

<PMDA's Consultation Service>

Requirements for individual products are assessed on a case-by-case basis and answered in PMDA's consultations (fees applicable).

If you seek a response to your question from us Japanese regulatory authority, we strongly recommend you to request PMDA's consultation service while making product-specific information readily available.

<http://www.pmda.go.jp/english/review-services/consultations/0002.html>

Consultation service on R&D or regulatory submission involves consultation fee, while topics to be discussed in such consultations may be clarified free of charge in a pre-consultation meeting.

Since required procedures, communication and forms with PMDA are all processed in Japanese, we strongly recommend you to appoint a Japanese Marketing Authorization Holder (MAH) if you intend to enter into Japanese market. Accordingly, it is also recommended to request for our consultation service through the intermediary of such MAH.

When you are requesting the free pre-consultation meeting only, accompanying an interpreter instead of the appointed Japanese MAH may be acceptable.

Consultation fees and other user fees are shown in Table 13 of PMDA's Annual Report.

Please note that fees may be changed without notice.

<http://www.pmda.go.jp/files/000214925.pdf>