Available Online at http://www.journalajst.com

ASIAN JOURNAL OF SCIENCE AND TECHNOLOGY

ISSN: 0976-3376

Asian Journal of Science and Technology
Vol. 6, Issue 01, pp. 1000-1002, January, 2015

RESEARCH ARTICLE

ASSESSMENT OF IMPLEMENTATION OF GOOD MANUFACTURING PRACTICES (GMPS) AT PHARMACEUTICAL FIRMS IN KHARTOUM STATE-SUDAN

[1,2,*]Gamal Osman Elhassan, [3]Elrashed Elrayah, [1]Abu Bakr Abd Alrouf Alfadul, [4]Khalid Omer Alfarouq, [5]Jiyauddin Khan and [1]Akhter Javed

[1]Unaizah College of Pharmacy, Qassim University, Qassim, KSA
[2]Faculty of Pharmacy, Omdruman Islamic University, Khartoum, Sudan
[3]Central Medical Supplies, Federal Ministry of Health, Khartoum, Sudan
[4]Quality Assurance Department, Ministry of Health, Khartoum-State, Sudan
[5]School of Pharmacy, Mangement and Science University, Selangoor, Malaysia

ARTICLE INFO

Article History:
Received 26th October, 2014
Received in revised form
20th November, 2014
Accepted 07th December, 2014
Published online 30th January, 2015

Key words:

GMP,
Manufacturing,
Pharmaceuticals,
Specifications.

ABSTRACT

Good Manufacturing Practices (GMPs), the central part of quality system, is the consistent production of safe and effective product and ensuring that these activities are sustainable. It aims primarily at preventing mistakes and errors involved in any manufacturing activities, such errors are of two types' mix-up and cross-contamination GMPs are a legal codification of sound quality principles that have been used by pharmaceutical and healthcare manufacturing industries for over 50 years, (GMPs) are in effect in over 100 countries, and (GMP) compliance is a pre-requisite to exporting pharmaceuticals between countries (GMP) require that all manufacturing process are clearly defined, systematically reviewed, in the light of experience, and shown to be capable of consistently manufacturing pharmaceutical products, of the required quality that comply with their specifications, and that all necessary resources are provided including:

i. Appropriately qualified and trained personnel;
ii. Adequate premises and space;
iii. Suitable equipment and devices;
iv. Appropriate materials, containers, and labels;
v. Approved procedures and instructions;
vi. Suitable storage and transport;
vii. Adequate personnel, laboratories, and equipment for in-process controls;

This study aimed to assess the implementation of good manufacturing practices at pharmaceutical firms in Khartoum state-Sudan, the study was also aimed to assess the role played by local regulatory authority in (GMP) enforcement.

INTRODUCTION

(GMP) was first drafted in 1967 by World Health Assembly (WHA). GMP text was then reproduced (with some versions) in 1971. Considerable developments in (GMP) have taken place in the intervening years and important national and international documents, including new versions, have appeared ''Good practices in production and quality control'' provides guidance on action to be taken separately by production and by quality control personnel for the implementation of the general principles quality assurance.

Corresponding author:** [1,2]**Gamal Osman Elhassan
[1]Unaizah College of Pharmacy, Qassim University, Qassim, KSA
[2]Faculty of Pharmacy, Omdruman Islamic University, Khartoum, Sudan

Objectives

General Objectives

- To assess the implementation of the GMP in Sudanese pharmaceutical firms, and to identify the main problems facing it, and to suggest the possible solutions to strengthen the implementation
- To assess the role played by the national regulatory authority agency (Sudan Nation Medicines and Poisons Board), (SNMPB) in (GMP) regulation and enforcement.

Specific Objectives

- To explore (GMP) compliance systems by analyzing the current situation

- To evaluate the material being imported on the light of the recommended regulations and guidelines
- To investigate research and development departments and capacity to carry out product quality solutions
- To identifying the needs and problems encountered and to set recommendations
- To evaluate the role of the national regulatory authority agency (SNMPB) in implementation and enforcement of (GMP)

MATERIALS AND METHODS

Study design: Odd- cross sectional descriptive field-based study

The Sudan National Medicines and Poisons Board (SNMPB) usually conduct annual surveys of inspections for these firms using the checklist of inspection to investigate and monitor (GMP) implementation in these firms, so this provide a forum of examination for issues related to our study, therefore, this study is compared with the inspection reports of the survey conducted by (SNMPB) in the previous year (2011) to describe facts about (GMP) implementation in these firms.

