General FAQs for Good Distribution Practice:

1. What is Good Distribution Practice (GDP)?

Good Distribution Practice or GDP is defined as the measures that need to be considered in the storage, transportation and distribution of any registered product / notified cosmetics and its related material such that the nature and the quality of the intended use is preserved when it reaches the consumer.

2. Why do we require GDP?

GDP may guide those who involve in the supply chain of any registered product / notified cosmetics in conducting their activities while ensuring the maintenance of high standards of quality assurance and integrity of the distribution processes.

As stated under the license, it is compulsory for all license holders to comply with the requirements stated under the current Good Distribution Practice Guideline, to ensure that the products are well preserved for their intended quality, safety and efficacy when it reaches the end users.

According to Regulation 7 (1) (b) Control of Drug and Cosmetics Regulations 1984, unless being licensed, any person or company may not sell, import, supply or possess any registered products.

According to Section 12 (1) of the Sale of Drugs Act 1952, any person convicted of an offense in violation of the regulation may be liable to a fine not exceeding RM25,000 or to imprisonment not exceeding 3 years or to both. For the second offense, they could be fined not exceeding RM50,000 or imprisonment not exceeding 5 years or both. And under section 12 (2) of the Drugs Sales Act 1952, any body corporate who commits an offence against this regulation shall be liable on conviction to a fine not exceeding RM50,000 for the first offense and for a subsequent offence it shall be liable on conviction to a fine not exceeding RM100,000.

3. What is a GDP Inspection?

GDP inspection is an inspection conducted by NPRA or Pharmacy Enforcement Branch to verify the compliance status based on the requirements stated under current GDP guideline.

4. Who is subjected to GDP Inspection?

As a manufacturer / importer / wholesaler license holder, your company is responsible to fulfill GDP requirements and is subject to be inspected by NPRA or Pharmacy Enforcement Branch.

5. How do we prepare for GDP Inspection?

The scope of GDP inspection is based on the requirements stated in the current Guideline on Good Distribution Practice, available at our official NPRA website. You may refer to Annex 2: General Points to consider for Auditee for an overview of the scopes that will be covered during GDP inspection.

6. How long does an inspection may take?

The time required for an inspection depends on the scope of activities, the size of the site and the complexity of the relevant processes and can vary between half a day or up to two days.

7. **Do we need to undergo GDP Inspection prior to Importer / Wholesaler new license application?**

No need. You can apply new Importer / Wholesaler license beforehand and we will schedule a GDP Inspection afterwards.

However, if you intend to handle cold chain products or *Time and Temperature Sensitive Products* (TTSP), you need to undergo GDP Cold Chain Facility Inspection prior to license application by submitting official letter to Centre of Compliance and Quality Control, NPRA.

8. **What are the levels of GDP compliance?**

All the premises that has been inspected will be categorized into compliance level as below:

First-Time /Special Inspection	Satisfactory
	Unsatisfactory
Routine Inspection	Good
	Average
	Low

The compliance level will be determined based on inspection findings and informed via an official letter together with a GDP report.

9. **How frequent do we need to be inspected on GDP compliance?**

GDP inspection frequency may vary between once a year to up to once every 5 years.

10. **How NPRA determine inspection frequency?**

Inspection frequency will be determined based on risk factors such as compliance level, product ranges and size of company.

11. **What happens if we fail to comply with the GDP requirements?**

Companies who failed to comply with GDP requirements may face regulatory actions such as license revocation, suspension or cancellation of product registration.

12. **We are interested to import/wholesale registered products that are required to be stored under specific temperature. Is there any specific GDP requirement that we need to comply?**

Yes, the GDP compliance is applicable for all premises that handle registered products including cold chain products. The company requires to comply with the requirements stated under *Annex I: Management of Time and Temperature Sensitive Products, Guidelines of Good Distribution Practice**. The compliance level will be verified through ***GDP Cold Chain Facility Inspection*** carried out by NPRA.

It is mandatory for the importers/wholesalers of products that are required to be stored under specific storage conditions (also known as cold chain products or Time-Temperature Sensitive Products, TTSP) to understand and adhere to the requirements stated under the Annex-I.

(*Note: You may refer to *Supplementary Notes on Annex 1: Management of Time and Temperature Sensitive Products (TTSP) of Guideline on Good Distribution Practice* on the interpretation of certain clauses in the guideline.)

13. GDP Cold Chain Facility Inspection on our facility has been conducted by NPRA, what should we do next?

After the GDP inspection, the company is required to submit a Corrective Action Preventive Action (CAPA) report within a stipulated timeline for evaluation. Upon satisfactory evaluation, you may send in an application to the Licensing Section, Centre of Regulatory Coordination & Strategic Planning, NPRA to update your license to include the scope of cold chain management.

14. Our company is a licensed importer of the cold chain product, and we have appointed a third-party distributor to store and distribute our products. As we do not handle any physical goods, do we have to be inspected by NPRA?

Yes, as a licensed importer, your company is responsible to fulfill GDP requirements and is subjected to inspection by NPRA. It is also the responsibility of the license holder to ensure that the third party distributor/warehouse* (regardless the third party distributor/warehouse is licensed under NPRA) has the facility and capability to handle cold chain products so that the quality of the product will be preserved throughout the supply chain.

(*Note: Any appointed third-party distributor/warehouse operators might be subjected to inspection by NPRA)

15. We are currently operating a logistics company, do I need to have import/wholesale license to transport registered product?

Consider the following scenario:

Scenario	License Requirement
Our company offers logistic services only	No. However, the company is required to comply with the requirement of transportation as stated under the GDP guideline.
Our company offers warehousing & logistic services	No. However, the company is required to comply with the requirement of transportation as stated under the GDP guideline.
Our company acts as distributor for our clients. We involved in sales transaction, warehousing & logistics services.	Wholesaler License

16. Does NPRA issue any GDP certificates?

Currently, NPRA does not issue any GDP certificate to acknowledge GDP compliance nor permit any parties to issue such certificate on behalf.

17. Are we allowed to perform packaging activities in my business premise?

You may refer to the Explanatory Notes for Repacker as stated under the Drug Registration Guidance Document (DRGD) published by NPRA which can be obtained from our website (https://www.npra.gov.my) for further information.