

CURRICULUM VITAE (CV)



A. PERSONAL DETAILS

1. Full Name : Dr Zaril Harza Zakaria

2. Date of Birth : 19 August 1978

3. Place of Birth : Kuala Lumpur

4. Race : Malay

5. Religion : Islam

6. Marital Status : Married

7. Current Office Address : National Pharmaceutical

Regulatory Agency (NPRA) Lot 36, Jalan Universiti, 46200

Petaling Jaya, Selangor

Malaysia

8. Email : <u>zaril@npra.gov.my</u>

B. SERVICE DETAILS (DURATION OF SERVICE)

Employment:

May 2002 – May 2003	Provisionally Registered Pharmacist training, National Pharmaceutical Control Bureau, Petaling Jaya, Selangor.
June 2003 – Sept 2005	Assistant Director, New Chemical Entity Unit, Centre for Product Registration, National Pharmaceutical Control Bureau, Petaling Jaya, Selangor.
Sept 2005 – March 2009	Assistant Director, Investigational Product Evaluation Section, Centre for Investigational New Product, National Pharmaceutical Control Bureau, Petaling Jaya, Selangor.
March 2009 – July 2010	Senior Assistant Director, Head of Investigational Product Evaluation Section, Centre for Investigational New Product at the National Pharmaceutical Control Bureau, Petaling Jaya, Selangor.
July 2010 – July 2013	Principal Assistant Director, Head of Investigational Product Evaluation Section, Centre for Investigational New Product at the National Pharmaceutical Control Bureau, Petaling Jaya, Selangor.
July 2013 – July 2017	Senior Principal Assistant Director, Head of Investigational Product Evaluation Section, Centre for Investigational New Product at the National Pharmaceutical Control Bureau, Petaling Jaya, Selangor.
July 2017 – Dec 2019	Deputy Director, Head of Centre for Investigational New Product at the National Pharmaceutical Regulatory Authority.
Dec 2019 - Current	Head, Investigational Product Section, Centre for Product and Cosmetics Evaluation at the National Pharmaceutical Regulatory Authority

C. EDUCATION AND QUALIFICATION

No.	Academic Qualification	University	Year
1.	PhD in Pharmacokinetics	Aston University, UK	2018
2.	MSc. Clinical Research	Cranfield University, UK	2011
3.	Bachelor of Pharmacy (Hons)	Universiti Sains Malaysia, Malaysia	2002

D. EXPERTISE, CONTRIBUTION AND EXPERIENCE

Current Subject Matters Expert:

1. Experiences

		51 (5)	Duration		
No.	Fields	Place of Duty	From	Until	Total (Years)
1.	Evaluation of clinical trials including vaccines and First in Human (FIH) trials	Investigational Product Section, NPRA	2005	current	15
2.	Evaluation of new drugs including vaccines and clinical trials	New Drug Section, NPRA	2003	2005	2
3.	Good Clinical Practice (GCP) Inspector, inspecting Malaysian and Foreign Bioequivalence Centres, Malaysian Ethic Committees and clinical trial sites (including FIH sites) in Malaysia	Investigational Product Section , NPRA	2012	current	8

2. Professional Contributions

(a) International level

No.	Contributions	Year
1.	Zakaria Z, Badhan R. Development of a Region-Specific Physiologically Based Pharmacokinetic Brain Model to Assess Hippocampus and Frontal Cortex Pharmacokinetics. Pharmaceutics. 2018;10(1):14. (International Peer-reviewed journal)	2018
2.	Zakaria, Z. and R. K. Badhan. The impact of CYP2B6 polymorphisms on the interactions of efavirenz with lumefantrine: Implications for paediatric antimalarial therapy. European Journal of Pharmaceutical Sciences. 2018; 119: 90–101. (International Peer-reviewed journal)	2018
3.	Badhan R, Zakaria Z, Olafuyi O. The repurposing of ivermectin for malaria: a prospective pharmacokinetics-based virtual clinical trials assessment of dosing regimen options, Journal of Pharmaceutical Sciences. 2018, doi: 10.1016/j.xphs.2018.03.026. (International Peer-reviewed journal)	2018
4.	Zaril Zakaria, Alan Y.Y. Fong and Raj K. S. Badhan. Clopidogrel pharmacokinetics in Malaysian population groups: the impact of inter-ethnic variability. Pharmaceuticals. 2018; 11:74. (International Peer-reviewed journal)	2018
5.	Presentation given: Zaril Zakaria, Gavin Woodhall and Raj K Singh Badhan, 2016. A Mechanistic Pharmacokinetic Approach to the Development of Predictive Models for Central Nervous System Drug Delivery. LHS PG Research day, Aston University, Birmingham, UK.	2016
6.	Presentation given: Zaril Zakaria, Gavin Woodhall and Raj K Singh Badhan, 2016. PBPK Method to the Development of Predictive Models for Central Nervous System Drug Delivery. MathSys Summer School, University of Warwick, UK.	2016
7.	Presentation given: Zaril Zakaria, Gavin Woodhall and Raj K Singh Badhan, 2016. Bridging the gaps in CNS Drug Delivery: PBPK Method to the Development of Predictive Models. 7th APS International PharmSci Conference, University of Strathclyde, Glasgow, UK	2016

