REGULATORY AFFAIRS

CONTENTS

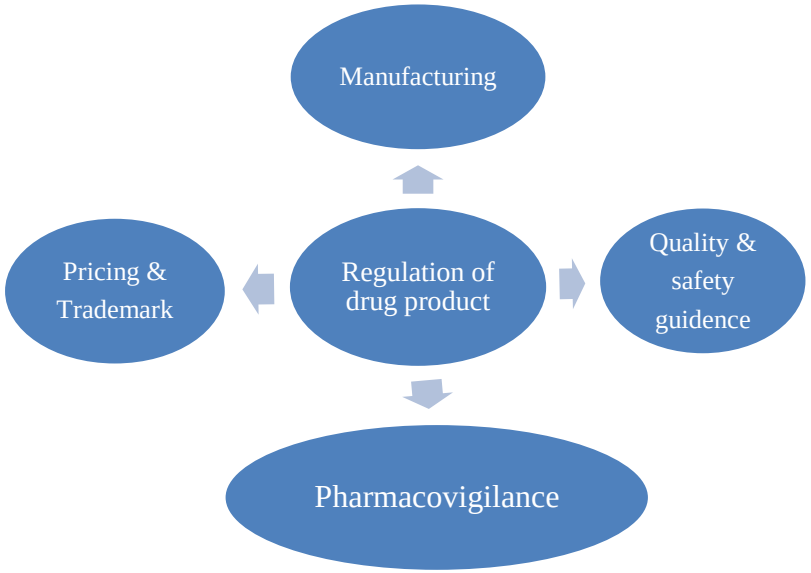
- Introduction
- Historical overview of Regulatory Affairs
- Regulatory Authorities
- Role of Regulatory Affairs department
- Responsibility of Regulatory Affairs professionals
- Drug Development Teams
- Non-clinical drug Development
- Drug Metabolism and Toxicology
- General consideration of Investigational New Drug
- Investigators Brochure
- New Drug Application
- Clinical research and its protocol
- Biostatistics in pharmaceutical
- Product Development
- Data presentation for FDA submission
- Management of clinical studies

INTRODUCTION

Regulatory Affairs (RB) also called Government affairs, is a profession developed from desire Government to protect public health by controlling the safety and efficacy of product in areas

Including p'ceuticals veterinary medicates, medical devices, pesticides, agrochemicals, foods Cosmetics and complementary medicines etc. Pharmaceutical Drug Regulatory Affairs (DRA) is dynamic field that includes scientific and Commercial aspect of Legal drug development.

REGULATION OF DRUG PRODUCTS INVOLVE FOLLOWING AREA



REGULATORY AUTHORITIES

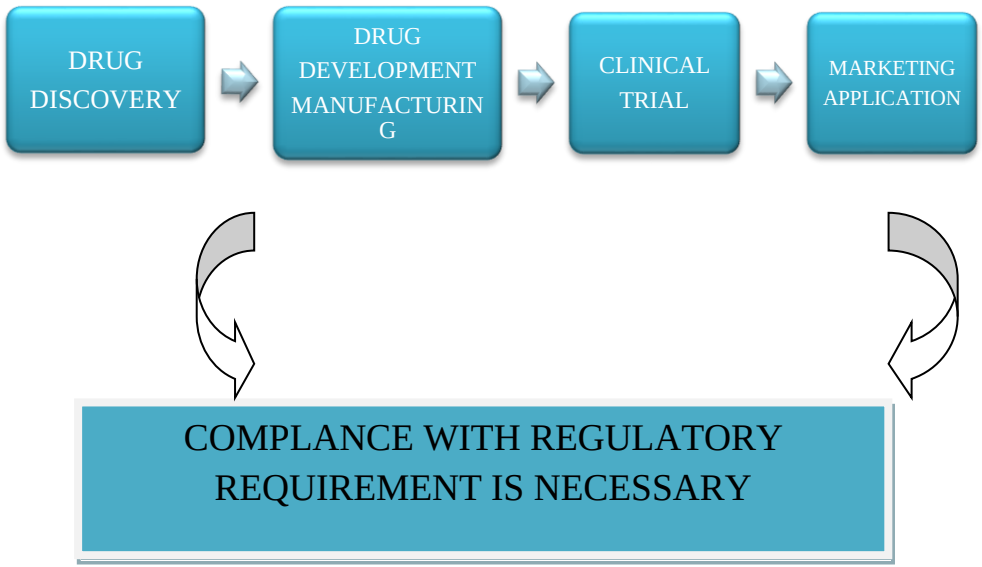
Public Health being the prime concern, it is necessary that the drug/drug product available for human/veterinary use and medical devices must not only be effective but also be safe for the intended use to ensure this various territorial regulatory bodies come into existence

