BIOETHICS AND CLINICAL TRIALS

Module designation	*Bioethics and Clinical Trials*
Semester(s) in which the module is taught	*2*
Person responsible for the module	1. Chrismawan Ardianto, S. Farm., Apt., M.Sc., Ph.D.**(Course Coordinator)** 2. Prof. Dr. Bambang Prajogo E.W., MS., Apt. 3. Dr. Aty Widyawaruyanti, M.Si., Apt.
Language	*Bahasa Indonesia*
Relation to curriculum	*~~Compulsory /~~ elective / ~~specialisation~~*
Teaching methods	*lecture, discussion, assignment*
Workload (incl. contact hours, self-study hours)	*(Estimated) Total workload:* *Contact hours (structured activities.): 90,67 hours* *Private study including independent learning activites*: *90,67 hours*
Credit points	*2 SCU / 6 ECTS*
Required and recommended prerequisites for joining the module	*NA*
Module objectives/intended learning outcomes	Students are: LO1: Able to realize excellence based on religious morals (excellence with morality), able to work together, and show a responsible attitude to work in their field of expertise independently LO2: Able to internalize the spirit of independence, struggle, and entrepreneurship LO5: Able to access and review information through an Information and Communication Technology (ICT) system, decide on a specific subject of study, maintain the feasibility of implementing research designs, conduct research, analyze data, conclude research results comprehensively, and create strategic issues based on the study that reflect the latest updates in the field of pharmaceutical sciences, and communicate them in the media and scientific forums at the national and international level through an interdisciplinary or multidisciplinary approach in the form of a thesis or other equivalent forms. LO6: Able to make decisions in the context of solving problems related to science and technology development based on analytical or experimental studies through collaboration with colleagues, colleagues in institutions and research communities at both national and international levels and utilizing research results for the benefit of the user and other communities. LO11: Able to develop systems for evaluating the bioavailability of drugs in the body, pharmaceutical products circulation permits, and their in-vitro and in-vivo evaluations with specific delivery systems with appropriate analytical methods. LO15: Able to plan and organize concepts and procedures for quality assurance and recommendations on pharmaceutical products, which include drugs, cosmetics, foods, and beverages as products and therapeutic goods

Content	This course will learn about applied chemical analysis methods, such as: a. spectroscopic instruments (UV-Vis, NMR, MS) b. chromatographic instruments (TLC, CC, HPLC, GC) c. in particular (ICT): d. HPLC and TLC-Scanner (densitometry) methods and instruments e. NMR and LCMS methods and instruments for: 1. detection, analysis of the presence of compounds (analytes) in the matrix of materials and products 2. Identification, comparative analysis with standard compounds and/or standard data 3. Standardization, analysis of compound content profiles and determination of levels of analytical markers or levels of active components on natural ingredients as raw materials for medicinal plants) and their products (herbal drugs), specifically those relevant to thesis research on natural ingredients from plants (substances containing polyphenol flavonoids, alkaloids) terpenoids.
Exams and assessment formats	*Mid term exam and final exam*
Study and examination requirements	*the final grade in the module is composed of 45% mid term exam, 45% final exam , 10% in-class participation and soft-skills assessment. Students must have a final grade of 70% or higher to pass*
Reading list	1. Have HT, Neves MDCP, Dictionary of Global Bioethics, 2nd edition, Springer Nature Switzerland AG, 2021 2. Chadwick RF, Schüklenk U This Is Bioethics: An Introduction, 1st edition, John Wiley & Sons, Inc. NJ, USA, 2021 3. BPOM, Pedoman Cara Uji Klinik Yang Baik, edisi 3, 2016 4. International Conference on Harmonization Good Clinical Practice (ICH GCP-E6-R2) Integrated addedum, 2016 *5.* Vela JM., Maldonado R, Hamon M., In Vivo Models For Drug Discovery, Wiley VCH Press, 2014