Policy Forum

Three decades of GMP implementation in Thailand: Hardships and success

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ABSTRACT: Thailand has implemented GMP for almost three decades. GMP Guidelines from the World Health Organization (WHO) were adopted starting in 1978. A few years later, those guidelines were revised twice in 1992 according to ASEAN's version and the WHO's version of GMP, respectively. In 2003, GMP was enforced by law after 25 years of voluntary compliance. In 2007, 153 out of 163 of modern pharmaceutical manufacturers have complied with GMP (93.87%). The rest are closing buildings and facilities for renovation in order to meet GMP requirements.

Keywords: GMP, FDA, Thailand

Pharmaceutical industries in Thailand have existed for more than 40 years. In the beginning, there were only two types of pharmaceutical industries. The first was midstream industry producing raw materials for both active ingredients and inert substances such as paracetamol, aluminium hydroxide compressed gel, magnesium hydroxide compressed gel, sorbitol, sodium chloride, and dextrose monohydrate. The second was downstream industry producing pharmaceutical products in formulations. Thailand never had upstream industry requiring massive investment for new drug development. Before the GMP system was implemented, the country was facing numerous problems including unexpected contamination of products, insufficient or excess active ingredient, and incorrect labels on containers. The Thai FDA took a caution approach to this crisis. The sole solution put forth at that time was the GMP system (*1*). Therefore, GMP Guidelines from World Health Organization (WHO) were adopted as the first Guidelines for Thailand's GMP in 1978 to ensure that products are consistently produced and controlled according to quality standards (*2*).

Since GMP compliance was voluntary and not compulsory in the beginning, compliance by pharmaceutical manufacturers was lacking, especially among local companies, though not among multinational companies. This was because of large investments to improve the standard of manufacturing and quality control. The big question was “Is it really worth spending our money to do this?” In response to this very challenging question, the Thai FDA then arranged many more training programs and provided more information and documents about GMP for both officials responsible for GMP implementation and pharmaceutical companies. Furthermore, the Thai FDA also worked closely with those manufacturers by setting up the Quality Improvement Team (QIT) to work as a board of consultants for companies in all matters relating to GMP. In 1987, Thailand, as a member of ASEAN, revised the aforementioned guidelines according to ASEAN's GMP, and these new guidelines became the second version of GMP Guidelines for Thailand. Later, in 1993, these GMP guidelines were revised again in order to comply with the WHO's 1992 version of GMP, and these become the current GMP guidelines for Thailand. At this stage, GMP compliance was still voluntary for pharmaceutical manufacturers.

Within the first 2 decades of GMP implementation, only 126 out of 175 modern pharmaceutical manufacturers (72%) complied with GMP. However, the Thai FDA consistently worked to further promote compliance with GMP among those pharmaceutical manufacturers. The average number of pharmaceutical companies obtaining GMP certificates gradually increased each year (Table 1). Eventually, in the year 2003 the GMP system was enforced by law after 25 years of voluntary compliance. The year 2007 marks almost three decades of GMP implementation in Thailand, and 153 out of 163 modern pharmaceutical manufacturers have complied with the GMP (93.87%). The rest are closing buildings and facilities for renovation in order to meet the GMP requirements (*3*).

In addition, Thailand has sought membership in the Pharmaceutical Inspection Convention/Pharmaceutical

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Table 1. Total number of modern pharmaceutical manufacturers that have obtained a GMP certificate[a]

Year	Total number of modern pharmaceutical manufacturers[b]	Total number of modern pharmaceutical manufacturers that have obtained a GMP certificate[c]
1978	188	0
1979	189	0
1980	189	0
1981	188	0
1982	187	0
1983	188	0
1984	189	0
1985	188	0
1986	187	0
1986	188	0
1987	189	0
1988	188	0
1989	188	59 (31.38%)
1990	188	79 (40.03%)
1991	184	95 (51.63%)
1992	180	105 (58.33%)
1993	180	112 (62.22%)
1994	178	117 (65.73%)
1995	180	122 (67.77%)
1996	175	122 (69.71%)
1997	175	126 (72.00%)
1998	176	130 (73.86%)
1999	176	130 (73.86%)
2000	174	127 (72.99%)
2001	172	131 (76.16%)
2002	174	134 (77.01%)
2003	174	133 (76.43%)
2004	171	141 (82.46%)
2005	166	151 (90.96%)
2006	162	153 (94.44%)
2007	163	153 (93.87%)

[a] Source: Thai FDA Annual Report and Thai FDA's Website (http://wwwapp1.fda.moph.go.th/drug/zone_search/files/sea001_008.asp)

[b] Modern pharmaceutical manufacturers: pharmaceutical manufacturers that produce drugs intended for use in the practice of modern medicine or treatment of animal diseases.

[c] The Thai FDA started issuing a GMP certificate in 1989.

Inspection Cooperation Scheme (PIC/S) since 2006 and its application is under consideration (*4*). In the meantime, more critical and harder steps are planned. The Thai FDA is adopting the current PIC/S GMP Guide as a mandatory requirement for manufacturers, and this process will be accomplished within the year 2008. Implementation is expected to be completed within one year afterwards.

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