Statens legemiddelverk
Norwegian Medicines Agency

# Good clinical practice
# a tool to refine fish research
## - an assessors view

**Hanne Bergendahl**
**Senior adviser, DVM**
**Norwegian Medicines Agency**

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# Good clinical practice

- **Directive 2001/82/EC on the Community code relating to veterinary medicinal products**

- **Application for a marketing authorisation (MA)**
  - Administrative data
  - Quality
  - Safety
  - Efficacy

- http://www.emea.eu.int/index/indexv1.htm

# Good clinical practice

- **”Small” markets for veterinary medicinal products**
- **VICH: The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products**
- **Authorities’ and industry’s cooperation**
  - EU, US, Japan, (Canada, Australia and New Zealand)
  - VICH Guidelines replace EU-guidelines
  - Harmonisation of technical requirements.
  - Trials to document medicinal products performed in such a way that they will be accepted in EU/USA/Japan

# Good clinical practice

- **Good manufacturing practice (GMP) - Quality**
- **Good laboratory practice (GLP) – Safety**

- **Good Clinical Practice (GCP) – Efficacy**
  - ALL CLINICAL FIELD TRIALS SHOULD BE CARRIED OUT ACCORDING TO GCP

# Good clinical practice

- **All clinical field trials should be carried out according to GCP**
- **GCP- VICH GUIDELINE 9 (step 7 Consensus Guideline)**
- **Objective of the GCP-guideline**
  - International ethical and scientific quality standard for clinical studies evaluating veterinary products

# Good clinical practice

- http://www.emea.eu.int/index/indexv1.htm

  **Or**

- http://vich.eudra.org/

# Good clinical practice

- **Guidance on the design and conduct of all clinical studies of veterinary products in the target species**
- **Ensure accuracy, integrity and correctness of data**
- **Public assurance about the integrity of the study data, due regard to animal welfare, protection of personnel, the environment and human and animal food chain**
- **Deviations from the Guideline to be justified**

# Good clinical practice

- **Contents of the GCP-guideline**
  - Glossary
  - The principles of VICH GCP
  - The Investigator
  - The Sponsor
  - The Monitor
  - The Study Protocol
  - The Final Study Report
  - Study Documentation

# Good clinical practice

- **Some key factors for GCP**
  - SOPs
  - Personnel - qualified and trained
  - Protocol – Review, Compliance
  - Selection of study animals
  - Informed consent
  - Record forms – accurate and clear case
  - Quality control checks
  - Accurate report
  - Reporting of adverse events

# Good clinical practice

- **Pre established written procedures (SOPs)**
  - To facilitate consistency in the performance of a specific function
  - A way of reducing/controlling the systematic errors
  - Avoid unnecessary repetition of definitive studies
  - A systematic framework of the study
  - Facilitate reviews of the study

# Good clinical practice

- **Personnel**
  - Qualified and trained for their task
  - Each individual involved is important
    - **Sponsor**
    - **Monitor**
    - **Investigator**
    - **Others – staff, animal owner, laboratory personnell etc**
  - Interactions between the various individuals involved to be recorded
  - Confidentiality
  - Discipline
  - Precision

# Good clinical practice

- **Protocols**
  - Design
  - Execution
  - Evaluation
- **Review**
- **Compliance**
- **Report**

# Good clinical practice

- **Design**
  - Guideline on statistical principles for veterinary clinical trials EMEA/CVMP/816/00 - Final

# Good clinical practice

- **Protocols**
  - Design
  - Execution
  - Evaluation
- **Review**
- **Compliance**
- **Final report**
  - Accurate
  - Comprehensive – complete description of objectives, methods, experimental materials, study results
  - Critical evaluation of results

# Good clinical practice

- **Selection of study animals**
- **Informed consent from owners**

- **Quality control checks and internal audits**

- **Reporting of adverse events**

# Good clinical practice

- **Some of NOMA's experiences in the Vet field**
  - Lack of laboratory and/or semi-field trials
  - Protocols - Lack of information
  - Discrepancies between protocols and reports
  - Statistics : does not take advantage of the "luxury" of having large populations
  - Too many variables – difficult interpretation of the results
  - Sampling : Large trials – sampling inadequate
  - Design - not suitable for the purpose
  - Time restraints – miss useful information
  - Lack of follow-up of outstanding questions

# Good clinical practice

- **Authorities open for a dialogue**
  - Planning of trials
  - Interpretation of Guidelines