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### Developing A Halal Built-In Work System For Pharmaceutical Manufacturing

Suraiya Abdul Rahman<sup>1,2\*</sup>, Shamsul Mohd Nor<sup>3</sup>, Nurulhuda Noordin<sup>4</sup> and Abu Bakar Abdul Majeed<sup>2</sup>

<sup>1</sup> Faculty of Pharmacy, University College MAIWP International, Jalan 31/10A, Taman Batu Muda, Batu Caves, 68100 Kuala Lumpur, Malaysia

<sup>2</sup> Faculty of Pharmacy, University Teknologi MARA (UiTM) Selangor, 42300 Puncak Alam, Malaysia

<sup>3</sup> ITMAM Foundation, Batu Caves, 68100, Selangor, Malaysia

<sup>4</sup> Faculty of Computer and Mathematical Sciences, UiTM, Malaysia

\*Corresponding author: Suraiya Abdul Rahman

E-mail address: suraiya@ucmi.edu.my

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#### ABSTRACT

Halal built-in is a systematic approach which integrates the requirement of halal in all aspect of manufacturing from research and development to raw material sourcing until delivery of finished products. It is a concept that is still under-developed and not a well-established in the pharmaceutical sciences industry despite the establishment of the MS 2424:2012, Malaysian Standard in Halal Pharmaceuticals-General Guidelines in 2012. Despite the introduction of the MS 2424:2012 Malaysian Standard on Halal Pharmaceuticals, its implementation remains inconsistent due to fragmented guidelines, a lack of integration between regulatory and Shariah principles, and an absence of a comprehensive work system framework. This qualitative case study investigates current Halal Built-In practices in Malaysia's pharmaceutical industry, identifies key Shariah-compliant references, explores challenges in its adoption, and proposes an integrated work system framework. Data collection involved semi-structured interviews with four key stakeholder groups: fiqh scholars, JAKIM certification officers, Ministry of Health (MoH) regulators, and pharmaceutical industry representatives. Using Steven Alter's Work System Method, nine critical elements—process, information, participants, technologies, products, customers, environment, infrastructure, and strategies—were analyzed through thematic analysis. Findings reveal varying levels of understanding and differing priorities among stakeholders. Fiqh scholars emphasize Shariah compliance and raw material purity, while MoH regulators focus on labeling policies and consumer preferences. Meanwhile, JAKIM officers and industry players demonstrate a more comprehensive grasp of halal certification requirements but highlight gaps in technical knowledge among manufacturers. Key challenges include the absence of a dedicated Halal Act, misalignment between regulatory policies and halal requirements, and limited cross-disciplinary collaboration. To address these challenges, the study proposes a Halal Built-In Work System Framework, integrating Islamic principles with operational efficiency, ethical values, and regulatory compliance. This framework offers a structured approach for pharmaceutical companies to seamlessly implement halal requirements, ensuring both compliance and market

competitiveness. Ultimately, the study underscores the growing importance of a holistic Halal Built-In system in strengthening Malaysia's position as a global leader in halal pharmaceuticals

**Keywords:** *Halal Built-In, Halal Pharmaceuticals, Work System Framework, Halal Certification, Shariah Compliance*

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## Introduction

The concept of halal has long extended beyond food to encompass pharmaceuticals, cosmetics, logistics, and services. The global halal pharmaceutical market continues to grow, driven by increasing awareness and demand for Shariah-compliant products. In the pharmaceutical industry, halal compliance requires stringent control over sourcing, processing, and certification to ensure that the final product meets both Shariah and regulatory standards. Despite Malaysia's proactive stance in introducing the MS2424:2012 Halal Pharmaceuticals - General Guidelines, (2012), the industry still faces challenges in its consistent implementation.

A systematic "Halal Built-In" approach that fully integrates halal requirements into every aspect of pharmaceutical production is essential to fill this gap. However, the concept of Halal Built-In—a systematic approach to integrating halal requirements throughout the manufacturing process—is still underdeveloped within the pharmaceutical sector.

### *Regulatory and Shariah Frameworks*

The whole teaching of Islam consisting of laws and way of life prescribe by Allah including the laws on halal and haram. The law of Allah and its inner meaning is not easy to grasp. Therefore, *Sharī'ah* is needed to regulate all human actions (Laldin, 2011). The main goal of the *Sharī'ah* is to bring about benefits for the people in regard to their issues in this life and the next. It is commonly accepted that the *Sharī'ah* works to secure advantages for the people or to keep them safe from evil and corruption in all its components (Afridi, 2016).

