OMICS International
conferenceseries.com

J Develop Drugs 2015, 4:4
http://dx.doi.org/10.4172/2329-6631.C1.012

4th International Summit on

GMP, GCP & Quality Control

October 26-28, 2015 Hyderabad, India

Good laboratory practices: A wake up call for pharmaceutical industries

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The globe is marching towards perfection. Basically, GLP is a regulation not a guideline. Industry needs greater performance with minimum investments, which is possible only if you adopt GLP. Consumer focuses on and expects quality for a good price. The thalidomide tragedy has opened the new vision for the regulations and has cautioned the world, the extent of toxicity by the drugs. The objective of "Good Laboratory Practice" (GLP) was brought to prevent such a disasters and also poor planning and execution and manipulation of the raw data as manipulation would promote or accelerate approval. GLP aims at:

- Securing efforts to generate high quality and reliable data pertaining to protection of man and the environment against various sorts of chemicals and without prejudice against explanation and evaluation of study's results,
- Mutual acceptance of data (MAD) of studies among countries so as to reduce a number of animal tests and trim costs.

Good Laboratory Practice (GLP) is a quality system laying down organization, procedures and requirements to plan, implement, document, archive and transfer of non-clinical studies and their results. GLP principles have been developed in the framework of OECD. GLP is the corner stone of the laboratory based activities in any organization. It is not a luxury but essential for the professional laboratories. The GLP assures the quality and integrity and experiments done under GLP are acceptable to countries covered under OECD memberships worldwide. It has the standard operating procedure which is the brain behind the performance which makes it as a system based and not individual based performance. The GLP is a team work consisting of Management, Study Directors, Performer, Quality manager, Archivist and their jobs are well defined. The Study Director is a blue-eyed boy of the management and holds the key of GLP. The management provides resources, Study Director performs and quality assurance units assures the quality and integrity of the study and Archivist preserves the all materials such as study plans, training records, amendments , deviations samples, raw data, etc., in his custody. The documentation is of prime importance. If not documented meaning is not done. There no dearth to prove excellence and meaning well planned is well executed to the satisfaction of sponsor. We need to answer the following:

- Do we need GLP?
- Can we achieve excellence?
- Can we guarantee quality and integrity?
- Is it a luxury?
- Does it involve risk?
- Are there any disadvantages?
- GLP is obviously so crucial to modern laboratory operations, but most importantly because good laboratory practice is an essential ingredient for any professional scientist.

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