

Provisional Translation (as of April 2026).

This English document has been prepared for reference purpose only. In the event of inconsistency and discrepancy between the Japanese original and the English translation, the Japanese text shall prevail.

PMDA/CPE Notification No. 0401008

April 1, 2020

To (Note)

Hiroyuki Arai, Director of Center for Product Evaluation,  
Pharmaceuticals and Medical Devices Agency  
(Official seal omitted)

### How Request Forms Related to a Trial of Consultations on Innovative Manufacturing Technologies for Drugs Are Received, etc.

We appreciate your understanding and cooperation with the operations including reviews of the Pharmaceuticals and Medical Devices Agency.

The implementation guidelines for face-to-face advice, confirmation of certification, etc. conducted by PMDA are specified in the “Implementation Guidelines for Face-to-face Advice, Confirmation of Certification, etc. Conducted by Pharmaceuticals and Medical Devices Agency” (PMDA Notification No. 0302070 of the Pharmaceuticals and Medical Devices Agency, dated March 2, 2012; hereinafter referred to as the “Implementation Guidelines Notification”).

We have decided to newly introduce a consultation system for innovative manufacturing technologies for drugs under the Implementation Guidelines Notification.

PMDA will implement these consultations on a trial basis for the time being, and handle the requests for implementation, etc. as follows, not according to the provisions in “4. Request for consultation” and “5. Notification of implementation, etc. of face-to-face advice” in Attachment 32 of the Implementation Guidelines Notification. Please inform the member companies of your association of this matter.

#### Note

##### 1 Request for consultation

As multiple departments are involved in one of these consultations and on-site confirmation is expected, the number of consultations that can be provided is limited. Therefore, prior to application for consultation, parties that wish to consult are invited twice a year, and applicants are selected from these parties by drawing.

When requesting a consultation on innovative manufacturing technologies for drugs, eligibility for these consultations needs to be confirmed first by checking the content in a pre-consultation meeting. Therefore, please enter necessary information in Attached Form 7 of the Implementation Guidelines Notification, the “Application form for inquiries in pre-consultation meetings for drugs” (hereinafter referred to as the “Application form for pre-consultation meetings”) and submit it to the Review Management Division, Office of Review Management via e-mail, fax, postal mail, or bringing it in person. In principle, the Application form for pre-consultation meetings will be received from 9:30 a.m. to 12:00

p.m. on the fourth Tuesday in April and October. However, we may change the date and time depending on the situation. Please check the PMDA website.

The person in charge at PMDA will communicate the eligibility for these consultations after the pre-consultation meeting. Please enter necessary information in Attached Form 23 of the Implementation Guidelines Notification, “Request form for consultations on innovative manufacturing technologies for drugs” (hereinafter referred to as the “Request form”) and submit it to the Review Management Division, Office of Review Management via e-mail, fax, postal mail, or bringing it in person. In principle, we will receive the Request form from 10:00 a.m. to 4:00 p.m. on the third Tuesday in May and November. If we change the date and time, we will provide instructions separately.

Please note that we do not accept the forms that arrive outside the designated hours.

(Points to consider)

- The contents of consultations shall be 1 technology per consultation, in principle.
- If various conditions can be applied in the same process, the consultation will be provided with the formulation manufactured most recently in mind. The definition of 1 technology as the scope of each consultation will be individually adjusted at pre-consultation meetings.
- No more than one application form for pre-consultation meetings or the Request form shall be received per company each time.

Contact for application and inquiry (if any):

Review Management Division, Office of Review Management, Pharmaceuticals and Medical Devices Agency

Shin-Kasumigaseki Building, 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013

Phone (direct) 03-3506-9556

Fax 03-3506-9443

E-mail address: [shinyaku-uketsuke@pmda.go.jp](mailto:shinyaku-uketsuke@pmda.go.jp)

Reception hours: From 9:30 a.m. to 5:00 p.m., from Monday to Friday (excluding non-business days such as national holidays). The Request form submitted according to 1 above will be received from 10:00 a.m. to 4:00 p.m. on the third Tuesday in May and November.

## 2 Number of consultations conducted

In principle, the application for up to one consultation will be handled each time.

## 3 Notification of implementation, etc. of consultations

(1) If it is judged difficult to implement because of the large number of requests, according to the scores based on the “points of technologies for which consultation is requested” in 4 below, the request for consultation will be handled in the descending order of the points. In addition, if it is still difficult to implement after the above selection, a lottery will be carried out. The specific method of lottery is shown in the table.





4 Points for technologies for which consultations are requested

For the technologies for which consultations were requested, their points shall be the scores based on the past applications.

When requesting a consultation on the same technology for which the Request form for consultations on innovative manufacturing technologies for drugs was submitted, but the consultation could not be provided because of PMDA's circumstances, the score will be as follows for each number of times the consultation was not provided.

Note that this score can be added only when a Request form for consultations for the same technology is submitted continuously every time. At the time of the consultation, the number of times the consultation was not provided becomes 0.

Number of times consultation was not provided	Score
Once	1 point
Twice	2 points
3 times	3 points
4 times	4 points
5 times or more	5 points