Estd. 1962
"A++" Accredited by NAAC(2021)
With CGPA 3.52

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शिवाजी विद्यापीठ, कोल्हापूर - ४१६००४,महाराष्ट्र
दूरध्वनी - ईपीएबीएक्स - २६०९०००, अभ्यासमंडळे विभाग दुरध्वनी विभाग २३१–२६०९०९३/९४

SU/BOS/Science/ 144 **Date: 09 / 01/ 2023**

To
The,
Head of Department,
Shivaji University, Kolhapur.

Subject :- Regarding syllabi of M. Sc. Part- I Medical Information Management **degree programme under the Faculty of Science and Technology as per National Education Policy 2020 .**

Sir/Madam,

With reference to the subject mentioned above, I am directed to inform you that the university authorities have accepted and granted approval to the syllabi and Nature of question paper of M. Sc. Part- I Medical Information Management under the Faculty of Science and Technology **as per National Education Policy 2020 .**

Sr.No.	Ad-hoc Board	Programme/ Course
1	Biotechnology & Biochemistry	Medical Information Management

This syllabi and nature of question paper shall be implemented from the Academic Year **2022-2023** onwards. A soft copy containing the syllabus is attached herewith and it is also available on university website www.unishivaji.ac.in (students Online Syllabus)

You are, therefore, requested to bring this to the notice of all students and teachers concerned.

Thanking you,

Yours faithfully,

Dy Registrar

Copy to:

1	The Dean, Faculty of Science & Technology	7	Appointment Section
2	Director, Board of Examinations and Evaluation	8	P.G.Seminar Section
3	The Chairman, Respective Board of Studies	9	Computer Centre (I.T.)
4	B.Sc. Exam	10	Affiliation Section (U.G.)
5	Eligibility Section	11	Affiliation Section (P.G.)
6	O.E. I Section	12	P.G.Admission Section

Syllabus
M. Sc. Medical Information Management
(New CBCS)
Department of Biochemistry
SHIVAJI UNIVERSITY, KOLHAPUR

In collaboration with

Hochschule Hannover – University of Applied Sciences and Arts, Germany

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Preamble:

In the recent years in this age of Internet and information technology, we have more information at our fingertips than ever before. Organizing this entire data and combating information overload is becoming more and more important. It is thus necessary for institutes like university to evolve a system, which is most accurate and more student friendly. Keeping this view in mind we have decided to start a master programme in Medical Information Management in collaboration with Hochschule Hannover – University of Applied Sciences and Arts, Germany. After completion of this two year M.Sc. course students can be accommodated in any national/multinational drug designing pharmaceutical company, academia as well as in Clinical Research Organizations (CROs).

Advances in biosciences, clinical medicine and medical technologies have enabled increasing personalized health care. The digitization of healthcare information facilitates new connections, insights and transparency. These developments will include medical information management in educational course format in the coming years and decades. Demographic change is leading to an increasing number of chronically ill and multimorbid patients. This would lead to an increasing need for information management. The years of delays in the introduction a nationwide telematics infrastructure and an electronic health card, as well as the delays in establishing a cross-sectoral quality assurance of health care show problem areas of modern medical information management. The advances in various interdisciplinary areas of bioscience,

clinical medicine and medical technology indicate an increasing need for clinical trials to progress and to make patients accessible. The value of clinical trials is not just to contribute to the development of new therapies but to take proper care of patients. For many participants it means a new drug/option they will be treated with as part of a study.

Clinical research includes planning, implementation, evaluation and publication of clinical trials. In this context, special knowledge is necessary about legal requirements at national and international level as well as all other related issues such as collaboration with institutions of higher education, centers of excellence and authorities, aspects of security of subjects / patients in clinical trials, patient information, insurance and ethical issues. For reimbursement of medicinal products, pharmacoeconomic data are required, that collection and analysis needs special training. Relevant aspects of benefit for patients such as adequate surrogate parameters and quality of life data require specific recording tools as well as rating benefits that are becoming increasingly important for clinical research and require specialized trained staff.

Medical Information Management course would be useful to train our students in rapidly developing and emerging areas of biosciences, clinical medicine, health sciences, health policy, IPR related activities, drug discovery and designing. These experts are continuously required in various clinical and pharmaceutical industries.

Intake capacity: 20 students per year

Eligibility: A candidate possessing B.Sc. degree with minimum 50% marks in Science (Chemistry/ Physics/ Nanoscience and Technology/ Statistics/ Mathematics/ Biochemistry/ Biotechnology/ Microbiology /Bioinformatics/ Botany/ Zoology / Computer Science/ Life Sciences) who have passed the entrance examination conducted by the Shivaji University, Kolhapur shall be held eligible for admission to M.Sc. in Medical Information Management course. Students from other Universities with above mentioned degrees and who have passed the entrance examination conducted by the University are also eligible.

Student/Faculty Exchange: Students and faculty exchange will be done as per MoU, which will be signed between Shivaji University, Kolhapur, Maharashtra, and Hochschule Hannover – University of Applied Sciences and Arts, Germany.

- **Program Structure:** Two year duration; Twelve Theory Papers and six informatics practical along with one research project (Master Thesis).

