

Drug Master File (CTD format) Training Program



18 – 20
December 2017

This training program is designed for Pharma professionals to provide an understanding on important topic Drug substance, API Vendor selection & Drug master file. This training program consists of 9 principal modules and 3 Question & Answer sessions. These modules cover the essential principles of Drug substance and Drug master file. Participants are expected to gain an understanding of current requirements and future international trends about DMF registration.

- Day 1:- Participants are expected to gain an understanding of API & DMF sourcing
- Day 2:- Participants are expected to gain an understanding of Drug Master File – Filing & Review
- Day 3:- Participants are expected to gain an understanding of DMF (CTD format) drafting

Training Grant is available under HRDF SBL Scheme

15 CPD points



Aims and Objectives

The aim of the course is to provide an in-depth understanding of API sourcing and Drug Master File (Preparation, filing and review) in the work place.

Who Should Attend

Key Personnel in any Aspect of Regulatory affairs & Quality Assurance, Directors, Managers, Executives, Quality Practitioners and any member of a pharmaceutical and related industry, those from Research and Development, Regulatory, Quality and Production will find this program relevant and beneficial to their job function.



Organised by:

mopi Malaysian Organisation of Pharmaceutical Industries

Presenter:


zodiacpharma


MYdossier
Partners for Export

For further details please visit www.mopi.org.my & www.zodiacpharma.com

COURSE OUTLINE

Day 1 and Day 2

The Program Outline will cover:

Brief information about DMF, API and API sourcing

- ❖ Facts about API Manufacturers and their documentation process
- ❖ Detailed discussion on technical and administrative points (which you need to consider before finalizing API procurement)
- ❖ General MOH queries related to DMF & Do or Do not –while replying MOH queries
- ❖ API samples, reference standards, Impurities RS – issues
- ❖ Demo for conversion from supplier DMF into filing Document dossier (CTD module 2 & 3 S part)
- ❖ Discussion on - Open Part of DMF and Close part of DMF
- ❖ Deep discussion on all parts of DMFs

Day 3

Workshop Title:- DMF Drafting for filing purpose

Objective of workshop:- After receiving DMF from supplier, reviewing and extracting information from DMF to Dossier S Part.

Drafting S part of ASEAN CTD dossier by using extracted information from supplier information.

* * Dates and Instructors are subject to change depending on attendance feedbacks and instructor availability. In case of a change, updated dates and instructor profile will be advised to the organizer and the attendees prior to the start of each course.

TIME SCHEDULE:

Day 1 (18.12.2017) – API & DMF sourcing

8.30 am Registration
9.00 am **Module 1 - Drug substance (API) & it's Documentation**
10.15 am Tea Break
10.30 am **Module 2 - How to select Drug substance (API) vendor**
12.15 pm Lunch
1.25 pm **Module 3 - Common MOH queries related to DMF and its ideal solution**
3.00 pm Tea Break
3.15 pm **Question & Answer session - 1**
5.00 pm End

Day 2 (19.12.2017) – Drug Master File – Filing & Review

8.30 am Registration
9.00 am **Module 4 - DMF – Administrative part Discussion**
10.15 am Tea Break
10.30 am **Module 5 - DMF – Technical part Discussion**
12.15 pm Lunch
1.25 pm **Module 6 - DMF – How to review before filing to MOH**
3.00 pm Tea Break
3.15 pm **Question & Answer session - 2**
5.00 pm End

Day 3 (20.12.2017) DMF (CTD format) drafting

8.30 am Registration
9.00 am **Module 7 - DMF (CTD format) drafting workshop – Part 1**
10.15 am Tea Break
10.30 am **Module 8 - DMF (CTD format) drafting workshop – Part 2**
12.15 pm Lunch
1.25 pm **Module 9 - DMF (CTD format) drafting workshop – Part 3**
3.00 pm Tea Break
3.15 pm **Question & Answer session - 3**
5.00 pm End

