



## Association of Toxicology (AoT), India

### Workshop Report

#### **Preclinical GLP Study Directors Workshop 8-10 October 2012 Veterinary College, Bangalore**

A workshop on 'Preclinical GLP Study Directors' was jointly organized by the American College of Toxicology and Association of Toxicology India in Association with Veterinary College, Bangalore during 8-10 October 2012 at Veterinary College, Bangalore. The objective of the 3 days workshop was to provide an intensive residential training in Good Laboratory Practice, with special emphasis on Study Director's role and responsibilities.

This kind of workshop is the first of its kind held in India with eight US experts who have spent their entire career on GLP and Study Director Relationships. Several experts from leading Contract Research Organizations, like Covance and Huntingdon were only too eager to teach our scientists. There was ample opportunity during the Workshop for participants to mingle with the speakers to clarify their doubts.

In many parts of the world it is a regulatory requirement that, studies undertaken to demonstrate the health or environmental safety of new chemical or biological substances shall be conducted in compliance with the principles of GLP. GLP is implemented through Standard Operating Procedures that describe the processes through which specific tasks are achieved, and the roles and responsibilities for the personnel involved in the studies.

The basis for the implementation of GLP is to provide assurance of test data from non-clinical studies related to the hazard assessment of chemical or pharmaceuticals or biological substance or medical devices, when manufacturers are seeking to register products for use. GLP provides an assurance to regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments. The safety data generated as per GLP are required for the registration of a wide range of products and product registration is usually sought in more than one country [Under 1981 decision of the OECD Council, data generated in an OECD member country under its national compliance monitoring program is accepted in other OECD member countries for the purposes of product registration (Mutual Acceptance of Data)]. In many parts of the world, it is a regulatory requirement that, studies undertaken to demonstrate the health or environmental safety of new chemical or biological substances shall be conducted in compliance with the principles of GLP.

The workshop on 'Preclinical Study Directors' was planned to specifically discuss the impact of GLP on the role and responsibilities of Study Directors. This highly focused workshop on Study Directors had multidisciplinary experts, who have hands-on experience with the US FDA/OECD regulations and as study directors. The workshop appraised the present situation in India on the safety evaluation and study directors involvement and responsibilities in GLP studies. The scope of OECD and FDA GLP principles were discussed in depth to ascertain its suitability in Indian scenario.

Dr. K.S. Rao, the President of Association of Toxicology (AoT) welcomed the participants and Dr. William (Bill) J. Brock, the US coordinator presented the opening remarks. Dr. Brock introduced all speakers and their affiliations. There were 139 registered delegates participated at the workshop. During the course of three days, we have been fortunate to listen to luminaries with hands on experience in GLP and related areas.

Following technical presentations were made by experts

| <b>Speakers</b> | <b>Topics</b>   |
|-----------------|---|
| K.S. Rao        | Arrangements and Introductions                        |
| William J Brock | Introduction to Course; Basics of Study Director Role |

|                             |   |
|-----------------------------|---|
| Kenneth Hastings            | GLP Regulations and the Study Director, Management, and QA                |
| Carol Auletta               | The Protocol - Development, Amendments, Deviations and Maintenance        |
| PV Mohanan                  | Pre-Study Preparation – Study Requirements, Test Article Characterization |
| Carol Auletta               | Study Conduct – Study Director Oversight and Study Management             |
| Suzanne Wolford             | Sub-Contracting – Multi-site Studies, Study Monitoring                    |
| Niraj Tripathi              | Clinical Pathology Endpoints and Basic Concepts of Interpretation         |
| Kevin Keane                 | Pathology: Necropsy and Gross Pathology                                   |
| Kevin Keane                 | Histopathology  |
| K.S. Rao<br>WJ Brock & L Fu | Carcinogenicity, Developmental and Reproductive and Genotoxicity Studies  |
| Suzanne Wolford             | Special Considerations for Biopharmaceuticals                             |
| Anthony Kiorpes             | Toxicokinetics for Study Directors  |
| Niraj Tripathi              | Biomarkers and Their Role in Clinical Pathology Assessment                |
| Suzanne Wolford             | Report Writing and Study Archives   |
| PV Mohanan                  | GLP Regulatory Inspections  |
| All Speakers                | Case Studies: Panel Discussion  |
| K.S. Rao & WJ Brock         | Course Closing and Final Thoughts   |

All the course participants applauded the speakers and gave extremely good feed-back on the value of this workshop to Indian scientists in the conduct of their studies as Study Directors. Many academicians and scientists who were new to this concept were highly appreciative of their intensive learning in these three days.

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Secretary -General  
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