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GMP deficiencies found by ANVISA in foreign inspections

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Statement of the Problem: Good Manufacturing Practices (GMP) main objective is managing and minimizing the risks inherent in pharmaceutical manufacture to ensure the quality, safety and efficacy of products. Pharmaceutical manufacture and regulation is an international business. Regulatory authorities and the pharmaceutical industry are seeking for maximum harmonization of GMP guidelines. The main objective of the present study is to evaluate the results of Brazilian Health Regulatory Agency (ANVISA) foreign inspections in the last two years (2015 and 2016), comparing with other regulatory authorities.

Methodology & Theoretical Orientation: Results were collected from a total of 255 inspection reports. The result of the inspection was grouped by company compliance status and country. The number and criticality of deficiencies were collected and grouped by area, according to current GMP regulation in Brazil. Deficiencies found more often were listed descriptively. In the period evaluated, 63.14% of ANVISA inspected companies were classified as satisfactory, 25.88% resulted in demand status and 12.55% of inspections concluded that the company did not comply with GMP (Unsatisfactory). In 19 inspections (10.16%), critical deficiencies were found; inspectors observed major deficiencies in 111 (59.36%); and minor deficiencies were observed in 165 (88.24%) of the inspected companies. The most common areas of deficiency were documentation (28.63%) and Premises (26.27%).

Conclusion & Significance: The pattern of deficiencies was like the findings of other regulatory agencies, showing that equivalent requirements are applied. Disclosure of the common deficiencies is a step forward on regulatory transparency, which can be useful for industry to improve GMP compliance. Therefore, producers are encouraged to allocate resources and training on these main issues, assuring quality and safe medicines supply for population.

Biography

Andrea R C Geyer has worked for ANVISA as an Inspector since 2005. She is an Industrial Pharmacist and has completed her MSc in Biological Sciences (Biochemistry). Currently, she is pursuing her PhD in Pharmaceutical Sciences at Brasilia University, studying the most common deficiencies found during ANVISA inspections.

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