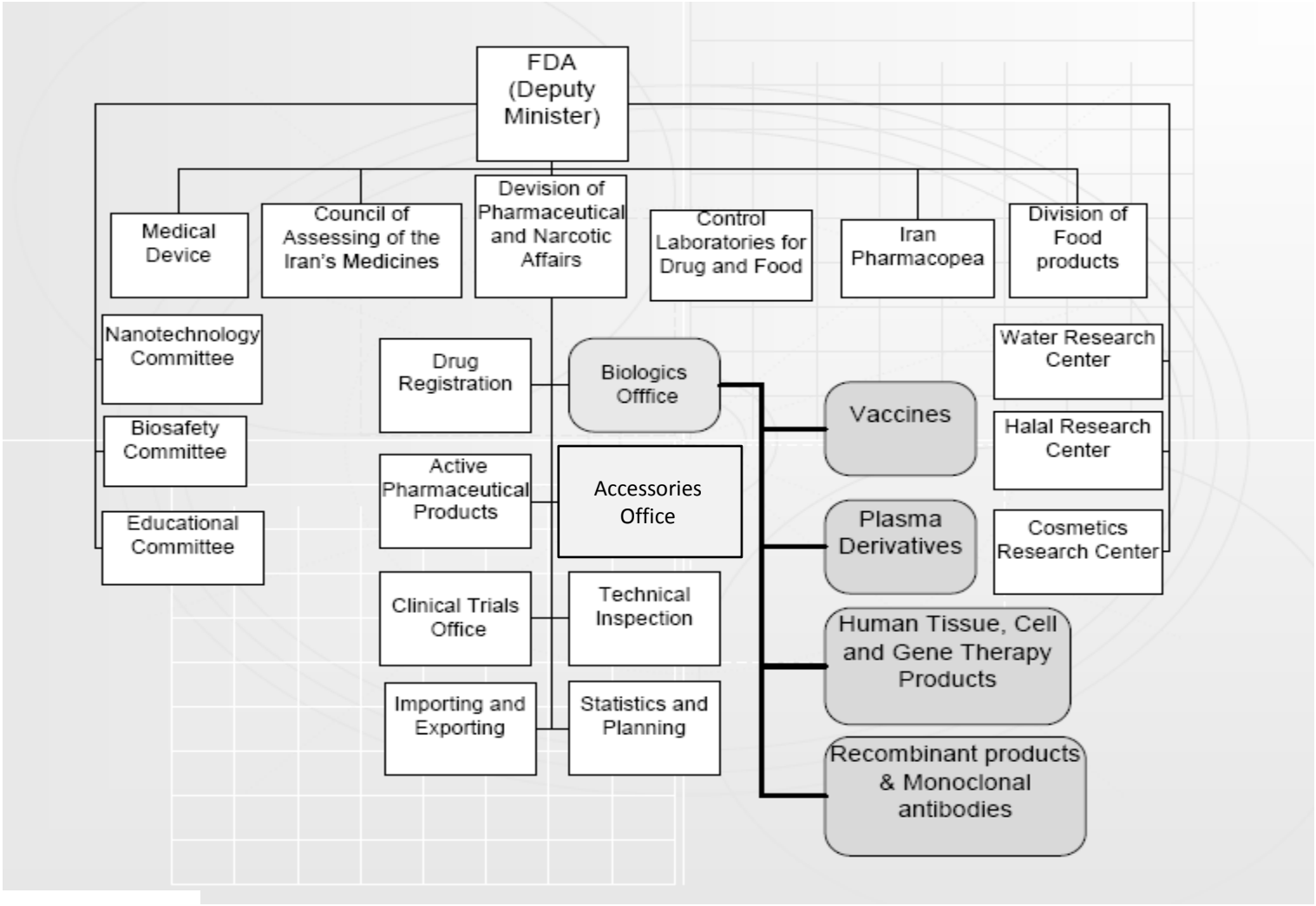
Iran FDA Regulations for registration of Pharmaceutical products

Organogram


FDA (Deputy Minister)
Medical Device
Council of Assessing of the Iran's Medicines
Devision of Pharmaceutical and Narcotic Affairs
Control Laboratories for Drug and Food
Iran Pharmacopea
Division of Food products
Nanotechnology Committee
Biosafety Committee
Educational Committee
Drug Registration
Active Pharmaceutical Products
Clinical Trials Office
Importing and Exporting
Biologics Offfice
Accessories Office
Technical Inspection
Statistics and Planning
Vaccines
Plasma Derivatives
Human Tissue, Cell and Gene Therapy Products
Recombinant products & Monoclonal antibodies
Water Research Center
Halal Research Center
Cosmetics Research Center

Registration

- Iran Drug List
- Registration

Who can apply?

