



Faculty of Information and Communication Technology

**HALAL COMPUTERISED SYSTEMS FRAMEWORK FOR THE
HALAL PHARMACEUTICALS**

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**HALAL COMPUTERISED SYSTEMS FRAMEWORK FOR THE HALAL
PHARMACEUTICALS**

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**A thesis submitted in the fulfillment of the requirements for the degree of
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DECLARATION

I hereby declare that this thesis entitled “HALAL COMPUTERISED SYSTEMS FRAMEWORK FOR THE HALAL PHARMACEUTICALS” is the result of my own research except as cited in the references. The thesis has not been accepted for any degree and is not concurrently submitted in candidature of any other degrees.

Signature :
Name : Raja Rina bt Raja Ikram
Date : 23-04-2013-.....

DEDICATION

To my beloved husband, mother and children...

ABSTRACT

This research aims to develop a framework to address halal regulatory industry requirements for computerised systems in the pharmaceutical industry. Computerised systems and software technology are heavily used to improve manufacturing and supply chain performance. Industry and religious authorities require a documented guideline to enforce halal certification whenever a manual operation is substituted by a computerised system. This research provides a critical analysis on the existing system in three main areas. First, an analysis of computerised systems used throughout the pharmaceutical supply chain. Second, the identification of critical points and controls required in halal pharmaceuticals based on the guidelines of two countries – Malaysia and Indonesia. Third, a review of existing regulatory requirements for Computerised Systems. A conceptual framework was designed and developed using the Hazard Analysis Critical Control Point (HACCP) method to identify critical control points that lead to haram contamination. The initial framework was then validated via a review of Manufacturing Execution System (MES) implementation, a case study of an Enterprise Resource Planning (ERP) implementation, a critical analysis of the international pharmaceutical industry standards, interview with subject matter experts and validation via prototype application. The outcome of this research would directly contribute to the gap in the current Halal Pharmaceuticals Guideline where usage of technology or computerised systems is not documented.

ABSTRAK

Penyelidikan ini bertujuan untuk membangunkan suatu rangka kerja sebagai panduan untuk penguatkuasaan farmaseutikal halal dalam bidang sistem berkomputer. Penggunaan teknologi untuk meningkatkan prestasi industri semakin meluas. Ahli industri dan pegawai penguatkuasa agama memerlukan panduan yang didokumentasi untuk pensijilan halal apabila suatu operasi manual diambil alih oleh sistem berkomputer. Suatu analisa kritikal telah dilaksanakan dalam penyelidikan ini dan dibahagikan pada tiga bahagian utama. Pertama, mengenalpasti dan menganalisa sistem berkomputer yang digunakan di industri farmaseutikal. Kedua, identifikasi titik pengawalan kritikal berdasarkan panduan farmaseutikal halal untuk dua negara – Malaysia dan Indonesia. Ketiga, menganalisa panduan penguatkuasaan industri farmaseutikal untuk sistem berkomputer. Suatu rangka kerja awal telah direka melalui kaedah *Hazard Analysis Critical Control Point* (HACCP) untuk mengenalpasti titik kawalan yang boleh menyebabkan kontaminasi haram. Rangka kerja awal ini kemudian divalidasi melalui penilaian kes implementasi *Manufacturing Execution System* (MES), *Enterprise Resource Planning* (ERP), analisa kritikal panduan penguatkuasaan industri, temuramah bersama ahli bidang masing-masing dan validasi melalui sistem prototaip. Hasil penyelidikan ini berpotensi untuk menyumbang kepada jurang di dalam panduan pensijilan farmaseutikal halal di mana penggunaan teknologi berkomputer tidak didokumentasikan.

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LIST OF ABBREVIATIONS

APS	-	Advanced Planning System
B2B	-	Business to Business
B2C	-	Business to Customer
BMS	-	Building Management System
CCM	-	Chemical Company Malaysia
CCP	-	Critical Control Point
CFR	-	Code of Federal Regulations
CLM	-	Council of Logistics Management
CMMS	-	Computerised Maintenance Management System
CP	-	Critical Point
CPG	-	Compliance Policy Guide
CRM	-	Customer Relationship Management System
EBRS	-	Electronic Batch Recording System
EC	-	European Commission
EDMS	-	Electronic Document Management System
EPS	-	Electronic Procurement System
ERES	-	Electronic Records and Electronic Signature
ERP	-	Enterprise Resource Planning

ERP	-	Enterprise Resource Planning
EU	-	European
FA	-	Factory Automation
FDA	-	United States Food and Drug Administration
GAMP	-	Good Automated Manufacturing Practice
GCP	-	Good Clinical Practice
GLP	-	Good Laboratory Practice
GMP	-	Good Manufacturing Practice
HACCP	-	Hazard Analysis Critical Control Point
HrACCP	-	Haram Analysis Critical Control Point
ICH	-	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ID	-	Identification
LeMS	-	Learning Management System
LIMS	-	Laboratory Information Management System
LoMS	-	Logistic Management System
MES	-	Manufacturing Execution Systems
MOPI	-	Malaysia Organisation Pharmaceutical Industry
MRP	-	Materials Resource Planning
PDM	-	Product Data Management
PIC/S	-	Pharmaceutical Inspection Co-operation Scheme
PLC	-	Programmable Logic Control

PPIC	-	Production Planning and Inventory Control
PRC	-	Pharmaniaga Research Centre
QC	-	Quality Control
SCADA	-	Supervisory Control and Data Acquisition
SOP	-	Standard Operating Procedure
TMS	-	Transportation Management System
URS	-	User Requirements Specifications
US	-	United States of America
WMS	-	Warehouse Management System

LIST OF PUBLICATIONS

Raja Ikram, R. R., Abd Ghani, M. K., Hasan Basari, A.S., 2012. “Halal Computer Systems Validation: Quality Assurance, Risk Assessment and Regulatory Compliance for the Pharmaceutical and Healthcare Industry”, International Conference of Engineering & ICT , Melaka, April 4th-5th 2012.

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