University	**Sept – Jan.**	**Feb.- July**	**Sept – Jan**	**March-July**
Shivaji University, Kolhapur **(Two Year duration)**	Sem I	Sem II	Sem III	Sem IV (Project) **(Student Exchange)**
		Common syllabus		
Hocshule Hannover University, Germany	-	Sem I	Sem II	Sem III (Project) **(Student Exchange)**

- **Exam Pattern:** CBCS, Semester Pattern (80 External/20 Internal evaluations).
- This course is as per NEP-2020 CBCS pattern

Semester I

600 Marks

CC 101 : Information Technology in Health Sciences
CC-102 : Introduction to Biological Sciences
CC-103 : Medical informatics
CC-104 : German Language A1
CCPR-105 : Laboratory Course I
AEC-106 : Mandatory Non-CGPA compulsory Ability Enhancement Course

Semester II

600 Marks

CC-201 : Research Methods and Statistics
CC-202 : Clinical Data and Quality and Management
CC-203 : Clinical Quality Management
CC-204 : Clinical Data Management-I
CCPR-205 : Laboratory Course II (Key Competencies)
SEC-206 : Mandatory Non-CGPA compulsory Skill Enhancement Course

Choice Based Credit System with Multiple Entry and Multiple Exit Option (NEP-2020)

M.Sc. Programme Structure M.Sc. Part – I (Level-8)

M.Sc. Medical Information Management

	Sr. No.	Course code	Teaching Scheme			Examination Scheme					
			Theory and Practical			University Assessment (UA)			Internal Assessment (IA)		
			Lectures (per week)	Hours (per week)	Credit	Maximum Marks	Minimum Marks	Exam. Hours	Maximum Marks	Minimum Marks	Exam. Hours
SEMESTER-I (Duration- Six month)											
CGPA	1	**CC 101:** Information Technology in Health Sciences	4	4	4	80	32	3	20	8	1
	2	**CC-102**: Introduction to Biological Sciences	4	4	4	80	32	3	20	8	1
	3	**CC-103**: Medical informatics	4	4	4	80	32	3	20	8	1
	4	**CC-104:** German Language A1	4	4	4	80	32	3	20	8	1
	5	**CCPR-105:** Laboratory Course I	16	16	08	200*	80	-	-	-	#
Total (A)			**-**	**-**	**24**	**520**	**-**	**-**	**80**	**-**	**-**
Non-CGPA	1	**AEC-106**	2	2	2	-	-	-	50	20	2
SEMESTER-II (Duration- Six month)											
CGPA	1	**CC-201:** Research Methods and Statistics	4	4	4	80	32	3	20	8	1
	2	**CC-202**: Clinical Data and Quality and Management	4	4	4	80	32	3	20	8	1
	3	**CC-203:** Clinical Quality Management	4	4	4	80	32	3	20	8	1
	4	**CC-204:** Clinical Data Management-I	4	4	4	80	32	3	20	8	1
	5	**CCPR-205**: Laboratory Course II (Key Competencies)	16	16	08	200*	80	-	-	-	#
Total (B)			**-**	**-**	**24**	**520**	**-**	**-**	**80**	**-**	**-**
Non-CGPA	1	**SEC-206**	2	2	2	-	-	-	50	20	2
Total (A + B)			**-**	**-**	**48**	**1040**	**-**	**-**	**160**	**-**	**-**

1. ***Practical Examination will be internal/external as per department choice**
2. **$ Question no. 1 of each question paper will be subjective (short answer question/objective questions)**
3. **# Duration of Practical Examination will be 5 days (1 inspection day and 4 Practical days)**

<table>
<tr><td>• Student contact hours per week : 32 Hours (Min.)</td><td>• Total Marks for M.Sc.-I : 1200</td></tr>
<tr><td>• Theory and Practical Lectures : 60 Minutes Each</td><td>• Total Credits for M.Sc.-I (Semester I & II) : 48</td></tr>
<tr><td>• CC-Core Course
• CCPR-Core Course Practical
• AEC-Mandatory Non-CGPA compulsory Ability Enhancement Course
• SEC- Mandatory Non-CGPA compulsory Skill Enhancement Course</td><td>• Practical Examination is annual.
• Examination for CCPR-105 shall be based on Semester I Practicals.
• Examination for CCPR-205 shall be based on Semester II Practicals.
• *Duration of Practical Examination as per respective BOS guidelines
• Separate passing is mandatory for Theory, Internal and Practical Examination</td></tr>
<tr><td colspan="2">• Requirement for Entry at Level 8:
A candidate possessing B.Sc. degree with minimum 50% marks in Science (Chemistry/ Physics/ Nanoscience and Technology/ Statistics/ Mathematics/ Biochemistry/ Biotechnology/ Microbiology /Bioinformatics/ Botany/ Zoology / Computer Science/ Life Sciences) who have passed the entrance examination conducted by the Shivaji University, Kolhapur shall be held eligible for admission to M.Sc. in Medical Information Management course. Students from other Universities with above mentioned degrees and who have passed the entrance examination conducted by the University are also eligible.</td></tr>
<tr><td colspan="2">• Exit Option at Level 8: Students can exit after Level 8 with Post Graduate Diploma in Medical Information Management if he/she completes the courses equivalent to minimum of 48 credits.</td></tr>
</table>

