



R. J. COLLEGE of Arts, Science & Commerce (AUTONOMOUS)

(Hindi Vidya Prachar Samiti's RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce)

Opposite Ghatkopar Railway Station, Ghatkopar (West), Mumbai 400086, Maharashtra, INDIA.

Website: www.rjcollege.edu.in Email: rjcollege@rjcollege.edu.in Tel No: +91 22 25151763 Fax No: +91 22 25150957

College is recognized under Section 2(f) & 12(B) of the UGC Act, 1956

Affiliated to UNIVERSITY OF MUMBAI II NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

13/06/2019

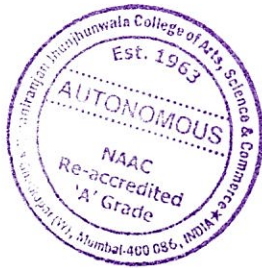
ADMISSION NOTICE FOR POST GRADUATE DIPLOMA PROGRAMS 2019-2020

DEGREE COLLEGE

The admissions of Post Graduate Diploma programs in-

1. Dietetics and Applied Nutrition
2. Regulatory Affairs
3. Clinical Studies Data Management and Medical Writing
4. Horticulture and Landscape Designing

will commence from 1st July 2019. Students must fill the form. The eligibility criteria and fee structure is available on the college website. Admission will be on fulfilment of criteria. Students must pay the fees.




Principal

PRINCIPAL
RAMNIRANJAN JHUNJHUNWALA COLLEGE
OF ARTS, SCIENCE & COMMERCE (AUTONOMOUS)
Ghatkopar (W), Mumbai-400 086, Maharashtra, INDIA

2019: Star College Status by DBT

2008: Best College by University of Mumbai 2010: IMC RBNQ Award 'Performance Excellence' for the year 2009

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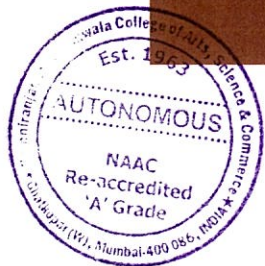
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BROCHURE



Postgraduate Diploma in

Regulatory Affairs



Ushu
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O 5894	Title	:	Post Graduate Diploma in Regulatory Affairs
O 5895	Eligibility	:	B.Pharm, B.Sc (Botany, Zoology, Chemistry, Biochemistry, Biotechnology, Microbiology, Life Sciences), PhD's and Pharmaceutical Professionals
R 8196	Duration of the Course	:	1 Year
R 8197	Fee Structure	:	Rs. 20,000/-
R 8198	Intake Capacity	:	40 Students
R 8199	Teacher Qualifications	:	B.Pharm, M.Pharm, Science Graduate, Post graduate, PhD's and Pharmaceutical Professionals
R 8200	Standard of Passing	:	

- Candidate who secures minimum 50% marks in each paper be declared to have passed the examination in that subject.
- A candidate who fails to secure 50% marks in a paper will be allowed to reappear in that paper.
- Candidate can carry forward at his/her option the marks in the paper in which he/she has passed, in such a case student is entitled for award of class.
- Candidate who secures a minimum of 50% marks in each paper and an aggregate of 60% and above marks on the whole shall be declared to have passed the examination in the First Class.
- Candidate who secures a minimum of 50% marks in each paper and an aggregate of 70% and above marks on the whole shall be declared to have passed the examination in First Class with Distinction.




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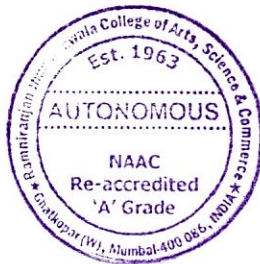
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Syllabus for Post Graduate

Diploma in Regulatory Affairs

Scheme of Examination

Paper	TITLE OF PAPER	MAXIMUM MARKS	MINIMUM MARKS	Credits	PAPER CODE
I	Regulatory Affairs	300	150	24 Credits	PGDRA001
II	Regulatory Affairs	300	150	24 Credits	PGDRA002
	Total	600	300	48 Credits	




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Syllabus for Post Graduate Diploma in Regulatory Affairs

Important to Regulatory Affairs in Pharma Industry

- Basic regulatory framework with respect to Regulated and Non-regulated market practices and procedures.
- Global Pharmaceutical Industry Scenario.

Paper I

24 Credits

Basic ICH Requirement

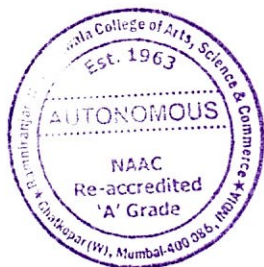
- ICH Topics
- Q1 -Stability
- Q2 -Analytical Validation
- Q3 -Impurities
- Q4 -Pharmacopoeia
- Q6 -Specifications
- Q7 -GMP API
- Q8 -Pharmaceutical Development
- Q9 -Quality Risk Management
- Q10 -Pharmaceutical Quality System
- Q11 -Development and manufacture of drug

Regulatory Filing systems for Active Pharmaceutical Ingredients in different countries.

