FREQUENTLY ASKED QUESTIONS (FAQs) ABOUT GMP INSPECTION BY NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)

QUESTIONS

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Good Manufacturing Practice (GMP) Section
Centre of Compliance and Quality Control
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Q1: WHAT IS GOOD MANUFACTURING PRACTICE (GMP)?

A: Good Manufacturing Practice (GMP) is a standard that should be followed by manufacturers of registered pharmaceutical/ veterinary/ health supplements/ traditional products and/ or notified cosmetics to ensure that the product manufactured is safe, efficacious and of quality.

Q2: WHAT IS THE DEFINITION OF 'MANUFACTURING'?

A: According to the Control of Drugs and Cosmetics Regulations 1984 (CDCR 1984), the term 'manufacturing' is defined as:

a) The making or assembling of the product;

b) The enclosing or packing of the product in any container in a form suitable for administration or application, and the labelling of the container, and;

c) The carrying out of any process in the course of any of the foregoing activities.

Q3: WHY IS GMP STATUS OF A MANUFACTURER REQUIRED?

A: GMP compliance is **one of the requirements for product registration and/ or notification of cosmetics**, as well as to apply for a Manufacturer's Licence with the Drug Control Authority (DCA).

Uncontrolled manufacturing operations may be detrimental to consumer health and safety. GMP status attained gives assurance that the product manufactured is safe, efficacious and of quality and thus gaining consumer confidence.

Q4: HOW WILL MANUFACTURERS BE INSPECTED?

A: An inspection upon every manufacturer of registered products or notified cosmetics is required based on the requirements of the following guidelines:

GMP / GDP Guidelines	Product Type / Category
PIC/S Guide to Good Manufacturing Practice for Medicinal Products www.picscheme.org	Pharmaceuticals (Poison and Non-Poison) Veterinary Products
Guidelines on GMP for Traditional Medicines & Health Supplements, 1st Edition, 2008. www.npra.gov.my	Traditional Products Health Supplements
Annex 1, Part 10: Guidelines for Cosmetic Good Manufacturing Practice, Guidelines for Control of Cosmetic Products in Malaysia, 1st Revision, February 2017. www.npra.gov.my	Cosmetics
Guidelines on GMP for Veterinary Premixes, 1st Edition, 2015 www.npra.gov.my	Veterinary Products (Premixes)
Guidelines on Good Distribution Practice (GDP), 3rd Edition, 2018. www.npra.gov.my	** For activities related to the storage and distribution by manufacturers, importers and wholesalers (where applicable)

There are a few types of GMP inspection:

- Initial Inspection: An inspection conducted on new cosmetics manufacturer that have not notified any cosmetics.
- Pre-licensing: An inspection conducted on new manufacturers as a pre-requisite to register products and for applying Manufacturer's Licence.
- Pre-approval: An inspection conducted on new production line of licensed manufacturers.
- Pre-certification: An inspection conducted on premises that are not regulated by Drug Control Authority.
- Verification: An inspection conducted following a punitive action. Depending on the condition, verification inspection can be combined with routine inspection.

Please refer to User Manual Quest 3+ System Module: Compliance and Licensing on how to apply for an inspection via Quest 3+ system at https://www.npra.gov.my/index.php/en/quest3-system-basic/user-manual-for-quest-module.html

Q5: IF I AM CURRENTLY MANUFACTURING PRODUCTS AT HOME, WILL AN OFFICER CONDUCT AN INSPECTION AT MY HOME?

A: As required by the CDCR 1984, all registered products and notified cosmetics are to be manufactured within GMP compliant premises. The premise should be licensed by the local town council, Department of Environment and/ or Fire and Rescue Department.

In order to encourage new entrepreneurs to produce registered products/ notified cosmetics within GMP compliant premises, each entrepreneur is given a choice whether to build their own factory or appoint a GMP compliant contract manufacturer.

