

REGULATORY PERSPECTIVES – BA/BE STUDIES



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REGULATORY AUTHORITY MISSION

- “ASSURE THAT SAFE AND EFFECTIVE DRUGS ARE MARKETED IN THE COUNTRY AND ARE AVAILABLE TO THE PEOPLE”

REGULATORY PROCESS

- Differs from country to country
- Demands safety and quality of product
- Encourages efficacy and need for product
- Approves protocols and examines data
- Original data available
- Two way process; authority and company trying to produce a safe and effective product
- Release for a specific purpose and use

DRUG REGULATORY AUTHORITY IN INDIA

- THE DRUG CONTROLLER GENERAL OF INDIA (DCGI)
- THE DRUGS AND COSMETIC ACT, 1940 ; DRUGS AND COSMETIC RULES, 1945
- SCHEDULE Y

WHEN IS A BA STUDY NEEDED IN INDIA

1. A new drug is launched in India for the first time. The first applicant conducts a clinical trial and a BA study
2. For the first four years or until inclusion in the Indian Pharmacopoeia, all applicants conduct BA studies
3. After four years BA study not required

APPLICATION

FOR INDIAN COMPANIES OR APPLICATION FOR
PRODUCT LICENSE FOR INDIA

- Apply along with Form 122 A, B or C for new drug application (Refer D&C Act for definition of new drug)
- BA/BE Protocol, ICF, CRF and EC permission letter

APPLICATION CONT..

FOR INTERNATIONAL STUDIES

- Apply in Form 12 (for old drugs) for a test license to import the drugs (Sch Y Sec. 1.2. Permission for Trials)
- Form 44 (for new drugs) for BA/BE studies (include pilot studies)

After DCGI Clearance:

- DGFT for export of plasma samples
- NCB for narcotic drugs

OTHER DOCUMENTATION

- Protocol
- Investigator and Center details
- Letter of intent from Sponsor
- EC permission letter
- If women and post-menopausal women are included, then justification for inclusion

BE/BA INDIAN GUIDELINES

- SCOPE

When is BE/BA study required and when not

PROOF OF EQUIVALENCE

(For oral dosage forms-pk studies)

DESIGN AND CONDUCT

Study design

Study conductions

Bioanalytical methodology

DOCUMENTATION

FACILITIES FOR CONDUCTION BE/BA

MAINTENANCE OF RECORDS,RETENSION OF SAMPLES.

Study population

Characteristics to be investigated

Statistical evaluation

REGULATORY ISSUES

- Release and strict implementation of BE guidelines
- Ensure only GCP/GLP conforming centres are operational through strict audits
- Prevent inferior products to enter market

REGULATORY GUIDELINES

- THE FOOD AND DRUG ADMINISTRATION-USFDA
- INTERNATIONAL CONFERENCE OF HARMONISATION-ICH
- WORLD HEALTH ORGANISATION WHO
- THERAPEUTIC GOOD ADMINISTRATION AUSTRALIAN TGA
- HEALTH CANADA
- MINISTRY OF HEALTH BRAZIL ANVISA
- EMEA THE EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS

REGULATORY BODIES

- EASTERN EUROPE
RUSSIA, HUNGARY, CZECH REPUBLIC, POLAND
- ASIA
- AFRICA
- LATIN AMERICA
- NEW ZEALAND
- UK
- ARGENTINA
- AUSTRIA
- BELGIUM
- OTHER COUNTRIES

WEBSITE

- www.fda.gov
- www.fdawarningletter.com
- www.ich.org
- www.anvisa.gov.br



THANK YOU