- EU - ASMF, CEP, EU DMF
- US - DMF application, preparation and annual report.
- Semiregulated Markets- Requirement of API.
- Genotoxic Impurities, Elemental Impurities, Polymorphic form and characterization.
- Various types of DMF
- CTD -Module 1,2,3
- Quality Overall Summary (QOS)
- Quality by design concept applicable to API
- Post approval changes and handling deficiencies

Regulatory Filing systems in Europe.

- EMEA Procedures -Centralized, Decentralized, Mutual recognition and National procedure.
- CTD-Module 1, 2, 3, 4, 5 (including QOS, quality design concept and bioequivalence).
- Variation and Renewals
- Query-Response.



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Paper II

24 Credits

Regulatory Filing systems in US.

- Various Types of application - IND, NDA and ANDA.
- CTD- Module1, 2, 3 and CTD Overall summary -Module1, 2, 3 including quality overall summary and Quality by design CTD module. Module 4 and 5 (including Bioequivalence).
- Post approval changes.

Registration procedures in various countries:

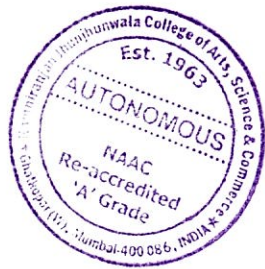
- Australia
- New Zealand
- Canada
- South Africa/Africa
- Latum
- DCGI(India)
- Asia
- Russia/CIS

Pharmacovigilance in EU/US

- Interviews for Regulatory Opening.
- Case study for both US and EU

AUDIT Checklist

- Prior Approval Inspections (PAI)
- Out of Specifications (OOS), Inspection and Audits, Deviations and Change Controls
- Annual Product Reviews (APRs) for Pharmaceuticals



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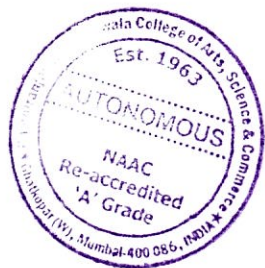
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References:

- Stability Testing of New Drug Substances and Products Q1A(R2)
- Validation of Analytical Procedures: Text and Methodology Q2(R1)
- Impurities in new drug substance Q3A(R2)
- Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances (Q6A)
- Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (Q7)
- Organization of the Common Technical Document For the Registration of Pharmaceuticals for Human Use M4
- DISSOLUTION Guidance (USP pharmacopoeia Chapter 711)




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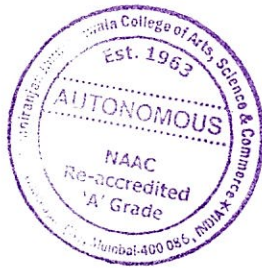
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PG Diploma in Regulatory Affairs

REPORT

The PG Diploma in Regulatory affairs commenced on 31st July 2019. All industries follow. The rules laid down by the regulatory authorities have to be followed strictly. The coordinator of the program was Dr. Dilip Tripathi an expert in regulatory affairs. The session were interactive with active participation of students. Dr. Dilip not only guided students but also helped students in preparing for the interviews. Students were evaluated continuously and on successful completion of the course 30 students were given Post Graduate Diploma certificates.



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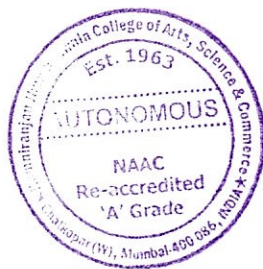
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LIST OF STUDENTS WHO COMPLETED THE COURSE

SR NO	NAME OF THE STUDENTS	ROLL NO
1	Sanghamitra .V. Gawai	201
2	Nutan Balkrishna Bavkar	204
3	Gauri Bhave	205
4	Sonali Ganjave	208
5	Vrishali Gaonkar	209
6	Jobin George	210
7	Saurabh Gurav	212
8	PRANITA PRAMOD HULE	213
9	Trupti Kavale	215
10	Poonam Patil	221
11	Sagar Sudhakar Phad	222
12	Mrunal Posam	224
13	Nilesh Rane	226
14	MADHURA RANE	227
15	YASH V. THANAWALA	233
16	Sonali. G. Vadher	234
17	Gauri Rajendra Vartak	235
18	Chandini Yadav	236
19	Jigna .V.Gogri	239
20	MANALI DILIP DESHMUKH	241
21	Manali M Shukla	231
22	Prajakta Prakash Sawant	229
23	Siddhi Phadte	223
24	Karishma Kacharekar	214
25	PANKAJ TANDEL	232
26	Shivani Parab	237
27	Janhavi S. Ghaisas	211
28	Supriya Murkute	220
29	PRAJAKTA RANE	228
30	Ashwin Singh	240



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CERTIFICATE OF MERIT



This is to certify that

SANGHAMITRA VISHNU SAROJ

has secured

"A+"

in Postgraduate Diploma in Regulatory Affairs

in the examination held in Oct 2020.

Controller of Examination
CONTROLLER OF EXAMINATION
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