Good Manufacturing Practise

- **Documentation**

- 3 point course in Master education in Nuclide Technique
- Uppsala University Spring term 2007

Apoteket

Hospital pharmacy, Uppsala University Hospital

Uppsala University

- GMP
- =
- Great Mountains of Paper

Good Manufacturing Practise

- In Good we trust…
- all other need documentation

- Läkemedelsinspektörens bön

Documentation in GMP

- Steering documents
- Accounting documents

Document hierarchy

- Policies — Aims
- Procedures — What to do,why,
  - Site Master File — how and where
- Instructions
  - Standard operating procedures
- Operation manuals, monographs (SPC)
- — How to perform
- Batch records — Tracing document
- Quality records — Release document

Site Master File

- From Pharmaceutical Inspection Convention, PIC
- Prepared by the manufacturer
- ”Specific and factual GMP information”
- Succint, not exceeding 25 A4 pages
- Individually numbered pages
- Use plans, drawings or schemes

Documentation

- **Header**

  - **Company** **Name of document**
  - **Page no(out of)**
  - **Valid from 20040506** **Substitutes**
  - **Issued by** **Store (no of documents)**
  - **Approved by**
  - **Settled by**

Site Master File

- Organisation
- Objectives, procedures, capacity
- Personell (education, hygiene)
- Building and equipment
- Documentation
- Product specifications
- Quality control
- Contract laboratories
- Internal inspections

Site Master File

- Chapter 1
- Aims and objectives
- Organisation
- Responsibity
- Production and capacity
- Quality management
- Address and telephone

Site Master File

- Chapter 2:
- *Personnell*
  - *Organisation chart*
  - *Qualification, Experience,*
  - *Responsibility*
  - *In house education and training-card*
  - *Hygiene, infection*

Site Master File

- Premises and equipment
  - Production site (site plan)
  - Ventilation system
  - Water supply system
  - Equipment for drug preparation
  - Qualification, validation, calibration
  - Maintenance, service and control
  - Cleaning of production site

Site Master File

- Production
  - General description
  - Raw material, control
  - Start controls
  - Process controls
  - Quality controls
  - (Storage…..

Site Master File

- Documentation
  - Orderform
  - Master document (Monograph)
  - Batch record and Quality Control
  - ”Delivery protocol”
  - ….

Site Master File

- Quality control and inspection
  - Release of preparatiion
  - Labelling of container
  - Incidents
  - Self inspection
  - External contractors
  - Change of documents
  - Historical revisions

Documentation in GMP

- **The job is not finished until the paperwork is done**

Monograph

- *General headings*
- Name of product(all),manufacturer,address
- Composition (formula, solvent, container)
- Method of preparation (process, validation)
- Control of starting materials (analysis etc)
- Other ingridients (description, impurities
- Quality control (identity,purity, res.solvent)
- Stability and stability limits
- Masters (chromatogram, sterility, solvent)

Batch protocol

- Chemicals
  - manufacturer, quality
  - batchnumber, signature
- Equipment
  - manufacturer, identification number,
- Procedure
  - Each step documented and signed
- Quality control
  - pH, identity, purity, sterility tests, signed
- Approval

Standard Operating Procedures

- *Header*
- Aims
- Responsible person
- People concerned
- General information
- Legitimity
- Normal routine procedures