

Recent Regulatory Advancements on Cell and Gene Therapy Products in Japan

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Updates on Regulations and Notifications

Release Testing Exemption of the Imported Products

Questions and answers (Q&A) on release testing of the imported regenerative medical products

May 30, 2024, PSB/MDED, PSB/CLD Administrative Notice

- If criteria [1]-[4] described in the notice are all met, release testing of the imported product by the domestic manufacturer in Japan is not always necessary.



Q&A on release testing of the imported products

Revision of “the Standards for Biological Raw Materials” (On-going)

“the Standards for Biological Raw Materials”

Latest partial revision on 2018, MHLW Notification No. 37

- Now in Japan, for HIV, HBV, HCV and HTLV, a second test must be conducted on the donor screening tests for allogeneic human cells in consideration of the window period.
 - If a donor has been tested for NAT with sufficient sensitivity in the first test, a second test will not be required. (risk-based approach)



The Standards for Biological Raw Materials (Current version)

PMDA Washington D.C. Office General Consultation Service

1. Scope of Consultation

- Information on regulations or procedures under the PMD. Act. of Japan
- A general explanation of basic matters for practical regulatory application of new seeds for drugs, medical devices, and regenerative medicine products
- An explanation of PMDA's services, and support in selecting one or more consultation categories provided by PMDA's review team in Japan



PMDA
Washington D.C.
Office Information

2. How we provide a general consultation

1. Please fill out the “Application Form for General Consultation” and submit to the following e-mail address. You may submit materials necessary for the purpose of the consultation with a list of attached materials.

Consultation[at]dc-office.pmda.go.jp

2. We will contact you to schedule a general consultation by e-mail.
3. A consultation will be provided at PMDA Washington D.C. office or via an online meeting using Microsoft Teams. (normally for 30 minutes or less per application)



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