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The Importance of a Standardized Islamic Manufacturing Practice (IMP) for Food and Pharmaceutical Productions

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ABSTRACT

As Muslims, the search for lawful (halal) and wholesome (tayyib) products such as food and medicines is not only a part of ibadah and to get pleasure of Allah SWT. In fact, it can also nourish the bodies and souls due to the permssibility and purity of the products. Currently, the awareness of some doubtful and questionable ingredients in the food and pharmaceutical products in the market has increased. Since the 23rd meeting of the Standing Committee for Economic and Commercial Cooperation (COMCEC) on November 2007, OIC has organized a conference and its sequential meeting on The OIC Halal Food Standard. Three main documents – OIC General Guidelines on Halal Food, Guidelines for Bodies Providing Halal Certification, and Guidelines for the Authorized Accreditation Body Accrediting Halal Certification Bodies – have been finalized. However, the concern is now wider and more complex in nature incorporating not only the traditional aspects but also the biopharmaceutical manufacturing processes and other relevant processes. Thus, there is an urgent need for a comprehensive guideline. The concept of Islamic Manufacturing Practice (IMP) has been introduced in Malaysia to fill this void but unfortunately, the contents of the IMP are still equivocal and limited. This paper discusses about some aspects of manufacturing processes in food and pharmaceutical industries that reflect the importance of a standardized IMP.

Key words: IMP, halal, manufacturing, food, pharmaceutical

Introduction

The Arabic word 'halal' literally means permissible and in translation it is usually used as lawful (Khawaja, 2001). Opposite to halal is haram, which means unlawful or forbidden. The concept of halal product is based on Islamic Shar'iah. When discussing about halal products, the word tayyib is always included. Tayyib in accordance to the translation of Qur’an by Abdullah Yusuf Ali means wholesome, pure, clean and nourishing (Abdullah Yusuf Ali, 2005). The concept of halal and tayyib was also described by Zainorni Mohd Janis, Senior Executive of Standard Management Department of Standards and Industrial Research Institute of Malaysia (SIRIM): “The wholesomeness concept of Halal food covers the lawful requirements of the Shar’iah law (law of Islam) and the requirements for good food, in terms of hygiene, sanitation and safety. To achieve the wholesomeness concept, both aspects need to be adhered to and implemented together. Failure in any of it will cripple the wholesomeness concept of Halal food ...” (Janis, 2004)

The concept of halal is wider and more comprehensive. Contrary to the popular belief that the word halal is only used in the context of consumables or food products, today it has a wide range of application starting from inter-relationship, clothing and manner, social and business transaction, trade and financial services to investments or any others which is parallel to the guidance specified by Islam. However, this paper is only focusing on the consumable products like food and pharmaceutical products.

As Muslims, consuming halal and tayyib products is an order from Allah and it is an essential part of the Islamic faith. There is no doubt for this obligation as Allah has emphasized the consumption of halal materials in Surah Al-Baqarah in Qur’an.

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In general, GMP is a basic guideline for product quality assurance. The history of GMP began in 1941 after nearly 300 people were killed by one’s company’s sulfathiazole tablets, a sulfa drug tainted with the sedative, phenobarbital. The incident caused Food Drug Administration (FDA), to revise manufacturing and quality control requirements, leading to what would later called GMP (Immel, 2001). FDA is an agency within the U.S. Public Health Service that oversees medications, food safety, cosmetics, medical and veterinary products and much more. They are responsible for ensuring that foods are safe, wholesome and sanitary, human and veterinary drugs, biological products and medical devices are safe and effective, cosmetics are safe, and electronic products that emit radiation are safe. GMP for manufacturing, processing, packing, or holding finished pharmaceutical products was first published in 1963 (Immel, 2001).

**Good Manufacturing Practice (GMP):**

Good Manufacturing Practices (GMP) is a term that is recognized worldwide for the control and management of manufacturing, testing and overall quality control of food and pharmaceutical products. There are various definitions for GMPs such as follows:

“Good Manufacturing Practices (GMP) is a set of standards for the food and drink industry aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use (David, 2011)…” GMP is that part of quality assurance which ensures that products are consistently produced and ensuring that products are consistently manufactured to a quality appropriate to their intended use (David, 2005).

