



R. J. COLLEGE of Arts, Science & Commerce (Empowered 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

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

Affiliated to UNIVERSITY OF MUMBAI || NAAC Re-Accredited 'A' Grade (CGPA: 3.10)

BROCHURE

Hindi Vidya Prachar Samiti's

RAMNIRANJAN JHUNJHUNWALA COLLEGE (AUTONOMOUS)

(Also known as R. J. College of Arts, Science & Commerce as per UGC Notification)

Affiliated to UNIVERSITY OF MUMBAI || Recognized by UGC under 2f & 12B
NAAC Accredited 'A GRADE' with CGPA 3.50

Knowledge is all Ambrosia

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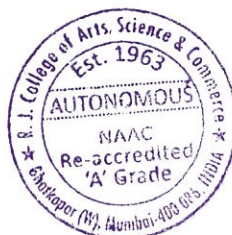
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Postgraduate Diploma in Regulatory Affairs

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rjcollege@rjcollege.edu.in
+91 22 25151763
Opposite Railway Station, Ghatkopar (W),
Mumbai 400 086, Maharashtra, INDIA.



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2011: 'Best Teacher Award' by Government of Maharashtra 2013: DST-FIST 2014: DBT STAR College

2012 & 2014: Jnan Jyoti Award by Govt. of Maharashtra 2016: ISO 14001:2015 2017: ISO 27001:2013



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Hindi Vidya Prachar Samiti's Ramniranjan Jhunjunwala College of Arts, Science & Commerce

Post Graduate Diploma in Regulatory Affairs



Hindi Vidya Prachar Samiti's
Ramniranjan Jhunjunwala College
Of Arts, Science & Commerce
(Autonomous College)

Affiliated to
UNIVERSITY OF MUMBAI

Syllabus for the Post Graduate Diploma

**Program: Post Graduate Diploma in
Regulatory Affairs**

Program Code: **RJSPGDRA**

(Revised Syllabus Academic year 2020-2021)

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Post Graduate Diploma in Regulatory Affairs

Post Graduate Diploma in Regulatory Affairs

Program Code: RJSPGDRA

Preamble:

The post graduate Diploma in Regulatory Affairs is designed to produce trained manpower who are highly qualified to manage the regulatory process for companies innovating in new product developed. Regulatory affairs is a profession developed by the government to protect public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicine. This program will help in training manpower to work in an ever-growing industry. There is a wide variety of careers in the regulatory affairs. Regulatory professionals can work as Regulatory affair specialist, manager, director, compliance specialist, food safety inspector, Director of quality assurance.

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Post Graduate Diploma in Regulatory Affairs

Title: Post Graduate Diploma in Regulatory Affairs

Eligibility: B.Pharm, B.Sc (Botany, Zoology, Chemistry, Biochemistry, Biotechnology, Microbiology, Life Sciences), PhD's and Pharmaceutical Professionals

Duration of the Course: One Year (Part- time) Blended teaching weekends

Fee Structure:

Tuition Fee	:	25,000.00
RFID	:	150.00
Examination Fees	:	500.00
Application form fees	:	Rs 100.00

Intake capacity: 40 students

Faculty: Drawn from Industry and Academia Proficient in areas of horticulture, Botany, plant propagation, consultant

Standard of Passing

a. Candidate who secures minimum 50% marks in each paper be declared to have passed the examination in that subject.

b. A candidate who fails to secure 50% marks in a paper will be allowed to reappear in that paper.

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Post Graduate Diploma in Regulatory Affairs

- c. 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.
- d. 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.
- e. 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.

