

Regulatory consideration on development of biological products for treatment of cancer

Luo Jianhui

CDE SFDA, P.R.China

General introduction

- Legal compulsion

Drug Law of China; September 1984, update February 2001;

- Regulatory requirement

Regulation for the Implementation of Drug Registration; August 2002;

Management of Drug Registration, 1999 , update, July 2007;

- Guideline documents

1999, update and add-on since 2005;

Management of Drug Registration

Section 3 clinical trial of drugs

- item 31 , clinical trial, phase I to phase IV;
- item 36, quality control by NICPBP;
- item 44, prerequisite for international multi-center study;

International clinical trial application or registration application

- **44.2 special requirements for
international multi- center trial;**
- **44.5 clinical data requirements for
registration;**

Guideline documents

- 57 documents available concerning chemical drug, Chinese herbs drug and biologics;
- 15 documents concerning biological products;
- 6 documents concerning quality control of mammalian cell substrate, non-clinical and clinical study of therapeutic or prophylactic biological products, or validation of analytical assay used for quality control of biological products;

Basic Structure and function of Regulatory Authority

SFDA

CDE

Biologics division

Evaluation of
IND or BLA application

NICPBP

Testing laboratory

Quality control
Testing products for clinical trial
Checking Batch release on market

Others

Advancing procedure of cancer

Disease & Cancer cell

Outcome

sensitive

growth

relapse

cachexia, dying

under control

metastasis

resistant

lost control, death

Key aspects to consider

Tumor cell nature, malignance and behavior ?

Therapy adopted, radiation, chemical drug, operation, biotherapy ?

Patient's physical condition, response to therapy, tolerance to treatment, quality of life ?

Medical practice, patient's willingness, therapy availability , ethical consideration?

Clinical trail design

For therapeutic vaccine or cell therapy:

What kind of clinical trail should be considered of for cancer patient at different disease stage ?

Should early cancer patients be involved in explorative clinical trail ?