He also emphasized in Surah Al-Mu’minun:

\[ \text{O ye messengers! Enjoy all things good and pure (tayyib), and work righteousness: for I am well-acquainted with (all) that you do (Abdullah Yusuf Ali, 2005).} \]

A part from attaining Allah’s pleasure, consuming halal and tayyib food can deeply affect one’s personality and religious practice. It enlightens one’s heart and brings the feeling of gratification and devotion towards Allah because of the permissibility, cleanliness and the purity of the food. Furthermore, one’s dua’ can be accepted by Allah SWT if the person is not consuming haram food. Anas (may Allah be pleased with him) said to the Prophet Muhammad (peace and blessing be upon him) (Al-Asfahani in Al-Targhib, 2011):

“O Messenger of Allah! Supplicate to Allah for me to make my Du’a’ acceptable”

The Prophet Muhammad (peace and blessing be upon him) then replied:

“O Anas! To have an acceptable Du’a’, you must eat only the Halal (Lawful) since a person may be deprived of his Du’a’ being answered for forty days because of eating a mouthful of Haram food”

Having halal food is a healthy diet because the food is clean, nutritious and does not contains dangerous and toxic ingredients (Quadri et al., 2009). Oppositely, eating haram food such as pork is not only prohibited in Islam but it also harmful to human health in a great many regards. This harm still persists today, despite all the precautions that are taken. No matter how clean the farms and environments on which the pig are raised may be, the pigs are not by nature a clean-living animal. It often plays in, and even eats, its own excrement. Pork meat contains high levels of cholesterol and lipids (Omojola et al., 2009). It has been scientifically proven that these significant amounts of cholesterol and lipids in pork represent a serious threat to human health. Thus halal and tayyib food must be viewed as a kind of universal healthy food. It is suited for everyone’s consumption and not only for Muslims.

Since the past five years, the awareness among Muslims of halal and tayyib food and pharmaceutical products has increased. Muslims are now widening their concerns. Previously, it is limited to the traditional aspects such as the ingredients of the food and pharmaceutical products but now it includes the methods and processes used throughout the products manufacturing. Currently, most of halal food and pharmaceutical industries are based on an adaptation of existing processes and production guidelines. The halal concept was not included in the current guidelines and has not yet been taken as a benchmark because the development of halal procedures and guidelines from the ground up is still lacking. Consequently, Muslims have not yet designed optimum methods for halal production and they are still facing halal problems. Thus, there is urgent need for a comprehensive guideline of halal and tayyib food and pharmaceutical productions. Meanwhile, the concept of Islamic Manufacturing Practice (IMP) has been introduced by small community of Muslims producers in Malaysia to fill this void (IMP, 2010), but unfortunately, the content of the IMP are still equivocal and limited. This paper is discussing on some aspects of manufacturing processes in food and pharmaceutical industries that reflect the importance of having a standardized IMP.
GMP is also sometimes referred to "cGMP". The letter ‘c’ in front of GMP means ‘current’ and it indicates that methodologies, technologies and systems of manufacture, testing, design and control that employed by manufacturers are up-to-date to reach and maintain the quality standard. The quality approach of GMP ensures manufacturing companies to minimize or eliminate instances of contamination, mix-ups, and errors in their production processes. This in turn, protects the consumer from purchasing a product, which is not effective or even dangerous. According to World Health Organization (WHO), GMP covers all aspects of the manufacturing such as follows:

“manufacturing process; validated critical manufacturing steps; suitable premises, storage, transport; qualified and trained production and quality control personnel; adequate laboratory facilities; approved written procedures and instructions; records to show all steps of defined procedures have been taken; full traceability of a product through batch records and distribution records; and systems for recall and investigation of complaints.”(Gillian et al., 1997)

The development of these requirements and the quality standard in GMP is based on Western perspectives. The guideline is mainly focusing on the safety, hygiene and cleanliness aspect including the prevention of contaminants and toxic substances to the products. Although there is continuous revision and evaluation on GMP by FDA, WHO and other standard agencies, but only take the current technologies and food safety hazards into account without considering the religious aspects of Muslim consumers although their products are exported to Muslims countries. Consequently, there are still products in the Muslims market which are proven to be safe by GMP but still, they are not halal and tayyib. Muslims consumers are still doubt with the hidden source of ingredients and method applied by the producers. The shortcoming of GMP is now a big concern in Muslim countries because most of the food and pharmaceutical products are imported from non-Muslim countries.