MAJOR REGULATORY AGENCIES INCLUDE

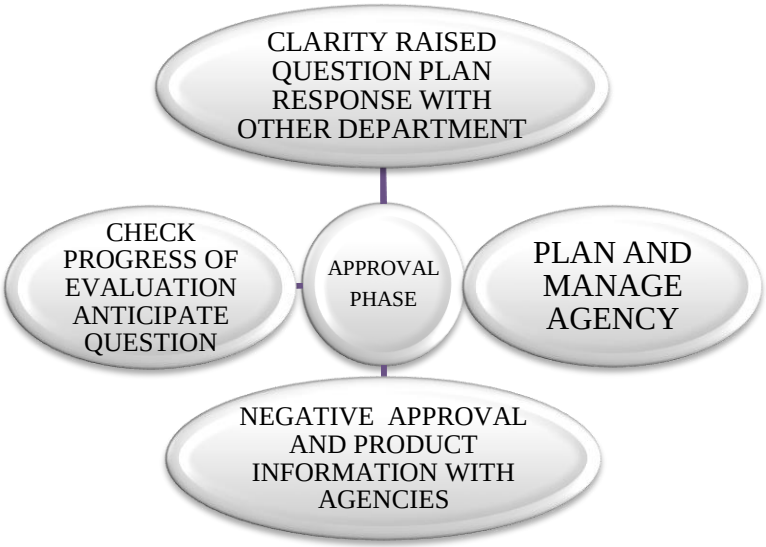
- World Health Organization
- United States Food and Drug Administration
- European Medicines Agency
- Therapeutic Goods Administration
- Health Canada
- Pharmaceutical and Medical Devices Agency
- Central drugs Standard Control Organization
- Medicines and Healthcare Products Regulatory Agency

ROLE OF DRUG REGULATORY AFFAIRS DEPARTMENT

IN DEVELOPMENT PHASE



IN APPROVAL PHASE



IN POST APPROVAL PHASE

ROLE OF DRUG REGULATORY AFFAIRES DEPARTMENT

DRUG DEVELOPMENT

NON CLINICAL DRUG DEVELOPMENT

- In vitro studies- cell lines, cell free system
- Drug formulation
- Chemistry, Manufacturing &control
- In vivo efficacy studies- animal model & proof of study
- Non clinical safety studies
- Get idea for drug target
- Toxicity endpoint
- Efficacy end point

GENRAL CONSIDERATION OF INVESTIGATIONAL NEW DRUG (IND)

IND is a program by which any pharmaceutical company can approach to obtain permission for the initiation of human clinical trials to ship and experimental drug across state lines before a marketing application

