



**Centurion**  
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# OUTSOURCING BA AND BE TO CRO.

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## What is outsourcing?

- Outsourcing is the business practice of hiring a party outside a company to perform services and create goods that traditionally were performed in-house by the company's own employees and staff.

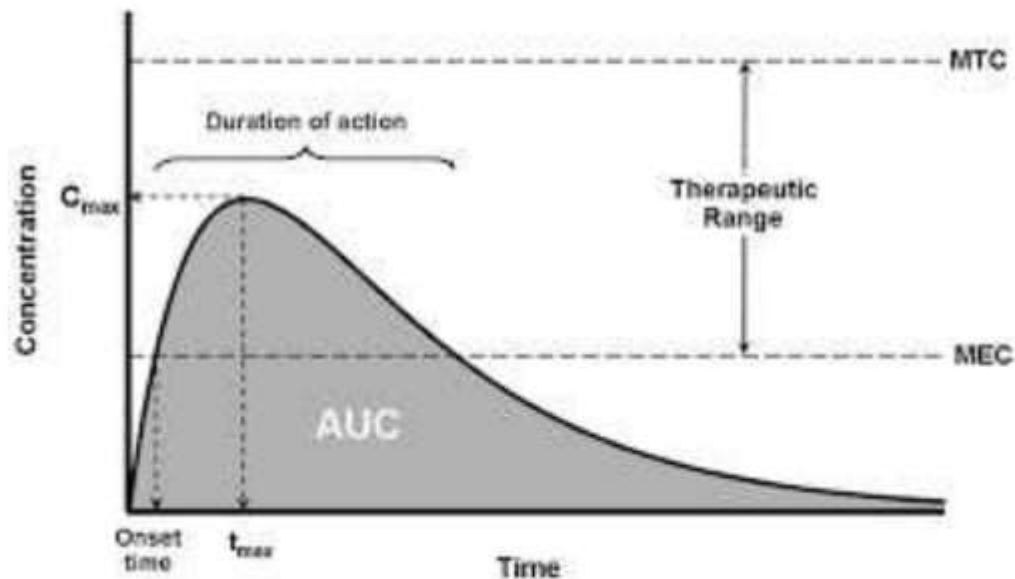


- Outsourcing was first recognized as a business strategy in 1989 and became an integral part of international business economics.
  
- Outsourcing is generally done to reduce the costs and improving the efficient resources within a company. Ex of outsourcing is bioavailability, bioequivalence, R & D department etc.

## Bioavailability:

- Measurement of the amount and rate at which the drug from administered dosage form, reaches the systemic circulation and becomes available at the site of action.
- Bioavailability describes the concentration of drug in systemic blood in relation to the amount of drug given.

## Therapeutic relevance:



## Objective:

- In R & D of suitable dosage form.
- Determination of influence of excipient, patient related factors and drug interaction on the efficiency of absorption.
- QC of dosage form etc.

## Bioequivalence:

It is a relative term which denotes that the drug substance in two or more identical dosage form, reaches the systemic circulation at the same relative rate and to the same relative extent i.e; their plasma concentration-time profiles will be identical without significant statistical differences.

## Types of equivalence:

- **Chemical Equivalence:**

It indicates that two or more drug product contain the same labelled chemical substances as an active ingredient in the same amount.

- **Pharmaceutical Equivalence:**

This term implies that two or more drug products are identical in strength, quality, purity, content uniformity and disintegration and dissolution characteristics. They may however, differ in containing different excipients.



## Therapeutic equivalence:

This term indicates that two or more drug products that contain the same therapeutically active ingredients elicit identical pharmacological effects and can control the disease to the same extent.

## CRO (Contract Research Organisation):

- A contract research organisation(CRO) is an organisation that provide support to the pharmaceutical, biotechnology and medical device industries in the form of research services outsourced
- It offers various pharmaceutical research that is essential for conducting clinical trials, the ICH technical requirements for registration of pharmaceuticals for human use.

## Identification of appropriate CROs

- It is important that your CRO has validated corporate procedures for all segments of clinical study conduct.
- These procedures are used to ensure that all aspects of a study, including but not limited to clinical conduct, laboratory analysis, data management, biostatistics, pharmacokinetics, and medical writing, are performed in compliance with Good Clinical Practices (GCP), Good Laboratory Practices (GLP), and other applicable regulatory practices and guidelines.

## Assessment of Capabilities

1. Clinical capabilities
2. Bio analytical capabilities
3. Pharmacokinetic capabilities
4. Timeline assessment

## CRO Qualification

### 1. Due diligence

- If the pharmaceutical firm has used the CRO in the past, they should objectively evaluate their past experience with this CRO.
- If the experience was good, the firm should identify those components that were successful and insure that they are used for their new study.
- However, caution should be exercised and due diligence pursued if the new study requires a different subject population or analytical technique.

#### Example:

A CRO may specialize in recruiting healthy male and female volunteers, but may have difficulty in the recruitment of postmenopausal females.

## 2. Clinical site qualification

The sponsor should conduct a site qualification visit. In addition to a eGCP site audit, this evaluation should include an assessment of the area mentioned below;

### Clinical site evaluation

- Assess the volunteer (or patient) population pool
- Evaluate CRO procedures for handling an unexpected and serious adverse event (AE) investigation.
- Assess training records for the clinical team.
- Evaluate CRO's ability to coordinate plasma/urine shipments to different bio analytical facilities
- Assess ability to coordinate functional handoffs (e.g. Timely delivery of protocol to clinic, samples to lab, bio analytical data to the pharmacokineticist)
- Assess clinical project management capabilities

## Clinical data management

- Assess the validation of the data collection system
- Evaluate query generation, SOPs, CRF and database correction, change control

- Evaluate clinical deliverables, CRFS (CRO or sponsor format) Data Base (when applicable)
- Blood/plasma/urine collection procedures/SOPS and transport procedures to bio analytical unit.
- Content of the written clinical report (i.e., CRO clinical report to be incorporated into the final study report)

### 3. Bio analytical site qualification

- Candidate CROs for bio analytical laboratory work (for drug, metabolite or biomarker assay) should also be assessed.
- The company audit should also include cGLP compliance and an assessment of the laboratory's inspection history. Copies of the inspection history with all FDA 483s and EIRs should be reviewed.
- Laboratory project manager should be assessed for their ability to coordinate all processes with client, clinic and pharmacokinetic.

#### 4. Pharmacokinetic site qualification

- The pharmaceutical firm should also qualify the CRO site (or department) that is responsible for PK and statistical analyses and completion of the final integrated report. During the pharmacokinetic site audit, following areas should be assessed:

- Qualification of pharmacokinetic and statistical personnel.
- Validation of pharmacokinetic and statistical programs (usually SAS).
- Compliance with 21CFR(code of federal regulation) Part 11. At the time of this publication, full and complete compliance with Part 11 was not being enforced. However, the CRO should have a written plan and timeline for bringing all post laboratory functions into compliance.

Thank you!