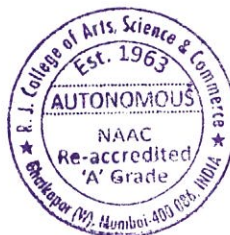
Medium of Instruction English

Scheme of evaluation:

There would be continuous evaluation with internal assessment of MCQ, quiz, presentation, assignment, 40% weightage,

External evaluation: Subjective with 60% weightage

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Post Graduate Diploma in Regulatory Affairs

Semester	TITLE OF PAPER	MAXIMUM MARKS	MINIMUM MARKS	Credits	Course CODE
I	Regulatory Affairs-I	300	150	24 Credits	RJSPGDRA101
II	Regulatory Affairs-II	300	150	24 Credits	RJSPGDRA102
	Total	600	300	48 Credits	

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PGD in Horticulture and Landscape Gardening

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.

Semester I RJSPGDRA101

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

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PGD in Horticulture and Landscape Gardening

- 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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Hindi Vidya Prachar Samiti's Ramniranjan Jhunjhunwala College of Arts, Science & Commerce PGD in Horticulture and Landscape Gardening

Semester II RJSPGDRA201

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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PGD in Horticulture and Landscape Gardening

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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LIST OF STUDENTS WHO ENROLLED FOR POSTGRADUATE DIPLOMA IN REGULATORY AFFAIRS

Sr No	Full Name	Roll no
1	TELAWADE ANKITA KAILAS ARCHANA	1001
2	CHATTERJEE SHREYA SANDEEP KAKOLI	1002
3	POWALKAR ADITYA DEVENDRA DIPIKA	1003
4	KANDASWAMY VAGITA THANGARAJ LAXMI	1004
5	BHOJANE ABHISHREE ANIL ANITA	1005
6	SINGH MADHULIKA SANTOSH SARITA	1006
7	SAWANT SAYALI NETAJI TANUJA	1007
8	SHINDE BHAKTI SABAJI SNEHA	1008
9	CHAUHAN SANI ARVIND GEETADEVI	1009
10	RAMRAO SHUKLANGI GHOLAP KRUPALI	1010
11	PATIL KRUNALI GAJANAN PRADNYA	1011
12	GHADGE SRINATH VILAS VIJAYA	1012
13	POOJARY SHOBETHA RAJU GEETHA	1013
14	PAWAR BLOSSOM RAJENDRA POORNNIMA	1014
15	BAGWE ASHISH ANIL APARNA	1015
16	JAMKHANEWALA NAIF AHMED NAVID AHMED NUZHAT NAVID	1016
17	TANK SHRUTI JAYANTIBHAI JAYABEN	1017
18	UPADHYAY ANURAG SANTOSH MEERA SANTOSH UPADHYAY	1018
19	PATIL BHAGYASHREE RATNAKAR SHOBHA	1019
20	KADAM SNEHAL LALASAHEB SAVITA	1020
21	DHEPE SHREYA NAMDEV NALINI	1021
22	JAISWAL POOJA RAMJEET REKHA	1022
23	SALGAONKAR GAURI GOKULDAS DAKSHA	1023
24	BANDBE MITALEE MANOHAR MEGHA	1024
25	YADAV SURAJ UMASHANKAR RITA	1025
26	GOVEKAR PRASAD KESHAV LAKSHMI	1026





