

LIBYAN INTERNATIONAL MEDICAL UNIVERSITY

Form Name : Block Catalogue

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Basic information:

Program on which the Block is offered	PharmD
Qualification Awarded	Bachelor of PharmD (BPharmD)
Block title - Code - Year	Professional Development– 3501– Fifth Year
Block Type	Professional Stage II
Total contact Hours / week [47 hrs.]	(Lectures: 6, Tutorials: 1, RBL: 4, Group Discussion: 3, Group Presentation: 1, Self-study: 31.5, Exams: 0.5)
ECTS Hours	20
Pre-requisites for this Block	Drug Chain Management, Pharmaceutical Calculation, Hospital Pharmacy, Health system, Nutrition, Health Care Economics, Medical Ethics and Professionalism and Communication Skills.
Week period	10

Block Description:

This block introduces students to pharmacy operations management, pharmacy financial resources oversight, personnel management and Basic and applied economic theory and principles, pharmacoeconomic analysis of the cost of drug therapy to health care systems and society, and application of pharmacoeconomic research principles in the determination of alternatives producing the best health outcomes for invested resources. This block also covers human resources, medication-use process management, developing and marketing of services, innovative services provision and related issues in professional pharmacy practice. Problem-based learning strategies are utilized in this block to assist in combining clinical expertise, patient characteristics and medical evidence for decision-making.

Block Objectives:

By the end of this Block the student should be able to:

- Provide proper health care services to patients.
- Demonstrate comprehensive knowledge, clear understanding and essential skills in Pharmaceutical, social and management sciences.
- Attain multi-disciplinary professional skills required for pursuing their careers.
- Be critical thinkers and decision and policy makers.
- Be a self- and life-long learner.
- Communicate effectively with patients and caregivers.
- Function as key members with interprofessional teams working to optimize patient health outcomes.
- Demonstrate ethical behaviors and adhere to professional rules and legal requirements.

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Learning and Teaching Methods, & Assessment Methods

Learning and Teaching Methods:

- Research-Based Learning (RBL)
- Lectures
- Tutorials
- Self-learning

Assessment methods:

- **Continuous assessment:**
 - Assignments
 - Group Presentation
 - Group Discussion
 - Mini-review
 - Open-book/open-web exam
 - Assessments (MCQs, problem solving, short notes)
- **Final-Block exam:**
 - Theoretical

Weighting of Assessment:

Continuous assessment:	70%
• Research-Based Learning	Weeks 3, 6, 8 & 10
• Weekly Exams	Weeks 1,2,4,5,7 & 9
• 2 Assessments	Weeks 4 & 7
• Other Activities (Assignments, Group Discussion & Group Presentation)	Weeks 1-10
• Attendance	Week 1-10
Final Exam:	30%
• Theoretical	At the end of the Block
Total:	100%

Assessment Schedule:

Continuous assessment:	During the block
• Research-Based Learning	20%
• Weekly Exams	6%
• Assessment 1	8%
• Assessment 2	6%
• Other Activities (Assignments, Group Discussion & Group Presentation)	20%
Final exam:	At the end of the year
• Theoretical	30%

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Examination Regulations:

- If the student absenteeism is more than 25 % he/she cannot attempt the final exam.
- The total required percentage to pass this course is at least 60 %

List of textbooks and references:

• Course Notes:

- PowerPoint presentations, videos and other materials related to lectures, tutorials and practical sessions are uploaded to the Moodle by experts on weekly basis according to teaching schedule.

• Essential Books(Text Books):

- Kieso, D. W., & Weygandt, J. J. (2015). Study guide [to accompany] Accounting principles [by Jerry J. Weygandt, Donald E. Kieso, Paul D. Kimmel], 12th edition. Hoboken, NJ: John Wiley & Sons.
- Needles, B. E., Powers, M., & Crosson, S. V. (2011). Principles of Accounting (11th ed.). South-Western College West.
- Carpenter, M.A., Bauer, T., Erdogan, B. and Short, J., 2010. Principles of management. flatworld Knowledge.
- New drug approval process : accelerating global registrations / edited by Richard A. Guarino, MARCEL DEKKER, INC. NEW YORK. ISBN 0-203-02162-2 Master e-book ISBN
- Jhon Forbat, 2007, Entrepreneurship: The Seeds of Success, Harriman House LTD, 3 A Pens Road Petersfield Hampshire GU32 3 EW, UK
- Philip Kotler, (1980), Marketing Management: Analysis, Planning & Control, 4th Edition, Prentice Hall, Inc., Englewood Cliffs, New Jersey.
- Rascati, K., 2013. Essentials of pharmacoeconomics. Lippincott Williams & Wilkins.
- An Introduction to Pharmacovigilance by Patrick Waller (2010)
- USA Legal and Regulatory System (Chapter 1). Legal Handbook for Pharmacy Technicians.
- Saudi Arabia Pharmaceutical Country Profile. Published by Saudi Food and Drug Authority in Collaboration with the World Health Organization. (2012).
- Model Standards of Practice for Canadian Pharmacists. Published by the National Association of Pharmacy Regulatory Authorities. (2009).
- Egypt Pharmaceutical Country Profile. Published by the Ministry of Health Egypt in Collaboration with the World Health Organization. (2011).
- Health Insurance Portability and Accountability Act (HIPAA). (2019).