Malaysia, as one of the developed Muslim countries has greatly supported and emphasized on the halal and tayyib concept. Malaysia has encouraged the food and pharmaceutical producers to adapt and maintain the additional requirements and standard other than GMP to meet the Halal requirement. Those requirements and standards include Hazard Analysis and Critical Control Point (HACCP), Sanitation Standard Operating Procedures (SOPs), ISO 9000, Codex Alimentarius, and Good Hygienic Practice (GHP) (Abdul Talib et al., 2008). In addition, Research and Standards of SIRIM have developed a comprehensive Halal Food Standard called MS1500:2004 that helps the food manufacturers to control and provide guidance in the products processing in order to satisfy the Shar’iah, HACCP and GMP. As stated by the Zainorni Mohd Janis:

“The MS1500:2004 lays out comprehensive requirements according to Shar’iah law and also the requirements of food manufacturing and food servicing chain from processing to handling, distribution, storage, display, servings, packaging and labeling. The aesthetic aspects - hygiene, sanitation and food safety - are also included as part of the requirement” (Janis, 2004).

In other word, a general guideline of Malaysian standard on production, preparation, handling and storage of halal food products has been gazette by the Malaysian government. However, the standard is still limited to producers in Malaysia. A big issue is most of the doubtful and questionable products are imported from other countries. Unfortunately, Malaysia has been emphasizing halal products and yet still consumes non-halal products. For example, product made from pig such as gelatin powder-a colorless, odorless mixture of proteins extracted from the skin, bones and cartilage of pigs. It is used to thicken and stabilize various jellies, desserts etc (Nuruddin, 2007).

The scenario is more obvious for biopharmaceutical industries. Biopharmaceutical is another branch of pharmaceutical industries that produce the medicines by using bioconversion process. A lot of high value medicines such as monoclonal antibodies and vaccines are produced using this method. The concern of biopharmaceutical products is regarding the production process which use mammalian cell and serum as the media to culture the cells. The fact is that most producers of biopharmaceutical products for the global market are non Muslims and Muslims countries are still lacking and far away in producing their own biopharmaceutical products. For the Muslims, being the certifying body alone is still insufficient if coordination is left to the producers. In addition, if certification standards differ from one Muslim country to the next, one cannot claim that the Muslims are in control (Nuruddin, 2007). As Malaysia is still importing food and pharmaceutical products from non-Muslim countries, thus the presence of non-halal food and pharmaceutical products without proper labeling is still occurring.

Halal issues do not have a geographic boundary. It is a global issue that vital to the Muslim world including the non-Muslim countries. In May 25, 2009 TIME Magazine has mentioned that the current Muslims in the world is 1.6 billion and the number is increasing, particularly in the major metropolitan cities across the U.S. In other published reports, it is quoted that the global halal food trade market is about $150 billion with the Muslim buying-power at about $600 billion (Quadri et al., 2009). In the US alone, the buying-power of Muslims is about $20 billion strong. These figures are very promising. Non-Muslim producers must have halal assurance when they sell their products to Muslim consumers. By assuring the product is halal, they can widen their market because the concept of halal is comprehensive and the halal products food and pharmaceutical products are

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Gillian & al., 1997; Abdul Talib et al., 2008; Zainorni Mohd Janis, 2004; Janis, 2004; Nuruddin, 2007; Quadri et al., 2009.
marketable to both Muslim and non-Muslim consumers. If the halal is taken as the highest standard of products over and above those GMP, HACCP, ISO, GHP and all other quality assurance, we can have a main guideline that covers all of these thus reducing the time and the cost for compliance.