### *Concept of Halal Built-In Work System*

Halal Built-In emphasizes embedding halal principles into every phase of pharmaceutical manufacturing, from research and development to product delivery. Unlike traditional post-production certification, this approach ensures that halal considerations are intrinsic to the entire work process. The Work System Method by Steven Alter serves as a foundation for analyzing and designing this integrated system, focusing on nine critical elements: processes, information, participants, technologies, products, customers, environment, infrastructure, and strategies (Alter, 2013).

This article explores the development of a Halal Built-In Work System Framework, addressing current gaps, stakeholder perspectives, and proposing a structured solution embedding the essence of shariah to enhance compliance and spiritual elements to the proposed framework.

## Methodology

This study employed a qualitative case study design to explore the implementation of the Halal Built-In system in Malaysia's pharmaceutical industry. The case study approach was selected to gain in-depth insights from multiple stakeholders and to capture the complexity of integrating Shariah principles with technical manufacturing processes and regulatory requirements. The qualitative case study design was guided by Steven Alter's Work System Method (WSM). A total of 12 semi-structured interviews were conducted with four stakeholder groups.

### *Participant Selection and Sampling*

A purposive sampling strategy was used to select participants with specific expertise and roles in the halal pharmaceutical ecosystem. A total of 12 participants were selected and grouped into four categories:

- Fiqh Scholars (n = 3): Experts in Islamic jurisprudence and Shariah law.
- JAKIM Certification Officers (n = 3): Authorities responsible for halal certification processes.
- Ministry of Health (MoH) Regulators (n = 3): Policy makers and compliance officers overseeing drug safety and labeling.
- Pharmaceutical Industry Representatives (n = 3): Individuals from manufacturing firms with halal certification or actively pursuing it.

Participants were selected based on their experience, involvement in halal policy development, and engagement in pharmaceutical operations or certification.

### *Data Collection Procedures*

Data were collected through semi-structured, face-to-face interviews, guided by a protocol developed using the nine WSM elements: processes, participants, information, technologies, products/services, customers, environment, infrastructure, and strategies.

Each interview lasted between 60–90 minutes and was conducted in either English or Malay, depending on the participant's preference. Interviews were audio-recorded with informed consent, transcribed verbatim, and anonymized for confidentiality.

Supplementary data were collected from relevant documents and policy manuals, including:

- Malaysian Halal Pharmaceutical Standard (MS 2424:2012 and 2019)
- Halal Certification Procedures Manual (MPPHM)
- Drug Registration Guidance Document (DRGD)

- Fatwas and circulars relevant to pharmaceutical ingredients and processes

### *Data Analysis*

Data were analyzed using thematic analysis, with a deductive-inductive coding approach. Initial codes were developed based on the WSM framework, and new codes were added inductively as themes emerged from the data. The initial theme used the nine WSM elements: processes, participants, information, technologies, products, customers, environment, infrastructure, and strategies (Suraiya Abdul Rahman, 2023).

### *Data Triangulation and Validation*

Triangulation was employed to enhance the trustworthiness and validity of the study's findings. The following types of triangulations were applied:

**Data Source Triangulation:** Data were gathered from four distinct stakeholder groups to capture varied perspectives across religious, regulatory, and industrial domains.

**Methodological Triangulation:** Multiple data sources—interviews, document reviews, and policy analysis—were used to validate emerging themes.

**Analyst Triangulation:** Coding and interpretation were peer-reviewed by two qualitative researchers with expertise in Islamic jurisprudence and pharmaceutical policy, respectively.

**Theory Triangulation:** Findings were interpreted using both local guidelines, fiqh references (e.g., MHMS and shariah publications) and systems thinking (Alter's, 2002), allowing for a multi-dimensional understanding of the halal built-in system.

These triangulation strategies ensured rigor, credibility, and dependability, and helped mitigate potential researcher bias.

## Results

The qualitative case study revealed rich insights into the current state of Halal Built-In practices within Malaysia's pharmaceutical industry. Analysis of data highlighted variations in stakeholder understanding, critical challenges, and the necessity for an integrated framework to streamline halal compliance in pharmaceutical manufacturing.

