explain its best and worst features.

answered question	75
skipped question	167
	<b>Response Count</b>
<a href="#">Show replies</a>	75

7. If your firm uses a commerical software application for complaint handling and processing, what is the name of the firm that developed the application?

answered question	140
skipped question	102
	<b>Response Count</b>
<a href="#">Show replies</a>	140

8. If your firm uses a commerical software application for complaint handling and processing, please describe its best and worst features.

answered question	122
skipped question	120
	<b>Response Count</b>
<a href="#">Show replies</a>	122

9. Regardless of the method of communication used, which of the following groups provide the most complaints to your firm about your devces?

**9. Regardless of the method of communication used, which of the following groups provide the most complaints to your firm about your devces?**

	answered question	240
	skipped question	2
	Response Percent	Response Count
Health care professionals	33.8%	81
User facilities	25.4%	61
Patients	7.1%	17
Your service representatives	17.9%	43
Your distributors	9.6%	23
Other (please specify) <a href="#">Show replies</a>	6.3%	15

**10. Is an acknowledgement routinely sent to the individual who reported the complaint?**

	answered question	240
	skipped question	2
	Response Percent	Response Count
Yes	62.5%	150
No	37.5%	90

**11. When does your firm send correspondence to the complainant following closure of the complaintt?**

	answered question	238
	skipped question	4
	Response Percent	Response Count
Never	2.1%	5
Always	33.6%	80

**11. When does your firm send correspondence to the complainant following closure of the complaint?**

When requested by the complainant	38.7%	92
When requested by sales or service personnel	5.9%	14
When a failure investigation is conducted	6.3%	15
When a corrective action has been implemented	3.8%	9
Other (please specify) <a href="#">Show replies</a>	9.7%	23

**12. In those cases where a corrective action is implemented, how often does your firm send a summary of the corrective action to the complainant?**

	answered question	237
	skipped question	5
	<b>Response Percent</b>	<b>Response Count</b>
<b>Always</b>	21.9%	52
<b>Most of the time</b>	14.8%	35
<b>Sometimes</b>	23.6%	56
<b>Rarely</b>	<b>27.8%</b>	<b>66</b>
<b>Never</b>	11.8%	28

**13. Are all service calls screened for issues that meet the definition of a complaint?**

	answered question	229
	skipped question	13
	<b>Response Percent</b>	<b>Response Count</b>
<b>Yes</b>	<b>85.2%</b>	<b>195</b>
<b>No</b>	14.8%	34

**14. If service calls are screened to determine if they meet the definition of a complaint, are potential complaints reported through the established complaint handling process?**

	answered question	212
	skipped question	30
	Response Percent	Response Count
Yes	98.1%	208
No	1.9%	4

**15. Are all service reports that represent an MDR-reportable events considered to be a complaint and processed in accordance with 21 CFR 820.198**

	answered question	224
	skipped question	18
	Response Percent	Response Count
Yes	96.9%	217
No	3.1%	7

**16. When do you consider a complaint closed?**

	answered question	240
	skipped question	2
	Response Percent	Response Count
When a failure investigation is initiated	1.3%	3
When a failure investigation is completed	20.8%	50
When corrective action has been initiated, or it is determined that no action is required	41.7%	100
When corrective action is completed	23.8%	57

**16. When do you consider a complaint closed?****Other (please specify)**[Show replies](#)

12.5%

30

**17. In your evaluation of incoming complaints, what criteria does your firm use as a basis for not investigating the complaint? (Please check all that apply.)**

answered question

239

skipped question

3

**Response  
Percent****Response  
Count****A failure investigation is  
already open for the  
device**

38.1%

91

**An adequate  
investigation of the  
alleged complaint failure  
mode has already been  
performed**

54.8%

131

**A corrective action is  
already open for the  
same failure mode**

51.5%

123

**The device was not  
properly used**

22.6%

54

**Complaint does not  
involve a possible failure  
of the device, labeling or  
packaging to meet  
specifications**

34.3%

82

**Complaint does not  
involve an event that is  
potentially reportable  
under the MDR  
regulation**

7.1%

17

**Firm is unable to obtain  
the device for analysis**

21.3%

51

**Complaint is for a  
product not  
manufactured by the  
firm**

55.2%

132

**17. In your evaluation of incoming complaints, what criteria does your firm use as a basis for not investigating the complaint? (Please check all that apply.)**

Other (please specify) <a href="#">Show replies</a>	12.1%	29
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**18. What is your firm's goal for the time to close a complaint?**

answered question		240
skipped question		2

	Response Percent	Response Count
Less than 30 calendar days	37.9%	91
31 - 45 calendar days	17.9%	43
46 - 60 calendar days	22.5%	54
More than 60 calendar days	5.4%	13
Other (please specify) <a href="#">Show replies</a>	16.3%	39

**19. What is the maximum number of calendar days that you believe it is acceptable for a complaint to remain open?**

answered question		228
skipped question		14

	Response Count
<a href="#">Show replies</a>	228

**20. What information do you trend? Please check all that apply.**

answered question		239
skipped question		3

	Response Percent	Response Count
Number of complaints by individual device type	84.1%	201

