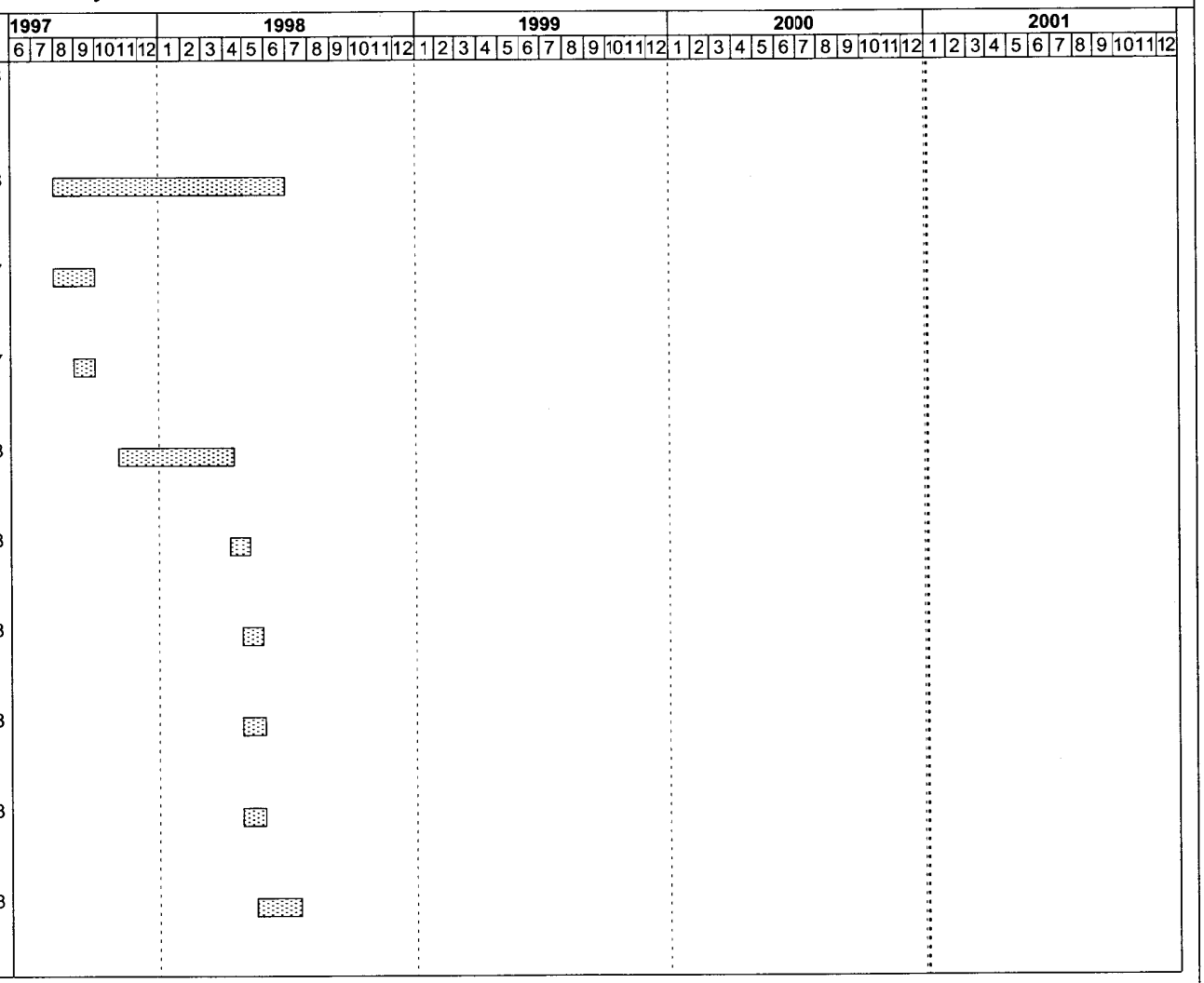
Rollout for U.S.-EC MRA Implementation

Pre-Entry | Transitional | End of Transit. Operational

ID	Task Name	Start	Finish
1	**Pre-Ratification Phase (Pre-Entry)**	6/20/97	12/7/98
2	Develop 20 Additional Guidance Documents	8/1/97	6/30/98
3	Issue Plain Talk Overview	8/1/97	9/30/97
4	Establish Center WG	9/1/97	9/30/97
5	Develop Criteria for Designating EU CABS	11/3/97	4/15/98