8.	Presentation given: Zaril Zakaria, Gavin Woodhall and Raj K Singh Badhan, 2016. PBPK in the CNS Drug Delivery: Drug Disposition across the BBB, BCSFB, Hippocampus and Frontal Cortex. PKUK Conference, London UK.	2016
9.	Presentation given: Zaril Zakaria and Raj K Singh Badhan, 2017. A Mechanistic Pharmacokinetic Approach to the Development of Predictive Models in HIV-malaria Co-infection in Children Accounting for Induction of CYPs 3A4 and 2B6 – a Lumefantrine and Efavirenz Case Study. 26th PAGE Meeting, Budapest, Hungary	2017
10.	Presentation given: Zaril Zakaria and Raj K Singh Badhan, 2017. A PBPK Approach to the Development of Predictive Models in HIV-malaria Co-infection in Children. LHS PG Research day, Aston University, Birmingham, UK.	2017
11.	Presentation given: Zaril Zakaria and Raj K Singh Badhan, 2017. Impact of CYP2B6 polymorphisms on the interactions of efavirenz with lumefantrine: implications for paediatric antimalarial therapy. PKUK Conference, Great Malvern, UK. (Best Poster Award)	2017

(b) National Level

No.	Contributions	Year
1.	Speaker at GCP Workshops for the module "Regulatory Aspects for Clinical Trials in Malaysia".	2005 - current
2.	Editorial Board for Malaysian Guidelines for GCP Inspection 2010	2010
3.	Editorial Board for Malaysian Guideline for Application of CTIL and CTX 2009	2009
4.	Editorial Board for Malaysian Guideline for Independent Ethics Committee Registration and Inspection	2016
5.	Independent Expert to the Medical Research and Ethics Committee, Ministry of Health Malaysia.	2009 - current

6.	Secretary to the National Committee for Clinical Research, Ministry of Health Malaysia.	2018 - current
7.	Secretariat to the National Committee for Clinical Research, Ministry of Health Malaysia.	2005 - 2017
8.	Member to the National Committee on Ethics of Research on Cell and Cell-Based Therapies, Ministy of Health Malaysia (NCERT) 2019/2020	2019
9.	Member to the Committee of the National Action Plan on the Feasibility of Development of Cannabinoid Industry for Medicinal Use 2019.	2019
10.	Member to the Technical Working Group: Clinical Research on The Twelveth Malaysia Plan (RMK-12) 2019	2019

E. Involvement and Exposure

1. Presenters in international/national/organisational level

No.	Contributions	Year
1.	Presentation given: Zaril Zakaria, Gavin Woodhall and Raj K Singh Badhan, 2016. A Mechanistic Pharmacokinetic Approach to the Development of Predictive Models for Central Nervous System Drug Delivery. LHS PG Research day, Aston University, Birmingham, UK.	2016
2.	Presentation given: Zaril Zakaria, Gavin Woodhall and Raj K Singh Badhan, 2016. PBPK Method to the Development of Predictive Models for Central Nervous System Drug Delivery. MathSys Summer School, University of Warwick, UK.	2016
3.	Presentation given: Zaril Zakaria, Gavin Woodhall and Raj K Singh Badhan, 2016. Bridging the gaps in CNS Drug Delivery: PBPK Method to the Development of Predictive Models. 7th APS International PharmSci Conference, University of Strathclyde, Glasgow, UK	2016