TYPES OF IND

INVESTIGATOR

- submited by physican

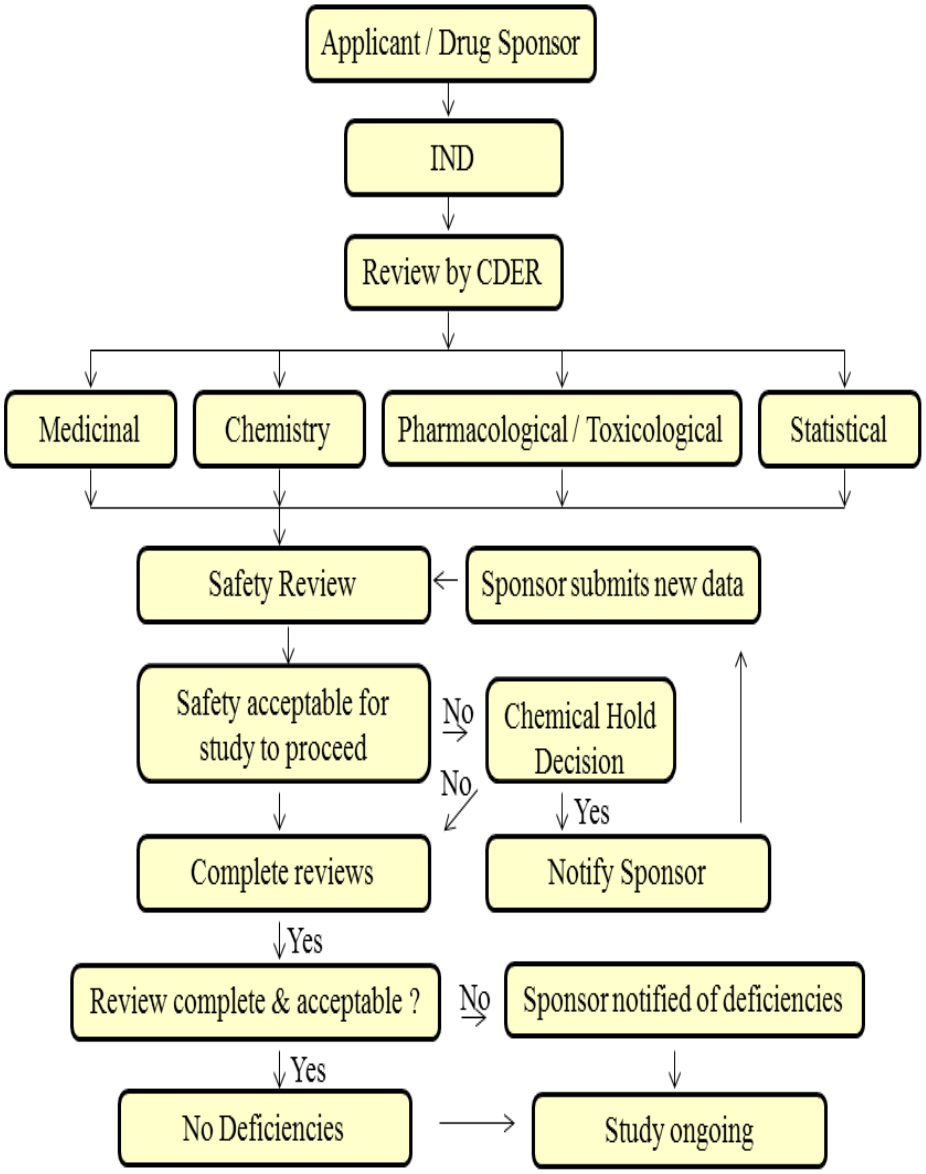
EMERGENCY

- to get authority use of drug in emergency

TREATMENT

- use in treatment of life threatening condition

IND APPLICATION



Investigational New Drug Application (IND)

INVESTIGATOR BROCHURE

IB is a collection of clinical and non clinical data on investigational product that is relevant to study of product in human project.

