~~Title text goes here~~

FDA Survey

No Blanks

1. Which of the following is your main NDA review function?

	Responses	Percent
Chemistry, Manufacturing, and Controls	48	12%
Clinical	107	27%
Microbiology (product quality and clinical efficacy)	13	3%
Pharmacology/Toxicology	52	13%
Clinical Pharmacology and Biopharmaceutics	44	11%
Pharmacovigilance	12	3%
Regulatory Project Management	46	12%
Statistics	38	10%
Trade Name (OPDRA)	6	2%
Labeling (DDMAC)	14	4%
Other	16	4%
Total	396	100%

3. Which level of NDA review, including administrative review, do you primarily conduct?

	Responses	Percent
Primary review	265	68%
Secondary review (e.g., team leader)	64	16%
Tertiary review (e.g., division director)	23	6%
Other	36	9%
Total	388	100%

5. In which office within CDER do you work? (If you work for more than one office, please select the office for which you do the majority of your work.)

	Responses	Percent
ODE I	60	15%
ODE II	43	11%
ODE III	37	9%
ODE IV	53	14%
ODE V	28	7%
Office of New Drug Chemistry	49	13%
Office of Biostatistics	34	9%
Office of Clinical Pharmacology and Biopharmaceutics	38	10%
Office of Post Marketing Drug Risk Assessment	21	5%
Division of Drug Marketing, Advertising, and Communication	17	4%
Other	10	3%
Total	390	100%

8. Since you have been at CDER, about how many NDAs have you reviewed partially or fully?

	Responses	Percent
Less than 5	95	25%
5-10	87	22%
11-15	65	17%
16-20	27	7%
More than 20	113	29%
Total	387	100%

9. Based on your experience, to what extent do you agree or disagree with the following statement, "The NDA review process allows for in-depth, science-based reviews."

	Responses	Percent
Strongly agree	141	37%
Somewhat agree	173	45%
Neither agree nor disagree	22	6%
Somewhat disagree	37	10%
Strongly disagree	8	2%
Total	381	100%

10. In the time you have been at CDER, has the NDA review process gotten better or worse in terms of allowing for in-depth, science-based reviews?

	Responses	Percent
Much better	38	10%
Somewhat better	79	21%
No change	143	38%
Somewhat worse	95	25%
Much worse	22	6%
Total	377	100%

12. Based on your experience, how often do NDAs, including amendments submitted during the PDUFA time clock, contain enough data to adequately assess the SAFETY of a drug?

	Responses	Percent
All of the time	6	2%
Most of the time	203	56%
Some of the time	115	32%
Rarely	31	9%
Never	6	2%
Total	361	100%

13. In your opinion, to what extent would additional SAFETY data improve CDER's ability to adequately assess the safety of a drug?

	Responses	Percent
To a great extent	128	36%
To some extent	180	51%
To a small extent	44	12%
To no extent	2	1%
Total	354	100%

14. Based on your experience, how often do NDAs, including amendments submitted during the PDUFA time clock, contain enough data to adequately adequately assess the EFFICACY of a drug?

	Responses	Percent
All of the time	14	4%
Most of the time	228	68%
Some of the time	83	25%
Rarely	8	2%
Never	1	0%
Total	334	100%

15. In your opinion, to what extent would additional EFFICACY data improve CDER's ability to adequately assess the efficacy of a drug?

	Responses	Percent
To a great extent	94	29%
To some extent	160	49%
To a small extent	66	20%
To no extent	6	2%
Total	326	100%

16. Based on your experience, how often do NDAs, including amendments submitted during the PDUFA time clock, contain enough data to adequately assess the QUALITY of a drug?

	Responses	Percent
All of the time	7	2%
Most of the time	183	57%
Some of the time	97	30%
Rarely	26	8%
Never	7	2%
Total	320	100%

17. In your opinion, to what extent would additional data on the QUALITY of the drug improve CDER's ability to adequately assess the quality of a drug?

	Responses	Percent
To a great extent	97	30%
To some extent	153	48%
To a small extent	63	20%
To no extent	8	2%
Total	321	100%

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18. Based on your experience, to what extent do you agree or disagree with the following statement, "For a PRIORITY NDA, there is enough time under the PDUFA time clock of 6 months to conduct an in-depth, science-based review."

	Responses	Percent
Strongly agree	16	4%
Somewhat agree	73	20%
Neither agree nor disagree	66	18%
Somewhat disagree	122	33%
Strongly disagree	96	26%
Total	373	100%

19. Based on your experience, to what extent do you agree or disagree with the following statement, "For a STANDARD NDA, there is enough time under the PDUFA time clock of 10 months to conduct an in-depth, science-based review."

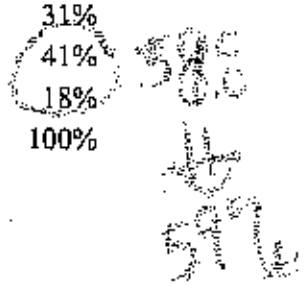
	Responses	Percent
Strongly agree	70	19%
Somewhat agree	162	43%
Neither agree nor disagree	49	13%
Somewhat disagree	76	20%
Strongly disagree	18	5%
Total	375	100%

20. Based on your experience, to what extent do secondary reviews, and interactions with secondary reviewers, provide a reliable check on the quality of the primary review?

	Responses	Percent
To a great extent	159	43%
To some extent	155	41%
To a small extent	49	13%
To no extent	11	3%
Total	374	100%

21. Based on your experience, to what extent do you have the time to participate in professional development activities that contribute to your ability to conduct an effective review?