Q6: WHAT IF I WOULD LIKE TO BUILD A NEW MANUFACTURING PREMISE?

A: Kindly refer to the diagram below as a guidance before setting up a new manufacturing premise.

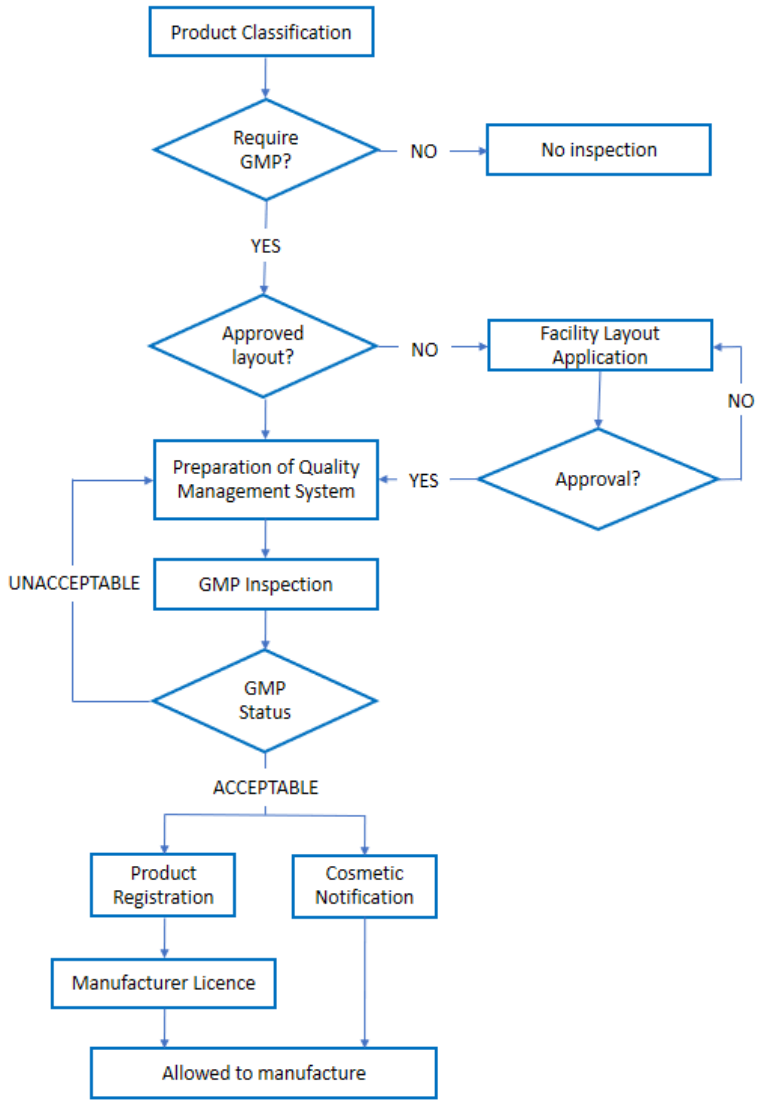

Figure 1: Setting up GMP Manufacturing Facility Process Flow

The manufacturer may submit an application for the Evaluation of Manufacturing Plant Layout (BPFK-503) to the Good Manufacturing Practice Section, Centre of Compliance and Quality Control for evaluation and approval. The form is accessible at https://www.npra.gov.my/easyarticles/images/users/1050/BPFK-503-Borang-Penilaian-Pelan-Susun-Atur-v1.2020.pdf

Q7: WHAT ARE THE LEVELS OF GMP COMPLIANCE?

A: GMP compliance is rated as Acceptable or Unacceptable. The level of compliance is determined by the weaknesses/ non-conformances found during an inspection.

Q8: IS AN INSPECTION CARRIED OUT ONLY ONCE OR WILL IT BE DONE ROUTINELY?

