**BBS 3202 DRUG DEVELOPMENT, REGISTRATION, MARKETING AND REGULATORY ISSUES**

**Course description**

This course covers Drug development, Drug registration, Marketing and regulatory issues.

 The course involves tutorials, lectures and seminars.

**Course Objectives**

To describe the process of Drug discovery involving identification of New Chemical Entity(NCE) also known as New Molecular Entities(NMEs) and assessing their safety, [toxicity](http://en.wikipedia.org/wiki/Toxicity), [pharmacokinetics](http://en.wikipedia.org/wiki/Pharmacokinetics) and [metabolism](http://en.wikipedia.org/wiki/Metabolism) prior to human clinical trials.

 To understand the many aspects of drug development focused on satisfying the [regulatory requirements](http://en.wikipedia.org/wiki/Regulatory_requirement) of drug licensing authorities. These generally constitute a number of tests designed to determine the major toxicities of a novel compound prior to first use in man.

To discuss the principals of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and appreciate its role as a project that brings together the regulatory authorities to discuss scientific and technical aspects of pharmaceutical product registration.

To outline the various steps taken in Marketing of a pharmaceutical product,

**Course outline:**

Drug discovery as the process by which drugs are discovered and/or designed.

Controlling disease and infection at the molecular and physiological level and to target specific entities based on this knowledge.

Description of drug discovery process involves the identification of candidates, synthesis, characterization, screening, and assays for therapeutic

Drug targets, screening and design. [Clinical](http://en.wikipedia.org/wiki/Clinical_trial) Trials.

**Course coordinator:**

Prof. Jasper Ogwal-Okeng

**Requirements**

60 contact hours equivalent to 4 CU

**Mode of assessment**

Progressive assessment 40%

End of Semester exam 60%.

**Reading materials**

1. [Goodman and Gilman's pharmacological basis of therapeutics: /](http://81.199.17.5:8000/cgi-bin/gw_42_20a/chameleon?host=81.199.17.5%2b1111%2bDEFAULT&search=SCAN&function=INITREQ&SourceScreen=INITREQ&sessionid=2006101809571219106&skin=default&conf=.%2fchameleon.conf&lng=en&itemu1=4&u1=4&t1=Goodman%20and%20Gilman%27s%20%20pharmacological%20basis%20of%20therapeutics%3a%20%20%2f&pos=1&prevpos=1&beginsrch=1)[New York : MacGraw-Hill , 1996](http://81.199.17.5:8000/cgi-bin/gw_42_20a/chameleon?host=81.199.17.5%2b1111%2bDEFAULT&search=SCAN&function=INITREQ&SourceScreen=INITREQ&sessionid=2006101809571219106&skin=default&conf=.%2fchameleon.conf&lng=en&itemu1=2009&u1=2009&t1=New%20York%20%3a%20MacGraw-Hill%20,%201996&pos=1&prevpos=1&beginsrch=1)

2. Basic and clinical pharmacology/[New York : MacGraw-Hill , 2002](http://81.199.17.5:8000/cgi-bin/gw_42_20a/chameleon?host=81.199.17.5%2b1111%2bDEFAULT&search=SCAN&function=INITREQ&SourceScreen=INITREQ&sessionid=2006101809571219106&skin=default&conf=.%2fchameleon.conf&lng=en&itemu1=2009&u1=2009&t1=New%20York%20%3a%20MacGraw-Hill%20,%201996&pos=1&prevpos=1&beginsrch=1)

3. Pharmacology/Churchill and livingstone, 2002

4. Clinical pharmacology/ Curchill and livingstone, 2002