⇩

Comprehensive document

⇩

Information about Investigational product

⇩

Obtained during clinical trials

⇩

Information in short simple

⇩

Non-promotional form

- THE FOLLOWING INFORMATION SHOULD BE INCLUDED IN IB

1.Title page

- Sponsor
- Trade name
- Release date
- Date

2.Confidential statement

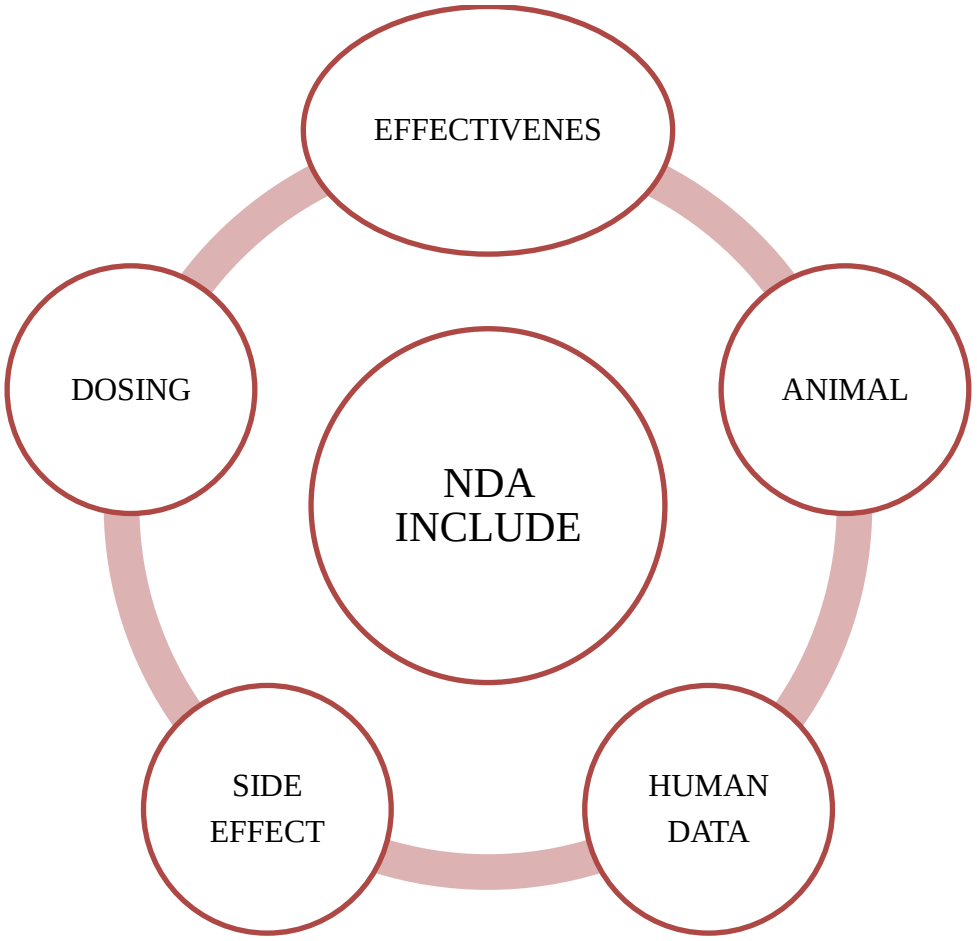
3. Content of IB

- Table of content
- Summary
- Introduction
- Physical,chemical,pharmaceutical properties and formulation

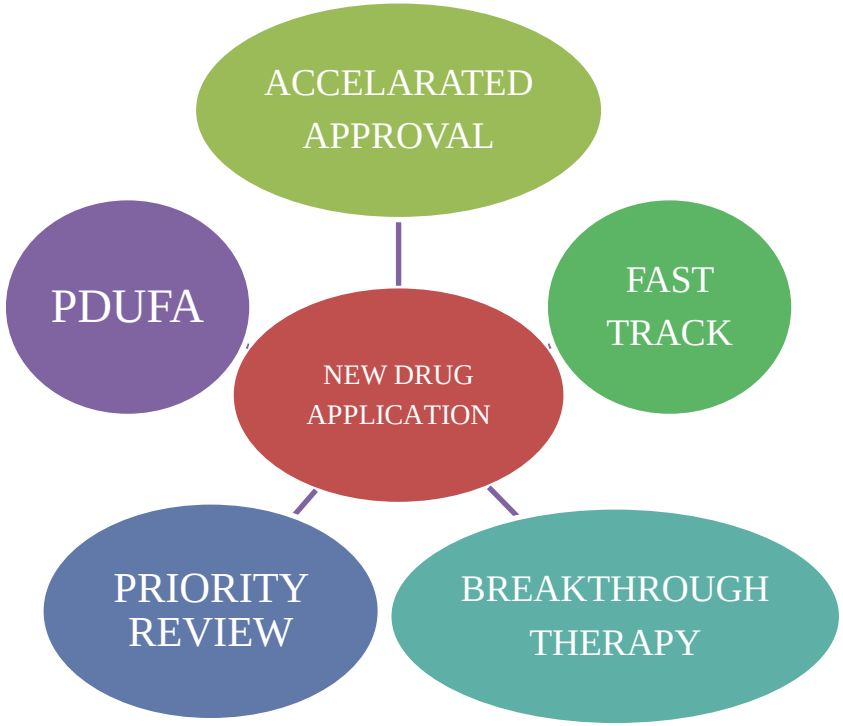
NEW DRUG APPLICATION

It include thousands of pages to the FDA for review and approval

It is vehicle through which drug sponsor formally propose that FDA approve new pharmaceutical for sale and marketing in US



❖ NEW DRUG APPLICATION HAVE



Once FDA has reviewed the NDA it issues one of the below mentioned three action letter