6	Publish Proposed FR on EU/MRA & Receive Comments	4/10/98	5/11/98
7	Submit Criteria to EU for EU CABS	5/1/98	5/29/98
8	Receive Criteria for US CABS	5/1/98	6/1/98
9	Select Joint Sectorial Committee Rep	5/1/98	6/1/98
10	Issue NOA and Draft Guidance Document on CDRH Implementation Plan	5/20/98	7/20/98



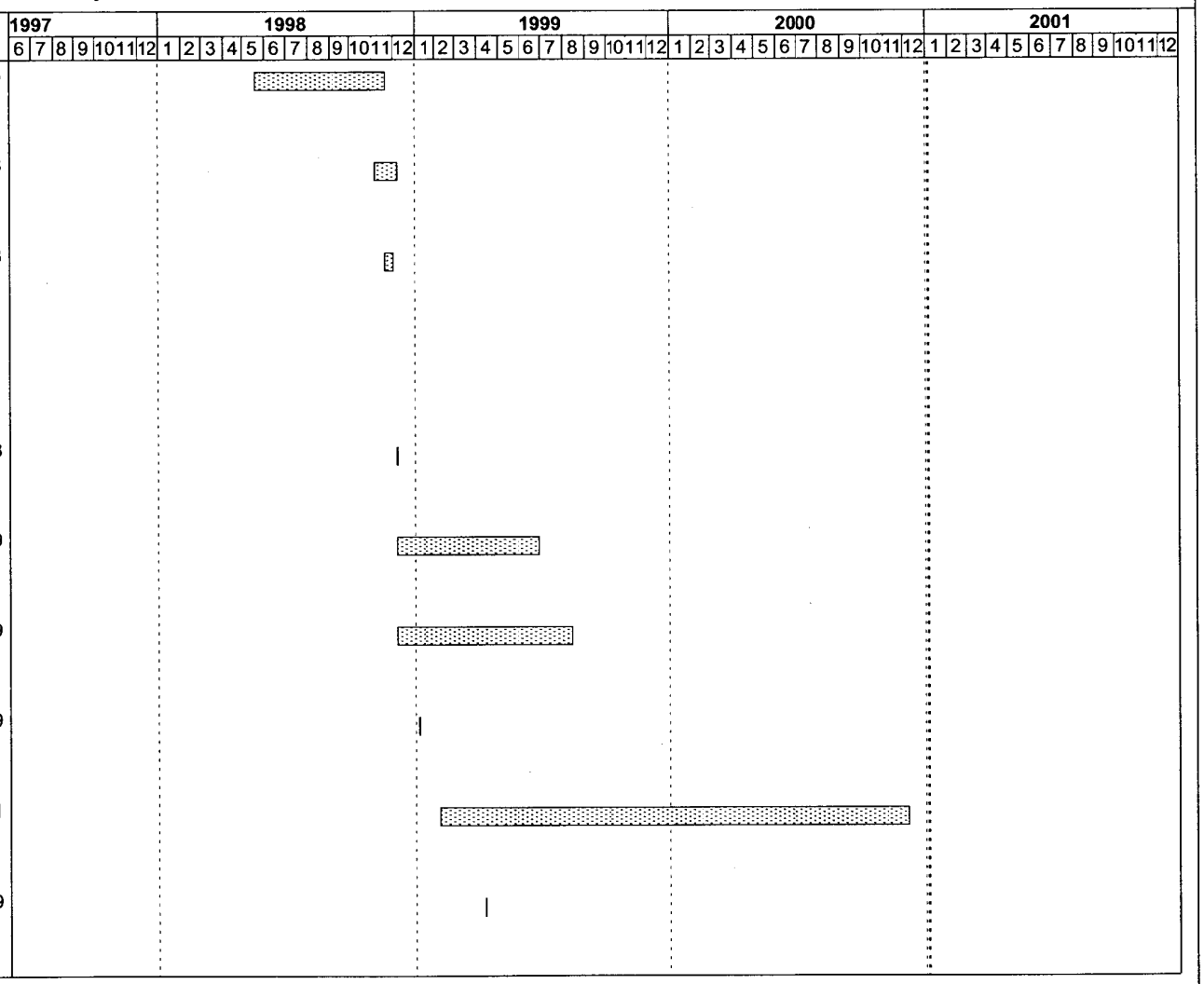
Project: US-EC/MRA Implementation2
Date: 1/4/01

