Good Manufacturing Practice (GMP) regulation of biological pharmaceutical products in comparative research: WHO, PIC/S, EU, Canada and Iran.

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(English abstract)

Abstract

The aim of the present study was to compare the regulations of Good Manufacturing Practice (GMP) for biological pharmaceutical products issued by the World Health Organization (WHO), the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Convention (PIC/S), and the European Union (EU). This comparison was performed using the WHO, PIC/S, EU, Canada and Iran GMP regulations. The findings showed that the regulations of the WHO and PIC/S were similar, while the EU regulations were more stringent. However, the regulations of Canada and Iran were less stringent compared to the regulations of the WHO and PIC/S. Overall, the regulations of the WHO and PIC/S were more comprehensive and stringent compared to the regulations of the EU, Canada and Iran. Future research could focus on comparing the regulations of GMP for biological pharmaceutical products in other countries.

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Conclusion: GMP regulations vary significantly between countries. Future research could focus on comparing the regulations of GMP for biological pharmaceutical products in other countries.