4.	Presentation given: Zaril Zakaria, Gavin Woodhall and Raj K Singh Badhan, 2016. PBPK in the CNS Drug Delivery: Drug Disposition across the BBB, BCSFB, Hippocampus and Frontal Cortex. PKUK Conference, London UK.	2016
5.	Presentation given: Zaril Zakaria and Raj K Singh Badhan, 2017. A Mechanistic Pharmacokinetic Approach to the Development of Predictive Models in HIV-malaria Co-infection in Children Accounting for Induction of CYPs 3A4 and 2B6 – a Lumefantrine and Efavirenz Case Study. 26th PAGE Meeting, Budapest, Hungary	2017
6.	Presentation given: Zaril Zakaria and Raj K Singh Badhan, 2017. A PBPK Approach to the Development of Predictive Models in HIV-malaria Co-infection in Children. LHS PG Research day, Aston University, Birmingham, UK.	2017
7.	Presentation given: Zaril Zakaria and Raj K Singh Badhan, 2017. Impact of CYP2B6 polymorphisms on the interactions of efavirenz with lumefantrine: implications for paediatric antimalarial therapy. PKUK Conference, Great Malvern, UK.	2017
8.	Speaker at GCP Workshops for the module "Regulatory Aspects for Clinical Trials in Malaysia".	2005 - current

2. Involvement in conferences/seminars in international/national/organisational level

No.	Title	Year	Venue	Organisation
1.	Life Health Sciences Post Graduate Research day, Aston University, Birmingham, UK.	2016	Birmingham, UK.	Aston University
2.	MathSys Summer School, University of Warwick, UK.	2016	University of Warwick, UK.	University of Warwick
3.	7th APS International PharmSci Conference, University of Strathclyde, Glasgow, UK	2016	University of Strathclyde, Glasgow, UK	University of Strathclyde
4.	PKUK Conference, London UK.	2016	London UK.	PKUK

5.	26th PAGE Meeting, Budapest, Hungary	2017	Budapest, Hungary	PAGE
6.	LHS PG Research day, Aston University, Birmingham, UK.	2017	Birmingham, UK	Aston University
7.	PKUK Conference, Great Malvern, UK.	2017	Great Malvern, UK.	PKUK
8.	National Regulatory Conference 2013	2013	Petaling Jaya	NPRA
9.	13th Scientific Meeting, 4th National Conference for Clinical Research	2010	Kuala Lumpur	MOH, Malaysia
10.	The 2nd Meeting of The Joint Sectoral Committee on MRA for BE Study Report of Generic Medicinal Product	2019	Jakarta, Indonesia	ASEAN

3. Trainings/Courses/Workshops attended

No.	Courses	Year	Organisation
1.	Attachment training for one month at PMDA, Tokyo, Japan on 'The PMDA Mid-Term Training Program for International Drug Regulatory Authorities on Evaluation of First in Human Clinical Trial', 2014	2014	PMDA, Japan
2.	National Regulatory Conference	2008	NPRA
3.	Conference on BABE Practice	2012	NPRA
4.	7 th National Conference on Clinical Research	2013	NPRA
5.	8 th Annual Conference: The New Clinical Research Environment in India	2013	India
6.	Workshop: Research Methodology (Quantitative)	2014	NPRA

7.	National Regulatory Conference	2015	NPRA
8.	Participant in the Workshop on Organisation for Economic Cooperation and Development (OECD) Good Laboratory Practice (GLP) 9 – 10 April 2012	2012	OECD/NPRA
9.	Participated in the Workshop on Ethics of Cell Therapies November 2014	2014	MOH, Malaysia
10.	Biosimilars – A two days interactive training course	2008	NPRA
11.	Preliminary Workshop: Review of Drug Development in Clinical Trials	2008	APEC
12.	GCP Training for Regulatory Authority	2008	APEC
13.	Basic Workshop on Good Clinical Practice/Clinical Research Inspection	2008	APEC
14.	OECD Good Laboratory Practice Workshop	2008	OECD
15.	Advanced Workshop: Review of Drug Development in Clinical Trials	2009	APEC
16.	Multi-regional Clinical Trials Workshop – Inaugural Workshop of the APEC Harmonisation Centre	2009	APEC
17.	ASEAN Workshop on MEDRA and its application in safety drug monitoring	2010	MEDRA
18.	Joint CRC Biotechcorp Clinical Research and Governance of Ethics	2010	MOH, Malaysia
19.	Training in Blood Products	2011	NPRA
20.	Outcome Based Budgeting Workshop	2011	NPRA

