COMPANY PROFILE 2022

Expert Consult Ltd.
Integrated Solutions

DISTRICT 2, 6 OCTOBER CITY,
CAIRO, EGYPT
+2010 910 818 00
expertconsulteg.com

Expert Consult Ltd.
Integrated Solutions

INTRODUCTION

Bioequivalence has always gained significant attention from the Regulatory Authorities throughout the world, being one of the most important aspects of generic drug product development, and of the most expensive and time-consuming steps in product lifecycle.

In many instances, pharmaceutical manufacturers face many problems in this area. In order to save time and cost of avoidable failure and repetition of BEstudies, pharmaceutical manufacturers may utilize services of relevantly qualified experts to under-take the BE study management on behalf of them.

ABOUT US

Expert Consult has been established in 2019 to be a leading Egyptian consulting company in the field of bioequivalence and related services. Our mission is to provide our partners with the best quality end to end integrated solutions for their product development and submission, including consultancy and technical support throughout the product lifecycle, timely, thorough and well-organized auditing and monitoring activities, as well as focused carefully designed on-demand training programs. experts to undetake the BE study management on behalf of them.

Dr. Khaled Abozeid, the founder of Expert Consult has a vast practical experience in pharmaceutical R&D, bioequivalence, biostatistics as well as teaching and training.

WHY WE EXIST?

Based on several years of his experience he realized that the lack of subject domain expertise team in the CROs is causing generic pharmaceutical companies to face challenges, financial loss and product failures during product development and/or BE study phase. Unfortunately, these challenges were not being handled and are considered beyond the scope of a BA/BE CRO resulting in a huge gap which needs to be fulfilled by a third party that combines a deep understanding of formulation & development issues and have great BE and analytical understanding, a unique combination which is lacking in most of the existing CROs.

In many instances, pharmaceutical manufacturers face many problems in this area. In order to save time and cost of avoidable failure and repetition of BE studies, pharmaceutical manufacturers may utilize services of relevantly qualified

During his long association and exposure with pharmaceutical and CRO industries, Dr. Khaled and his team of like-minded industry experts identified the gap in the knowledge and understanding of each other's domains between bioequivalence, formulation development and regulatory teams. He decided to fill this gap, to mitigate the risk of bio-failures and this led to conceptualization of Expert Consult to fulfill the specific needs of product developers, which need expertise beyond what typical CROs can offer.
We have been successfully delivering solutions to many national and multinational generic companies focusing on Egyptian and GCC submissions.

WHAT DO WE DO ?

We provide consulting and complete project management services to generic pharmaceutical companies for bioequivalence and related activities starting from the early R&D phase to provide a deep insight to your generic product development with a risk mitigation strategy for bioequivalence program in order maximize the success rate of biostudies and hence, to save a lot of money for your organization.

With our experienced & qualified team, Expert Consult takes complete ownership of your bioequivalence studies and ensures that they get completed efficiently and successfully by carefully evaluated & selected CROs.

We also support pharmaceutical industry professionals with well-designed technical and professional training programs covering many aspects of pharmaceutical industry, including bioequivalence, biostatistics, design of experiments and many other topics.

OUR COFOUNDERS

Ass. Professor Dr.Khaled Abozeid

Ass. Professor Dr. Khaled Abozeid,

Dr. Khaled has more than 20 years of experience in the area of product development, and bioequivalence. He gained his Ph.D. degree in pharmaceutics and industrial pharmacy. Due to his deep level of experience in the field of bioequivalence Dr. Khaled was selected in 2014 as a member of the scientific committee of the EDA that is responsible for reviewing the BE studies submitted for marketing authorization. During this period, he collaborated with the committee member in setting down the Egyptian guidelines and regulations for BE study conduct in Egypt. After that, he delivered consultancy services for many pharmaceutical companies in BE

Dr. Youssry Abo Elsoaud

Dr. Youssry Abo Elsoaud

After graduation from the faculty of pharmacy, Dr. Youssry brings a diverse experience focusing on communications, networking, business development as well as research and academia. He has earned a master's degree in business administration from the Arab academy for science technology (AASTMT).
Throughout his career, Dr. Youssry has worked in treatment company for pharmaceutical industries as international business development manager where he was responsible for building strong business networks and identifies new business opportunities in diversified sectors of health care industry, fostering the company's own brands by creating new private label products, manufactured in different countries over the globe, providing financial guidance and legal oversight for securing the necessary approval of capital expenditures, licensing arrangements and new product launches, conducting pharmaceutical market analysis and feasibility study in several African countries (Ethiopia, Tanzania, Rwanda, Angola, Guinea, Cote D'Ivoire and Cameron).