SEMESTER I		
CC 101: Information Technology in Health Sciences		**60 Hrs**
Credit I	**INTRODUCTION TO COMPUTERS** Introduction, electronic components of the CPU, Microprocessor chip, motherboard. Computer as a digital calculator, principle of digital computers, structure of the digital computers: arithmetic unit, central unit, memory unit, Input and output. **HISTORY AND DEVELOPMENT OF COMPUTERS** Generations of computers; (I, II, III, IV and V), classifications of computers; analog computers, digital computers, mainframe, and mini-frame computers	**15 Hrs**
Credit II	**DATA INPUT OUTPUT, MEMORY AND COMPUTER CODING** **DATA INPUT OUTPUT:** Punched card reader, paper tape reader, magnetic tape, floppy disk, magnetic disk, optimal scanner, voice data, data entry terminal, teleprocessing monitor, visual display unit, modern input devices, Output devices; CRT, printer, plotter. **MEMORY:** Primary memory or main memory; magnetic core memory, semi-conductor memory, RAM, ROM, PROM, EPROM, EEPROM. Secondary memory or auxiliary memory or storage devices; Hard disk, diskette, magnetic tape, ZIP disk devices, CD-ROM, DVD, virtual memory, cache memory. **COMPUTER CODING:** Number system, binary number system, decimal number system, binary to decimal inter-conversion, octal number system, hexadecimal number system, fundamentals of logical concepts	**15 Hrs**
Credit III	**LANGUAGES, FLOW CHARTS AND OPERATING SYSTEMS** Machine level languages, assembly level languages, high level languages. **OPERATING SYSTEMS:** DOS, windows, UNIX/LINUX, Mac OS. **MODERN COMPUTING MACHINES:** Workstations, parallel processing computers, HPC, supercomputers, zero client system. **INTERNET AND RELATED PROGRAMMES:** History of Networking and internet, WWW, HTML, HTTP, telnet, FTP, computer domains, internet browsers, TCP/IP, LISTSERV	**15 Hrs**

Credit IV	**HEALTH SCIENCE INFORMATICS** Introduction to information, scope, components of heath care informatics; introduction, standardized languages in practice. Health IT architecture; information technology architecture models in health care organization, service oriented structures. Concept of bio-signal processing and medical imaging.	**15 Hrs**

Suggested Readings

- Introduction to database system by J. M. Martin, Prentice-Hall.
- Developing Bioinformatics Computer Skills (2001) Cynthia Gibas and Per Jambeck, O'Reilly Media, Inc.
- Computer fundamentals 6th edition (2007) P. K. Sinha & Priti Sinha, BPB Publications

CC-102 : Introduction to Biological Sciences		60 Hrs
Credit I	**Anatomy and Physiology** The cellular level of organization; structure of the cell, comparison of animal cell with evolutionary related cellular forms, cellular functions. Structure and function of the brain Central Nervous System, Peripheral and Autonomic Nervous system, Neurotransmitters. Anatomy of heart and the cardiovascular system, circulatory system, kidneys and excretory system, lungs and respiratory system, digestive system, reproductive system, Lymphatic & Immune Systems. Hormones; Anterior posterior pituitary hormones, contraction and regulation of skeletal muscle and smooth muscle.	**15 Hrs**
Credit II	**Pharmacology** History and development of drug discovery, Basic Principles of pharmacology: molecular and cellular drug targets, drug-receptor interactions, agonism, antagonism, drug metabolism, pharmacogenomics, and pharmacokinetics. Introduction to toxicology: overview of the field of toxicology covering the basic principles, target organ toxicity, the toxicity of a limited group of compounds, and an introduction to modern molecular toxicology.	**15 Hrs**
Credit III	**Epidemiology** Introduction to epidemiology, Determinants of health, measuring disease occurrence (frequency), surveillance, infectious disease epidemiology, direct and indirect standardization, data sources and secondary analysis, epidemiologic study design.	**15 Hrs**

Credit IV	**Biochemistry** Proteins- Chemical structure and General properties of amino acids, classification of proteins on the basis of size, shape, degree of association, complexity and according to biological functions (Enzymes, transport, storage, contractile, structural, defense and regulatory). Types of protein structures. Carbohydrates- Classification, characteristics and functions of monosaccharides, disaccharides – polysaccharides. General scheme of carbohydrate metabolism. Lipids- Classification of lipids. Fatty acids - general formula, nomenclature and chemical properties. Structure, function and properties of simple, complex, acylglycerols, phosphoglycerides, sphingolipids, waxes, terpenes, steroids and prostaglandins Nucleic acid- Structure of nucleoside, nucleotide. Experimental evidence for nucleic acids as genetic material, Watson and Crick model of DNA, types of DNA.	**15 Hrs**

Suggested Readings

- Lehninger's Principles of Biochemistry 5th edition, Nelson, D. L. and Cox, M. M. (2000) 10.1007/978-3-662-08289-8
- Anatomy and Physiology by Dummies 2nd edition, Donna Rae, Norris, M., & Siegfried, D. R. (2011). Hoboken, NJ: Wiley Publishing, Inc.
- Basic & Clinical Pharmacology (2012), Bertram G. Katzung, New York: McGraw-Hill Medical.
- Biochemistry by Lubert Stryer (2002) Berg, J. M., Tymoczko, J. L., Stryer, L., & Stryer, L. New York: W.H. Freeman
- Bioinformatics; Methods and applications; Genomics, Proteomics and Drug Discovery 3rd edition (2011), Rastogi, S. C. and Mendiratta and Rastogi, P. New Delhi : PHI Learning Private Limited