**20. What information do you trend? Please check all that apply.**

Number of complaints by product family	73.6%	176
Number of complaints by failure mode	79.5%	190
Number of complaints by failure mechanism confirmed by failure analysis	43.5%	104
New complaints per period (e.g., month, quarter, etc.)	<b>86.2%</b>	<b>206</b>
Average days to complaint closure	67.4%	161
Complaints closed per period	57.3%	137
Total complaints remaining open per period	73.2%	175
Other (please specify) <a href="#">Show replies</a>	15.9%	38

**21. If your firm has a cross-functional team that meets regularly to discuss newly reported failure modes, trends, and the effectiveness of corrective actions, how often does the team meet?**

	answered question		<b>227</b>
	skipped question		<b>15</b>
		<b>Response Percent</b>	<b>Response Count</b>
Weekly		25.1%	57
Biweekly		6.6%	15
Monthly		<b>30.4%</b>	<b>69</b>
Quarterly		11.5%	26
Firm does not utilize team meetings for this analysis		16.3%	37
Other (please specify) <a href="#">Show replies</a>		10.1%	23

**22. For complaints that COULD AFFECT PATIENT OR USER SAFETY, how many complaints for the same reported failure mode will trigger a failure investigation?**

	answered question	237
	skipped question	5
		<b>Response Percent</b>
		<b>Response Count</b>
<b>1</b>		<b>82.7%</b>
<b>2 - 4</b>		7.6%
<b>5 or more</b>		2.1%
<b>Triggers have not been implemented</b>		7.6%

**23. For complaints NOT HAVING a significant impact on safety and effectiveness, how many complaints for the same reported failure mode will trigger a failure investigation?**

	answered question	236
	skipped question	6
		<b>Response Percent</b>
		<b>Response Count</b>
<b>1</b>		<b>39.0%</b>
<b>2 -4</b>		22.9%
<b>5 or more</b>		16.9%
<b>Triggers have not been implemented</b>		21.2%

**24. How does your firm address complaints that require corrective action?**

	answered question	238
	skipped question	4
		<b>Response Percent</b>
		<b>Response Count</b>
<b>Corrective action is handled as part of the complaint</b>		22.7%

**24. How does your firm address complaints that require corrective action?**

management system

Corrective action is initiated through a CAPA process that is separate from the complaint management system	<b>77.3%</b>	<b>184</b>
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**25. Below is a list of challenges that firms have in meeting the requirements of 21 CFR 820.198. Please rank the level of difficulty for each of the following with 1 being the most challenging and 5 being the least challenging.**

	answered question						239
	skipped question						3
	1	2	3	4	5	Rating Average	Response Count
Obtaining sufficient details about the event or malfunction from the firm's sales, service and clinical personnel	17.6% (36)	<b>27.3%</b> <b>(56)</b>	23.9% (49)	15.6% (32)	15.6% (32)	2.84	205
Obtaining sufficient details about the event or malfunction from the device user	<b>35.9%</b> <b>(74)</b>	29.1% (60)	15.0% (31)	16.5% (34)	3.4% (7)	2.22	206
Obtaining the device back from the customer	10.4% (23)	17.6% (39)	<b>37.1%</b> <b>(82)</b>	18.6% (41)	16.3% (36)	3.13	221
Obtaining commitments from other departments to conduct a failure investigation or initiate corrective action in a timely manner	11.7% (25)	17.8% (38)	16.0% (34)	<b>29.1%</b> <b>(62)</b>	25.4% (54)	3.38	213

25. Below is a list of challenges that firms have in meeting the requirements of 21 CFR 820.198. Please rank the level of difficulty for each of the following with 1 being the most challenging and 5 being the least challenging.

Having sufficient resources in the complaint handling function	21.7% (48)	12.7% (28)	14.9% (33)	21.7% (48)	<b>29.0% (64)</b>	3.24	221
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26. Which of the challenges listed above is the most difficult at your location?

answered question	202
skipped question	40

Response  
Count

[Show replies](#)

202

27. In your experience what is the most effective technique you have observed to encourage your IN-HOUSE and FIELD PERSONNEL to report complaints?

answered question	209
skipped question	33

Response  
Count

[Show replies](#)

209

28. In your experience what is the most effective technique you have observed to encourage your CUSTOMERS to report complaints?

answered question	193
skipped question	49

Response  
Count

[Show replies](#)

193

29. In your experience what is the most effective technique that your firm uses to get the device back from the customer who made the complaint?

29. In your experience what is the most effective technique that your firm uses to get the device back from the customer who made the complaint?

answered question	205
skipped question	37
	<b>Response Count</b>
<a href="#">Show replies</a>	205

30. In the following space, please provide any additional comments on the areas covered by this survey or complaint handling in general.

answered question	72
skipped question	170
	<b>Response Count</b>
<a href="#">Show replies</a>	72