Islamic Manufacturing Practice (IMP):

Before Islam has emerged as a religion in the Arabian Peninsula, it has since become a global phenomenon spanning different regions and cultures across the world. From this perspective the history and development of Islam can be read as a struggle between consistency and diversity. On one side, it has been a remarkable achievement to maintain the relative coherence of the practice and belief systems of Islam over such vast distances.

Islamization has two fold jobs: first: expanding, upgrading and modernizing Islamic disciplines, second: connecting all other disciplines to Islamic faith and values. In an effort to ennoble and enrich the quality of civilization, one should make reference to what has been mentioned in the Qur’an on matters concerning consumerism. In other words emphasis should be on both the halal aspect and the tayyiban aspect. If certification imposed by the authorities is simply to differentiate between halal and non-halal alone, the quality of the products and services can be called into questioned. Many assume that the Muslims are unable to be primary producers as reasons to consider the participation of non Muslims in production (Nuruddin, 2007).

The concept of Islamic Manufacturing Practice (IMP) has been introduced in Malaysia but unfortunately it is still unofficially and not recognized by the government. The history and definition of IMP is still equivocal. In one source, it was stated that the founder of IMP is Tuan Hj. Ahmad Tajuddin (IMP, 2010). He with the delegation of IMP is attempting to get the cooperation, support and recognition of IMP as a model for halal certification which actually meets with the Islamic law to be adopted by all Muslims (IMP, 2010). According to IMP community:

“IMP is intended to provide a guideline under an appropriate system for managing Shar’iah Compliance. It is also intended to ensure that all manufacturers meet the requirements for quality, efficacy and purity towards the halaalan thoyyiba products” (IMP, 2010).

The establishment of a small community called IMP Community and a website has become a platform for them to organize small seminars in order to educate people about IMP. Meanwhile, the second source stated that the IMP was first used by Sidratul Enterprise, a 100% local company. In year 2005, Sidratul Enterprise came out with IMP as its standard operating practice (Sidratul Enterprise, 2006). The company claimed that Sidratul had created her own history of being the only industry practicing IMP as its standard of operation today. Moreover, the IMP is towards pattern application with SMIDEC and SIRIM in order to archive the halaalan thoyyiba standard that provides the excellence products in accordance with syara’ requirements.

Unfortunately, the concepts and the contents of their IMPs are still narrow and weak. Theirs IMPs are only recognized by small scale producers who are majority Muslims. Furthermore, the idea of only Muslims worker are qualified by IMP is also impractical because most of the pharmaceuticals and food productions are still dominated by non-Muslims consumers. It is more beneficial if, the IMP can provide a guideline which is applicable for Muslims and non-Muslims producers if they have intention to sell their products in Muslims markets. With a good intention and a proper approach, IMP can be accepted by the whole world. The weaknesses of the present IMP development cause the lack of information about IMP available in the web search engines.

Nevertheless, the idea of Islamic Manufacturing Practice – IMP has a high potential and commercial value similar to GMP if further improvements are supported by most Muslim countries especially the Organization of Islamic Conference (OIC). They should acknowledge and recognize the importance of having a standardized international guideline of IMP. Besides, the IMP is an index based on the principle of halalan tayyiban thus from the perspective of quality, if one is certified by the IMP, one would not worry about many things since the certification body is assumed to have the capacity to look into those matters. All people must understand that most of the Islamic guidelines are comprehensive and they are applicable to non-Muslims too, however most of non-Islamic guidelines are limited and not applicable to Muslims.

The importance of a standardized IMP:

In this study, the importance of a standardized IMP is discussed based on some main requirements in GMP.

Raw Material:

Raw and ingredients that will be used in the production must be from halal sources - clean, safe, hygiene – and not come from non-halal sources. Non-halal sources are defined as:
Alcoholic drinks and intoxicating drugs, pork and its by-products, meat of dead animal, blood, and meat of animals not slaughtered according to Islamic requirements, products that contain any of the above items” (Quadri et al., 2009).

