

Global Regulations of Medicinal, Pharmaceutical, and Food Products

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14 Regulations in Gulf Cooperation Council (GCC) Countries

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14.1 INTRODUCTION

The Gulf Cooperation Council (GCC) is a regional intergovernmental, political and economic alliance that comprises six countries in the Middle East: Saudi Arabia, United Arab Emirates (UAE), Kuwait, Bahrain, Oman and Qatar. These countries have a combined population of over 50 million and a GDP of more than \$1.5 trillion. Active Pharmaceutical Ingredients (APIs) are the chemical compounds that make up the active ingredient in a drug product. APIs are the substances responsible for the therapeutic effect of a drug and are typically produced through chemical synthesis or biological processes. They are used to manufacture finished dosage forms, such as tablets, capsules and injectables. The regulation of APIs is critical to ensure the safety, efficacy and quality of pharmaceutical products. According to the research results, the Gulf Cooperation Council (GCC) region is considered an emerging market for pharmaceutical exports and bilateral trade [1]. The pharmaceutical industry in the GCC countries started some 25 years ago with the main idea of decreasing the cost of medications, which was increasing rapidly. Some of the GCC countries have started manufacturing pharmaceutical products under the license of major pharmaceutical companies but soon discovered that generics saving and raw materials can be purchased much cheaper than from the major pharmaceutical companies they manufacture for. The GCC pharmaceutical plants practically kicked off their partners and moved into the line of generics, competing with the major companies. The GCC pharmaceutical companies got some success in reducing the prices of the raw materials but this was at the expense of the quality of their products [2–5].

The Gulf region is an important market for pharmaceuticals and the demand for high quality drugs is increasing rapidly. The GCC countries have recognized the importance of regulating APIs and have developed regulatory frameworks to ensure that pharmaceutical products meet the necessary standards. API regulations play a critical role in the healthcare systems of GCC countries. These regulations are designed to ensure that APIs used in the production of pharmaceuticals meet stringent quality standards. By enforcing these regulations, the GCC countries aim to prevent the entry of substandard or counterfeit APIs into their markets, safeguard public health and maintain consumer confidence in the pharmaceutical industry. The purpose of this chapter is to provide an overview of the regulatory framework for APIs in the GCC