Mr. T.C.Tak is founder and CEO of Zodiac Pharma, India. All dossiers and related registration documents are prepared under guidance and observation of Mr. T. C. Tak. He is also worked as regulatory affairs consultant for Global assessment of VMP registration regulations (World Bank Group project tilted EBA). His foresightedness can be well showed by his endeavors which area from Pharma dossier sale, regulatory affairs, handling MOH inquiry, and dossier training for small to medium size pharmaceutical companies to help them to overcome the challenges within the rapidly evolving global pharmaceutical market. He drives the company's vision, strategy and growth as it provides interesting and unique ways for client and learner to serve their purpose. More than 2000 CTD (Dossier & DMF) and ASEAN CTD dossier prepared under his guidance in past 5 years. He is having more than 9 years experience in CTD DMF, dossier, ASEAN CTD and ROW dossiers. He did his B.Pharm & M.Pharm from Manipal collage of Pharmaceutical Sciences, Manipal University, Udupi, Karnataka. He also did certificate course in intellectual property rights from World Intellectual Property Organization (WIPO), Geneva, Switzerland. He Qualified GATE Examination (conducted by IITs & IISc) with ALL INDIA RANK 198. After his postgraduate, he worked on the post of Executive in Pharma MNC companies at Bangalore and Hyderabad. His core areas of during job were in dossier writing, global dossier management and international marketing. During that period, he got opportunity to work with global leader – Pfizer, Ranbaxy, Sandoze, Teva, Lupin, DRL, Mylan, Stride arcolabs, Apotex Canada etc.

In year 2008, Mr. T.C.Tak founded Zodiac Pharma. Presently, Zodiac Pharma involves in below activities:

- Regulatory affairs (DMF & Dossier) consultancy
- Global Dossier Management
- Dossier sale & licensing
- International Business consultancy
- Export management & consultancy
- Industrial & corporate Training

Trainer's Brief Profile

METHODOLOGY:

Lectures, workshops, case studies and group activities.

ASSESSMENT:

A variety of assessment strategies will be used and may include assignments, classroom engagement, projects and presentations. Participants will be informed of the assessment method, date of assessment and percentage contribution at the start of the module.

Registration Fee per participant per module:

(The fee includes course materials, lunch and refreshments)

MOPI Member – 3 day Course

30 days before commencement of course RM2,000.00
29 – 14 days before commencement of course RM2,300.00

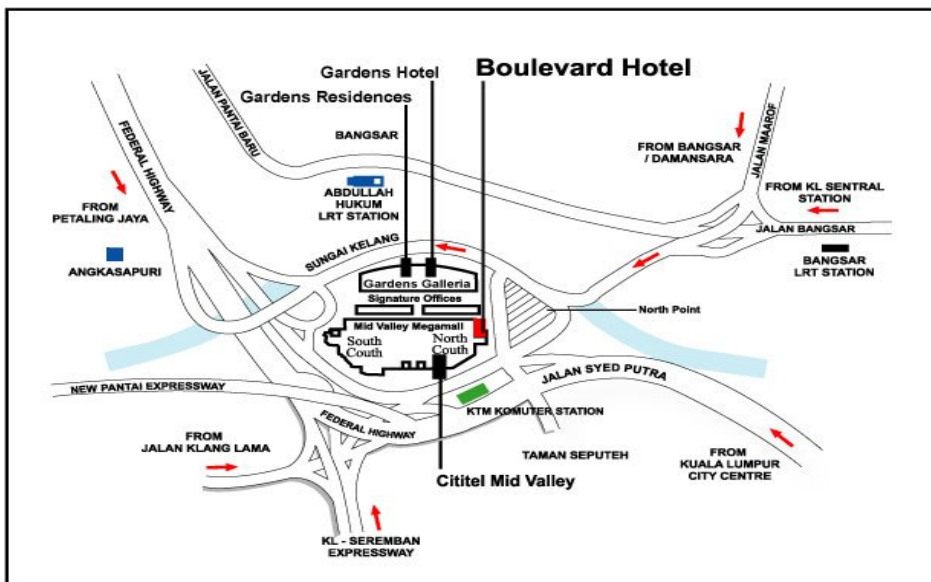
Non-MOPI Member – 3 day Course

30 days before commencement of course RM2,500.00
29 – 14 days before commencement of course RM2,800.00