Task | External Tasks | Project Summary

Rollout for U.S.-EC MRA Implementation

Pre-Entry | Transitional | End of Transit. Operational

ID	Task Name	Start	Finish
11	Call for US CABS	5/20/98	11/20/98
12	Publish FR on EU/MRA	11/6/98	12/7/98
13	Evaluate US CABS	11/20/98	12/1/98
14	**Post-Ratification (Transitional)**	12/7/98	12/5/01
15	Nominate US CABS to EU	12/7/98	12/7/98
16	Determine Information to be Included in Reports	12/7/98	6/28/99
17	Develop and Conduct First Training Program for EU CABS/CA	12/7/98	8/13/99
18	Issue NOA and Final Guidance Document on CDRH Implementation Plan	1/6/99	1/6/99
19	FDA Proposes and EU Accepts First expansion of devices (class II) eligible under MRA	2/8/99	1/2/01
20	Receive EU Nominated CABS	4/12/99	4/12/99



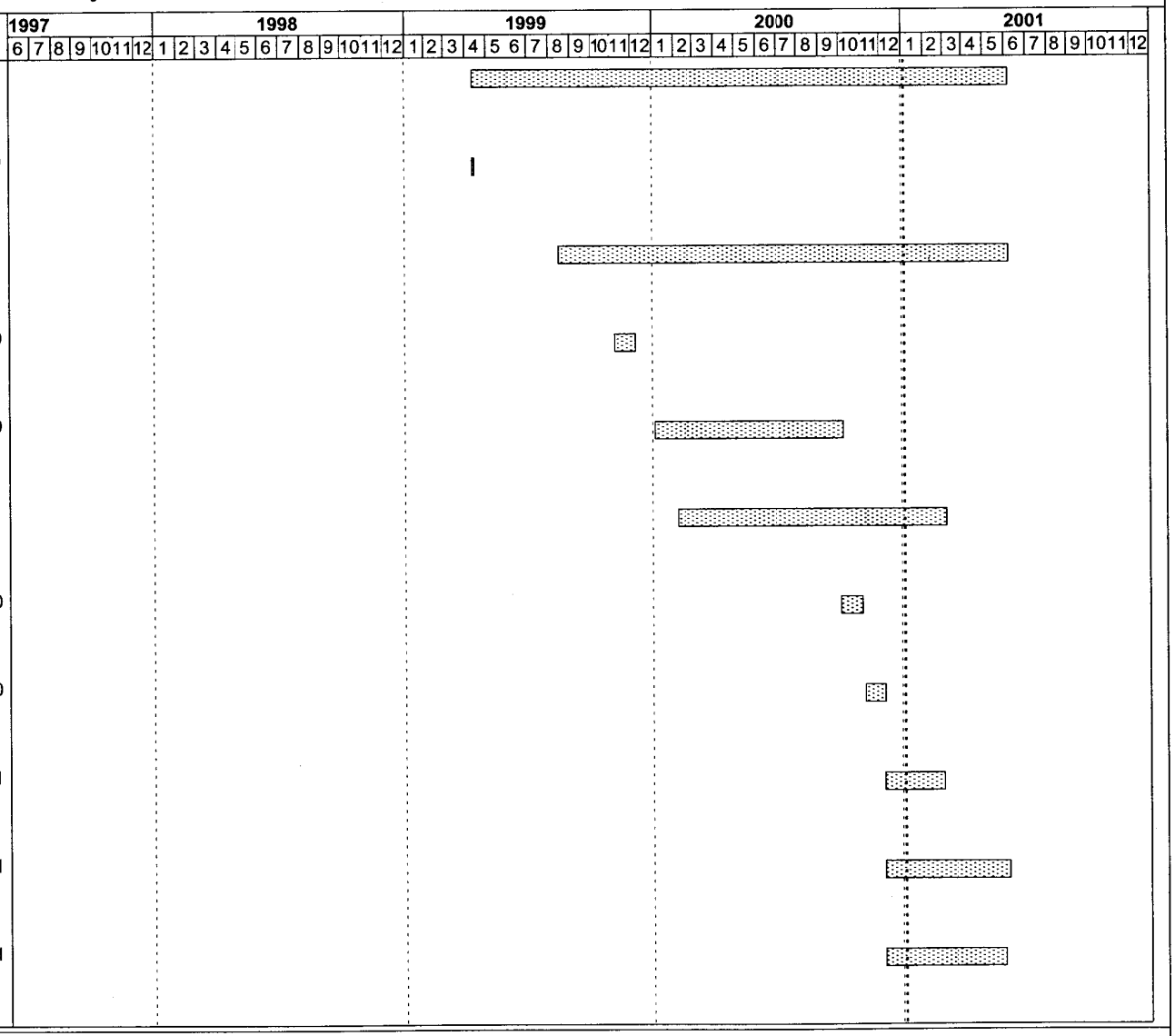
Project: US-EC/MRA Implementation2
Date: 1/4/01