Dr.Mohammad Elnady

Dr.Mohammad Elnady

Dr.Mohammad has a unique blend of both business and regulatory experience and qualifications he gained from his 15 years' experience in the pharmaceutical industry. After graduating in pharmaceutical science from the University of Cairo, he has held posts in the fields of R&D and production of pharmaceutical dosage forms then, after completing postgraduate certificate in business management from the American university in Cairo (AUC). He has senior management roles in business development in pharmaceutical industry including opening new markets in local & export markets which allowed him to deal with different regulatory health authorities & business environment.
He successfully leaded his team in cooperation with colleagues from other departments within the company in many regulatory projects either for Egyptian drug authority or related health authorities in many African countries, ASEAN & GCC.

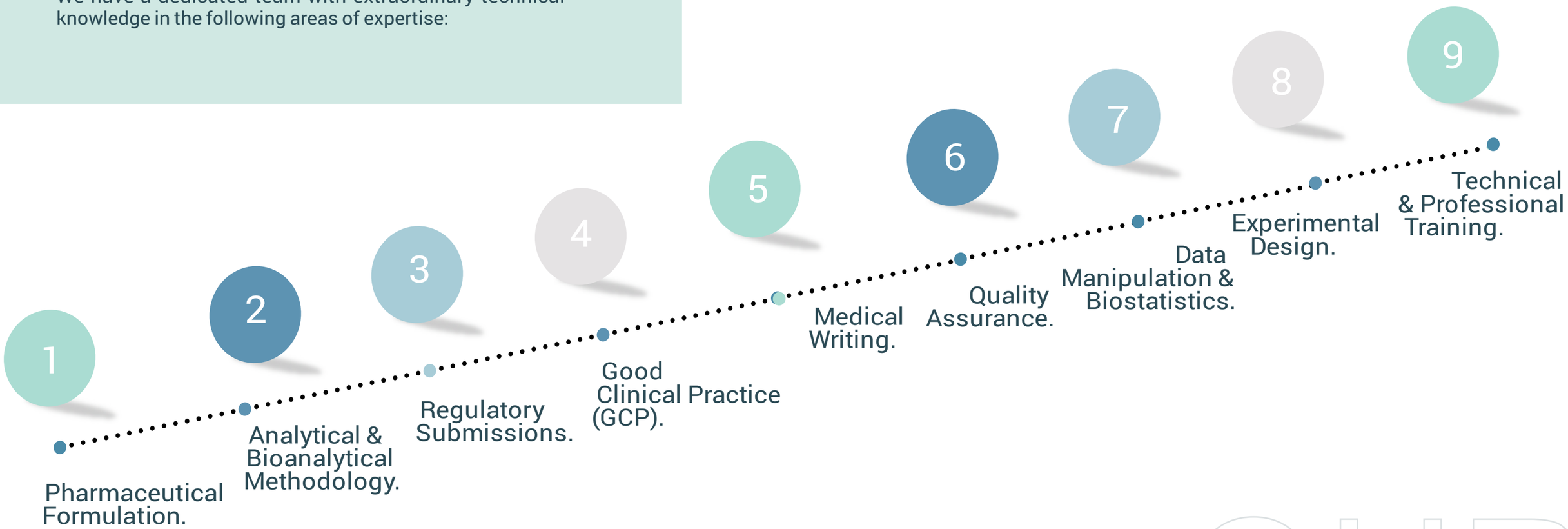
Dr. Heba Ali ElRamly

Dr. Heba Ali ElRamly

Dr. Heba has more than a decade of experience in the Clinical Pharmacy research. She spent more than 10 years in academia delivering clinical academic courses which included clinical pharmacy, clinical pharmacokinetics, therapeutics and advanced therapeutics, drug and poison information. She got her Ph.D degree in pharmacoeconomics from Ain Shams University. In addition, she collaborated in and supervised several clinical research in different therapeutic areas. she has a wide experience in scientific and medical writing, teaching, and training.

OUR TEAM

We have a dedicated team with extraordinary technical knowledge in the following areas of expertise:

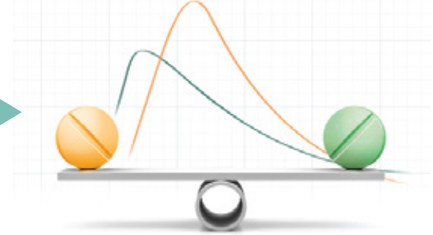


OUR TEAM

OUR SERVICES

1. BIOEQUIVALENCE STUDY MANAGEMENT
2. BIOSTATISTICAL SERVICES
3. TRAINING SERVICES

1 BIOEQUIVALENCE STUDY MANAGEMENT



1 R&D Phase : Formulation and Dissolution profile optimization.

From the pharmaceutical aspect, the similarity factor (f2) could be a good judgment criterion for the similarity between the generic and the brand products, while from the biopharmaceutical point of view it does not guarantee that the product will pass the BE testing.
In Expert Consult, through our highly professional experts, we could help the R&D department during product development to reach the optimum dissolution profile in order to mitigate the risk of bio-failure.
We analyze the DP not only from the pharmaceutical point of view, but also from the biopharmaceutical aspect which does not only rely on the similarity factor f2, but take into consideration the pharmacokinetic parameters and the physicochemical characteristics of the drug molecule as well.
In some cases where the similarity factor is not applicable (e.g, due to high variability), we help the sponsor to apply the most suitable model dependent or model-independent approaches for successful regulatory submission.

2 Clinical & Bioanalytical Phase

a CRO Selection & Qualification Auditing.

Appropriate CRO selection is the first step towards increasing chances of a successful outcome. There is a need of mapping your requirements and CRO capabilities to check the perfect fit. Probably you need to check on this on a case-by-case basis.

1. We provide this service to our clients to help them in selecting the best CRO for each product; based on our experience with the CROs working in MENA region, taking into consideration the type of product, type and design of the study, the API, and the previous history of the CRO with similar products/studies.

2. We also provide quality audit to assess the CRO qualification regarding, facilities, quality system, data integrity, IT, organization, and personnel. This is to ensure that BE studies will be conducted, and the data will be recorded, analyzed, and accurately reported.

according to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Documentation Practice (GDP) and the applicable guidelines and regulatory requirements.
According to our SOPs, our experienced auditors, using carefully designed checklists to perform the auditing activities that include but not limited to:

- Review SOPs to ensure that procedures and systems used in the conduct of the study are in compliance with applicable guidelines and regulations.
- Assess compliance with the GCP and GLP guidelines.
- Review the Site Master File and organization chart, qualifications, and training of the CRO project team members, workload and turnover rate.
- Assess the Quality Management System, including Quality Manual and Policy
- Review QA unit reporting structure and auditing practices.
- Review calibration and maintenance plans and procedures.
- Assess vendor qualification and managements.
- Assess computer system procedures and documentation including those for security, backup and recovery.
- Assess prior regulatory inspection history and interpretation.

b Study Planning & Protocol Development/Revision

A well-designed study protocol is the first and key point in the success of the BE study. The BE protocol depends on multiple factors such as drug physicochemical and pharmacokinetic characteristics, formulation type, relevant health authority regulations, study design, bioequivalence criteria and the type of volunteers required etc.
Many BE studies usually fail to meet the BE criteria or even may be rejected by the regulatory authority due to inappropriately designed protocol.
Our experts will work with the CRO in the protocol development to assures its compliance with all relevant guidelines and its suitability to the drug molecule regarding study design, sample size, proposed statistical approach, sampling schedule, clinical and bioanalytical plans

as well as all other scientific and regulatory aspects (e.g., detection and dealing with outliers and missed samples)

C BE Study Monitoring (Clinical Phase, Bioanalytical Phase & Data Management).

Auditing/monitoring all study related activities to ensure that the study is conducted, and the data are recorded, analyzed, and accurately reported according to the protocol, sponsor's Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Documentation Practice (GDP) and the applicable guidelines and regulatory requirements.
According to our SOPs, our experienced monitors perform the monitoring activities using carefully designed checklists to assess the following:

- The adherence to all aspects of GCP, GLP and GDP during the study.
- All documentations and quality system that is applied by the CRO to ensure plausibility, integrity and consistency of data.
- Presence of any observations, which may raise concerns about the quality or validity of the subject-related data, e.g. laboratory tests; sampling time recording; inclusion and exclusion criteria; adverse event frequencies and severities (profiles) not consistent with the known profile for the product; deviations from dosing regimens, adherence to dietary and exercise restrictions (where applicable).....etc.
- Presence of any observations which raise concerns about the quality or validity of the sampling process or study sample analyses, e.g.: inconsistencies between the numbers of samples collected, analyzed and reported; insufficient information to confirm the integrity of the samples (e.g. regarding storage and stability); management of repeated sample analyses and missing samples is not described adequately; large number of samples re-assay.... Etc.
- Presence of any observations which raise concerns about the quality or validity of the analytical method e.g.: bioanalytical method has not been fully validated before study sample analyses; the method validation data and the acceptance criteria are inadequate; the data presented are inconsistent with the described and planned methodologies.....etc.
- Presence of any observations which raise concerns about the quality or validity of the study in general, e.g. the amount of missing values/drop outs not meet the expectation; absence of relevant SOPs; doubts on the compliance with current requirements and guidelines; implausibility/inconsistency of clinical or analytical data; absence of powerful QA system.... etc.
- Review of CRF and assess data integrity and source document management.
- Review records and procedures concerning interactions with the IRB.
- Review records and procedures concerning Investigational Drug products (IDP) receiving, storage, dispensing and accountability.
- Review records and procedures concerning interactions with AE reporting

3 Medical Writing & Data Review Phase:

3. Medical Writing & Data Review Phase:

a. Pharmacokinetic Calculations & Statistical Analysis.