- Fiqh Experts focused on upstream Sharī'ah issues such as fatwa, najis avoidance, and ingredient permissibility.
- MoH Regulators prioritized consumer protection, labeling constraints, and medication compliance challenges.
- JAKIM Officers demonstrated cross-disciplinary understanding of halal certification, Shariah rulings, and quality systems.
- Industry Players showed practical knowledge of supply chains and GMP but lacked depth in *Sharī'ah* knowledge.

### *Challenges in Implementing Halal Built-In Work System*

Across all stakeholder groups, several key challenges emerged:

1. Absence of a Dedicated Halal Pharmaceuticals Act: The lack of a specific legislative framework for halal pharmaceuticals limits enforcement and standardization.
2. Misalignment of Regulatory and Shariah Requirements: Differences between NPRA's focus on product safety and JAKIM's halal compliance create conflicting priorities.
3. Fragmented Guidelines and Multiple Standards: Diverse and sometimes contradictory halal guidelines complicate implementation efforts.
4. Technical Knowledge Gaps: Limited understanding of pharmaceutical processes among Shariah scholars, and insufficient fiqh

knowledge among industry players, hampers holistic compliance.

5. Resource Constraints: SMEs struggle with the financial and human resources needed to adopt comprehensive halal built-in systems

The outcome from the study also shows that the current practice of halal Built-in and halal certification requirements focuses more on the physical and mechanistic paradigm and lacks spiritual and ethical values. Halal is a faith-based practice as a sign of obedience to Allah, is not only about meeting material and documents requirements related to the demands of producing halal products but also needs to showcase comprehensive Islamic values. It should be understood that 'halal' does not just cover things related to the physical substance of the product but also includes a comprehensive and unique network and a mutually integrated cycle.

### *Proposed Halal Built-In Work System Framework*

To bridge the gap, a Halal Built-In Work System Framework is proposed, incorporating:

1. Islamic legal foundations (Sharī'ah and Usul al-Fiqh) as the core reference
2. The nine elements of the Work System Method (WSM) for operational structuring
3. Integration with Good Manufacturing Practice (GMP) and Halal Assurance System (HAS)
4. Emphasis on conscience-based values and ethical decision-making.

The halal built-in work system integrates the following WSM as per Alter's (2013) elements with Shariah-based values:

Table 1. Halal Built-In Work System Elements

WSM Element	Halal Built-In Integration Focus
Processes	Embed halal checkpoints at each manufacturing stage—R&D, sourcing, production, packaging, and distribution.
Participants	Multi-disciplinary teams including Shariah advisors, QA/QC staff, R&D chemists, procurement officers, and regulators.
Information	Establish centralized halal knowledge management (including fiqh references, fatwas, ingredient databases, and SOPs).
Technologies	Use halal-compliant materials, validated systems for traceability, and software to support decision-making and audits.
Products	Ensure every output (active ingredients, intermediates, and finished products) adheres to halal standards and maqasid.
Customers	Design patient-centered strategies to meet religious sensitivities and improve trust, especially for chronic medications.
Environment	Align company policy with both national halal strategy and global pharmaceutical regulations, as well as cultivate spiritual and value-based culture.
Infrastructure	Institutionalize Halal Internal Committee (IHC) and audit mechanisms aligned with MS2424 and HAS.
Strategies	Integrate halal policy in business models; pursue R&D for halal alternatives; advocate for Halal Act enactment.

This above holistic elements can be integrated into a work system snapshot (Alter, 2013) for easy reference and ensures continuity of compliance across the value chain, replacing the ad hoc and reactive approach currently practiced in many firms.

The snapshot can be seen in table 2. This framework guides organizations to internalize

halal as a management philosophy, rather than a compliance burden. It promotes traceability, accountability, and continuous improvement through training, cross-functional alignment, and spiritual motivation. The framework is intended to serve as both a guiding blueprint and a compliance tool, enabling pharmaceutical companies to internalize halal requirements throughout their supply and production chain, not merely at the certification endpoint.