	Responses	Percent
To a great extent	39	10%
To some extent	116	31%
To a small extent	156	41%
To no extent	66	18%
Total	377	100%



22. Would you like to see more written guidance from CDER on how to perform your review or review function?

	Responses	Percent
Yes	90	24%
No	282	76%
Total	372	100%

24. Based on your experience, how helpful do you find the review template for your discipline?

	Responses	Percent
Very helpful	65	17%
Somewhat helpful	150	40%
Rarely helpful	51	13%
Not at all helpful	46	12%
I have not used the template for my discipline	26	7%
Not applicable; there is no template for my NDA review function	40	11%
Total	378	100%

25. Have you ever been pressured to approve or recommend approval for an NDA despite reservations about the safety, efficacy, or quality of the drug?

	Responses	Percent
Yes	63	18%
No	297	82%
Total	360	100%

27. Based on your experience, to what extent do you agree or disagree with the following statement, "The NDA review process adequately integrates information across review disciplines."

	Responses	Percent
Strongly agree	99	26%
Somewhat agree	184	48%
Neither agree nor disagree	44	12%
Somewhat disagree	43	11%
Strongly disagree	11	3%
Total	381	100%

74%

283/381

28. Based on your experience, how helpful is interacting with your immediate supervisor during the NDA review in terms of contributing to an effective NDA review process?

	Responses	Percent
Very helpful	206	54%
Somewhat helpful	122	32%
Rarely helpful	40	11%
Not at all helpful	11	3%
Total	379	100%

29. Based on your experience, how helpful is interacting with the sponsor during the NDA review in terms of contributing to an effective NDA review process?

	Responses	Percent
Very helpful	146	39%
Somewhat helpful	190	50%
Rarely helpful	37	10%
Not at all helpful	5	1%
Total	378	100%

30. Based on your experience, how helpful is interacting with the sponsor during the IND phase in terms of contributing to an effective NDA review process?

	Responses	Percent
Very helpful	232	64%
Somewhat helpful	110	30%
Rarely helpful	17	5%
Not at all helpful	5	1%
Total	364	100%

31. Based on your experience, how helpful are advisory committees in providing independent advice to CDER?

	Responses	Percent
Very helpful	69	19%
Somewhat helpful	210	59%
Rarely helpful	63	18%
Not at all helpful	16	4%
Total	358	100%

32. Based upon your experience, to what extent does the work environment at CDER allow for the expression of differing scientific opinions related to NDA decisions?

	Responses	Percent
To a great extent	109	29%
To some extent	192	50%
To a small extent	69	18%
To no extent	12	3%
Total	382	100%

33. Based on your experience, to what extent does CDER have adequate procedures in place to address scientific disagreements that arise between review team members?

	Responses	Percent
To a great extent	62	17%
To some extent	164	45%
To a small extent	97	27%
To no extent	40	11%
Total	363	100%

35. Based on your experience, how often does waiting for sponsors to respond to CDER data requests contribute to delays in the NDA review process?

	Responses	Percent
All of the time	36	10%
Most of the time	113	30%
Some of the time	191	51%
Rarely	29	8%
Never	3	1%
Total	372	100%

36. Based on your experience, how often do submissions by sponsors not requested by CDER contribute to delays in the NDA review process?

	Responses	Percent
All of the time	11	3%
Most of the time	51	14%
Some of the time	214	60%
Never	26	7%
Rarely	55	15%
Total	357	100%

37. Based on your experience, how often does the process of CDER and sponsors trying to reach an agreement over the labeling contribute to delays in the NDA review process?

	Responses	Percent
All of the time	16	4%
Most of the time	99	27%
Some of the time	181	50%
Rarely	60	17%
Never	7	2%
Total	363	100%

38. Based on your experience, how often do reviewer workloads contribute to delays in the NDA review process?

	Responses	Percent
All of the time	69	18%
Most of the time	143	38%
Some of the time	127	34%
Rarely	24	6%
Never	10	3%
Total	373	100%

40. Based on your experience, how often are NDAs formatted in such a way that reviewers need to spend time reorganizing the data and information before beginning their review?

	Responses	Percent
All of the time	39	11%
Most of the time	114	31%
Some of the time	178	48%
Rarely	36	10%
Never	2	1%
Total	369	100%

41. Based on your experience, how would you describe the amount of quality improvement activities that CDER conducts to monitor and improve the NDA review process (e.g., retrospective reviews of past NDA decisions)?

	Responses	Percent
Too much	38	12%
Just the right amount	133	41%
Not enough	156	48%
Total	327	100%

42. How confident are you that CDER's final decisions adequately assess the safety of a drug?

	Responses	Percent
Completely confident	48	13%
Mostly confident	194	52%
Somewhat confident	117	31%
Not at all confident	17	5%
Total	376	100%

64%

43. How confident are you that CDER's final decisions adequately assess the efficacy of a drug?

	Responses	Percent
Completely confident	60	16%
Mostly confident	229	62%
Somewhat confident	72	19%
Not at all confident	9	2%
Total	370	100%

78.1%

44. How confident are you that CDER's labeling decisions adequately address key safety concerns?

	Responses	Percent
Completely confident	44	12%
Mostly confident	216	58%
Somewhat confident	91	24%
Not at all confident	21	6%
Total	372	100%

69.89% ≈ 70%

45. How confident are you that CDER adequately monitors the safety of prescription drugs once they are on the market?

	Responses	Percent
Completely confident	21	6%
Mostly confident	102	28%
Somewhat confident	~~172~~	47%
Not at all confident	71	19%
Total	366	100%

243

~~66~~ 70

Somewhat or Not

243/366 = 66%

52. What is the best time of day to call you at the above number? (OPTIONAL)

	Responses	Percent
Morning	44	60%
Afternoon	29	40%
Total	73	100%