Task | External Tasks | Project Summary

Rollout for U.S.-EC MRA Implementation

Pre-Entry | Transitional | End of Transit. Operational

ID	Task Name	Start	Finish
21	Evaluate EU Nominated CABS for Transitional Period	4/12/99	6/6/01
22	Conduct First Training of US CABS	4/12/99	4/14/99
23	Exchange Reports, Monitor & Assess EU CABS	8/16/99	6/6/01
24	Prepare 1st Annual Report	11/8/99	12/7/99
25	Access and Submit Supporting Evidence to EU	1/5/00	10/6/00
26	Receive EU Supporting Evidence	2/7/00	3/5/01
27	Issue NOA & Draft MRA Implementation Plan for Transition	10/3/00	11/2/00
28	Prepare 2nd Annual Report	11/7/00	12/7/00
29	Develop System to Exchange Adverse Event Reports	12/7/00	12/5/01
30	Develop Criteria for Assessing CAES for Listing	12/7/00	6/6/01
31	Develop and Conduct Second Training Program for EU CABS/CA	12/7/00	5/31/01



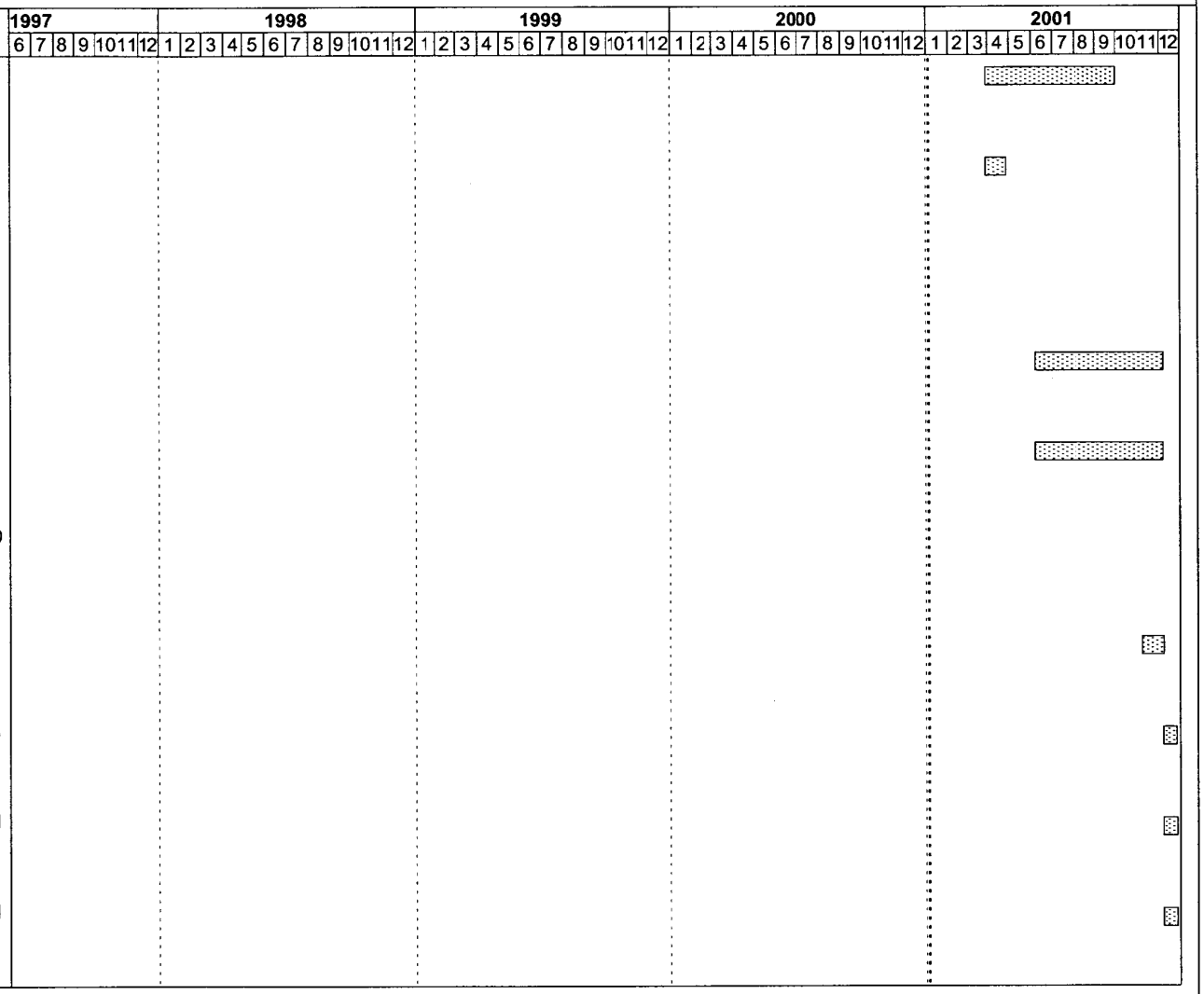
Project: US-EC/MRA Implementation2
Date: 1/4/01

Task | External Tasks | Project Summary

Rollout for U.S.-EC MRA Implementation

Pre-Entry | Transitional | End of Transit. Operational

ID	Task Name	Start	Finish