Table 2: Proposed Halal built-in Work System Snapshot

Proposed Halal built-in Work System Snapshot				
Adapted Work System Snapshot Template				
Customers		Products		
<ul style="list-style-type: none"> <li>Government Hospitals</li> <li>MINDEF/Armed forces Tengkuz Mizan hospital</li> <li>Patients/end user.</li> <li>Mass market</li> <li>Export to Middle East and OIC countries</li> <li>Independent pharmacy</li> <li>High traffic outlet like 7Eleven.</li> </ul>		<ul style="list-style-type: none"> <li>Pharmaceuticals products such as over the counter products, health supplements, traditional products and ethical products. Eg: Metformin, the diabetes drug, which is already halal, the doctor will prefer to take Halal</li> </ul>		
Major Activities and Processes				
In-bound phase	Production phase	Out-bound Phase		
<ul style="list-style-type: none"> <li>Raw Material Selection</li> <li>Packaging Materials</li> <li>Materials/ Raw Material Control/Istihalah</li> </ul>	<ul style="list-style-type: none"> <li>Sertu (Islamic Cleansing)</li> <li>Processing/production</li> <li>Halal Internal Audit/self-inspection</li> <li>Quality Control</li> <li>Halal Certification</li> </ul>	<ul style="list-style-type: none"> <li>Complaints and Product Recall</li> <li>Transportation &amp; Distribution</li> </ul>		
Spiritual And Values Building Campaign and Activities MHMS 2020/ Halal Built-in HAS Traceability Halal Risk Control & HCP Identification				
Participants	Information		Technologies	
<ul style="list-style-type: none"> <li>JAKIM</li> <li>JAIN</li> <li>Mufti</li> <li>Workers</li> <li>Dedicated Halal Executive</li> <li>Head of the site.</li> <li>Internal Halal committee</li> <li>The Halal representative from every department.</li> <li>Vendors, suppliers, logistics provider.</li> <li>Health care provider and private health care providers.</li> <li>Relevant Stakeholders, academicians, government.</li> <li>Leaders &amp; Top Management team</li> <li>Shari'ah advisors</li> </ul>	<b>Document for HAS Manual</b> HAS Manual Halal Policy IHC organization Chart SOPs to explain implementation of the activity for every process in detail. Halal Critical Control Point (HCP) Training SOPs/Plan <b>Raw Material</b> Halal certificate, Material specification, production process flow chart, Certificate of Origin/declaration of the ingredient source (free from animal and alcohol from khamar). MSDS COA GMP statement TSE/BSE statement. Drug Master File (DMF) Product Technical Information Manufacturing Formula CEP if any Critical Ingredients Suppliers contact number supplier audit report Supplier Approved List <b>SOPS</b> Integrated with GMP material purchasing, new material purchasing, production, co-production & non-conformance. Dedicated Halal SOP SOP for halal material selection, Sertu, halal certification application, product recall & internal halal audit (IHA)		<b>Document for Halal File</b> Halal File application form address and contact Product List Labelling information <b>Licences</b> SSM, PBT Manufacturing licence from NPRA employee training and check-up <b>Certificates</b> GMP Register with NPRA (MAL number) <b>Records</b> Batch Manufacturing Record Training records Pest Control Cleaning, record <b>Others</b> Internal Halal Committee meeting report & minutes Audit Report Lab test result for porcine if necessary. Information on Muslim worker Financial reports, Sertu history	<ul style="list-style-type: none"> <li>Use existing GMP certified production tools and technology.</li> <li>Internet connectivity</li> <li>Social media platform</li> <li>Telephones</li> <li>Email</li> <li>Database of halal raw materials from JAKIM</li> </ul>

From the snapshots, a summary of the recommended Halal Built-in Work System, can be easily referred as a quick guidance for a new beginner to get an overview of the elements that they need to put in place in order to produce a halal pharmaceutical that meet the Shari'ah requirement and qualify for halal certification. This finding firstly reveals that, to establish a Halal built-in Work system that comply to

JAKIM halal certification requirement is not very complicated and can be viewed with a one-page summary snapshot, and secondly there are room for improvement in the current halal pharmaceutical industry practice to make the halal built-in work system more seamless and encourage more pharmaceutical companies to go for halal.

## **Conclusion**

This study proposes an integrated Halal Built-In Work System Framework tailored for pharmaceutical manufacturing, designed to operationalize Shariah principles while fulfilling regulatory and quality requirements. The proposed framework draws from the nine core elements of the Work System Method (WSM), combining them with Islamic jurisprudence and industrial best practices. With enhanced collaboration, targeted training, and policy alignment, Malaysia can reinforce its leadership in the global halal pharmaceutical sector. Future research should focus on piloting this framework in pharmaceutical manufacturing environments and assessing its impact on compliance and market competitiveness.

