

**WORLD HEALTH ORGANIZATION / INTERNATIONAL PHARMACEUTICAL FEDERATION
TRAINING WORKSHOP ON PHARMACEUTICAL DEVELOPMENT,
WITH A FOCUS ON PAEDIATRIC FORMULATIONS
MUMBAI, INDIA, APRIL 2008**

Background

A Training workshop on Pharmaceutical Development with Focus on Paediatric Formulations is planned to take place in Mumbai, India, from 28 April to 2 May 2008.

It is generally recognised that there is a paucity of background scientific and clinical data, information and knowledge to inform the pharmaceutical development and design of paediatric medicines. Particular concern relates to paediatric forms of products listed in the Essential Drug List, including antimalarial and tuberculosis products as well as FDC products for HIV/Aids treatment.

Given this background, a WHO Training Workshop in Pharmaceutical Development with a focus on paediatric medicine will be provided in Mumbai, India in April 2008. Participants will be from India with a qualification and experience in Regulatory Affairs, and/or pharmaceutical manufacturing. The primary target participant group will be local manufacturers, with additional participation by personnel from the Indian Food and Drug Administration.

The aims of the Training Workshop

- To provide a forum for exchanging and sharing information, knowledge and good practice in developing, formulating and manufacturing paediatric medicines
- To deliver an instructional programme in suitable form covering topics relevant to the course theme, ranging from elementary physiology and paediatric pharmacokinetics and toxicology, pre-formulation studies and excipient properties and selection, to manufacturing, scale-up, quality, regulatory and product performance (bioavailability) and stability issues.
- To provide a series of relevant, timely case studies in the paediatric medicine field, with opportunities for group discussion and feedback
- To discuss a concept document that focuses on points to consider in pharmaceutical development and paediatric formulations
- To link, where possible, the instruction programme, discussion sessions and case studies to the implementation of the WHO prequalification programme
- To encourage general debate between attendees and expert instructors on issues raised during the course, and discuss options for implementation of information provided in the training programme

On completion of the training workshop, the course structure, content, format and aims will be critically assessed and reviewed by both attendees and faculty taking into account feedback from participants and instructors. This analysis will help to inform discussions related to

**WORLD HEALTH ORGANIZATION / INTERNATIONAL PHARMACEUTICAL FEDERATION
TRAINING WORKSHOP ON PHARMACEUTICAL DEVELOPMENT,
WITH A FOCUS ON PAEDIATRIC FORMULATIONS
MUMBAI, INDIA, APRIL 2008**

repeating the Training Workshop on Pharmaceutical Development for Paediatric Formulations and guide any redesign of the course.

**WORLD HEALTH ORGANIZATION / INTERNATIONAL PHARMACEUTICAL FEDERATION
TRAINING WORKSHOP ON PHARMACEUTICAL DEVELOPMENT,
WITH A FOCUS ON PAEDIATRIC FORMULATIONS
MUMBAI, INDIA, APRIL 2008**

Topics to be covered

The programme is planned in such a manner that the topics covered will be as follows:

Day 1. (Clinical considerations and Ethics)

- General Introduction that focuses on differences between neonates, children and adults;
- Differences in age groups
- Differences in pharmacokinetics and pharmaco-dynamics in children
- Ethical aspects in the conduct of clinical trials;
- Bio-availability and bio-equivalence studies;
- Biopharmaceutical Classification System (BCS);
- Pharmacovigilance.

Day 2. (Pharmaceutics)

- Scientific principles (including selection of appropriate excipients, colorants, flavours, and active pharmaceutical ingredient properties);
- Dosage form design and manufacture (focusing on tablets, dispersible tablets, capsules, powders, granules, syrups, suspensions, suppositories);
- Fixed Dose Combinations including bilayer tablets;
- Selection of packaging materials.

Day 3. (Pharmaceutical development)

- Introduction to development pharmaceutics;
- Quality by Design; ICH Q8, Q9 and Q10;
- Analytical Method Development;
- Stability testing.

Day 4. (Prequalification)

- Introduction to the Prequalification programme;
- Dossier requirements;
- Dossier maintenance including Variations;
- Inspections including GMP and GCP.
- Discussion on a concept paper ("Points to consider")

**WORLD HEALTH ORGANIZATION / INTERNATIONAL PHARMACEUTICAL FEDERATION
TRAINING WORKSHOP ON PHARMACEUTICAL DEVELOPMENT,
WITH A FOCUS ON PAEDIATRIC FORMULATIONS
MUMBAI, INDIA, APRIL 2008**

Monday, 28 April 2008

Time	Topic	Presenter
	Registration of participants	
	Opening Ceremony, welcome address, introduction of participants	
	Introduction: <ul style="list-style-type: none"> • The need for paediatric medicines: A WHO perspective • Essential medicines and paediatric dosage forms 	
	From neonates to adolescents: <ul style="list-style-type: none"> ○ Developmental physiology. ○ Paediatric pharmacokinetics and pharmacodynamics, toxicology 	
	Ethical considerations in clinical trials	
	Bio availability and bio equivalence studies Biopharmaceutical Classification System	
	Pharmaco-vigilance and safety of medicines in children	
	CASE STUDY	
	PRESENTATION OF CASE STUDY OUTCOME	

Tuesday 29 April 2008

Time	Topic	Presenter
	Dosage form design and manufacture (Tablets, capsules, syrups etc)	
	Scientific principles: Excipients, colorants, flavours, and active pharmaceutical ingredient properties	
	Practical problems in developing Fixed Dose Combinations and bilayer tablets	
	Selection of packaging materials	
	CASE STUDY	
	PRESENTATION OF CASE STUDY OUTCOME	

**WORLD HEALTH ORGANIZATION / INTERNATIONAL PHARMACEUTICAL FEDERATION
TRAINING WORKSHOP ON PHARMACEUTICAL DEVELOPMENT,
WITH A FOCUS ON PAEDIATRIC FORMULATIONS
MUMBAI, INDIA, APRIL 2008**

Wednesday, 30 April 2008

Time	Topic	Presenter
	Introduction to development pharmaceuticals <ul style="list-style-type: none"> • Laboratory batches, pilot batches, full-scale batches • Definitions and purpose • Scale-up issues • Packaging Setting (tentative) acceptance criteria for manufacturing process validation	
	Industry perspective on practical approaches and experiences in development pharmaceuticals	
	Quality by Design; ICH Q8, Q9 and Q10	
	Analytical Method Development <ul style="list-style-type: none"> • Originator and multisource generic FPPs <ul style="list-style-type: none"> ○ Specifications ○ Stability • Parallel development of analytical methods for cleaning validation 	
	Stability testing of APIs and finished products.	
	CASE STUDY	
	PRESENTATION OF CASE STUDY OUTCOME	

Thursday, 1 May 2008

Time	Topic	Presenter
	Introduction to the Prequalification programme.	
	Applications for prequalification: Dossier requirements <ul style="list-style-type: none"> • Multisource (generic) products • Products from ICH regions New products that are not considered as Innovators or Generics	

**WORLD HEALTH ORGANIZATION / INTERNATIONAL PHARMACEUTICAL FEDERATION
TRAINING WORKSHOP ON PHARMACEUTICAL DEVELOPMENT,
WITH A FOCUS ON PAEDIATRIC FORMULATIONS
MUMBAI, INDIA, APRIL 2008**

	Dossier maintenance including Variations	
	Inspections including GMP and GCP	
	Discussion on a concept paper ("Points to consider")	
	Workshop evaluation by participants	
	Closing	