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Good Manufacturing Practices in Thailand

In Thailand, Good Manufacturing Practices (GMP) were first implemented in 1979 for local pharmaceutical manufacturers under the Drug Act 1967 (B.E. 2510). In 1984, the Thai Food and Drug Administration (FDA) campaigned seriously for the pharmaceutical industry, and ultimately managed to update pharmaceutical standards, with the first Guidelines to Good Manufacturing Practices being issued in 1987. Also, as a way to standardize pharmaceutical factories, the Thai FDA began to officially grant GMP Certificates in 1989.

By 2001, Thailand had adopted GMP Guidelines based on internationally recognized World Health Organization (WHO) standards, and in the same year, the Thai FDA applied the new guidelines to all local manufacturers and overseas manufacturers that intended to export drugs into Thailand.

GMP Accreditation

As an ASEAN member, Thailand has implemented ASEAN GMP. In order to comply with the ASEAN Sectorial Mutual Recognition Arrangement (MRA), which was signed on April 10, 2009, Thailand must standardize its GMP guidelines to be in line with those of other ASEAN countries. In 2011, the Thai FDA issued GMP regulations and launched GMP Guidelines that complied with ASEAN GMP standards and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S)—this provided guidance to local manufacturers and raised overall standards.

In order to maintain the same GMP standards for both local and overseas manufacturers, the Thai FDA launched the Notification of GMP Accreditation of Overseas Manufacturers on October 1, 2012. Under this Notification, overseas pharmaceutical manufacturers, which had never before been recorded in the Drug Product Registry of Thailand, needed to be accredited by the Thai FDA before Marketing Authorization (MA) could be obtained. Pharmaceutical import companies must also submit an application for GMP accreditation before or at the same time as drug registration.

Required Documents

The documents to be submitted to the Thai FDA for GMP accreditation are separated into two schemes, Non-PIC/S members and PIC/S members, based on the overseas manufacturer's country. If the overseas manufacturer is from a country that is a PIC/S member, the documents for GMP accreditation will be the PIC/S member checklist. The amount of documents for a PIC/S member to submit is less than that for a Non-PIC/S member. The required documents include:

1. A Plant Master File for PIC/S or Non-PIC/S members or Certified/Audited by PIC/S, complying with the requirements stated in the Notification of the Ministry of Public Health Re: Good Manufacturing Practices (GMP) and Requirements for Manufacturing of Modern Drugs in accordance with the Drug Act 2012 (B.E. 2555).
2. The production details of the imported product, including details about the place and manufacturing area, production equipment involved in the manufacturing of each category of imported product, plant layout, and a flowchart and other relevant information indicating all manufacturing processes, including the premises.
3. The latest GMP inspection report, issued by the authorized government agency of the country of origin or the International Certificate Organization (if applicable).
4. A current Certificate of GMP, issued by the authorized government agency of the country of origin.

Under the four topics above, there are more than 100 documents to be submitted for PIC/S members and more than 200 documents to be submitted for Non-PIC/S members to the Thai FDA for GMP accreditation. All documents are reviewed by an FDA team of experts. Afterwards, all questions, requests, or suggestions will be sent to the applicant to answer and/or submit additional documents. A slide or video presentation of the manufacturer needs to be prepared to explain the manufacturing process, such as important zones of production, flow of production, etc.

The applicant is required to arrange for the translation of certain information which needs to be in Thai and submit it together with the English version. A company representative may be requested to meet with the subcommittee to explain and answer the expert team's questions. A Corrective Action and Preventative Action (CAPA) proposal may need to be presented to the subcommittee for evaluation. In complex cases, an inspection at the site of manufacturing may be required by the Thai FDA.

If manufacturing practices are considered to be GMP compliant and the CAPA proposal meets requirements, the Thai FDA will issue a GMP Certificate to an overseas manufacturer for the purpose of product registration. The same GMP Certificate may be used for other product registration applications if they have the same scope/type of manufacturing during the validity of the GMP Certificate, which is normally three years after the date of issuance. The GMP Certificate of an overseas manufacturer must therefore be renewed every three years.

Since its implementation in October 2012, only 10 manufacturers from PIC/S member countries have received GMP accreditation. Meanwhile, manufacturers from Non-PIC/S member countries are still pending accreditation. Due to limited staff and expert teams in the Thai FDA, along with the requirement to submit a large number of documents for manufacturers from Non-PIC/S member countries, it is more difficult for a Non-PIC/S member to be granted a GMP Certificate than it is for a PIC/S member.

Overseas manufacturers are not required to pay for GMP accreditation at any stage of the application.

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Renewal and Ongoing Audits

As the GMP Certificate issued for an overseas manufacturer has to be renewed every three years, it seems that the Thai FDA is trying to control/audit all manufacturers with products registered in Thailand. Meanwhile, local manufacturers normally have to renew their GMP Certificates every two years.

The GMP accreditation regulation of overseas manufacturers does not, however, affect manufacturers with products that were submitted for drug registration before October 1, 2012, because the manufacturer's name and address are available in the Thai FDA database. It would be possible to have them audited if product registration renewal was required. Unfortunately, there is no requirement in Thailand for product registration renewal every five years, unlike other countries in ASEAN such as Singapore, Malaysia, etc. Therefore, these overseas manufacturers are still awaiting audit by the Thai FDA. For the time being, there are no measures to manage the audit of these manufacturers. To complete the GMP system in Thailand, the Thai FDA has the burden to eliminate the gap between new and old overseas manufacturers. This leaves many observers wondering how best to control products from overseas manufacturers that have never been audited by the Thai FDA.

Comparisons among ASEAN Countries

Thailand is not currently a PIC/S member, so in order to ascend to the accepted list of ASEAN MRA, Thailand must develop its pharmaceutical GMP system to be on par with other ASEAN countries. This will reduce pharmaceutical trade barriers before the ASEAN Economic Community (AEC) is implemented in December 2015.

ASEAN countries have country-specific regulations that differ due to the laws and regulations of each country. As in Thailand, GMP accreditation in Singapore came into effect on April 1, 2004, and all overseas manufacturers registering medicinal products in Singapore after that date have to meet the PIC/S GMP standard. Malaysia, too, now requires the GMP accreditation of manufacturers outside Malaysia to be taken into consideration before products are registered. Malaysia adopted the PIC/S Guide to GMP for medicinal products in 2002.

In Malaysia and Singapore, old manufacturers with products that have already been registered, but have never been audited, will be audited and inspected when Marketing Authorization is renewed. If the manufacturer does not pass inspection, Marketing Authorization will not be granted. For Cambodia, Lao PDR, Myanmar, Philippines, and Indonesia, however, the GMP accreditation requirements for new overseas manufacturers are not as stringent as those seen in Malaysia and Singapore. The development of GMP accreditation in those countries will likely grow in the future to be on par with other ASEAN countries.