CC-103 : Medical Informatics		60 Hrs
Credit I	**Genome Analysis and their applications in Health:** Introduction and history, rough and final draft of human genome project, goals of the human genome project, Nucleic acids, genome information, applications of human genome project, techniques used and data analysis, ethical and social issues, International Human Genome Sequencing Consortium, types of Single Nucleotide Polymorphism (SNPs) and analysis, NCBI, BLAST. Gene Sequencing methods, Next Generation Sequencing (NGS), early detection of diseases using genome analysis.	**15 Hrs**
Credit II	**Structural biology and drug discovery:** Protein sequence information, composition and properties, physicochemical properties based on sequence, sequence comparison, Pair-wise sequence alignment, gaps, gap-penalties, local and global sequence alignment, multiple sequence alignment, useful programs, ClustalW, BioEdit. Protein Structure Prediction; Homology modeling, prediction of protein structure from sequences, functional sites, Protein folding problem, three-dimensional structure determination. Protein identification and characterization by ExPASy server; Primary structure analysis and prediction.	**15 Hrs**
Credit III	**Virtual Screening for Drug Discovery** Introduction, drug discovery area, pharmacogenetics and pharmacogenomics applications, parameters in drug discovery, cell cycles, identification of drug target molecules, drug design and its approaches, computer-aided drug designing methods; virtual screening, computer aided molecular design (CAMD), molecular modeling methods; molecular modeling packages and their uses in drug designing and discovery. ADME and toxicity Predictions, QSAR studies for drug designing.	**15 Hrs**

Credit IV	**Databases and Informatics** Concept of data, data models, data representation, flow charts, data mining, various types of databases; protein sequence databases; primary and secondary protein sequence, nucleic acid databases and structural databases, PubChem, ZINC database and file formats, medical databases, literature databases. Database related programs; Oracle, SQL, VB, Database management System (DBMS), RDBMS. Applications of Medical Informatics	**15 Hrs**

Suggested Readings

- Lehninger's Principles of Biochemistry 5th edition, Nelson, D. L. and Cox, M. M. (2000) 10.1007/978-3-662-08289-8
- Anatomy and Physiology by Dummies 2nd edition, Donna Rae, Norris, M., & Siegfried, D. R. (2011). Hoboken, NJ: Wiley Publishing, Inc.
- Basic & Clinical Pharmacology (2012), Bertram G. Katzung, New York: McGraw-Hill Medical.
- Biochemistry by Lubert Stryer (2002) Berg, J. M., Tymoczko, J. L., Stryer, L., & Stryer, L. New York: W.H. Freeman
- Introduction to Bioinformatics, (2001) Atwood, T. K. and Parry-Smith, D. J. Pearson Education Asia, Delhi, India
- An introduction to Computational Biochemistry. (2002) C. Stain Tsai, A. John Wiley and Sons, Inc., publications
- Bioinformatics; Methods and applications; Genomics, Proteomics and Drug Discovery 3rd edition (2011), Rastogi, S. C. and Mendiratta and Rastogi, P. New Delhi : PHI Learning Private Limited

CC-104 : German Language A1		60 Hrs
Credit I	**Reading** i. The pupils recognise the following types of text: dialogue; interview; advertisement; programme of a performance (cinema, theatre, concert, sport); a television and radio programme; notice; folder page of books, of audio cassettes, of videocassettes and of CDs; articles in dictionaries and lexica; a form to be filled in; menu; poem, short story, diary, comics, picture novel, greeting card, personal letter, email letter, announcement, invitation. ii. The pupils can understand the following types of text globally and/or selectively: leaflet, catalogue, label, transport timetable, city map, a programme of a performance (cinema, theatre, concert, sport), T.V. & radio programme, advertisement, notice, article in a dictionary and lexicon, menu, personal letter, e-mail letter, columns in a newspaper and magazine, comics, cuttings of reports, poem, short story, short texts of information. iii. The pupils understand in detail the type of problem and the instructions in the text book as well as short announcements, signs denoting advice and forbiddings, simple forms, invitations and greeting cards. iv. The pupils make use of the following strategies while reading: - they recognise the correlation between text and picture. - they recognise personal names, numbers and dates. - they recognise the meaning of punctuation marks and text typography. - they establish the correlation between the title of a text and main points of information. - they recognise the parts of speech and clauses, word roots, prefixes, suffixes and endings of words of those learnt as well as internationalisms. - they recognise the communicative function of the types of text listed	**15 Hrs**