Allah SWT says in surah Al-Ma’idah verse 3:

“All liquor contains alcohol but not all alcohol is liquor. Alcohol which was derived from the liquor production processes is haram and considered as filth but alcohol which are derived from non-liquor production processes is not filth but Haram to be drank because it is poisonous and harmful. Soft drinks which are made with the same way as the liquor production process either contained a little alcohol or its alcohol has been distilled are haram to be drink. Soft drinks which are not made for liquor or any intoxicating drinks and are not produced in the same way as the liquor processes are halal. Cordials which contain any flavouring substances derived from alcohol for the purpose of stabilizing the soft drinks are allowed to be used as drinks, if the alcohol is not made from a liquor production process and the quantity of alcohol in the flavours is too little and not resulting in drunken condition or any side effect. Alcohol that is produced from the food production processes as the by-product is non-filth and allowed to eat. Medicines and fragrances, which contain alcohol, are allowed to be used” (Ahmed Robin Wahab, 2004)

Meanwhile, according to Khattak, the amount of alcohol must be reduced to less than 0.5% in the final flavouring product. Certain countries or customers require lower allowances or even absence of alcohol for products brought into their countries (Khattak, 2010).

Food additives are not natural nutrition for humans or their pets. Children are suffering the most from food additives because they are exposed to food chemicals from infancy, and human bodies were not meant to be exposed to the degree of chemicals and food additives that we are currently. Some of the dangerous chemicals and food additives are Acesulfame K, Butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT), Monosodium Glutamate (MSG) and Sulphites (Hull, 2011). Acesulfame K is a sugar substitute sold in packet or tablet form, in chewing gum, dry mixes for beverages, instant coffee and tea, gelatin desserts, puddings and non-dairy creamers. Tests have showed that the additives cause cancer in animals, which means it may increase cancer in humans. BHA and BHT as accordance to the International Agency for Research on Cancer of WHO are considered to be possibly carcinogenic to humans, and the State of California has listed it as a carcinogen. These two closely related chemicals are added to oil-containing foods to prevent oxidation and retard rancidity but the uses are totally unnecessary.

Meanwhile Japanese chemist identified MSG as the substance in certain seasonings that added to the flavour of protein-containing foods but unfortunately too much MSG can lead to headaches, tightness in the chest, and a burning sensation in the forearms on the back of the neck (Hull, 2011). Finally, sulfites are a class of chemicals that can keep cut fruits and vegetables looking fresh. Until the early 80’s they were considered safe, but currently six scientific studies were found to prove that sulfites could provoke sometimes severe allergic reactions. The FDA has identified at least a dozen fatalities linked to sulfites. All of the deaths occurred among asthmatics (Hull, 2011). In GMP, the FDA does not require companies to disclose the ingredients of their flavor additives as long as all the chemicals in them are considered GRAS (generally recognized as safe). This enables companies to maintain the secrecy of their formulas, such as Cola’s secret formula or Colonial...
Sander’s secret recipe. It also enables hiding numerous ingredients in order to keep the label simple (Khattak, 2010). Thus, it is seriously important to have an IMP that discloses the ingredients of the products especially during the auditing and inspection for IMP compliance.

**Quality Management and Personnel:**

Quality management is the highest priority for any company to be qualified by International Standard Organization (ISO). In fact, it is also vital for the GMP and thus IMP. The quality managements is defined as follows:

“The aspect of management function that determines and implements the quality policy ... includes strategic planning, allocation of resources and other systemic activities for quality, such as quality planning, operations and evaluations” (Ebied, 2004).

The attainment of desired quality requires the commitment and participation of all members of the organization whereas the responsibility for quality management belongs to top management. The quality systems are also influenced by the objectives of the organization, by the product and services. Abdullah bin Mas’ud reported: The Prophet (PBUH) said,

“Truth leads to piety and piety leads to Jannah. A man persists in speaking the truth till he is enrolled with Allah as a truthful. Falsehood leads to vice and vice leads to the Fire (hell), and a person persists on telling lies until he is enrolled as a liar” (An-Nawawi, 1987).

