2025 Current Fiscal Year Report: Device Good Manufacturing Practice Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2025

3. Committee or Subcommittee	3b. GSA Committee No.
Device Good Manufacturing Practice Advisory Committee	841

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	05/17/1987		

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Statutory (Congress Created)

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 360c-j	05/28/1976	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 0 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 0

Meetings and Dates

No Meetings

	Current FY	Next FY

18a(1). Personnel Pmts to Non-Federal Members	$0.00	$0.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$0.00	$0.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	$0.00	$0.00
18d. Other (all other funds not captured by any other cost category)	$0.00	$0.00
18e. Total Costs	$0.00	$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

20a. How does the Committee accomplish its purpose?

The Device Good Manufacturing Practice Advisory Committee reviews proposed requirements for good manufacturing practices (GMPs) governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices. The committee reviews and provides recommendations on proposed GMP regulations and on petitions for exemption from GMP's

regulations.

20b. How does the Committee balance its membership?
By law, the composition of this committee is: three government representatives (local, state and federal); two health professionals; two industry representatives; and two representatives from the general public.

20c. How frequent and relevant are the Committee Meetings?
The committee meets approximately once a year or as required. In FY 2024 no meeting was held and none is planned for the coming year.

20d. Why can't the advice or information this committee provides be obtained elsewhere?
This statutory committee is required under the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act.

20e. Why is it necessary to close and/or partially closed committee meetings?
N/A

21. Remarks
Although this committee did not meet in FY 2024, considerable time was devoted to reviewing applications for new nominees, maintaining associated records for these activities, and streamlining paper processes within FDA. In addition, time was also spent in the routine care and maintenance of the committee: the development of a financial report for this website; updating the roster and number of vacancies on our website; completing the annual ethics report; reviewing financial disclosures of current members, providing ethics training and also

reviewing financial disclosures for potential committee members. The Agency will continue to publish request for nominations in the Federal Register Notices to receive nominations to fill current and up-coming vacancies. Update on the following committee members: Scott Sardeson (7/30/2020 -5/31/2024), Gordon Gillerman (12/08/2021 - 5/31/2024), and Elise Owen (01/11/2022 -5/31/2024) profile was accidentally deleted but was re-entered.

Designated Federal Officer

James P Swink Public Health Analyst, Center for Devices and Radiological Health/FDA

Committee Members	Start	End	Occupation	Member Designation
Culbertson, Jeri	12/08/2021	05/31/2025	Infection Prevention Consultant	Special Government Employee (SGE) Member
David, Yadin	01/11/2022	05/31/2025	Principal, Biomedical Engineering Consultants, LLC	Special Government Employee (SGE) Member
Dimmick, Lisa	04/24/2018	05/31/2026	Team Leader, Medical Radiation Team, U.S. Nuclear Regulatory Commission	Regular Government Employee (RGE) Member
Kuo, Chiaoyun (Benson)	01/11/2022	05/31/2026	Director, Regulatory Consulting Center, Assistant Professor, Department of Regulatory and Quality Sciences, School of Pharmacy, University of Southern California	Special Government Employee (SGE) Member
Phillips, Robert	04/24/2018	05/31/2025	Vice President, Quality and Technology, North America, Siemens Healthineers	Representative Member

Ray, Edward	06/01/2024	05/31/2028	Associate Professor of Surgery, Cedars-Sinai Medical Center, Los Angeles, CA	Special Government Employee (SGE) Member

Number of Committee Members Listed: 6

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Device Good Manufacturing Practice Advisory Committee supports FDA's mission and strategic action plan by reviewing proposed regulations and guidance documents intended to ensure the safety and effectiveness of medical devices and making recommendations to the Agency.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments
NA

What are the cost savings associated with this committee?

	Checked if Applies
None	☐
Unable to Determine	☑
Under $100,000	☐
$100,000 - $500,000	☐
$500,001 - $1,000,000	☐
$1,000,001 - $5,000,000	☐
$5,000,001 - $10,000,000	☐
Over $10,000,000	☐
Cost Savings Other	☐

Cost Savings Comments
The utilization of the Device Good Manufacturing Practice Advisory Committee enables the Agency to obtain required and frequently scarce input from external medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?
2

Number of Recommendations Comments
The Committee made 2 recommendations from FY 03 through FY 24.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
75%

% of Recommendations Fully Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature and therefore, the Agency has the option of not implementing the

advice. This number representatives an approximation of the percentage of recommendations that the agency has fully implemented or plans to fully implement.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
0%

% of Recommendations Partially Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments
Information is made available to the public when appropriate, and feedback is sometimes indirect. Actions are publicly available when implemented, e.g., publishing a final regulation or guidance document, which requires the support of various internal FDA components.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☑
Proposed legislation	☐
Approved grants or other payments	☐
Other	☐

Action Comments
NA

Is the Committee engaged in the review of applications for grants?
No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	

Access Comments

N/A