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A guide to an effective clinical trial protocol in cGMP & cGCP as a tool for sustenance of ethical principles and regulatory requirements in the pharmaceutical and research industry

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The clinical trial protocol is the foundation upon which the study design is built. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), the primary goal of a trial is to generate new knowledge about a potential medicine so that regulatory authorities can determine whether the medicine is safe and effective and the primary purpose of clinical trial is to advance the knowledge of researchers and regulators so that new treatments and cures can be developed. A guide to an effective Clinical Trial Protocol in cGMP & cGCP as a tool for sustenance of ethical principles and regulatory requirements in the pharmaceutical and research industry is a contemporary perspective on how professionals in the medical, pharmaceutical and research industries can utilize available resources in developing their clinical trial protocol based on sound scientific and ethical doctrines or principles with the primary intention of protecting research subjects or participants while adding meaning to the necessity for the continuation of research practices in our society. Additionally, a well articulated clinical trial protocol and subsequent amendment(s) in practice, as the case may be, will further enhance professionals' understanding and limitation(s) with greater emphasis on risk management, continuation of the study and importantly when to stop if it is deemed necessary or if the risk/benefit ratio becomes high enough to compromise either the study participants and or compromise ethical principles as enunciated in the Declaration of Helsinki, the Belmont report and the GCP principles contained in the International conference on harmonization (ICH)

Biography

Peter Odeh is a Medical Laboratory Scientist/Medical Technologist and Clinical Laboratory Scientist of international repute. He is the Vice President, Medical and Technical services of ROPAN (NIG) LTD. and also a Research Scientist with SNBL Clinical Pharmacology Center in Baltimore Maryland. He is a recipient of many awards including the International Travel Grant Award and the Gallwas Membership Grant Award of the American Association for Clinical Chemistry in Orlando Florida in the year 2002; the McAuley Silver Award for outstanding leadership and quality of work at Mercy Medical Center in Baltimore, Continuing Education Certificate of Excellence by the American Medical Technologists Institute for Education and most recently the Mother Mary Lange OSP Service Award from the Archdiocese of Baltimore. At SNBL, he worked with regulatory bodies and company staff in upgrading the clinical laboratory into a moderate to complex testing diagnostic center which is registered with COLA.

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