

UNIVERSITI TEKNOLOGI MARA

**DEVELOPING HALAL BUILT-IN
WORK SYSTEM FOR
MANUFACTURING OF
PHARMACEUTICALS**

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ABSTRACT

Halal built-in is a systematic approach which integrates the requirement of halal in all aspect of manufacturing. However, the Malaysian Standard in Halal Pharmaceuticals, and guidelines for halal certification in Malaysia are diverse and missing an overview of an efficient work system framework. Furthermore, the standards and guidelines emphasise more on the technical requirements, lacking emphasis on values, spiritual or conscience elements. This qualitative case study was conducted to 1) explore the current practices in implementing halal built-in system adopted by the Malaysian halal industry stakeholders for manufacturing halal pharmaceuticals, 2) elucidate the references that have been used by the halal industry stakeholders as guidance for production of *Shari'ah* compliant pharmaceuticals 3) discover the challenges that need to be overcome to successfully implement a halal built-in system 4) propose a framework of halal pharmaceutical built-in work system. Data were collected through face-to-face semi-structured interview with experts, selected through purposive sampling and divided into four groups, namely the *fiqh* expert, JAKIM officers, Ministry of Health regulators (MoH) and pharmaceutical industry players. Three participants were interviewed from each group. The interview protocol was developed based on Steven Alter's Work System Method (WSM) consisting of nine (9) elements. The data from transcribed interviews were assessed using thematic analysis. Outcome of the study showed that, with regards to the current practice of halal built-in work system implementation, the four groups of participants seem to have differing depth and polarised knowledge of the current practice in halal built-in system. *Fiqh* experts were polarised towards the upstream elements such as *Shari'ah* and *fatwa* matters. Instead, MoH participants' responses were mostly skewed towards the downstream of the halal built-in, focusing more on the end user's, such as patients' demand for halal medicine, doctors' concern on medication non-compliance, and MoH's halal logo policy. JAKIM and the industry participants showed more comprehensive knowledge on halal built-in system, since they were actively involved. Regarding the second objective, similar polarisation of knowledge on references and lack of cross discipline expertise that are important for adopting the halal built-in concept was observed. MoH and industry players relied mostly on *fatwa* as their source of *fiqh* information while *fiqh* experts were well versed in more *fiqh* references but lacked the knowledge on technical references. JAKIM officers, with Islamic studies background seem to have knowledge in both aspects. On objective three, the three most common issues raised by all group of participants were 1) manufacturers' lack of understanding of halal principles and halal certification documentation and application 2) MoH's prohibition of having halal logo on the label of prescription medicines 3) lack of enforcement in halal industry and unavailability of a 'Halal Act' in Malaysia. The potential solution includes attending more awareness programs and training, conduct research to support the halal logo policy change and potential legislative efforts to establish a Halal Act or enactment. In light of the findings, the study introduces a framework for a Halal built-in work system which integrates the nine WSM elements and incorporated *fiqh* principles as the core, to create a holistic system that encompasses ethical values and spirituality. The framework which provides a clear overview of the elements required for a halal built-in work system, aims to serve as a practical reference for the industry, potentially alleviating implementation barriers and promoting growth within the halal pharmaceutical market. Keywords: Halal Built-in, Halal Pharmaceutical, Work System Method, Halal Work System

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TABLE OF CONTENTS

	Page
CONFIRMATION BY PANEL OF EXAMINERS	ii
AUTHOR'S DECLARATION	iii
ABSTRACT	iv
ACKNOWLEDGEMENT	v
TABLE OF CONTENTS	vi
LIST OF TABLES	x
LIST OF FIGURES	xii
LIST OF ABBREVIATIONS	xiii
CHAPTER ONE INTRODUCTION	1
1.1 Background Information	1
1.1.1 Halal	1
1.1.2 Halal Industry	3
1.2 Problem Statement	5
1.3 Research Questions	7
1.4 Research Objectives	8
1.5 Significance of Study	9
CHAPTER TWO LITERATURE REVIEW	10
2.1 Introduction	10
2.2 Fundamentals of <i>Fiqh</i> and <i>Sharī'ah</i> Law	10
2.2.1 <i>Sharī'ah</i> and <i>Fiqh</i>	10
2.2.2 Relationship between <i>Sharī'ah</i> and <i>Fiqh</i>	11
2.2.3 Categories in the Subject of <i>Sharī'ah</i>	13
2.2.4 Components of <i>Sharī'ah</i> Law	14
2.2.5 Sources of <i>Fiqh</i> and <i>Sharī'ah</i> Law References	16
2.2.6 Overview of Islamic Jurisprudence (<i>Usul Fiqh</i>) & Islamic Legal Maxim (<i>Qawa'id Fiqhiyyah</i>)	20
2.2.7 Islamic School of Thoughts (<i>Madhhab</i>)	23

CHAPTER ONE

INTRODUCTION

1.1 Background Information

1.1.1 Halal

Halal is a Qur'ānic term that signifies permissible, lawful and allowed, according to the *Sharī'ah* law as stated in the Holy Qur'ān. The opposite of halal is haram or non-halal which means forbidden, unlawful, and not allowed. In the Manual Procedure for Halal Certification Malaysia (JAKIM, 2014) it was explained that the term halal can also be broken down to the word halla, yahillu, hillan wahalalan which means to be allowed or permitted by *Sharī'ah* ruling. Anything which lies within the grey area and does not fall clearly under the halal or haram category is classified as 'shubhah', which means questionable or dubious.

Muslims should not only avoid haram matters, but they are also advised to avoid consuming shubhah food or drinks until the status becomes clear. It is reported by Bukhari, Muslim, Abu Daud, Ibn Majah and Darimi, as:

“What is halal is clear. And what is haram is also clear. And in between those two is a dubious area in which many people do not know about. So whoever distanced himself from it, he has acquitted himself (from blame). And those who fall into it, he has fallen into a state of haram”.

Based on the narration, the Prophet (peace be upon Him) has asked his people to stay clear of *shubhah* matter. *Halalan toyibban* is another widely known term which simply means allowed and permissible for consumption with relation to *Sharī'ah* law as long as they are safe and not harmful (Che Rosmawati et al., 2015). There are many verses in the *Qur'ān* which explains about Halal. Among others are the two verses below:

يَا أَيُّهَا النَّاسُ كُلُوا مِمَّا فِي الْأَرْضِ حَلَالًا طَيِّبًا وَلَا تَتَّبِعُوا خُطُوَاتِ الشَّيْطَانِ ۚ إِنَّهُ لَكُمْ عَدُوٌّ مُّبِينٌ (١٦٨)

“O ye people! Eat of what is on earth lawful and good; and do not follow the footsteps of the evil one for he is to you an avowed enemy. (Al-Qur'ān 2:168. Translation by Yusuf Ali)