	under point (i). - they work with word card indexing. - they perceive the foreign culture in that they take a critical look at their own culture in the process. - they make use of the knowledge, skills and strategies which they have acquired in the lessons of their mother language or their first foreign language, when deducing pieces of information from text or making connections between them. v. The pupils can handle reference works (e.g., dictionaries, grammars). **Notions:** The contents of teaching include the speaking material which allows the expression of the following notions: Existence, Space and Time; Quantity and Quality, Logical Relationships; Definite and Indefinite Forms. - Existence: being, constancy, change, possibility, impossibility. - Space : dimensions, place, motion, direction. - Time : point in time (once, repeated, definite, indefinite), length of time (continuous, limited by time); general observations without concrete reference to time. - Quantity: can / cannot be added. - Quality : of persons, localities, things, objects, events and dealings. - Logical Relationships: connection. Opposition, cause, condition, comparison. - Definite and indefinite meanings.	
Credit II	**Listening:** The pupils are in a position to understand different German language texts globally or in detail through a direct contact or over the media. The texts should follow the standards of level A1 of the *Framework* and observe the phonetical and intonation variants of the German language. Of special significance in the training for the skill of *listening* is the inclusion of sight perception. i. The pupils understand questions and instructions of the teacher during	**15 Hrs**

	the lesson. ii. The pupils can create correlations between hearing texts and pictures. iii. The pupils can understand short dialogues between two or several partners who refer to themes and situations already dealt with. iv. The pupils can understand short everyday and especially tourist related information (e.g., at the post office, in a travel agency, at the railway station / airport). v. The pupils infer main announcements from conversations on themes and situations already dealt with. vi. The pupils can infer selective information from news, advertisements and programme information on Radio or in T.V. as well as from easy descriptive texts. vii. The pupils can understand short literary forms like poems and songs on the basis of directed explanation. viii. The pupils make use of the following strategies while listening: - they put forward hypotheses and examine them in the light of the intention of the statement of various types of text. - they recognise intonation models, linguistic and metalinguistic means of expressing affirmation and negation. - they make use of already known models of word building. - they recognise the communicative function of varied types of text. - they work with a dialogue – diagram. - they draw up the construction plan of a text they have heard. Language Interactivity: The language interactivity taken up in the teaching contents takes into account the basic functions of the language, namely the social, informative, appellative and affective. (i) making contacts - to welcome, to greet, to send greetings. - To address (even in letters). - To introduce oneself / others. - To ask how one is, to give information about it.	

	- To request, to thank. - To congratulate, to wish luck – to give thanks for it. - To invite, to accept, to refuse. - To express regrets. - To bid farewell (even in letters). (ii) giving information - to ask for information and to give it. - To present facts; to narrate, to report, to describe. - To list (enumerate), to verify by examples. - To complete / correct / disprove / confirm information. - To ask for correctness. - To show knowledge / lack of knowledge. - To give reasons. (iii) arranging things - to express wishes. - To make suggestions; to give / ask for advice. - To ask for / refuse / offer help. - To complain, to protest. - To express readiness / refusal. - To give / refuse / ask for permission; to forbid. - Information about / asking for intentions. - To ask if someone wants to do something, / is ready to do it. - To promise, to confirm. (iv) showing attitudes and expressing feelings Expressions of: - Agreement, refusal - Conjecture, certainty, persuasion. - Importance, insignificance. - Interest, curiosity, disinterestedness, indifference. - Preference, dislike, anger, - Joy, excitement. - Doubt, disappointment, annoyance.	

	- Anxiety, (fear), care, worry. - Relief, appeasing, satisfaction. - Trust, mistrust. - Impatience, expectation, hope. - Surprise, wonder. Topics: (i) I and my family : relatives,; relationships; dwelling /house; daily / yearly routine; activities in common; meals; feasts / celebrations; travelling. (ii) I and my friends : circle of friends / clique; free time (hobbies, sport, games, radio, T.V., music, reading, meetings, parties, pets); idols; dreams. (iii) I and my surroundings : school (subjects, timetable, school day) ; neighbours; my street, my city / village, (means of transport, shops, shopping, post office) Information about the German-speaking countries will be integrated in such topics and their various aspects. Areas, Roles and Places of Language Communication: The lesson prepares the pupils for a reasonable amount of communication in the following areas: Free time, school family, friends, services and for the use of German speaking mass media. Communicative language activity is realized at school, in public, on means of transport, on visits and on the road. The pupils reach their role competence as is described in the *Common European Framework for Languages* of the Council of Europe. Language material: (i) Phonetics Quality and quantity of vowels, **A**-sounds, **E**-sounds, **Ü**-sounds. **Ö**-sounds, the murmuring vowel, **h** at the beginning of the word, **ich**-	

	sound, **ach**-sound, **ng**-sound, accentuation of the word, structure, sentence accent and melody. (ii) Orthography The alphabet, **Aä**, **Oö, Uü, ei, ai, au, eu, äu, sp, st, ch, schg, tsch, ts, tz, chs, ng, ig, qu, ck, ss, ß.** (iii) Lexis Difference is to be made between a productive and a receptive vocabulary. The productive vocabulary comprises the basic vocabulary and the most common models of word-building, which are necessary for realising the above mentioned language interactivity in the parameters of the topics and their aspects already mentioned. The development of receptive skills presupposes and demands a receptive vocabulary that can be increased.	
Credit III	**Speaking:** The pupils realize in their statements ways of speaking which are mentioned in the subsequent part entitled *Contents*. i. The pupils reproduce the phonetic and intonation pattern correctly. ii. The pupils ask and answer questions in connection with the themes and situations already dealt with. iii. The pupils participate in conversation with their teacher and / or with their classmates in the course of the lesson. iv. The pupils hold short conversations with one or several partners (known or unknown) in the sphere of the themes and situations already dealt with. v. The pupils make short telephone calls. vi. The pupils make short announcements in connection with themes already handled. vii. The pupils make use of appropriate patterns of behaviour (mimics, gesticulations, body distance or nearness, etc) during conversation. viii. The pupils can make use of the following strategies while speaking: - they ask for and themselves provide additional / explanatory information.	**15 Hrs**

