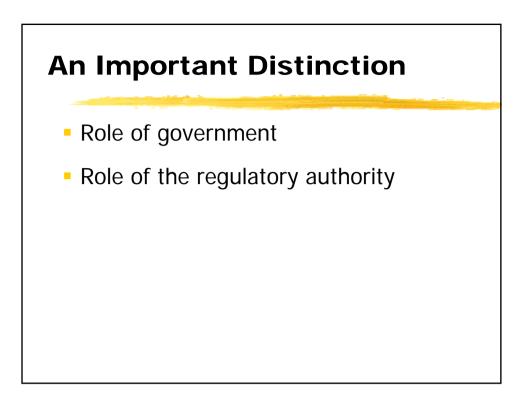


## ICH GCP: The Role of the Regulator

- ICH GCP does not contain a separate chapter on the roles and responsibilities of the regulator or regulatory authority
  - But does mention "applicable regulatory requirements" and "regulatory authority" in Definitions, in Principles, and in sections on the IRB/IEC, the Investigator, the Sponsor, and the Essential Documents

# International GCP: The Role of the Regulator

- The WHO (World Health Organization) "Guidelines for GCP" (1995) and Handbook for Implementation (2005) does include separate sections on the role of the Drug Regulatory Authority
- And the PAHO (Pan American Health Organization) "GCP Document of the Americas" includes a chapter on "GCP Compliance Monitoring by Regulatory Authorities" and an Annex: "Guide to Clinical Investigator Inspections"



#### **Role of Government in Clinical Studies**

- Establish a legal framework for GCP
  - Protect rights and safety of subjects (including requirements for informed consent and IEC review)
  - Ensure quality of studies/data, quality of regulatory decisions, and implementation of quality systems
  - Sanctions/penalties for violators
- Licensure of medical professionals
  - Qualifications of clinical investigators/staff
- Provide mandates to the regulatory authority

### Role of Regulatory Authority in Clinical Studies -1-

 Must act according to laws to implement and enforce the laws

#### Role of Regulatory Authority in Clinical Studies -2-

- In general, the regulatory authority bears responsibility for:
  - Allowing a protocol to proceed
  - Ensuring the quality of the investigational product
  - Ensuring subject rights and safety during a study
  - Assuring and using quality study data for regulatory decision-making

#### **Role of Regulatory Authority** in Clinical Studies –3-

- Inspecting the parties who conduct or oversee the study
- Receiving and acting on complaints about a clinical study
- Educating the parties who conduct or oversee the study

#### Allowing a Protocol to Proceed

- Should ensure that both scientific and ethical review have been performed
  - Regulatory Authority's Review
    - May include inspection of non-clinical (animal toxicology) studies/facilities supporting the protocol
  - Independent Review(s)
    - Expert review(s); Ethics Committee review
- Should include authority for the regulator to NOT allow the protocol to proceed or to require modification of the protocol before proceeding

#### Ensuring the Quality of the Investigational Product

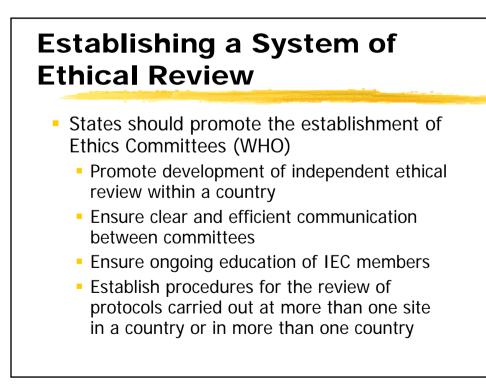
- In accordance with national/local laws and regulations, regulators may
  - Establish Good Manufacturing Practice (GMP) requirements for investigational products
  - Review manufacturing data submitted in support of research permits
  - Inspect manufacturing facilities
  - Establish requirements for the import of investigational products

#### Ensuring Subject Rights and Safety during the Study

- Should include the regulator's receipt and review of safety information (especially serious and unanticipated adverse experiences) during the study
- Should include knowledge by the regulator of safety concerns with the investigational product in other studies of the product
- May include the regulator's requesting or requiring independent data and safety monitoring boards (DSMBs) for the study

#### Ensuring Subject Rights and Safety during the Study

- Should include assurance to the regulator that informed consent and ethical (IEC) review is conducted prior to initiating the study and continued during the study
- Regulatory authorities also need to be alert to the issue of subject confidentiality and any applicable national/local laws and regulations for handling private medical information
- Regulators should have the authority to stop a study if they find that subjects are or will be exposed to an unreasonable risk