Settings*:* local pharmaceutical firms at Khartoum state.

Sample size: Seven pharmaceutical firms were selected randomly, sample is indicative rather than informative and shown to be feasible within the available time and resources, the quantitative data obtained from these samples is sufficient to describe the current situation in these firms.

Sampling procedure: Sample was calculated using computerized statistical package technique which require internet accessory and involve a high confidence level to show representative sample.

Every firm is visited separately, the visit include production area, storage area and quality control laboratory. The design, construction, and practices within these areas were observed and the headquarters of these areas were interviewed on the bases of checklist of inspection for pharmaceutical firms which designed on (GMP) requirements, finally, a separate interview is carried out with each quality assurance headquarter about the whole (GMP) principles related to his firm and he filled the checklist format .Then a visit was made to the local regulatory authority body Sudan National Medicines and Board (SNMPB) which represent the complementary part of this study .and structural interview was conducted with seven key personnel in department related to our issues to monitor their views about the board's efficiency in (GMP) enforcement.

Data collection tool: Is the checklist of inspection for pharmaceutical firms published by the Sudan National Poisons and Medicines Board (SNPMB) which depend on the current WHO (GMP) requirements and structural interview with key personnel in (SNPMB) this structural interview is designed on board's policy.

Statistical package: Data analysed using the computerized descriptive statistics in which cross- tabulation process is used to summaries categorical data and create a contingency tables.

RESULTS

Table 1. Personnel (Training and Qualification)

Firm	Key personnel	Presence of organization chart	Proper training
1	100%	100%	75%
2	100%	100%	100%
3	100%	100%	75%
4	100%	100%	75%
5	100%	100%	100%
6	100%	100%	75%
7	100%	100%	75%

As shown from the above table (1) 71.42% firms lack of proper training in term of training programme

Material

The following table (2) demonstrate that (0/7) 0% firm do not have system to asses and qualify supplier for starting material.

Table 2. Materials

Firm	System to assess and qualify supplier for starting material	SOPs for handling material	Maintained record for starting materials
1	0%	100%	100%
2	0%	100%	100%
3	0%	100%	100%
4	0%	100%	100%
5	0%	100%	100%
6	0%	100%	100%
7	0%	100%	100%

Premises suitability

The following table (3) show incomplete premises suitability where (2//7) 38.57% of firms were found not having HVAC system

Table 3. Premises suitability

Firm	Suitable size	Design	Construction	Services
1	100%	100%	0%	100%
2	100%	100%	100%	100%
3	100%	100%	0%	100%
4	100%	100%	100%	100%
5	100%	100%	100%	100%
6	100%	100%	100%	100%
7	100%	100%	100%	100%

Structural interview with key personnel in local regulatory authority Sudan National Medicines and Poisons Board (SNMPB)

Key personnel	Views	Percentage
7/7	No training courses for both inspectorate and manufacturers.	100%
7/7	Weakness of inspectorate programs.	100%
0/7	Absence of political commitments for local manufacturing	0%
4/7	Weakness of pharmacists knowledge in RA towards GMP	57.14%
2/7	Turn-over problems.	28.57

DISCUSSION

Personnel Training and Qualification: Only two firms (28.6%) achieved the full score in training while the remaining

scored 75%, as they had no continuous training program. The same two firms scored 100 % in the study conducted in 2011while the remainder scored 75%. This reflect the fair knowledge of the local manufacturers about training as GMP requirement, specially continuous training programme as a sustainable activity to assure consistent production of safe and quality products.

Material as in 2011 all the firms had no system to assess and qualify supplier for starting materials. This is because more regulatory requirements(in form of written programme or SOPs) are needed by these firms to build strict systems for handling such articles lick prohibited acts, penalties, and enforcement to mandatory regulate the guidelines on import procedure for pharmaceutical products, and that pharmaceutical products are not lick other commodities, and to prevent the infiltration of illicit products into supply system, these firms must show strict commitment to WHO certification schemes on the quality of pharmaceutical products moving in the international commerce.