	- they signal lack of understanding and demand from their partner an appropriate reaction. - they direct the conversation according to their own interests and / or change the subject. - they make use of clichés in order, e.g., to cope more easily with situations in which they are under pressure of time. - they make use of paralinguistic means.	
Credit IV	**Writing** i. The pupils fill in tables with key words according to a text they have read or heard. ii. The pupils fill in easy forms, write greeting cards, invitations and short personal announcements. iii. The pupils lay down vocabulary cards according to a preset pattern. iv. The pupils write short texts to photos and pictures. v. The pupils make use of the following strategies while writing: - they employ preset patterns and examples with sense. - they use reference works for self correction of mistakes. Form 1 - Grammar o W-Frage: *Wie heißen Sie?* o Aussage: *Ich heiße / Ich bin ...* o Personalpronomen: *ich, Sie, du* o Verbkonjunktion *(ich, Sie, du): heißen, kommen, sprechen, sein.* o Präposition *aus: Ich komme aus Finnland* o Possessivartikel: *mein / meine* o Personalpronmen: *er / sie, wir, ihr, sie* o Verbkonjunktion: *leben, haben ...* o Preposition *in: Sie leben in Helsinki.* o Ja- / Nein-Frage: *Kennen Sie ...?* o Nullartikel: *Haben Sie Äpfel?* o Bestimmter Artikel: *ein / eine* o Negativer Artikel: *kein / keine*	**15 Hrs**

	o Plural der Nomen: *Tomaten, Eier,* o Verbkonjunktion: *essen* o Bestimmter Artikel: *der / die / das* o Lokale Adverbien: *hier / dort* o Prädikatives Adjektiv: *Sie ist schön.* o Personalpronomen: *er / sie /es.* o Negation *nicht: Das Bad ist nicht klein.* o Verbkonjugation*: gefallen* o Trennbare Verben: *Timo steht früh auf.* o Verbkonjugation: *sehen, arbeiten.* o Verbposition im Satz o Präpositionen *am, um, von...bis: Am Sonntag um acht Uhr.* o Akkusativ: *den Salat, einen Tee, keinen Saft.* o Ja- / Nein-Frage und Antwort: *ja, nein, doch* o Verbkonjugation: *lesen, treffen, schlafen, fahren, nehmen, „möchten“* o Modalverben*: können, wollen* o Satzklammer: *Ich kann nicht tanzen.* o Perfekt mit *haben: hat...gelernt* o Perfekt mit *sein: ist...gefahren* Form 2 – Topics: o Beruf und Arbeit Berufe benennen und erfragen. Informationen über Vergangenheit und Gegenwart austauschen. Von Ereignissen und Aktivitäten in der Vergangenheit berichten. Praktikumsbörse: Anzeigen verstehen. Ungewöhnliche Berufe. Kurztexte verstehen. o In einer fremden Stadt Anweisungen geben / Abläufe erklären. Anweisungen und Ratschläge geben. Über Erlaubtes / Verbotenes und Regeln sprechen.	

	Informationsbroschüren verstehen. An der Hotelrezeption: nachfragen, um Erklärungen und Verständnishilfen bitten. o Gesundheit Körperteile benennen. Über das Befinden sprechen. Über das Befinden anderer sprechen. Das Aussehen beschreiben. Anweisungen und Ratschläge geben und verstehen. Einen Brief (Anfrage) schreiben. Einen Termin vereinbaren. o In der Stadt unterwegs Nach dem Weg fragen und den Weg beschrieben. Verkehrsmittel benennen. Ortsangaben machen. Orte und Richtungen bestimmen. Fahrpläne: Informationen entnehmen. Durchsagen verstehen. Am Bahnhof: um Auskunft bitten. o Der Kunde ist König Zeitangaben verstehen und machen. Zeitliche Bezüge nennen. Um Serviceleistungen bitten. Höfliche Bitten und Aufforderungen ausdrücken. Einen Informationstext verstehen. Schriftliche Mitteilungen und Telefonansagen verstehen. o Neue Kleider Kleidungsstücke benennen und bewerten. Gefallen / Missfallen ausdrücken. Vorlieben und Bewertungen ausdrücken. Einen Zeitungsartikel verstehen. Vorlieben erfragen, eine Auswahl treffen.	

