Course name: Biostatistics and DoE for Pharmaceutical Applications

Course Coordinator: Dr. SouvikBasak, Assoc. Professor, BCRCP

Course Level: Certificate Course

Course Objective: To make students understand Biostatistics and DoE in Pharmaceutical Profession and Industry and Enabling them apply the techniques in relevant fields

Total no. of Units: 20

Total no. of classes: 20 + 4 (Exam)

Total Credit Hours: 40

Mode of teaching: Online

Resourceto be Procured: Statistical software (Minitab Academic License) – Please see attachment.

Target Audience: UG & PG Pharmacy Students

Proposed Course Structure:

Unit	Topic to be Covered	Hours (h)
1	**Introduction of Biostatistics ->** Areas of application of Biostatistics in Pharmaceutical Industry and Profession, central tendency of dispersion, Mean, Median, Mode, Standard Deviation, Standard Error of Mean, Variance, Continuous and Discrete Series, concept of parametric and non-parametric test	2
2	**Concept of Distribution ->** Frequency distribution, Class, Range, Interval, BINs, Discrete and Continuous frequency distribution, Correction factor, Kurtosis, Gaussian (normal), Binomial, Poisson, Probability Distribution	2
3	**Determination of Sample size and Hypothesis Testing** -> Power Analysis, Type of errors, confidence Intervals, Null and Alternate hypothesis, Acceptance and Rejection of hypothesis, **Z-test, Chi-SquareTest**	2
4	**F-test**-> Origination and utility of F-test, Data input for F-Test, Result Analysis (Hands on training on relevant software)	2
5	**T-test**-> Various t-test, Post Hoc tests, Bonferroni's T-test, Tukey's honest significant difference test, Dunnett t-test, One tailed and two tailed distributions, Paired T-test, Equal and Unequal Variance, Interpretation of results and applications (Hands on training on Microsoft Excel, SPSS, Minitab etc.)	2
6	**ANOVA**.-> One way ANOVA, Two Way ANOVA, Confidence Interval, Performance of ANOVA (Hands on with Software)	2
7	**Principal Component Analysis (PCA)** -> Theory, Concept of Eigenvalues and Eigenvectors, Values of Dimension reduction, Hands on performance in Software	2
8	**Regression Analysis ->** Concept of Regression, Multiple Linear Regression (MLR), Spearman's Rank Correlation Coefficient, Pearson Correlation Coefficient, Demonstration of MLR in Process output, Drug Design	2
9	**Non Parametric Tests->** Wilcoxon Ranked Sign Test, Wilcoxon Ranked Sum test or Mann-Whitney U-Test, Kruskal-Wallis Test, Friedmann test	2
	Mid-term Examination	2
10	**Design of Experiment (DoE)**-> Use of Process variables for DoE, Factorial design, Treatment or Levels, Latin square design, Signal to noise ratio	2
11	**2^K factorial design->** Treatment or levels of 2^k factorial design, use of Microsoft Excel or Minitab for 2^k factorial design	2

12	**Central Composite Design (CCD), Box-Behnken design (BBD) ->** 2D and 3D concepts, Centre, Star and Axial Points, α-value, Calculation of α-value from the factorial design and its levels, CCC, CCI and Face CCD models	2
13	**Use of Minitab for CCD, Factorial design ->** Data Input in Minitab, Analysis, setting various parameters and plots in Minitab, solving a real industry problem of process optimization	2
14	**DoE by Taguchi Method ->** Data Input in Minitab, Analysis, setting various parameters and plots in Minitab, solving a real industry problem of process optimization, Randomization, Replication, Significance analysis of process optimization by Taguchi Method	2
15	**Applications of ANOVA in realistic process ->** Case-I: ANOVA in formulation design, Case-II: ANOVA in analysis of drug's or formulation's effects on various groups	2
16	**Measurement system Analytics (MSA) ->** Data input, analysis and optimization using various software or program	2
17	**Statistical Process Control (SPC) ->** Data input, analysis and optimization using various software or program	2
18	**Cluster Analysis->** Concept of Cluster and Factor Analysis, Data grouping, Plots, Key factors isolation, Practical examples	2
19	**Project/ Case study-I** A realistic case study would be given by the course instructor and the analysis and/or outputs would be provided by the students	2
20	**Project/ Case Study-II** A realistic case study would be given by the course instructor and the analysis and/or outputs would be provided by the students	2
	Final Examination	2.0

Proposed by IT CELL, BCRCP:

Prof. S. Ray	Dr. Amit K Halder	Dr. SouvikBasak	Dr. FalguniPatra	Mr. S. Banerjee