



## Bioanalytical laboratory design; critical planning for 21<sup>st</sup> century bioequivalence laboratory

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Generic pharmaceuticals need to confirm to the same standards of quality, efficacy and safety as required of the originator's product. Therefore, accurate drug measurements and other laboratory tests is the key for trusted research and the outcome recommendations. The world of laboratory science is ever changing and challenging. In the 21-century, qualitative methods, which are gaining increased use in drug measurements business, are designed to get the optimal accuracy. Process analysis bioanalytical laboratory involved in the bioequivalence and the scientific/economics outcomes must be designed based on the latest edge of technology. The most important factor for successful bioanalytical laboratory is accuracy. The second major challenge is following the regulations. For the new laboratory to be competing with current laboratories, it must start with high throughput analysis equipments to turn data faster with a low sample analysis cost. Interfacing chromatography and spectrophotometer instruments create powerful systems. Increasing pumps pressure and decreasing column particle size improve analysis and shorten analysis time. The wining laboratory must be capable of fast analysis. This laboratory should hire and well train qualified analytical scientists to carry out testing. Sample analysis required extra pretreatment steps to improve sensitivity and/or selectivity. Testing equipments must work with little or no human interventions and must be rugged with few moving parts. Dealing with large amount of samples and generated data is also, an important issue. Value of money must also be considered for reducing sample cost and generation funds. In summary, the four pillars of laboratory success are; accuracy, regulation, batch analysis time and sample cost.

### Biography

Dr. Rezk is the founder of the clinical pharmacology and analytical chemistry core laboratory at University of North Carolina-Chapel Hill. Honors; include the UNC Chancellor's award for innovation, and the State of North Carolina Governor's award for innovation in science. He acts as the PI for many HIV-research projects. Dr. Rezk published 35 papers in reputed journals and 30 scientific abstracts. Currently, Dr. Rezk is in charge of developing BE/BA unit and clinical pharmacology research center in KSA. His research interests include innovation in analytical chemistry, clinical pharmacology. Recently, he added a focus on better laboratory science practice for improving generic drugs.