	Im Kaufhaus: um Hilfe / Rat bitten. o Feste Das Datum erfragen und nennen. Über Personen und Dinge sprechen. Gründe angeben. Einen Termin schriftlich absagen und zusagen. Einladungen lesen und schreiben. Feste nennen. Glückwünsche ausdrücken. Form 2 – Grammar: o Wortbildung Nomen: *der Lehrer □ die Lehrerein;* *der Kaufmann □ die Kauffrau* o Präteritum *sein, haben: war, hatte* o Modalpräposition *als: Ich arbeite als Programmierer.* o Temporale Präpositionen *vor, seit für: vor einem Jahr.* o Modalverben: *müssen, dürfen.* o Satzklammer: *Sie müssen einen Tisch reservieren.* o Pronomen *man.* o Imperativ: *Gehen Sie zur Touristeninformation.* o Possessivartikel: *dein, sein, ihr, unser...* o Modalverb *sollen* o Satzklammer: *Wir sollen zu Hause bleiben.* o Präposition mit: *Ich fahre mit dem Auto.* o Lokale Präpositionen *an, auf, bei, hinter, in, neben, über, unter, vor, zwischen:* *Wo...? – Auf dem Parkplatz.* o Lokale Präpositionen *zu, nach, in: Wohin...? - Zum Buchladen.* o Temporale Präpositionen *vor, nach, bei, in: Wann...? – In einer Stunde.* o Temporale Präpositionen *bis, ab: Ab wann...? - Ab morgen.* o Höflichkeitsform Konjunktiv II: *würde, könnte.* o Satzklammer: *Könnten Sie bitte Kaffee kochen?*	

	o Verben mit verschiedenen Präfixen*: an-, aus-, auf-, zumachen.* o Demonstrativpronomen *der, die das: der Rock □ Der ist super!* o Frageartikel *welch-: Welches Hemd?* o Demonstrativpronomen *dies-: Dieses Hemd gefällt mir.* o Komparation *gut, gern, viel.* o Verbkonjugation: *mögen.* o Personalpronomen im Dativ: *mir, dir,…* o Verben mit Dativ: *gefallen, gehören, passen, stehen.* o Ordinalzahlen: *der erste...* o Personalpronomen im Akkusativ: *mich, dich...* o Konjunktion *denn* o Verbkonjugation: *werden.*	

Suggested Readings

- As per the A1 German Language norms.

CCPR-105 : Laboratory Course I	**(120 Hrs)**
A	**100 Marks**
•	Computer basic knowledge; hardware, connection cables, typing, Windows 98/XP, Internet browsers, search engines.
•	LAN connections, setting up the IP address, network security. Internet surfing and searching information, downloading and installing software.
•	Hands on session with Microsoft Word.
•	Microsoft Excel (Spreadsheet Application).
•	Hands on session with Microsoft Access (Database related applications).
•	Creation of computer presentation with MS Power Point.
•	Introduction to Oracle for creation of database.
•	Introduction to literature database at NCBI and querying the PUBMED database using the ENTREZ search engine.
•	Getting the amino acid sequences by exploring and querying the protein sequence database.
•	Getting the gene sequences by exploring and querying the nucleic acid databases.
•	Introduction to RCSB PDB database.
•	3-D Protein structure visualization and measurement of bond length, bond angle and torsion angles using graphics and command line RasMol.
•	Analysis of Drug-receptor interactions using Chimera.
B	**100Marks**
•	Introduction to small drug molecule databases eg. PubChem, ZINC
•	Similarity search using the Blast and interpretation of the results.
•	Pair-wise and multiple sequence alignment by using ClustalW.
•	Introduction of BioEdit.
•	Protein Structure Prediction (Homology Modeling) using SPDBV.
•	Model Building and Energy minimization.
•	Calculation of molecular properties of drug molecules using SPARTAN.
•	Introduction UNIX/LINUX commands.
•	Data transfer; ping, telnet, ftp.
•	Drug-receptor structure stability using molecular dynamics simulation with the help of GROMACS.
•	Molecular Docking and Drug designing by using AutoDock.
•	Toxicity analysis using ADMET SAR online tool.
•	Pharmacokinetic analysis of drug molecule using T.E.S.T
•	QSAR analysis of drugs using T.E.S.T.

AEC-106	**Mandatory Non-CGPA compulsory Ability Enhancement Course**	**30 Hrs**

SEMESTER II		
CC-201 : Research Methods and Statistics		**60 Hrs**
Credit I	**Foundation of Research** i) Characteristics of scientific Research, ii) Formulation of Research Problem, iii) Research Process, iv) Literature Review, **v)** Sampling, Data collection, Data Analysis, Report writing	**15 Hrs**
Credit II	**Research Design** i) Concept and features of Research Design, ii) Types of Research Design, iii) Concept of cause and effect, iv) Correlation and Causation, **v)** Types of variables	**15 Hrs**
Credit III	**Hypothesis Testing** i) Definition, ii) Research Hypothesis, iii) Statistical Hypothesis, iv) Qualities of Good Hypothesis, **v)** Hypothesis Testing	**15 Hrs**
Credit IV	**Data and Measurement and Statistical Data Analysis** i) Measuring of Data, ii) Primary Data, Secondary data, iii) Measurement Techniques iv) Attitude Scaling Techniques v) Sampling types vi) Cleaning of data, Coding, editing vii) Tabular presentation of data viii)Frequency tables ix) Univariable Analysis x) Bivariable Analysis xi) Linear Regression Analysis xii) Test of Significance	**15 Hrs**

Suggested Readings

- Epidemiological Research Methods (1996) Don McNeil. New York : John Wiley
- Epidemiology and Statistics for Public Health Research (2018). Broschiertes Buch. Lap Lambert Academic Publishing
- Medical Biostatistics 4th Edition (2017) Abhaya Indrayan, Rajeev Kumar Malhotra Chapman & Hall/CRC Biostatistics Series, CRC Press
- Principles of Biostatistics 2nd Edition (2018) Marcello Pagano, Kimberlee Gauvreau, CRC Press
- Biostatistics: The Bare Essentials, 3rd Edition (2007) Geoffrey R. Norman, David L. Streiner PMPH publishers USA