A: In general, all manufacturers of registered products/ notified cosmetics will be inspected routinely. The frequency for inspection is determined according to the risk level of the product manufactured, as well as the latest GMP compliance rating.

For pharmaceutical manufacturers, inspections will be scheduled according to the Risk Based Inspection Planning module, which takes into account aspects such as site complexity, process complexity, product complexity, number of deficiencies from the recent inspection, any changes to the site after the previous inspection, product complaints and/ or regulatory actions received.

Q9: HOW MUCH DOES A GMP INSPECTION COST?

A: Please refer to the document (Caj Baru Bayaran Pemeriksaan Amalan Perkilangan Baik bagi Premis Tempatan dan Luar Negara) displayed under 'Circulars & Directives' on the NPRA website at https://www.npra.gov.my/images/Circulars_Directive/Regulatory_Information/page-16/Caj-Baru-Bayaran-Pemeriksaan-APB.pdf

Q10: HOW IS A GMP INSPECTION CONDUCTED?

A: Prior to an inspection, an officer is appointed as the lead inspector and will determine the date of inspection, as well as a proposed inspection plan. Each inspection is led by a lead inspector and may be joined by other inspectors. The number of inspectors required is based on the size of the facility, type of product manufactured and inspection scope.

- An inspection is preceded by an Opening Meeting, during which the objective, related guidelines, scope and inspection areas will be explained.
- After the Opening Meeting, the inspection of the manufacturing premises, store premises, laboratory and documentation system shall commence.
- At the end of the inspection, the lead inspector (and other accompanying inspectors) will present inspection findings during a Closing Meeting. The GMP compliance status will be determined during the Premises Inspection Evaluation Committee Meeting.

Q11: WILL INSPECTION FINDINGS BE DISCUSSED OR REPORTED?

A: Generally, a Good Manufacturing Practice (GMP) Inspection Report will be issued after each inspection is conducted. The manufacturer is expected to provide feedback regarding corrective and preventive actions (CAPA) taken towards each reported finding within a stipulated timeframe. The format for CAPA feedback can be access via this link: https://www.npra.gov.my/index.php/en/component/content/article/2-uncategorised/988-capa?Itemid=437

Q12: WHAT HAPPENS IF A MANUFACTURER DOES NOT COMPLY WITH GMP REQUIREMENTS?

A: Punitive actions can imposed on manufacturers and will be determined by the Premises Inspection Evaluation Committee Meeting.

Registered products manufacturers:

i) New product registration application will be rejected
ii) Product registration renewal will not be allowed
iii) Currently registered products will be suspended

Notified cosmetics manufacturers:

i) New cosmetic notification application will be rejected
ii) Renewal of cosmetic notification will not be allowed

The Manufacturer's License may be revoked by the Director of Pharmaceutical Services, according to Regulation 17(1) of the Control of Drugs and Cosmetics Regulations 1984.

Q13: DO NOTIFIED COSMETICS MANUFACTURERS REQUIRE A MANUFACTURER'S LICENCE?

A: Currently, no Manufacturer's Licence is required for cosmetics manufacturers. A cosmetics manufacturer is allowed to manufacture a cosmetic product once it is notified. However, the manufacturer is still required to comply with GMP requirements.

Q14: WHAT IS GMP CERTIFICATE?

A: A GMP Certificate is issued for the purpose of exporting locally manufactured registered products. It endorses that the local manufacturer complies with the current GMP requirements. These certificates are required by the overseas regulatory agencies for the purpose of product registration in the respective countries.

The application of GMP Certificate by local manufacturers shall be submitted online via the QUEST3+ system. Please refer to User Manual Quest 3+ System Module: Compliance and Licensing on how to apply for GMP Certificate via Quest 3+ system at https://www.npra.gov.my/index.php/en/quest3-system-basic/user-manual-for-quest-module.html

For further clarifications, please contact
Officer on Duty, Centre of Compliance and Quality Control at 03-78018445.