

Post Graduate Diploma in Regulatory Affairs



Hindi Vidya Prachar Samiti's  
**Ramniranjan Jhunjhunwala 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)*





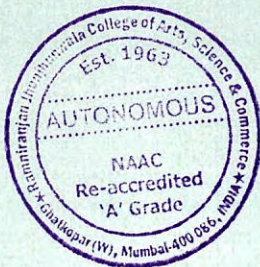
**Post Graduate Diploma in Regulatory Affairs**

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**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.





### **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**

- 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.





**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,

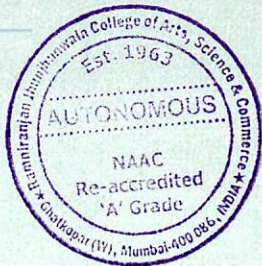
External evaluation: Subjective with 60% weightage





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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
	<b>Total</b>	<b>600</b>	<b>300</b>	<b>48 Credits</b>	





**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







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

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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 || NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

## Admission Procedure Booklet

[admission21-ppt-PG-FY](#)

### STEP 1: Filling of the Online admission Form

Online Registration on the portal

<https://admission.rjcollege.edu.in//firstyear/#/login>

<https://admission.rjcollege.edu.in//firstyear/#/first-register>

Students who have passed TY in 2021-22 can use their login id and password of TY for Login <https://admission.rjcollege.edu.in//firstyear/#/login> and students of other college and previous years should register fresh on portal <https://admission.rjcollege.edu.in//firstyear/#/first-register>

7. If there are any changes in dates, the revised schedule will be notified on the website, and students are requested to abide by this and keep looking into this page for notification
8. Portal will open on 10 June 2022.
9. Admission to for PGD Programs will be based on Sem V Marks. Hence, Students applying are required to enter the Sem V marks obtained and total marks in the Educational Details Tab. If you don't have marks obtained and total marks in the marksheet get a conversion certificate from your parent college.
10. Students are required to enter the correct mobile no (WhatsApp no) and email id while filling the online form since all communication will be sent on the same email id and WhatsApp no.
11. Students have to fill all the details correctly.
12. Students of Hindi Linguistic Minority should tick on Hindi Minority Option as Yes and if you have marked Yes then only you will be considered under Hindi Linguistic Minority Quota.

### STEP 2: Admission

8. Admission will be on First cum First basis for Postgraduate Diploma Courses. Once you submit your form wait for 24 hours. The fee payment tab will get activated. Once the seats are full the admission will close. No Merit List.
9. All Admission are provisional, subject to verification of documents and fulfilling the eligibility criteria for the course applied. If the documents and eligibility criteria is not fulfilled, the admission will be cancelled.
10. Your admission will be cancelled if any false information is provided for eg. Wrong entry of Sem V marks, not falling under Hindi Minority Quota, Failed or have pending ATKT in any of the semester.
11. The admission is based on merit and the College does not accept any donation for any admission.
12. The Principal decision will be final and principal reserves the right to refuse admission for non-fulfilment of eligibility criteria of UGC and University of Mumbai
13. First preference will be given to students of 2021-22 batch
14. Refund rules are available on the website for reference.



  
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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

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

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## PGD in Regulatory Affairs

Eligibility	: Any Science Graduate
Duration	: 1 Year
Class Time	: Sunday (11.00 am to 2.00 pm)
Fees	: Rs. 26200/-
Syllabus	: <a href="#">Link</a>



  
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## LIST OF STUDENTS WHO ENROLLED FOR THE COURSE IN 2022-2023

SR NO	Full Name	Roll No
1	VIKRANT MOHAN ASHA	1019
2	ANGANE SANAVI PANDURANG PRAMILA	1017
3	ANGRE AISHWARYA RAMESH PRIYANKA	1011
4	BABAR ROHINI GORAKH VIMAL	1030
5	BHANDI SANJAYKUMAR BISWAMBER JAYANTI	1012
6	CHAURASIYA VINAY KANHAIYALAL ANITA	1026
7	GHODKE MADHURA CHANDRASHEKHAR SUMANGALA	1013
8	GORIVALE ASHWIN BALKRISHNA KAVITA	1043
9	JADHAV ARCHANA ASHOK MEENA	1003
10	JADHAV SHUBHAM SUBHASH SHAILA	1041
11	KADAM NIKITA KISAN NANDA	1002
12	KADAM PRIYANKA VIJAY SHOBHA	1035
13	KALE SAKSHI BHARAT SHUBHANGI	1005
14	KALE VAISHNAVI CHANDRAKANT RASHMI	1010
15	KANE NEHA UTTAM MANISHA	1004
16	KAZI NIDA IMTIAZ NAZIMA	1036
17	KULKARNI ROHIT RASIK RACHANA	1031
18	LOKHANDE SHEETAL MADHUKAR LALITA	1040
19	LOTLIKAR LOKE VEERAJA MAHESH SUCHITA	1037
20	MALI PRAJYOT PRAKASH LATA	1009
21	MARALE KAJARI PRAKASH MEENA	1006
22	MAURYA SANDHYA MANOJKUMAR SANGEETA	1028
23	MUNDRA AMRIT KAUR SURINDER SINGH MANPREET KAUR	1001
24	PATHAK PRIYANKA RAJESH RITA	1015
25	PATIL KAMLESH RAMESH KALPANABAI	1038