21.	Workshop: Training of Trainers Good Governance of Medicines	2012	NPRA
22.	NPCB Bioequivalence Inspection Guidelines	2013	NPRA
23.	Bioequivalence Study- Bianalytical Part at InfoKinetics	2013	NPRA
24.	IRB Standard Review Procedures Training Agenda	2013	NPRA
25.	ASEAN Variation Guideline Workshop	2013	ASEAN
26.	Workshop on BABE Inspection: Clinical and Bioanalytical Aspects	2014	NPRA
27.	Workshop: Research Methodology (Qualitative)	2014	NPRA
28.	Workshop on Ethics of Cell Therapies	2014	NPRA
29.	TGP Orientation and TGP Inspirational Leadership Podium: Strategic Shift Towards Leadership Excellence	2015	MOH, Malaysia
30.	Knowing Yourself, Knowing Others: Personality Development Instrument	2015	MOH, Malaysia
31.	Workshop: Paradigm Change for Officers Selected for Overseas Scholarships	2015	Department of Public Services
32.	Workshop: Leadership and Organisational Management for U48 – U54	2015	NPRA
33.	Research Skills and Professional Development – For Life and Health Sciences	2015	NPRA

F. AWARDS AND RECOGNITIONS

No.	Awards / Recognitions	Recognition Body	Year
1.	Recipient of the Ministry of Health Malaysia's Exemplary Performance Award 2008 (National)	MOH, Malaysia	2008
2.	Recipient of the Ministry of Health Malaysia's Exemplary Performance Award 2012 (Organisation)	NPRA	2012
3.	Certified as a Good Clinical Practice (GCP) and Bioequivalence (BE) Inspector 2014	NPRA	2014
4.	Successfully completed a course in Good Clinical Practice and GCP Certified October 2005	NPRA	2005
5.	Successfully completed the Course for Lead Auditor/Auditors for the MS ISO9001:2008 Quality Management System October 2014.	Malaysian Standards	2014
6.	Recipient for Federal Training Gifts (Scholarship) Session 2015/2018 (PhD)	MOH, Malaysia	2014
7.	Recipient for Federal Training Gifts (Scholarship) Session 2010/2011 (MSc)	MOH, Malaysia	2009

G. CONTRIBUTIONS BEYOND FORMAL DUTIES

No.	Contributions	Year	Organisation
1.	Talent Grooming Programme, Ministry of Health Malaysia Cohort 1/2014	2014	MOH, Malaysia
2.	Presentation given: Zaril Zakaria, Gavin Woodhall and Raj K Singh Badhan, 2016. A Mechanistic Pharmacokinetic Approach to the Development of Predictive Models for Central Nervous System Drug Delivery. LHS PG Research day, Aston University, Birmingham, UK.	2016	Aston University, UK
3.	Presentation given: Zaril Zakaria, Gavin Woodhall and Raj K Singh Badhan, 2016. PBPK Method to the Development of Predictive Models for Central Nervous	2016	University of Warwick, UK

	System Drug Delivery. MathSys Summer School, University of Warwick, UK.		
4.	Presentation given: Zaril Zakaria, Gavin Woodhall and Raj K Singh Badhan, 2016. Bridging the gaps in CNS Drug Delivery: PBPK Method to the Development of Predictive Models. 7th APS International PharmSci Conference, University of Strathclyde, Glasgow, UK	2016	University of Strathclyde, UK
5.	Presentation given: Zaril Zakaria, Gavin Woodhall and Raj K Singh Badhan, 2016. PBPK in the CNS Drug Delivery: Drug Disposition across the BBB, BCSFB, Hippocampus and Frontal Cortex. PKUK Conference, London UK.	2016	Royal Society of Chemistry, London, UK
6.	Presentation given: Zaril Zakaria and Raj K Singh Badhan, 2017. A Mechanistic Pharmacokinetic Approach to the Development of Predictive Models in HIV- malaria Co-infection in Children Accounting for Induction of CYPs 3A4 and 2B6 – a Lumefantrine and Efavirenz Case Study. 26th PAGE Meeting, Budapest, Hungary	2017	PAGE Meeting, Budapest, Hungary
7.	Presentation given: Zaril Zakaria and Raj K Singh Badhan, 2017. A PBPK Approach to the Development of Predictive Models in HIV-malaria Co-infection in Children. LHS PG Research day, Aston University, Birmingham, UK.	2017	Aston University, UK
8.	Presentation given: Zaril Zakaria and Raj K Singh Badhan, 2017. Impact of CYP2B6 polymorphisms on the interactions of efavirenz with lumefantrine: implications for paediatric antimalarial therapy. PKUK Conference, Great Malvern, UK. (Best Poster Award)	2017	PKUK Conference, Great Malvern, UK
9.	Peer Reviewer for Malaysian Journal of Pharmacy (MJP) 2019	2019	MJP

10.	Peer Reviewer for Malaysian Journal of Medicine & Health Sciences 2020	2020	Malaysian Journal of Medicine & Health Sciences
11.	Member of Professional Association of Diving Instructors (PADI)	2005	PADI International
12.	Member of Malaysian Lifeguard Association.	2002	National Lifeguard Association