Zaril Harza Zakaria

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Date of Birth: 19 August 1978 Malaysian Nationality

EDUCATION & QUALIFICATIONS

2010 - 2011 *Cranfield University, Bedfordshire, UK*

MSc Clinical Research

Main subjects include, Regulatory Requirements and Marketing-Research Interface, Research Governance and Ethics, Research Design and Methodology, Practical and Scientific Perspectives of Translational Medicines and Statistical Analysis and Interpretation.

Individual Thesis: 'Rationale and Trends Underlying the Request for Additional Studies and Trials Following Drug Product Approval: Regulatory and Payer Perspectives' (for Quintiles, UK). The purpose of this research is to investigate factors that influence the request for additional post-approval studies and trials and the impact of these factors. These in turn could assist the pharmaceutical industry to better anticipate and plan for regulatory and payer requests and furthermore, ensure that patients are given access to life-saving medicines sooner, with evidence for decision-making made available earlier.

Group Project: 'Training for Clinical Researchers in Emerging Pharmaceutical Markets (China)' (for Institute of Clinical Research (ICR), UK). The purpose of this project was to evaluate the requirements for suitable training approaches in accordance with ICR standards for clinical research in emerging pharmaceutical markets, specifically in China. Working within a team of seven, the project involved meeting with the client, detailed planning of the work process and preparation and presentation of reports.

1998 - 2002 *University Sciences Malaysia, Penang, Malaysia*

Bachelor of Pharmacy (Hons)
Specialization: Pharmacy
Minor: Management Studies

Core subjects included Clinical Pharmacy and Therapy, Clinical Pharmacokinetics, Pharmacy Practice, Dosage Forms and Design, Pharmacoinformatics, Pharmaceutical Analysis, Quality Assurance.

1996 -1998 *University Sciences Malaysia, Penang, Malaysia*

Matriculation

Two-year university level preparatory classes for the competitive entry exams to the School of Pharmaceutical Sciences, University Sciences Malaysia.

1995 *Selangor Sciences Secondary School, Kuala Lumpur, Malaysia*

Malaysia Certificate of Education: Grade One

EMPLOYMENT HISTORY

September 2005 - current

National Pharmaceutical Control Bureau, Ministry of Health Malaysia

Principal Assistant Director, Centre for Investigational New Product

Responsible in evaluating investigative products to be used in clinical trial in Malaysia before issuing Clinical Trial Import Licence and Permit for Exemption to Manufacture for local manufacturers.

Responsible in ensuring monitoring process for all serious adverse events/adverse drug reactions, drug accountability report and closing study reports are monitored and kept systematically.

Responsible in auditing/inspection at trial sites, at the sponsor and/or contract organization's facilities, or at other establishments deemed appropriate in ensuring strict adherence to the Good Clinical Practice (GCP) guidelines and other regulatory requirements being followed.

Member of the Medical Research And Ethics Committee, Ministry of Health Malaysia.

Secretariat for the National Committee for Clinical Research, Ministry of Health Malaysia.

Speaker for the Regulatory Aspects of Clinical Trial in Malaysia for Good Clinical Practice (GCP) Courses and Examiner for the GCP examinations.

June 2003 – September 2005

National Pharmaceutical Control Bureau, Ministry of Health Malaysia

Assistant Director, New Chemical Entity Unit, Centre for Product Registration

Responsible in evaluating new chemical entity products to be marketed in Malaysia.

Responsible in revising policy and procedures/guidelines related to new chemical entity products.

May 2002 – May 2003

National Pharmaceutical Control Bureau, Ministry of Health Malaysia

Pre-Registration Training (Internship)

Areas of training were based on the curriculum for Pre-Registration Pharmacist.

Duties assigned:

Centre for Product Registration, Centre for Post Registration and Surveillance, Centre for Organization Development, Centre for Good Manufacturing Practice.

COMPUTING SKILLS

Software: Project 2010, Word 2010, Excel 2010, Powerpoint 2010, Access 2010

Operating Systems: Windows 7

ACTIVITIES & INTERESTS

Member of Malaysian Lifeguard Association. Learned a lot about discipline, dealing with emergency situations and saving lives.

Member of Professional Association of Diving Instructors (PADI) which provides me with the opportunity to explore the ocean depth. Learned to appreciate the environment.

National driving licence (Malaysia) : category D

PROFESSIONAL/TASK INVOLVEMENT

	Involvement as committee/taskforce/project team	***Level***
1.	Member of the Medical Research And Ethics Committee, Ministry of Health Malaysia (Independent Expert)	National
2.	Secretariat for the National Committee for Clinical Research, Ministry of Health Malaysia	National
3.	Secretariat for the National Committee for Good Laboratory Practice, Ministry of Health Malaysia	National
4.	Member of the Technical Working Group for Biotechnology Products Committee, Ministry of Health Malaysia	National
5.	Member of the Advance therapy Products (ATP) Meeting, Ministry of Health Malaysia	National
6.	Member for the Preparation of Training Modules for Training of Trainers Good Governance for Medicines, Ministry of Health Malaysia	National
7.	Appointed as Member in Action Committee for NPCB's Credentialing and Privileging for Pharmacists	National
8.	Appointed as System Administrator for NPCB's Computer System	Organisational
9.	Chairman for Committee for Fire Prevention and Safety, NPCB	Organisational
10.	Appointed as Lead Auditor for NPCB's Assets Audit	Organisational
B.	***Involvement in Quality Improvement project***	
1.	Appointed as Chairman for 5S Audit Committee, NPCB	Organisational
C.	***Involvement in research***	
1.	Master of Science Research (Qualitative and Quantitative Analysis) : Rationale and Trends Underlying the Request for Additional Studies and Trials Following Drug Product Approval: Regulatory and Payer Perspectives (for Cranfield University, UK)	International
D.	***Publication/Report***	
1.	Rationale and Trends Underlying the Request for Additional Studies and Trials Following Drug Product Approval: Regulatory and Payer Perspectives (Thesis Publication for Cranfield University, UK)	International
E.	***Presentations in Course / Seminar / Conference***	
1.	Speaker for the Regulatory Aspects of Clinical Trial in Malaysia for Good Clinical Practice (GCP) Courses and Examiner for the GCP examinations conducted by Ministry of Health and Institutes for Higher Education throughout Malaysia	National
2.	Speaker and Trainer for the Training Session on Guidelines for the Application of CTIL and CTX organised by Klinsel Sdn. Bhd.	National
3.	Plenary Speaker at the 2nd Pharmaceutical Research Conference for Pharmacy Students and Young Graduates 2013 organised by Cyberjaya University College of Medical Sciences	National

REFEREES

Dr Nicola White
Cranfield University
E-mail: n.white@cranfield.ac.uk

Dr Kamaruzaman Saleh
National Pharmaceutical Control Bureau,
Ministry of Health Malaysia
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