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## Izrada halal integrisanog sistema rada za farmaceutsku proizvodnju

Suraiya Abdul Rahman<sup>1,2</sup>, Shamsul Mohd Nor<sup>3</sup>, Nurulhuda Noordin<sup>4</sup> and Abu Bakar Abdul Majeed<sup>2</sup>

<sup>1</sup> Farmaceutski fakultet, Univerziteti Koledž MAIWP International, Jalan 31/10A, Taman Batu Muda, Batu Caves, 68100 Kuala Lumpur, Malezija

<sup>2</sup> Farmaceutski fakultet, Univerzitet tehnologije MARA (UiTM) Selangor, 42300 Puncak Alam, Malezija

<sup>3</sup> ITMAM Foundacija, Batu Caves, 68100, Selangor, Malezija

<sup>4</sup> Fakultet računarskih i matematičkih nauka, UiTM, Malezija

Autor za korespondenciju: Suraiya Abdul Rahman

E-mail adresa: suraiya@ucmi.edu.my

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### Sažetak

Halal integrisani sistem rada predstavlja sistematski pristup koji integriše zahtjeve halala u sve aspekte proizvodnje – od istraživanja i razvoja, preko nabavke sirovina, pa sve do isporuke gotovih proizvoda. Riječ je o konceptu koji je još uvijek nedovoljno razvijen i nije čvrsto uspostavljen u industriji farmaceutskih nauka, uprkos uvođenju malezijskog standarda MS 2424:2012 Halal Pharmaceuticals – Opće smjernice još 2012. godine.

Iako je standard MS 2424:2012 uspostavljen, njegova implementacija ostaje nedosljedna zbog fragmentiranih smjernica, nedostatka integracije između regulatornih i šerijatskih principa, kao i odsustva sveobuhvatnog okvira radnog sistema.

Ova kvalitativna studija slučaja istražuje postojeće prakse halal integrisanog pristupa u farmaceutskoj industriji Malezije, identifikuje ključne šerijatski usklađene izvore, analizira izazove u njegovoj primjeni i predlaže integrisani okvir radnog sistema. Prikupljanje podataka obuhvatilo je polustrukturirane intervjue s četiri ključne grupe učesnika: učenjaci fikha, službenici za halal certifikaciju iz JAKIM-a, regulatori iz Ministarstva zdravstva (MoH) i predstavnici farmaceutske industrije.

Koristeći Steven Alter-ovu metodu radnog sistema (Work System Method), analizirano je devet ključnih elemenata: proces, informacije, učesnici, tehnologije, proizvodi, korisnici, okruženje, infrastruktura i strategije, putem tematske analize.

Rezultati ukazuju na različite nivoe razumijevanja i različite prioritete među akterima. Učenjaci fikha naglašavaju šerijatsku usklađenost i čistoću sirovina, dok regulatori iz MoH-a fokus stavljaju na politike označavanja i preferencije potrošača. U međuvremenu, službenici JAKIM-a i predstavnici industrije pokazuju šire razumijevanje zahtjeva za halal certifikaciju, ali ističu nedostatke u tehničkom znanju među proizvođačima.

Ključni izazovi uključuju nedostatak posebnog zakona o halalu, neusaglašenost između regulatornih politika i halal zahtjeva, te ograničenu interdisciplinarnu saradnju.

Kao odgovor na ove izazove, studija predlaže halal integrisani sistem u okviru radnog sistema koji integriše islamske principe s operativnom efikasnošću, etičkim vrijednostima i regulatornom usklađenošću. Ovaj okvir nudi strukturiran pristup farmaceutskim kompanijama za dosljednu implementaciju halal zahtjeva, osiguravajući pritom i usklađenost i tržišnu konkurentnost.

Zaključno, studija naglašava rastuću važnost holističkog Halal integrisanog sistema u jačanju pozicije Malezije kao globalnog lidera u halal farmaceutici.

**Ključne riječi:** Halal Built-In (halal integrisani sistem), halal farmaceutski proizvodi, okvir radnog sistema, halal certifikacija, šerijatska usklađenost.

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