32	FDA Proposes and EU Accept Second Expansion of Devices (class II) eligible under MRA	3/30/01	9/30/01
33	Issue NOA and Final MRA Implementation Plan for Transition	3/30/01	4/27/01
34	**End of Transition**	6/7/01	12/6/01
35	Determine if CABS are Eligible for Listing	6/7/01	12/6/01
36	Review CABS Not Yet Listed & Identify Deficiency	6/7/01	12/6/01
37	**Operational Period**	12/7/10	12/7/10
38	Prepare 3rd Annual Report	11/7/01	12/7/01
39	Monitor CABS	12/7/01	12/27/01
40	Maintain Current List of CABS	12/7/01	12/28/01
41	Implement Adverse Event Reporting	12/7/01	12/28/01



Project: US-EC/MRA Implementation2
Date: 1/4/01

Task | External Tasks | Project Summary

Rollout for U.S.-EC MRA Implementation

Pre-Entry | Transitional | End of Transit. Operational

ID	Task Name	Start	Finish
42	Accept (Normally Endorsed) Report	12/7/01	12/28/01

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1998: 1 2 3 4 5 6 7 8 9 10 11 12
1999: 1 2 3 4 5 6 7 8 9 10 11 12
2000: 1 2 3 4 5 6 7 8 9 10 11 12
2001: 1 2 3 4 5 6 7 8 9 10 11 12

Project: US-EC/MRA Implementation2
Date: 1/4/01

Task | External Tasks | Project Summary