- A pharmaceutical company

  License

  Responsible Pharmacist

  Exclusive agent of Product License Holder

  (First Agreement)

Documents

- Original CPP stamped by Iran Embassy in country of origin
- Electronic Drug Master File in CTD format (company confirmation letter)
- Registration fee payment

Documents

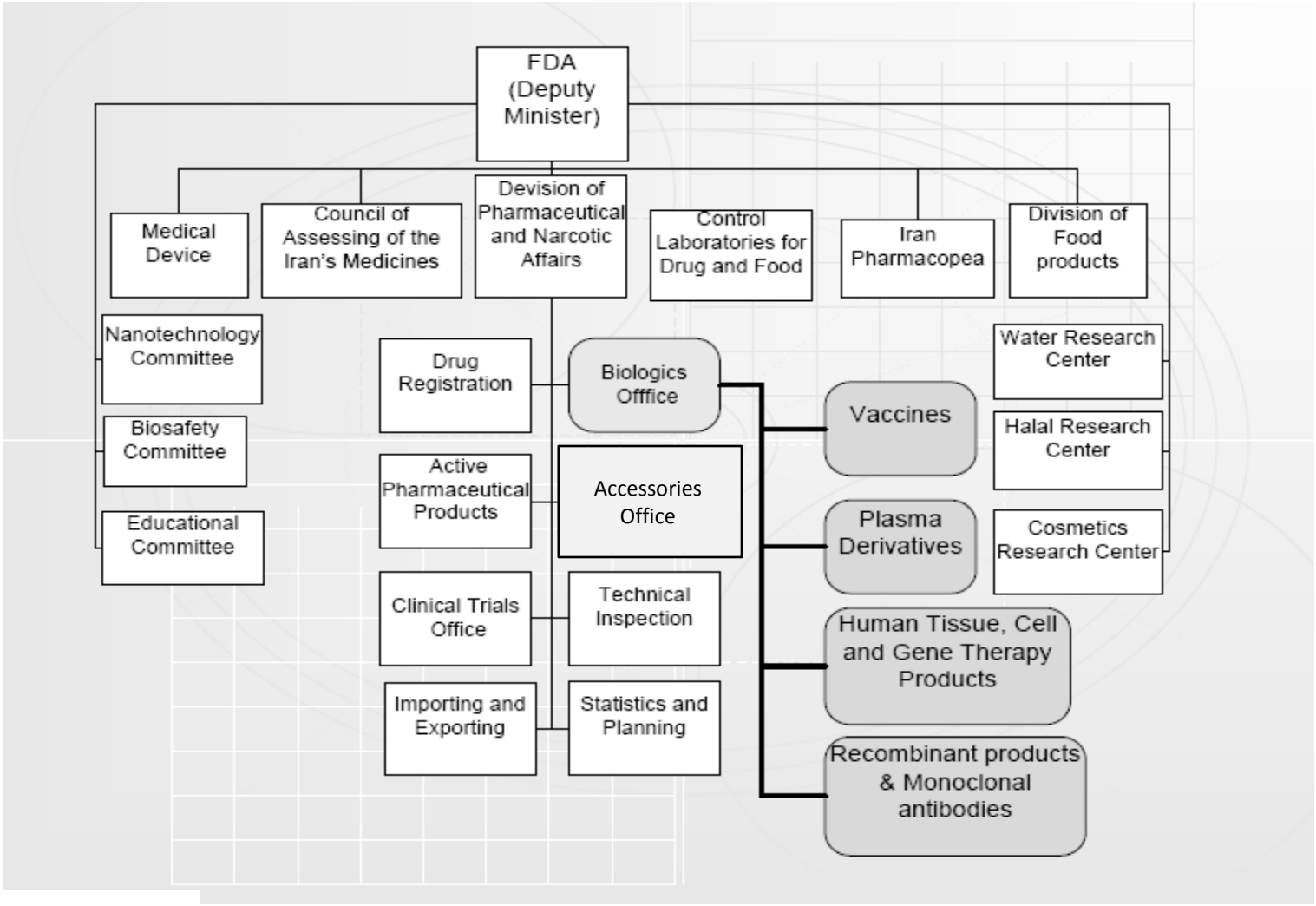
- Price confirmation
- All chromatograms for the batch mentioned in CTD (API & FDF)
- Persian translation of the brochure
- Exportation Certificate
- GMP approval (USFDA, EMEA, TGA, WHO)
- Samples sent to Control Labs in case needed

IRI.FDO
سازمان غذا و دارو

Thank you!

- Office of Biologics
- Biologics Regulation
- Registration Procedures

Organization Chart



Office of Biologics

- Vaccines: Bacterial , Viral and Recombinant Vaccines and therapeutic Serums
- Plasma derivatives: Immunoglobulin, Albumin , Anti-coagulant factors
- Human Tissue, Cell and Gene Therapy Products
- Recombinant products & Monoclonal Antibodies

Companies

- Active companies: 25
  - Vaccines 3
  - Plasma collection 4
  - Biotechnology 18

- Regulation on Vaccines
- Regulation on Plasma derivatives and Plasmapheresis Centers
- Regulation on Human Tissue, Cell and Gene Therapy Products
  - Legislation on Tissue, Cell and Gene Therapy Products, September 2014.
  - Regulation on Tissue, Cell and Gene Therapy Products, 3rd revision May 2015 IrFDA.
- Regulation on Recombinant Proteins and Monoclonal Antibodies

