Good Manufacturing Practices (GMP) in Homeopathy

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Homeopathy is a system of medicine based on the application of the principle of therapeutic similitude (*similia similibus curentur*) which stimulates the reaction of the organism by using medicines that cause similar effects with the underlying symptoms of disease. The second main principle is the usage of minimal doses to enhance the own natural immunity of human body. According to the recent surveys, the population in some countries (for instance India, Brazil, France, Russia, Germany, and etc.) shows high confidence in homeopathic treatment methods. Similarly as the manufacturers of conventional pharmaceuticals, the requirements to adhere to Good Manufacturing Practices (GMP) principles imply for manufacturers of homeopathic medicines. Indeed, most of the recognized manufacturers have already established relevant measures according to the GMP. Hence, the specific issues in the manufacturing and quality control of homeopathic medicines would be discussed. It has to be emphasized that failure to apply GMP could lead to substandard product quality or even major quality concerns such as misidentification, presence of impurity in starting material, contamination. Ultimately it may cause a serious risk to public health while the product recall from the market would be inevitable. However, the manufacturing in homeopathy poses some unique challenges which demands specifically competent personnel. Source materials (as mother tinctures), excipients, or final homeopathic product must comply with quality standards published in official pharmacopoeias or other officially recognized documents. The critical issue is handling toxic materials, materials, particularly fresh ones, that are prone to degradation processes and microbial contamination; and homeopathic medicines derived from animals or human sources. Some of these raw materials constitute potential safety hazards, even at highest dilutions. The properties of medicines can be also compromised by accidental contamination of starting materials, excipients, or by contamination of vessels in which the dilutions are made. Consistency of homeopathic product quality is assured not only by defining appropriate specifications but also by implementing standard manufacturing procedures validated according to GMP.

Keywords:

Homeopathic medicines; Good Manufacturing Practices (GMP); Quality control of medicines

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