SEMESTER-IV

GANPAT UNIVERSITY									
FACULTY OF MANAGEMENT STUDIES									
Program	MBA		Branch/Spec.		MBA (Pharmaceuticals) Elective Subject				
Semester	IV				Version	1.0.0.0			
Effective from Academic Year		2025-26			Effective for the batch Admitted in		June 2025		
Subject code	**IVA03GRA**		Subject Name		**Global Regulatory Affairs and ICH Compliance**				
Teaching scheme					Examination scheme (Marks)				
(Per week)	Lecture(DT)		Practical(Lab.)		Total		CE	SEE	Total
	L	TU	P	TW					
Credit	2	0	0		2	Theory	100		100
Hours	2	0	0		30	Practical			

Objective:
To provide MBA students with a strategic understanding of the global regulatory landscape and ICH guidelines, enabling them to integrate regulatory considerations into key business decisions to accelerate market access and ensure sustained compliance.

Course Outcome:
CO 1: The students will be able to explain the strategic role of regulatory affairs and the fundamental principles of ICH in harmonizing global drug development.
CO 2: The students will be able to analyze the regulatory requirements and strategic pathways for clinical development leading to a harmonized marketing application.
CO 3: The students will be able to evaluate the regulatory processes for marketing authorization and the critical importance of post-approval lifecycle management and pharmacovigilance.
CO 4: The students will be able to formulate a high-level global regulatory strategy, considering risk management, the impact of emerging technologies, and the role of regulatory intelligence.

Theory syllabus

Unit	Content	Hrs
1	Foundations of Global Regulatory Affairs, The Role of Regulatory Affairs in Business Strategy, Major Global Regulatory Agencies: FDA, EMA, PMDA, The International Council for Harmonisation (ICH): Mission & Purpose, The Three Pillars of Drug Approval: Quality, Safety, Efficacy, Introduction to GxP: GMP, GCP, GLP (Conceptual), The Pharmaceutical Product Lifecycle: A Regulatory View.	6
2	Pre-Market Strategy and Clinical Development, The Investigational New Drug (IND/CTA) Application, Clinical Trial Phases (I, II, III): A Strategic Perspective, Good Clinical Practice (GCP) for Managers, Expedited Regulatory Pathways: Fast Track, Breakthrough, Orphan Drug Designation & Its Business Impact, The Common Technical Document (CTD/eCTD) Format, Health Authority Meetings & Interactions.	8
3	Marketing Authorization and Post-Approval Management, The Marketing Authorization Application (NDA/BLA/MAA), The Agency Review & Approval Process, Good Manufacturing Practice (GMP) & Facility Inspections, Pharmacovigilance & Post-Market Safety Surveillance, Strategic Product Labeling & Promotion Compliance, Post-Approval Changes & Lifecycle Management, Generics & Biosimilars:	8

	Abbreviated Pathways.	
4	Global Strategy, Compliance, and Future Trends, Formulating a Global Regulatory Strategy, ICH Guidelines in Practice (Q, S, E, M Categories - Overview), The Role of Regulatory in M&A Due Diligence, Managing Regulatory Risk: Recalls & Warning Letters, Impact of Emerging Tech: AI, SaMD, Real-World Evidence (RWE), The Future of Harmonization & Regulatory Convergence, Regulatory Intelligence as a Competitive Tool, The Regulatory Function as a Strategic Business Partner	8
Practical content		
Reference Books		
1.	Pisano, Gary P. Science Business: The Promise, the Reality, and the Future of Biotech. Harvard Business Press, 2006.	
2.	Weinberg, Sandy. The Pharmagellan Guide to Biotech Forecasting and Valuation. Routledge, 2020.	
3.	Evens, Ronald G. The Development of Biopharmaceuticals: An Insider's Perspective. Wiley, 2010.	
4.	Blecher, M. B., et al. Fundamentals of US Regulatory Affairs. 11th Edition, RAPS - Regulatory Affairs Professionals Society, 2019.	
5.	Harvard Business Review. HBR's 10 Must Reads on Strategy. Harvard Business Review Press, 2011.	
6.	Gazarian, M. The Essential Guide to Clinical Research. Wiley-Blackwell, 2011.	
7.	Narahari, Y. Game Theory in Communication Networks. World Scientific Publishing Company, 2019. (For strategic decision-making concepts).	
8.	ICH Official Website (www.ich.org) for access to harmonized guidelines.	
9.	U.S. Food & Drug Administration (FDA) Official Website (www.fda.gov).	
10.	European Medicines Agency (EMA) Official Website (www.ema.europa.eu).	
11.	Badings, I., and Dagher, R. (Eds.). Textbook of Pharmaceutical Medicine. 7th Edition, Wiley-Blackwell, 2014.	