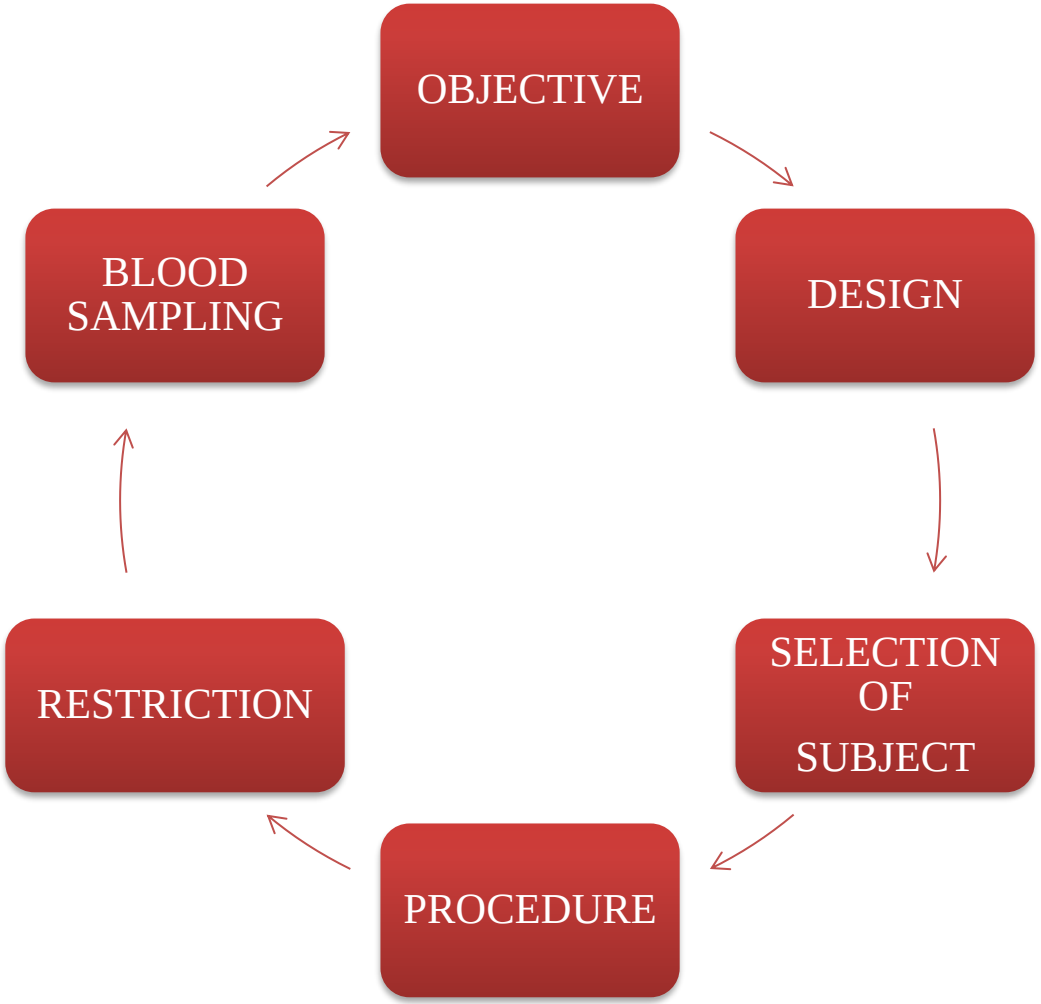
1. Approval letter – indicates the drug is approved

2. Approvable letter- indicates that the drug will be approved eventually but requires rectification due to few inadequacies such as labeling changes