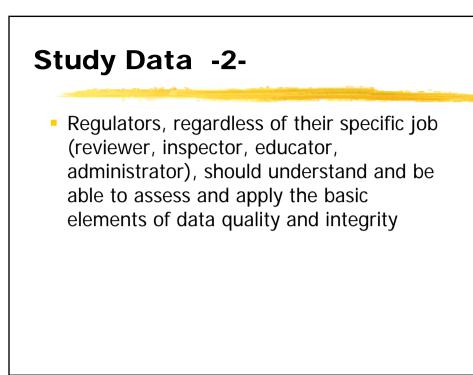


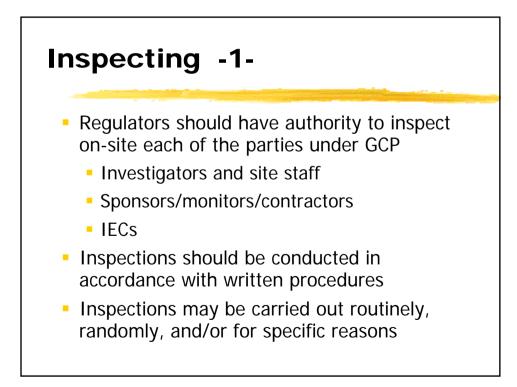
#### IEC: Regional Organizations

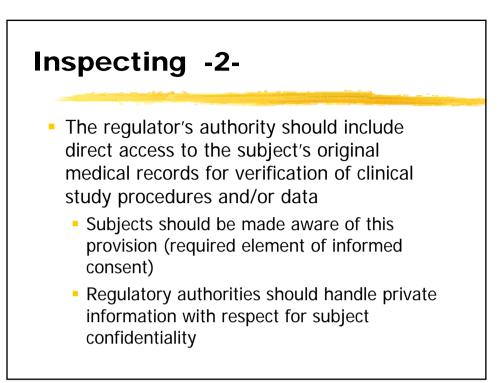
- Regional organizations or forums can encourage the exchange of information among IECs and assist in the development of high quality ethics committees
  - FERCAP (Forum of Ethics Review Committees of Asia-Pacific): Asia-Pacific forum initiated by WHO-TDR



- Regulators must be able to rely on the study data in making regulatory decisions
  - Allowing other studies of that investigational product to proceed
  - Approving the product for marketing
  - Labeling of the product

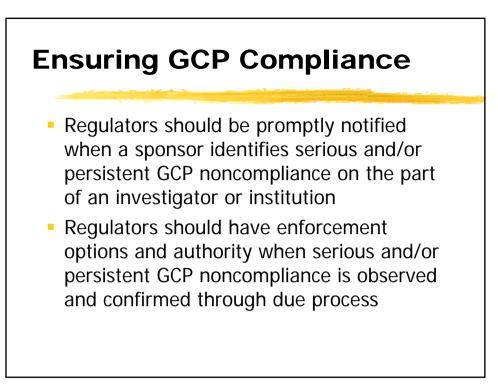


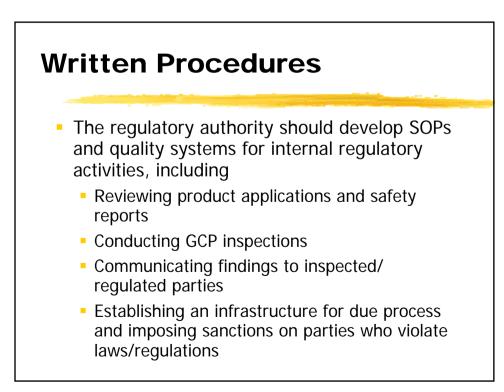




#### **Receiving and Acting On Complaints**

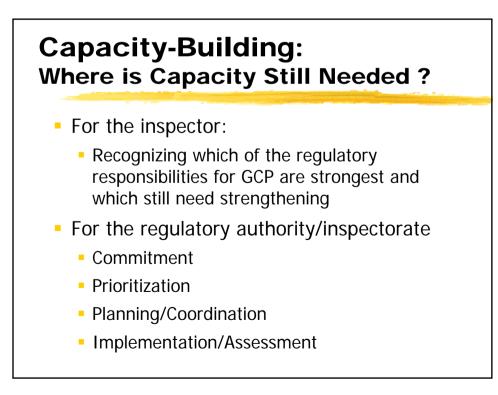
- Subjects and others involved in clinical studies should be able to report complaints (concerning subject safety, subject rights, data quality/integrity, or other aspects of study conduct) to the regulatory authority
- The regulatory authority should implement procedures to receive, review, evaluate, and as appropriate, follow-up (e.g., by inspection) on any such complaints





#### Regulatory Authority: Educational Role

- Regulators have a role in educating those parties that conduct or oversee regulated clinical studies
  - What is expected/required under national and local laws/regulations
  - Internationally recognized standards (GCP)
- Regulatory review and inspection should serve an educational as well as a compliance/enforcement function





The information within this presentation is based on the presenter's expertise and experience, and represents the views of the presenter for the purposes of a training workshop.