  
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26	PATIL KIRAN SURESH BABY	1022
27	PATIL NIKITA SANJAY SARALA	1034
28	PAWAR PRATIK MADHUKAR MADHAVI	1025
29	RAJBHAR LAXMI OMPRAKASH RAJBHAR SUSHILA	1014
30	RASAL SALONI SUDHIR MOTHER	1018
31	SAHANI SANTOSH VIRENDRA USHA	1027
32	SALEKAR ASHA TEJRAO GANGA	1008
33	SANAP GANESH JAGANNATH RADHA	1029
34	SAWANT KSHITIJA RAMCHANDRA RAJNEE	1044
35	SAWANT SMRUTI SAMEER SWATI	1032
36	SHAIKH ADNAN MOHD ALAMGIR ZARINA	1039
37	SHEMNA KASHISH MOHD GOUS RUBINA	1020
38	SHIDRUK SHITAL BHARAT KUSUM	1016
39	SONAWANE NABHA BHANUDAS NANDA	1042
40	SUTAR PRAJAKTA DILIP KARUNA	1024
41	SWAIN BINDIA KALIA CHHABI	1023
42	TIWARI ANKIT SHOBHNATH USHA	1021
43	VARMA ABHISHEK SANDEEP SANGEETA	1033



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## LIST OF STUDENTS WHO COMPLETED THE PROGRAM IN 2021-2022

Sr NO.	Name	RollNo
1	BAGKAR ADITYA AVINASH ANUSHREE	1
2	BHOSALE ROHIT DATTATRAY LATIKA	2
3	DESHMUKH RUTUJA VIJAYKUMAR POOJA	3
4	MAYEKAR SHRADDHA LAHU CHAYA	4
5	GHODAKE CHAITALI VIJAYKUMAR SWATI	5
6	JADHAV NAMRATA MOHAN SANGEETA	6
7	JAGTAP RAJPAL SHIVAJIRAO SHAU	7
8	KARANDE PREM KRUSHNAT SANGITA	8
9	PAL AJAY RAJENDRA NITA	9
10	PARVE VARAD KISHOR PADMINI	10
11	PATIL DHANASHREE HARIBHAU PUSHPA	11
12	PRAJAPATI TEJAL KISHOR VANITA	12
13	RABHADIA JAGRUTI GIRDHAR RATAN	13
14	SALVI GIRISH NARAYAN ARUNA	14
15	SAWANT MITALI SURESH SUVARNA	15
16	SHAIKH SALMAN RAZIN ZAHIRA	16
17	SHEWALE GUNJAN RAJENDRA SUNITA	17
18	SHIGWAN RUTUJA ABHIJIT ASAWARI	18
19	SURYAGANDH VIVEK ASHOK SHARDA	19
20	SHINDE SNEHAL AMBADAS USHA	20
21	SHITOLE PRIYA BAPU YOJANA	21
22	SIDDIQUE ADNAN REHMATULLAH ARIFA	22
23	THORAT VAIBHAV BHAV VANITA	23
24	WAGH ARCHANA AMEET PRABHAKAR LAHANUBAI	24
25	YADAV DEEPAK CHHABIRAJ ISHRAVTI	25
26	YADAV MANISHA ANIL SUSHEELA	26
27	YADAV NADINI AWDESH MEENA	27
28	YADAV POOJA BHIRGUNATH SHUSHILA	28
29	MER ANJALI JAGDISH ARTI	29
30	PAWAR ASHWIN RAJENDRA SNEHAL	30
31	KADAM RACHANA MANOJ MINAL	31
32	SHINDE ASHWINI DAYANAND SADHANA	32





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# **CERTIFICATE OF MERIT**



This is to certify that

**BAGKAR ADITYA AVINASH ANUSHREE**

has secured

**"A+"**

in Postgraduate Diploma in Regulatory Affairs

in the examination held in August 2022.

Controller of Examination

Certified as  
**TRUE COPY**

**Principal**

**Ramniranjan Jhunjhunwala College,  
Ghatkopar (W), Mumbai-400086.**

Principal

**Certificate ID: PGDRA-202122-01**

Date of Declaration: 6<sup>th</sup> September, 2022



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Principal

**Certificate ID: PGDRA-202122-02**

Date of Declaration: 6<sup>th</sup> September, 2022