RESPONSIBILITIES AND FUNCTIONS OF PHARMACEUTICAL DEVELOPMENT SECTION

PHARMACY DEPARTMENT

INPATIENT PHARMACY SECTION

PHARMACEUTICAL PROCUREMENT AND CONTROL SECTION

PHARMACEUTICAL DEVELOPMENT SECTION

Chief – George Grimes

Product Development Unit – George Grimes ggrimes@nih.gov 301-496-1031

Registration, inventory control, and record keeping of all investigational drugs used in the Clinical Center. Josette Blocker Joyce Downing
Scott Hotaling Tramaine Davis

Assist Investigators with filing of INDs with FDA.

Randomization, record keeping and packaging of blinded studies.
Judith Starling jstarling@nih.gov

Formulation of drug dosage forms not available from a sponsor.
Ram Agarwal Haksong Jin Shin Lee
Svetlana Frid Mike Kolf

Provide investigational drug information to Physicians, Nurses and Pharmacists.
Hope DeCederfelt

Analytical and Quality Control Unit – Gopal Potti, Ph.D. 301-496-2252

Drug analysis, quality control and stability studies for formulation section and the department.
Grace Lee Deborah Sperling Peng Yuan Jordan Petit

Development of analytical methods for new drugs.

Incompatibility studies of drug admixtures.

Applied research on drug stability, chemical kinetics and mechanism of drug degradation.

Clinical Pharmacokinetic Research Laboratory – Scott Penzak, Pharm.D. 301-496-2997

Analytical services for investigational drug level determinations in biological fluids.

Interpretation of drug levels in adjustment of dosage regimen in the clinical situation.
Bioavailability studies.
Raul Alfaro Christine Yuan-Yi Hon

Applied pharmacokinetic clinical research studies to resolve therapeutic drug monitoring problems.

The NIH Clinical Center

Robert DeChristoforo, MS, FASHP

April 27, 2012

Pharmaceutical Development Section

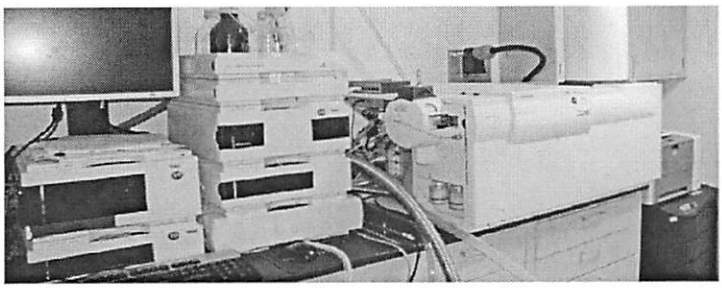
Pharmacy Department

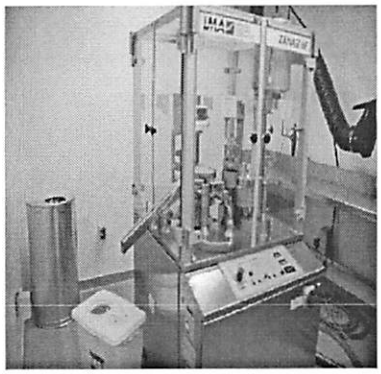
George Grimes, RPh, BS Pharm, Chief

In existence since 1956 - - - - New Facility 2010

Pharmaceutical Development Section

- Product Development
- Analytical and Quality Control
- Pharmacokinetics



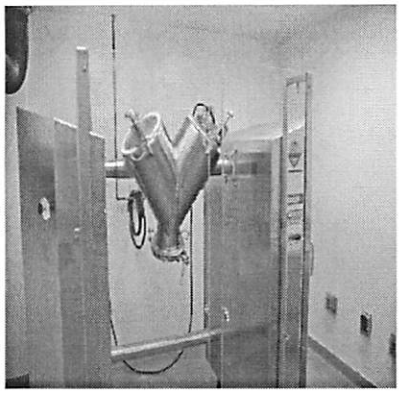


Pharmaceutical Development Section Functions

- Responsible for ~1100 investigational drugs currently studied at the CC including multiple strengths, placebos, and sponsor-supplied drugs. Approximately 350 manufactured on-site
- Formulates tablets, capsules, sterile parenterals and topical products, including placebos not available from sponsor
- Ensures that raw materials used and finished products are suitable for human use
- Maintain a GMP physical plant for the handling, packaging, labeling and manufacturing of dosage forms
- Maintains accountability records for sponsor and FDA review
- Assists in filing INDs

Manufacturing Capability

(8 hour day)



- 75,000 capsules
- 150,000 tablets
- 220 liters
- 5,000 syringes
- 8,000 vials (includes vaccines and biologics)