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27	MODAK AMOL ATMARAM APARNA	1027
28	SHETTY NIDHI UDAY VANITA	1028
29	DABHOLKAR POOJA VINAYAK VEDA	1029
30	BAPU SHIVANI GAIKWAD MAYA	1030
31	BAGUL DHANASHREE HEMANT KALPANA	1031
32	CHOUDHARY NAIMUDDIN NIZAMUDDIN SHAHIDA	1032
33	KADAM SHRADDHA DEEPAK MANISHA	1033
34	SOMOSHI BHUSHAN DASHARATH MINAKSHI	1034
35	THAKUR KHUSHI KIRTI GAYATRI	1035
36	CHANDAKKAR OMKAR ASHWINIKUMAR PRAJAKTA	1036
37	ROY PREETI BAPI DOLLY	1037
38	SHINDE ANUSHKA SATISH ALKA	1038
39	PRAJAPATI ANSHU BHOLENATH SARITA	1039
40	SHAIKH SHAHID RASHID SURAIYA	1040
41	SHINDE REEMA SUNIL SANTOSHI	1041
42	DEEKSHA GANGADHAR HARSHINI	1042
43	AHIRE DIGAMBAR NIMBA ANJANABAI	1043
44	BEHERE RINA VINOD PRATIBHA	1044
45	NEHA SUNIL SMITA	1045
46	HANDE ROHIT MOHAN ANITA	1046
47	PATIL AKANKSHA RAMESH ASHATAI	1047
48	BHILARE ANIKET PANDURANG SEEMA	1048
49	JAIWAR RACHANA UDAYBHAN RENU	1049
50	PATIL PRANALI ANIL SUWARNA	1050
51	SUTHAR BHAVESH VISHALAL USHA	1051
52	DONGARE SONALI ANAND KANCHAN	1052
53	KADAM SHALMALI HEMANT CHAITALI	1053
54	JADHAV DEEKSHA BHIMDAS MANSI	1054




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24	SOMOSHI BHUSHAN DASHARATH MINAKSHI	1034
25	THAKUR KHUSHI KIRTI GAYATRI	1035
26	CHANDAKKAR OMKAR ASHWINIKUMAR PRAJAKTA	1036
27	ROY PREETI BAPI DOLLY	1037
28	SHINDE ANUSHKA SATISH ALKA	1038




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2019: Star College Status by DBT

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

2011: 'Best Teacher Award' by Government of Maharashtra 2013: DST-FIST 2014: DBT STAR College

2015: ISO 41001:2015 2016: ISO 9001:2015 2017: ISO 27001:2013



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

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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

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29	SHAIKH SHAHID RASHID SURAIYA	1040
30	SHINDE REEMA SUNIL SANTOSHI	1041
31	SAPALIGA DEEKSHA GANGADHAR HARSHINI	1042
32	BEHERE RINA VINOD PRATIBHA	1044
33	HANDE ROHIT MOHAN ANITA	1046
34	PATIL AKANKSHA RAMESH ASHATAI	1047
35	JAISWAR RACHANA UDAYBHAN RENU	1049
36	PATIL PRANALI ANIL SUWARNA	1050
37	SUTHAR BHAVESH VISHALAL USHA	1051
38	DONGARE SONALI ANAND KANCHAN	1052
39	KADAM SHALMALI HEMANT CHAITALI	1053
40	JADHAV DEEKSHA BHIMDAS MANSI	1054




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CERTIFICATES

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(Empowered Autonomous College)
AFFILIATED TO UNIVERSITY OF MUMBAI

CERTIFICATE

This is to certify that
TELAWADE ANKITA KAILAS ARCHANA
has secured
'O' Grade
and earned **48 Credits**
In Postgraduate Diploma in Regulatory Affairs
In the examination held in September 2024 and result declared on 30 September, 2024.


Maj. Pravin Nayak
Controller of Examination


Dr. Himanshu Dawda
Principal

Certificate ID: PGDRA-202324-01

Hindi Vidya Prachar Samiti's
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(Empowered Autonomous College)
AFFILIATED TO UNIVERSITY OF MUMBAI

CERTIFICATE

This is to certify that
CHATTERJEE SHREYA SANDEEP KAKOLI
has secured
'A+' Grade
and earned **48 Credits**
In Postgraduate Diploma in Regulatory Affairs
In the examination held in September 2024 and result declared on 30 September, 2024.


Maj. Pravin Nayak
Controller of Examination


Dr. Himanshu Dawda
Principal

Certificate ID: PGDRA-202324-02




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2013 & 2014: 'Jagar Jaanivancha Award' by Govt. of Maharashtra 2016: ISO 14001:2015 2016: ISO 9001:2015 2017: ISO 27001:2013

2017: ISO 27001:2013 & by University of Mumbai (No.Aff./ICD/18-19/440 - 08.06.2018)