The use of inappropriate approaches during PK and statistical calculations (regarding for example dealing with outliers and missed samples, study design & statistical model) may lead to an avoidable study failure or rejection. On behalf of our partners, we manage the process of the PK & statistical calculation with the CRO. This is to ensure the adherence to the suitable and right approach for each particular study, taking into consideration all relevant scientific and regulatory aspects.

b. Review of Final Reports.

analysis and presentation of bioequivalence study is as important as the bioequivalence study conduct itself. Deep assessment of the documents before submitting to the regulatory authorities ensures a successful submission with minimum possibility of queries being raised
With years of experience in supporting generic bioequivalence submissions, Expert Consult provides a comprehensive review of the final reports, all related documents and appendices before submission to the regularity authority in order to assure compliance with all relevant guidelines and regularity requirements and hence minimize the probability of regulatory comments and enquiries.

4 Regulatory Support.

In many instances, before making investments, it is advisable to take scientific advice from relevant regulatory authorities. Controlled correspondence is an effective way to make a request, submit changes or obtain clarification on specific information from regulators. An adherence to applicable guidance's and addressing the issues clearly while writing controlled correspondences increases chances of accepting the request and getting specific and speedy response from the authority on requested query.
Our experienced team supports you in regulatory concerns, approvals and relevant documentation during pre- and post-study submissions which includes the following:

- Controlled correspondence with regulatory authority.
- Any regulatory inquiry response and justification
- Biowaiver Applications.

5 Failed BE study Analysis

When bioequivalence study fails to show bioequivalence, still such data - when subjected to proper investigation by experts - provides immense valuable insight and clear guidance to strategize the future course of action through the determination of the root cause of such failure.
The investigation should start from formulation strategy, pharmacokinetic parameters and dissolution data for establishing possible IVIVC correlation etc. Other factors such as study design, enrolled population, sample size, time points, bioanalytical issues, food effect, dietary factors are also critical and should not be missed. There can be multiple reasons behind failure of a BE study and repeating the study without knowing them may turn out to be another blunder.
An integrated approach should be planned with engagement of experts from formulation, biostatistics, clinical and bioanalytical as needed. Problematic areas need to be identified and studied in detail to make conclusions, while auditing and validating the data correctness.
Investigation of failed bioequivalence study is beyond the scope of a CRO and is a big loss to the sponsor financially as well as it delays the timelines. As a company you cannot expect the same team to find out the loophole in a study which conducted it. You need an independent entity to assess the BE study and help you with the root cause analysis.
Based on the detail Root Cause Analysis, we could sort out the reason for failure and put forth new strategies and further actions required, whether it is returning to the formulation development strategy or using different design approach or increasing sample size etc. Expert Consult has system based investigational approach and stepwise investigation strategy for investigating failed studies which has led to successful solutions and corrective measures to ensure a successful outcome at the end.

2 BIOSTATISTICAL SERVICES

We provide a comprehensive end to end biostatistical consultancy services that support pharmaceutical and medical professionals and researchers from planning through execution, interpretation and finally reporting and submission. Our services include study design, sample size calculation, statistical analysis plan (SAP) development and execution, results tabulation, visualization, interpretation and reporting for either regulatory or publishing submission.

3 TRAINING SERVICES

We offer professional level training courses in a variety of formats including in person, customized client site, and interactive online. we have successfully trained many professionals from small and large companies, government and academia.
Our tailored training courses covers the following areas:

1. Bioequivalence Studies
2. Clinical trials
3. GCP
4. Biostatistics basic and advanced topics
5. Design of Experiments
6. CTD and eCTD

OUR PARTNERS

1. SAJA PHARMACEUTICALS
2. BATTERJEE PHARMA.
3. HIKMA PHARMACEUTICAL
4. GLENNMARK EGYPT
5. BIOREMEDY PHARMA
6. INSPIRE PHARMA
7. HEFNY PHARMA GROUP

MAXIMIZING

YOUR **BIOSTUDY** SUCCESS
RATE IS **OUR GOAL..**

WE DON’T JUST CONSULT. WE SOLVE