Premises suitability: Only 5 (71.4)% of the firms achieved 100% in the construction while 28.6% scored 0% this because they had no Heating, Ventilation, and Air conditioning System (HVAC)system. The results of premises size, design and services remained the same as in 2011 survey, HVAC system is a crucial element in pharmaceutical facility design and construction not only to prevent cross- contamination in production area but also to keep a healthy work environment. And lack of such system explains the fact that pharmaceutical facility upgrading has implication on local manufacturers who are not always ready to put more investments in GMP.

The role of the regulatory authority (SNMPB) in (GMP) enforcement: From table: (Structural interview with regulatory authority's key personnel), all the interviewed key personnel 7/7 (100%) agreed that there is no training courses for both inspectorate and manufacturers, and weak inspectorate programmes. Also all personnel 7/7(100%) agreed that there is perfect political commitment, while 4/7 (57.14%) agreed that the pharmacist's knowledge in RA towards GMP is weak, and 2/7 (28.57%) of personnel agreed that there is turn-over problems. The fact, lacking of qualified pharmacists who have sufficient experience contributed to weak the role of the agency to achieve its objective in (GMP) enforcement.

Conclusion

Training for pharmaceutical personnel is much bigger than initial training on how to apply (GMP) requirements on the operation area and personal hygiene, and must be distinguished from continuous training programme. Training should be in written modules (programmes) (WHO, 1999) and be scheduled (WHO, 1999) in practical examples, case study, real documents, video materials, and final exam (WHO, 1999). The pharmaceutical firms which fail to conduct continuous training programme will never be able to develop and maintain an effective compliant system (GMPs, 1999), never be able to build up practical experience and case study (GMPs, 1999) and will lack of techniques necessary for application of the current GMP on the operating level (GMPs, 1999).

The importation of pharmaceutical products or materials moving in the international commerce on the basis of federal regulations of medications (GMPs, 1999) and guidelines on import procedures for pharmaceutical product (WHO, 1992) require serve organization (supplier or vender who serve pharmaceutical industry client) (WHO, 1992) lack of such organization will increase risks to public health and give rise to the most established offenses (adulteration and misbranding). In general pharmaceutical facility should be designed, constructed, and operated in accordance with the main GMP principles (WHO, 1992) to safely contain the material being handled by presence of an effective environmental control system, or heating, ventilating and air conditioning system (WHO, 1992). The absence of this system add potential risks to the quality of the manufactured products [(2)] and increases the possible harmful effects on the operator's health life upon handling products containing hazardous substances, and increases the contamination hazards to the public environment (WHO, 1992). Finally, we must adopt regionalization and harmonization of efforts between countries, such as FDA of USA, European union regulatory agencies and ASIAN regulatory authority body, which have adopted a joint regional PIC/S that have been focusing on harmonization of GMP requirements, training of inspectorates, exchange of information. Such harmonization provides joint discussions often resulted in supplemental guidance which proved useful to inspectorate. And Sudan as a WTO signatory member has an access to join such regional groups.

REFERENCES

Good Manufacturing Practices (GMPs) January 1999- supliment quality.com-hart of quality abstract

Good Manufacturing Practices for pharmaceutical products 1992, In: WHO Expert committee on specifications for pharmaceutical preparations. Thirty-second report. Geneva, World Health Organization, 1992:14-79 (WHO Technical report series, no.823)

International GMPs- Introduction By Michael H. Anisfield, senior consultant, Globpharm consulting, Dearfield, IL, USA

Good Manufacturing practice (GMP) for pharmaceutical products –WHO 1999. /http:// www.gmp1st.com/gmp.htm 12/8/2007

Good Manufacturing practices (GMP)/ Quality System (QS) Regulation. / http://www.fda.gov/ cdrh /devadvice / 32 html.2/7/2007

International GMPs- Drug Quality- GMP implementation Good Manufacturing Practices and Regulatory Affairs CHEE4020/7302 www.pharmabiz.com/specials/chronicle -index/ GMP-Ind.asp-25k /http://.fda.gov/cdr/gmp/gmp 2004/GMP-finalreport2004.htm 2/7/2007

GDPH, policy of nationalize national drug manufacturing, June 28, 2002

Managing Drug Supply-MDS3-Front Matter- November 2011. Michael H. Anisfeld, senior consultant, Globepharm consulting, Deerfield, IL, USA.

Assessment of Good Manufacturing Practices at locally Pharmaceutical Firms at Khartoum State (2007) by Dr. Maha Mohamed Ali (Sudan Medical Specialization Board).

****