

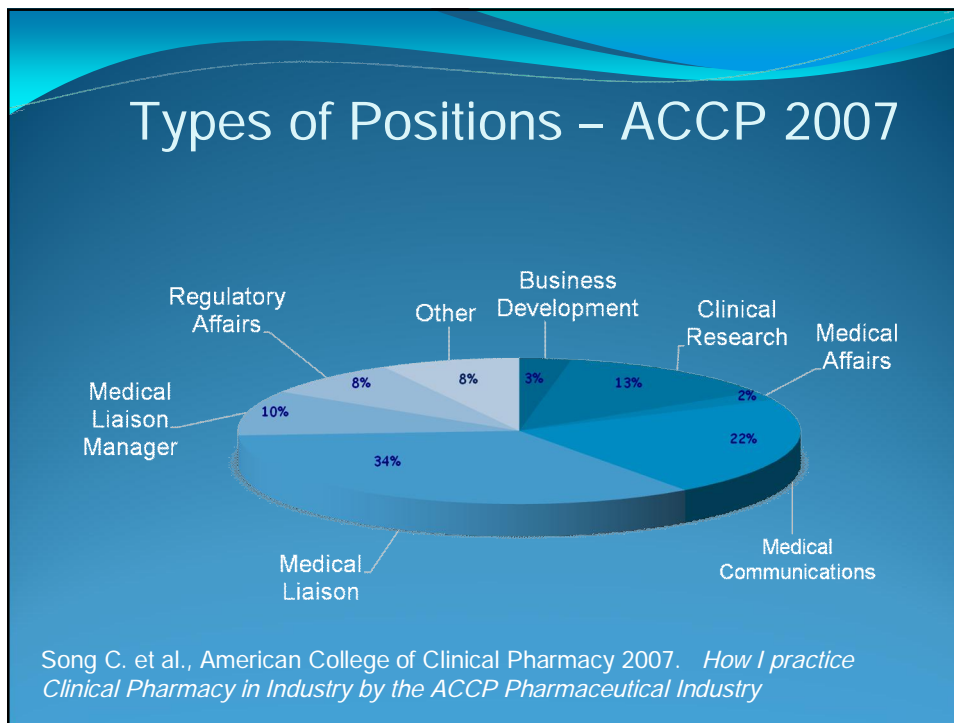
Roles of Pharmacists in Pharmaceutical Industry

Clinical Research

Minh Vo
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Objectives

- What do pharmacists do in industry?
- What do pharmacists do in clinical research?
- How is pharmacy background used in new drug development?



Functions

Research & Development <ul style="list-style-type: none">• Development strategy• Clinical studies• CTD	Regulatory <ul style="list-style-type: none">• Regulatory strategy• Regulatory submission• CTD
Medical Communications and Science Liaison <ul style="list-style-type: none">• Product specialist (medical community)• Communication with thought leaders• Product training• Field based (medical liaison)	



Clinical Pharmacology

- First in man
- Rising dose tolerability
- ^{14}C radiolabeled metabolic
- Linearity and proportionality
- Drug interactions

Clinical Pharmacology (cont.)

- Age/gender
- Race
- Hepatic/renal impairment
- Food effect
- Bioavailability/bioequivalence

Clinical Pharmacology (cont.)

- QTc prolongation
- Pharmacodynamics
- Pharmacokinetics/Pharmacodynamics

Clinical Pharmacology (cont.)

- Population pharmacokinetics
- Population pharmacodynamics
- Population pharmacokinetics/pharmacodynamics
- Exposure-response

Therapeutics

- Disease specific
- Efficacy
- Safety
- Dose finding and selection

Clinical Study

Clinical Study Protocol

Ethics Approval

Data Analysis

Investigator Training

Report Preparation

Screening Review

Result Interpretation

Study Monitoring

Product Labeling

Pharmacy Background and Clinical Research

- Knowledge in pharmaceutics and pharmaceutical chemistry
- Knowledge in pharmacology and toxicology
- Knowledge in patients and disease

Apply pharmaceutical knowledge to human health

Example – Clinical Pharmacology

- Atrial fibrillation (congestive heart failure)
- Congestive heart failure and pharmacokinetics
- QTc intervals (PK/PD modeling)
- Beta blocker drug interactions