• Recommended Books:

- Horngren, C., Datar, S. and Rajan, M., 2012. Cost Accounting. 14th ed. New York: Pearson Prentice Hall.
- Jiambalvo, J., 2018. Managerial Accounting. 6th ed. USA: Wiley.
- Hall, P., 2004. Principles of management.

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- **Periodicals and websites:**

– Riley, J., 2020. Accounting Concepts and Conventions | Business | Tutor2u. [online] tutor2u. Available at: <https://www.tutor2u.net/business/reference/accounting-concepts-and-conventions>

– Statement, P., 2020. Purpose of Income Statement | Key Concept | Purpose and Example. [online] EDUCBA. Available at: <https://www.educba.com/purposeof-income-statement/>

– Investopedia. 2020. What Smart Business Owners Should Know About CAPEX And OPEX. [online] Available at: <https://www.investopedia.com/ask/answers/112814/whats-differencebetween-capital-expenditures-capex-and-operational-expenditures-opex.asp>

– Thangavelu, P., 2020. Why Cash Management Is Key to Business Success. [online] Investopedia. Available at: <https://www.investopedia.com/articles/investing/041515/why-cash-management-key-business-success.asp>

– Beyond the Numbers. 2020. 8 Ways Poor Cash Flow Is Affecting Your Business - [online] Available at: <https://www.beyondthenumbers.com.au/costsofpoorcashflow/>

– Karmakar, R., 2020. Standard Costing: Meaning, Objectives, Advantages and Disadvantages. [online] Your Article Library. Available at: <https://www.yourarticlelibrary.com/accounting/standard-costing/standardcosting-meaning-objectives-advantages-and-disadvantages/66374>

– <https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory>

– <https://www.fda.gov/drugs/development-approval-process-drugs#FDA>

– <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review>

– <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

– <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-submit-emergency-use-authorization>

– <https://www.fda.gov/patients/learn-about-drug-and-device-approvals>

– <https://www.fda.gov/about-fda/transparency/fda-basics>

– https://www.who.int/medicines/technical_briefing/tbs/Drug_Regulation_History_Present_Future.pdf

– <https://www.nationalgeographic.com/history/magazine/2016/11-12/muslim-medicine-scientific-discovery-islam/>

– <https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process> <https://www.fda.gov/industry/fda-basics-industry/registration-and-listing>

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- <http://www.compoundchem.com/>
- Richard Jan Pech, An Entrepreneurial Decision Process Model Describing Opportunity Recognition, 2006, European Journal of innovation Management.
- Peter F. Drucker, 2006, Innovation and Entrepreneurship: Practice and Principles, 711 third avenue, New York, NY 10017, USA, PerfectBound, HarperCollins Publishers
- Donald F. Kuratko, 2016, Entrepreneurship: Theory, Process and Practice, Level 7, 80 Dorcas Street South Melbourne, Victoria Australia 3205, Cengage Learning Australia.
- Howard Frederick; Allan O'Connor; Donald F. Kuratko, 2016, Theory, Process and Practices of Entrepreneurship, Unit 48 Rosedale Office Park 331 Rosedale Road, Albany, North Shore 0632, NZ, Cengage Learning New Zealand.
- SIAPS. 2017. Applying Principles of Pharmacoeconomics to Improve Medical Product Selection and Use in Low- and Middle-income Countries: Trainer's Guide. Submitted by the Systems for Improved Access to Pharmaceuticals and Services Program to the US Agency for International Development.
- https://www.researchgate.net/publication/331311882_Pharmacoeconomics_Lecture_Note
- <https://bmcmidinformeddecisionmaking.biomedcentral.com/articles/10.1186/1472-6947-12-110>
- https://www.researchgate.net/publication/49668439_Is_There_a_Role_for_Pharmacoeconomics_in_Developing_Countries
- <https://www.who.int/news/item/27-02-2020-who-launch-e-eml>
- <http://archives.who.int/tbs/sel/s2296e.pdf>
- https://www.who.int/selection_medicines/list/en/
- <https://journals.seedmedicalpublishers.com/index.php/FE/article/view/638/735>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3341722/>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4080017/>
- <https://maphealth.ca/wp-content/uploads/CanadaEMLProcess.pdf>
- <https://pubmed.ncbi.nlm.nih.gov/8246705/>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3612711/>
- <http://www.med.mcgill.ca/epidemiology/courses/EPIB654/Summer2010/Modeling/Markov%20modles%20in%20med%20dec%20making.pdf>
- <https://pubmed.ncbi.nlm.nih.gov/8246705/>
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- https://www.researchgate.net/publication/312017691_What_is_the_budget_impact_of_a_new_treatment_or_new_health_technology_arriving_on_the_market/figures?lo=1&utm_source=google&utm_medium=organic
- <https://link.springer.com/article/10.1007/s10198-017-0933-3>