Regulation on Registration and Importation of Biological medicinal products, Aug 2015,

(REG-DPNA-BIO-001)

Regulation on Registration and Importation of Biological medicinal products, Aug 2015 (REG-DPNA-BIO-001)

- General Chapters
- Annexes

  Annex1: Tissue, Cell and Gene Therapy Products

  Annex2: Recombinant Proteins and Monoclonal Antibodies

- Dossier Assessment- Assessment Reports -Quality part of the dossier reviewed

  ICH, EMA, USFDA, WHO, WHOTRS(for Vaccine)

  - Accelerated procedure- Time table 60 days

    Justification for: the medicinal product is expected to be of major public health interest or needs
  - Normal procedure- Time table one year

- Adoption of GMP Inspection Request –**PIC/S GMP**
- Competent laboratory Testing
- Clinical Trials
- CTD

Three major concerns:

1. Safety of the products (Minimizing the ADR and ADE, Prevention of the spreading of the communicable diseases by donor selection and testing, Clinical trials)

2. Efficacy of the Products (Proof of Concept, Clinical trials)

3. Quality of the products (Production, Quality controls, Implementing GMP)

Risk-based Approach Regulation

- characterization and evaluation of quality attributes of the product and, followed by nonclinical and clinical studies
- Stepwise comparability exercises
  - Manufacturing Process
  - Characterizations
  - Specifications
  - Analytical Techniques
  - Stability

  Nonclinical evaluation

  Clinical evaluation

TB : Tissue Bank

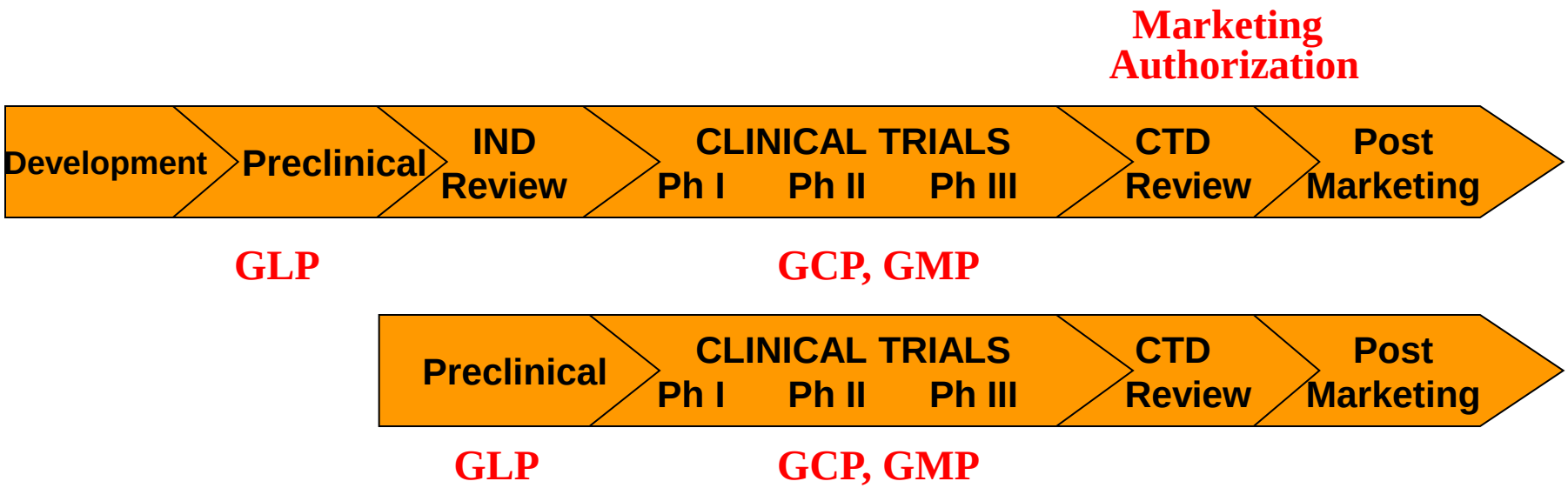
SB : Skin Bank

: Eye bank

CBB : Cord Blood Bank

ARC : Assisted Reproduction Center

- Clinical trials study is one of the registration steps and has been done according to international guidelines and standard protocols by respective committee.



- For minimally manipulated products it is not necessary to apply clinical trial based on current regulations.

- Review of protocols and clinical trials data is duty of clinical trial expert committee.

Our Responsibility

- Accreditation, designation, authorization/licensing of Biological Manufactures, Tissue and Cell Establishments
- Marketing authorization for the biologicals like vaccines, plasma derivatives, recombinants and tissue and cell-based products.
- Supervision of tissue and cell procurement, ***in Living Donor***, and testing
- Inspections and control measures to ensure compliance
- Vigilance and Surveillance of the products and activities

MAINTAINING THE PUBLIC HEALTH

IRIFDO
سازمان غذا و دارو

MANY THANKS TO YOUR ATTENTION