Islamic management, unlike the conventional management, looks at the management of organizations from the perspective of the knowledge from the revealed sources and other Islamic sources of knowledge. The application is compatible with Islamic beliefs and practices. There is no demarcation between the secular and the religious; human life is an organic whole. All human activities can be ibadah provided they are guided by Allah’s commandments. In Islamic management, the organizational objectives are both economic and non-economic and are subservient to the larger purpose of human existence; whereas in conventional management, organizational objectives are also both economic and non-economic in nature, but are subservient to organizational interests (Ahmad Sarji Abdul Hamid, 2007). That is why; leaders in top management must have good and strong inner qualities in performing their duties. This is to avoid personal interest that may lead the imbalance judgment towards certain companies. The management also must have clear objectives which is not only focusing the profit, but thriving well for the ummah. These values and attributes should also be applied to all personnel in the industries.

**Documentation and Quality Control:**

According to European Commission, a document is the written procedures, instructions, requirements, registration files and others that to be needed in storage, procedures, manufacturing and quality control (EC, 2010). Documentation is a prime necessity in quality assurance purposely to define the system of control, reduce the risk of error inherent in purely oral communication, insure that personnel are instructed in the details of, and follow the procedures concerned and permit investigation and tracing defective products. This is one of the important requirements in GMP that can be applied directly to IMP. All activities stated in the production areas should have documentations especially in the production line of pharmaceuticals. Therefore, any form of deviation in control environment and mis-operation can be traced and detected. Usually documentation is highly required during audit inspection as a proof for the running activities in the production line.

Meanwhile, according to European Federation of Pharmaceutical Industries and Associations, in most pharmaceuticals manufacturing, the processes may not be standardized or fully validated, thus testing takes on more importance in ensuring that each batch meets its specification (EC, 2010). The responsibilities of Quality Control should be described in writing, and should include but not necessarily be limited to responsibility for the followings:

“approving specifications, approving test procedures approving validation plans and reports, sampling, approving reference standards, analytical investigations and evaluation of results, testing materials, providing analytical reports, approving or rejecting raw materials, packaging materials and active ingredients gathering data to support retest dates, or stability testing”(EFPIA, 1996).

The requirements are also applicable to food manufacturing. It can be seen from stated responsibilities, validation and testing are the main concern in quality control. For IMP development, the requirements of validation and IMP should be clearly defined. Islamic perspectives and ethical principles must be included especially for the animal testing issues and quality inspections. Related personnel must be honest in doing the inspection. The results of inspections must be transparency for further improvement and correction although the correction it will consume more cost and time to ensure the products are safe, clean and the halal status of product is strictly and properly tested.
Transportation and shipping:

The concern in transportation and shipping aspects is quite similar with the storage and packaging requirements. In GMP, transportation and shipping of products should be conducted according to instructions given by or on behalf of the sponsor in the transportation and shipping order. Such transfers should be covered by standard operating procedures (EC, 2010). However, for IMP additional requirements must be included for halal and non-halal products. These products should be transported differently to avoid any exposure to contamination of halal products by non-halal product if leakage incident occurs along the journey. The conditions of the products in the vehicles should also be controlled and maintained to the quality standard. The transportation and shipping issue is also highlighted during the World Halal Forum Europe, held in November 2009 in The Hague, Netherlands (Marco, 2010). With halal now being a global business, led by multinationals and with logistics being inherently cross-border, an international halal logistics standard is important. The transportation and shipping is a part of the content of the proposed logistic standard. This standard should not be developed separately. It is more practical if it is included in IMP.

Conclusion:

It is clear that halal issues recognized safety and quality assurance. It means the product prepared must be up to the standards, which also include hygiene. Safety and quality assurance ensure that the halal products are also clean, safe and well taken care of, with good presentation and served in a proper manner, and of quality for everybody. The enormous potential of the worldwide demand for halal food and pharmaceutical must be seized by local manufacturers. This is an advantage when these manufacturers comply and adhere to the IMP. Allah says in Quran, verse 5:2

"Help you one another in Al-Birr and At-Taqwa (virtue, righteousness and piety); but do not help one another in sin and transgression" (Abdullah Yusuf Ali, 2005).

According to the verse, it is clear that development of IMP should be supported by all Muslims because it is a righteous deed in the search of halal. Thus, all Muslims should be united and with the big and strength unity, the development of a standard IMP can be achieved. OIC as the main organization of Muslim countries should champion the development of IMP.

References