Foreign Participant – 3 day Course

30 days before commencement of course USD \$700.00
29 – 14 days before commencement of course USD \$900.00

Registration
fee is
subjected to
6% GST



Training Venue:

**THE BOULEVARD
St Giles Premier Hotel**

**Hotel Address | Mid Valley
City|Lingkaran Syed Putra| 59200
| Kuala Lumpur| Malaysia
Tel: +60.3.22958000
Website: www.StGiles-Hotels.com**

Optional Hotel accommodations:

Cititel Mid Valley Tel: 603-2296 1188
Website: www.cititelmidvalley.com

Eastin Hotel, Petaling Jaya Tel: 603-7665
1111
Website: www.eastin.com

Crystal Crown Hotel, Petaling Jaya Tel : 603-
7958 4422
Website: www.crystalcrown.com.my

Armada PJ Hotel Tel: 603-7954 6888
Website: www.armada.com.my

BOOK YOUR SEAT NOW!!!

For further enquiries, please contact:
Mike/Janet, MOPI
GLOBAL BUSINESS & CONVENTION CENTRE,
MEZZANINE FLOOR, BLOCK A,
NO. 8, JALAN 19/1, SECTION 19,
46300 PETALING JAYA, SELANGOER, WEST MALAYSIA
Tel: 03-7931 9003 Fax: 03-7932 2730
E-mail: mike@mopi.org.my and admin@mopi.org.my
www.mopi.org.my

ADMINISTRATION DETAILS:

Important Notice: Payment is required with registration and must be received 2 weeks prior to the start of the relevant module to guarantee your place. Walk-in participants will only be admitted on the basis of space availability at the course and with immediate full payment by banker's cheque in favour of the "Malaysian Organisation of Pharmaceutical Industries".

Registration will be treated as confirmed only upon receipt of payment in full.

CANCELLATIONS & TRANSFERS:

- If a registrant is unable to attend, a substitute candidate is welcome at no extra charge. Please provide the name and the title of the substitute participant at least 2 working days prior to the relevant course.
- Notice of cancellation by fax/email is required 14 working days prior to commencement of each module and refund less RM500 as administration charge will be made. However a complete set of documentation will be sent to you.
- Regrettably, no refund can be made for cancellations received less than 10 working days prior to the commencement of each module. However a complete set of documentation will be sent to you.
- MOPI / SeerPharma reserves the right to cancel or reschedule the training modules. All efforts will be taken to inform participants of any change. MOPI / SeerPharma however will not be held liable for reimbursement of any claims or expenses should cancellation or rescheduling occur.

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REGISTRATION FORM Subject to Administration details MOPI Member Non-Member Foreign

Please register the following participant(s) for the above program. (To be completed in BLOCK LETTERS)

1 Name _____
Designation _____
Email address _____
 Vegetarian

2 Name _____
Designation _____
Email address _____
 Vegetarian

3 Name _____
Designation _____
Email address _____
 Vegetarian

4 Name _____
Designation _____
Email address _____
 Vegetarian

Enclosed cheque/bank draft No. _____ for RM _____ being payment for _____ participant(s) made in favour of the "Malaysian Organisation of Pharmaceutical Industries".

Registration Submitted by:

Name _____
Designation _____
E-mail _____
Telephone _____

Company Stamp (with Address, Telephone & Fax Number)

Registration Fee per participant per course:
(The fee includes course materials, lunch and refreshments)

MOPI Member – 3 day Course
30 days before commencement of course RM2,000.00
29 – 14 days before commencement of course RM2,300.00

Non-MOPI Member– 3 day Course
30 days before commencement of course RM2,500.00
29 – 14 days before commencement of course RM2,800.00

Foreign Participant– 3 day Course
30 days before commencement of course USD \$700.00
29 – 14 days before commencement of course USD \$900.00



Office Use Only

Registration Accepted on
Payment Accepted on