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- https://link.springer.com/chapter/10.1007/978-3-319-43742-2_24
- <https://www.csc2.ncsu.edu/conferences/nsmc/MAM2006/seneta.pdf>
- <https://kubicle.com/blog/how-to-construct-a-sensitivity-chart-in-excel/>
- <https://treeplan.com/wp-content/uploads/decision-trees-using-treeplan-206.pdf>
- WHO Policy Perspectives on Medicines: Pharmacovigilance: ensuring the safe use of medicines
- Talbot JC, Nilsson BS. Pharmacovigilance in the pharmaceutical industry. Br J Clin Pharmacol. 1998;45(5):427-43. doi:10.1046/j.1365-2125.1998.00713.x
- S Kumar, R Panwar, U Singh, Regulatory affairs in the pharmacy curriculum, Int J Research Develop Pharm Life Sci, 2013, Vol. 2, No.6, pp 690-698.
- <https://howtobecomeapharmacovigilanceexpert.wordpress.com/>
- <https://www.lawinsider.com/dictionary/regulatory-framework>
- Guidance for Industry & Investigators, Safety Reporting Requirements for INDs & BA/BE Studies, U.S. Department of Health & Human Services, Food & Drug Administration. Center for Drug Evaluation & Research (CDER), Center for Biologics Evaluation & Research (CBER), December 2012
- Sherman RB, Woodcock J, Norden J, Grandinetti C, & Temple R J. , New FDA Regulation to Improve Safety Reporting in Clinical Trials, N Engl J Med 365;1
- Management of Safety Information from Clinical Trials, Report of CIOMS Working Group VI, Geneva 2005
- <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.4>
- https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use_en-15.pdf
- <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.4>
- http://academy.gmp-compliance.org/guidemgr/files/vol9a_09-2008_en.pdf
- https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use_en-15.pdf
- <https://www.gov.uk/drug-safety-update/the-black-triangle-scheme-or>
- European Perspective on risk management & drug safety, Rain J., Wise L., Blackburn S., Eichler HG., Breckenridge A.,
- RISK MANAGEMENT, FDA Guidance for Industry,
- Risk Evaluation & Mitigation Strategy: Tipping the
- o Balance for FDA Approval, Brandon Burch, 2019
- <http://www.samedanltd.com/magazine/13/issue/162/article/3085>

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- Bihana K, Lebrun-Vignesa B, Funck-Brentanob C, Salem J, Uses of pharmacovigilance databases: An overview, Therapies (2020)
- Guideline on good pharmacovigilance practices (GVP), Module I – Pharmacovigilance systems & their quality systems, EMA, 2012
- Guidance for Industry, Good Pharmacovigilance Practices & Pharmacoepidemiologic Assessment, Food & Drug Administration, Center for Drug Evaluation & Research (CDER), Center for Biologics Evaluation & Research (CBER), 2005
- Guideline on good pharmacovigilance practices (GVP) Module II – Pharmacovigilance system master file (Rev 2)
- PROCEDURE FOR CONDUCTING PHARMACOVIGILANCE INSPECTIONS REQUESTED BY THE CVMP, EMA, 2009
- https://eur-lex.europa.eu/eli/reg_impl/2012/520/oj
- Callréus, T. Pharmacovigilance & Public Health Ethics. Pharm Med 27, 157–164 (2013). <https://doi.org/10.1007/s40290-013-0016-4>
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Block Policies:

Code of Ethics

Please refer to the below LIMU code of ethics

<http://limu.edu.ly/images/11/ethcode.pdf>

Code of Conduct

Please refer to the below PharmD program code of conduct

<http://repository.limu.edu.ly/handle/123456789/2135>

Academic integrity

Please be aware that cheating, plagiarism, in-class disruption and dishonesty are vigorously prosecuted and that LIMU has a zero-tolerance policy.