CC-202 : Clinical Data and Quality and Management		60 Hrs
Credit I	**Introduction to Clinical Research** i) Introduction and features ii) Outcome measures iii) Responsibilities and study documents iv) Ethics in Clinical Research	**15 Hrs**
Credit II	i) Introduction to GCP ii) Role of Investigators iii) Clinical Trial Protocol iv) CRF (Case Report Format) v) Informed consent	**15 Hrs**
Credit III	**Regulatory Affairs** i) CRF ii) ICH Guidelines for Clinical Trials iii) Documentation iv) Pharmacovigilance and Clinical Trials **v)** Drugs Approval Process	**15 Hrs**
Credit IV	**Information Management in Hospitals** i) Necessity of Standards of electronic health ii) Security issues iii) Healthcare Information Regulations of Standards iv) Health Record and Privacy v) Health Level Standards – HL7 vi) Integrated Health Information Systems **Hospital Information Systems** i) Definition, Structure and Application ii) System Advantages iii) Nursing Informatics iv) Automated Clinical laboratory Systems v) Pharmacy Information Systems vi) Electronic Health	**15 Hrs**

Suggested Readings

- Clinical Data Management 2nd Edition (2000) Richard K. Rondel, Sheila A. Varley, Colin F. Webb. Wiley publishers
- Principle and Practice of Clinical Research 4th edition (2017) John Gallin, Frederick Ognibene & Laura Lee Johnson. Elsevier academic press.
- Healthcare Information Management Systems Cases, Strategies, and Solutions. Ball, Marion J. Weaver, Charlotte A., Kiel, Joan M. 3rd edition (2004) Springer-Verlag New York

CC-203 : Clinical Quality Management		60Hrs
Credit I	**Introduction to Quality Management** i) Concept of Quality ii) Quality Systems iii) Quality Audits iv) Quality Control, Quality Assurance, v) Total Quality Management (TQM)	**15 Hrs**
Credit II	**Quality Management Tools** i) Site Level Quality Management ii) Quality Management Data Review Tool iii) Quality Management study wise Review Tool iv) Quality Management Summary Report v) Subject Record Review	**15 Hrs**
Credit III	**Quality Assurance and Pharmacovigilance (PV)** i) General Introduction of PV ii) Principles of PV iii) PV and selected organ clone iv) Pharmacovigilance systems v) Guidelines and laws governing PV	**15 Hrs**
Credit IV	**Pharmacovigilance Global Perspectives** i) Global PV and safety standards ii) Global regulations and guidelines iii) GCP/GMP/GLP guidelines for PV iv) Global audits **Quality Management Indian Perspectives** i) Epidemiology and Evidence Based Medicine ii) Drug Regulatory Authority iii) Guidelines for Pharmaceuticals iv) Guidelines for Neutraceuticals, Cosmetics v) Guidelines for Herbal and Alternative Medicine	**15 Hrs**

Suggested Readings

- A Practical Guide to Quality Management in Clinical Trial Research 1st Edition (2005) Graham Ogg. CRC Press

CC-204 : Clinical Data Management-I		60 Hrs
Credit I	**Data Acquisition (DAQ)** i) Importance of Data ii) Data Storage iii) Data Safety iv) Role of Data in Public Health Politics v) Data and Epidemiology studies	**15 Hrs**
Credit II	**Clinical Data Management** i) CDM Process ii) Collection, Integration, and availability of Data iii) Verification, Validation and quality control iv) Software's for CDM v) Clinical Trial Phase wise Data Management	**15 Hrs**
Credit III	**CRF (Case Report Form)** i) CRF and ECRF ii) CRF Requirements ICH Guidelines iii) ICH Guidelines iv) Disease wise CRF v) Comparative study of Indian and Global CRFs	**15 Hrs**
Credit IV	**Document Management System** i) HIS (Hospital Information Systems) ii) Document Management and work Management systems iii) Archiving Systems iv) Clinical Trial Management Systems v) PRO systems (Patient Reported Outcomes) **Hospital Management Systems in India** i) Present Scenario ii) NABH Guidelines for QC and QA iii) Role of HIS in Government Policy making iv) Public Health and HIS v) Private Hospital and HIS	**15 Hrs**

Suggested Readings

- Practical Guide to Clinical Data Management. Susanne Prokscha 3rd edition (2011), CRC Press

CCPR-205 : Laboratory Course II (Key Competencies)	**(120 Hrs)**
A	**100 Marks**
•	Introduction to Didactics
•	Different Didactic Skills
•	Didactic Methodology
•	Different models
•	Role of counseling
•	Counseling in clinical Trials
•	Motivational interview
•	Motivation and Psychology
•	Seminar activities
•	Types and Methods
•	Case studies
B	**100Marks**
•	Basics of HRM
•	Function of HRM
•	Theories of HRM
•	HRM in Clinical Trials
•	HRM in Healthcare
•	Role of HRM in corporate hospitals
•	eHRM
•	Software for eHRM
•	Cost, Benefits Ratio of HRM
•	CTMS
•	ePro

SEC-206	**Mandatory Non-CGPA compulsory Skill Enhancement Course**	**30 Hrs**