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Role of Good Laboratory Practice in Good Clinical Practice

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Role of good laboratory practice in good clinical practice: Research regulatory consists of basic research, disease recovery, drug recovery, preclinical development, clinical trials and manufacturing. Indeed, preclinical development through Good Laboratory Practices (GLP) have an important role in clinical trials to achieve Good Clinical Practice (GCP). Literature revealed that drug development process takes time line approximately 10 years starting from discovery ended with manufacturing. GLP is a Food and Drug Administration (FDA) regulation which embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, reported and archived. FDA believes that implementation of a GLP quality system would institute a risk-based approach, reduce regulatory burden and encourage science-based technology. GLP data has been cured using published methods for all most all pharmaceuticals and the required information for the role of laboratories in drug development that takes four stages. Medical laboratory services must meet the needs of all patients and the clinical personnel responsible for the care of those patients. Under GCP, the FDA requires that people be informed. GCP is an international ethical and scientific quality standard for designing, conducting, performing, monitoring, auditing, recording, analyzing and reporting of clinical trials. GCP also, are protected through existing ICH-GCP Guidelines with co-sponsors (voting right); European Commission, European Federation of Pharmaceutical Industries Associations (EFPIA), Japanese Ministry of Health, Labour and Welfare (JMHLW), Japan Pharmaceutical Manufacturers Association (JPMA), Pharmaceutical Research and Manufacturers of America (PhRMA) and FDA. This speech highlights areas of concern and shortcomings of keen applying GLP was built understanding the needs of pharmaceutical industry and laboratories afford GCP.

Biography

Salwa Elmeligie has completed her PhD at the age of 29 years from Cairo University and postdoctoral studies from Faculty of Pharmacy, Iowa University, USA. She is Head of Pharmaceutical Organic Chemistry Department, Faculty of Pharmacy, Cairo University. She is also Director of Quality Assurance Unit, Faculty of Pharmacy, October 6 University, also reviewer for Higher Education Institutions (HEIs), conducted by the National Authority of Quality Assurance and Accreditation of Education (NAQAAE), and credited trainer in Egypt. She has published more than 36 papers in reputed journals and has been serving as an editorial board member of repute in addition to attending more than 20 training courses in Quality Assurance systems.

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