3. Not approval letter- indicates drug cannot be approved

BIOEQUIVALANCE

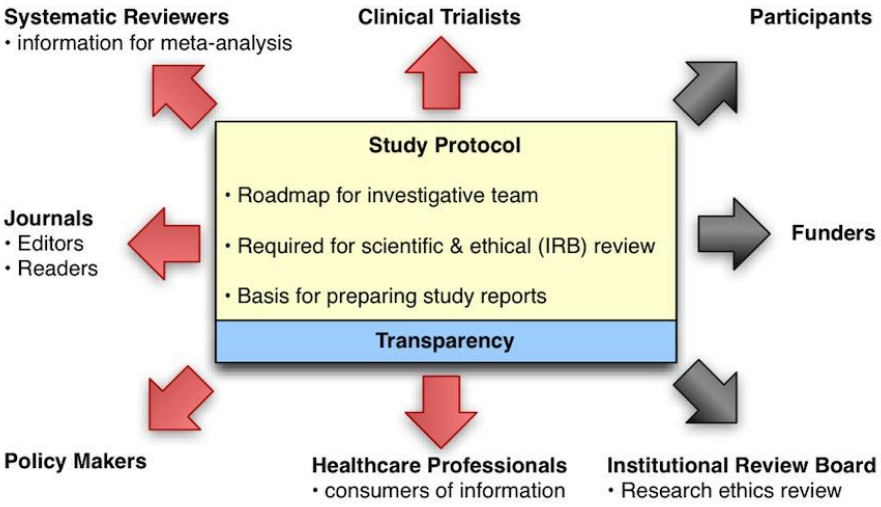
.IN VIVO STUDIES INCLUDE



CLINICAL RESEARCH PROTOCOL

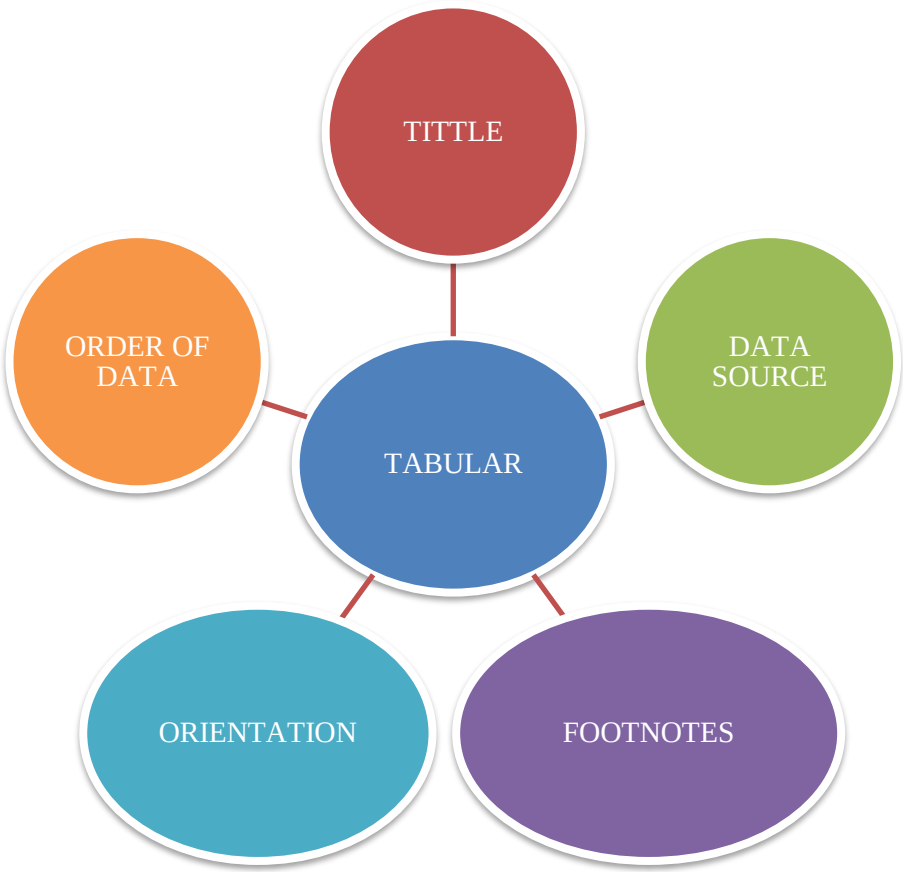
The contents of trial should generally include the following topics, however site specific information may be provided on separate protocol page or addressed in a separate agreement and some of the information listed below may be contained in other protocol referenced documents such as an investigators brochure

1. General information
2. Background information
3. Trial objective and purpose
4. Trial design
5. Assessment efficacy
6. Assessment safety
7. Statistics



DATA PRESENTATION FOR FDA SUBMISSION

1. TABULAR PRESENTATION



2 TEXT EXPOSITION

As drug product development progresses, the FDA expects that the investigational drug has the potential to meet the criteria for breakthrough therapy designation to support continuation of the expedited clinical development program, such that the potential benefits of enrollment in these complex clinical protocols continue to outweigh the potential for the increased risks to patients.

REFERENCE

1.B.P Mahesh, Dr M.S Prabhuswami Six Sigma Concept, International Journal& Advance Research Management Volume-1, Issues- 2010 page no : 20-22
.2. Dr.K.P Sampat Kumar Dr. Debjit Bhowmik Shambaditya Goswami Industrial Pharmacy 2, First Edition 2020 Nirali Prakashan Page no 4.8-4.28.
3. Dr.Swarnali Das Poul, Mrs Gunjan Jeswani Quality by Design, Pharmaceutical Quality Assurance PV Publication, Page no 60-63.
4. ." https://www.slideshare.net/NailaKanwal/regulatory-affairs-55362084
5. https://www.slideshare.net/sagarsavale1/investigational-new-drug-application-inda

DEPARTMENT- PHARMACEUTICS
SUBJECT - INDUSTRIAL PHARMACY-II
GUIDED BY -Ms. Adsare Vaishali A.
PREPARED BY- Ms. Gadhave Akanksha
Ms. Gorkatte Shivani
CLASS -Final year B.Pharmacy
ACADEMIC YEAR- 2021-22