HKCP ALUMNI BULLETIN

Issue–VI, June – 2012

From the Editors Desk:

Dear Alumni,

I am pleased to present a sixth issue of Alumni Bulletin. Good news is that M Pharm. course in Pharmaceitics will commence from July 2012 at H.K. College of Pharmacy , HK Campus Jogeshwari(w), Mumbai. The alumni interested in pursuing the course may contact Office staff for futher enquiry. The bulletin includes the eligibility criterias for M.Pharm admission.

In success secrets series we have introduced about a career in drug regulatory affairs by faculty Mr Shrikant Boharupi from the Department of Medicinal Chemistry. The job of regulatory affairs is keeping a track on ever changing legislation in all countries where company is looking to market the product. and advising both strategically and technically at the highest level. Role involves from development to marketing and even post marketing.

Please do send your opinions and suggestions to make our bulletin more and more informative and interactive. You can contribute by sending your articles any professional achievement .

Sushruta Mulay.

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Eligibility Criteria for M Pharm:

a) To appear in MAH-MPH-CET 2011 : 2011 :

The candidate who does not have valid GPAT-2011 score shall have to secure non zero score in MAH-MPH-CET 2011 to be eligible for claiming admission, subject to the condition that no GPAT qualified candidate is available in respective category.

Candidate who has passed B.Pharm degree or appeared in final year / final semester of B.Pharm from any AICTE approved institution affiliated with university (approved by UGC), subject to the condition that they must produce proof of passing B.Pharm. examination as per M.Pharm. admission eligibility criterion in original at the time of admission by counseling round.

Note: The MAH-MPH-CET 2011 examination will have the same curriculum, pattern (only objective questions) similar to GPAT 2011. However there will be no negative marking system in MAH-MPH-CET 2011.

b) For Admission to M.Pharm. through GPAT QUALIFIED CANDIDATES:

Candidate should be an Indian National and who possess Bachelors degree or equivalent in Pharmacy from an AICTE approved institutions, with at least 50 % marks (at least 45% marks in case of SC/ ST category belonging to Maharashtra State Only)

AND

Should have valid and qualified GPAT 2011 Score.

c) For Admission to M.Pharm. through MAH- MPH- CET 2011 Candidates:

Candidate Should be an Indian National and who possess Bachelors degree or equivalent in Pharmacy from an AICTE approved institutions, with at least 50% marks (at least 45% marks in case of SC/ ST category belonging to Maharashtra State Only)

AND

Should have Non zero Score in MAH- MPH- CET 2011, if the candidate has neither appeared for GPAT non having and qualified GPAT score.

d) Other eligibility criteria:

For Sponsored seats:

1. The eligible candidate as per rule no.1.6 should submit a Certificate from his/her employer strictly as per Annexure-II with following documents
   a. Appointment letter
   b. Joining letter
   c. Current experience certificate
   d. Sponsorship letter (As per Annexure II)
   e. Relieving letter (at the time of joining the course)
2. The candidates who have minimum 2 years experience are only eligible for claiming sponsored seats.
3. No reservation is available for SC/ST category candidates for sponsored seats. However preference will be given to SC/ST candidates in case of equal merit.

1) Pharmaceutics	I Pharmaceutics II Pharmacology, Toxicology and Therapeutics III Medicinal Chemistry IV Advanced Pharmaceutics V Biopharmaceutics and Pharmacokinetics

Examination Scheme :

SEMESTER I

Subjects	Teaching	Examination	
	Hours/ week	Hours	Marks
Core Subject I	2	2	50
Core Subject II	2	2	50
Core Subject III	2	2	50
Elective I	2	2	50
Elective II	2	2	50
			Total 250

SEMESTER II

Subjects	Teaching	Examination	
	Hours/ week	Hours	Marks
Core Subject IV	2	2	50
Core Subject V	2	2	50
Elective III	2	2	50
Elective IV	2	2	50
Seminar	2	2	50
			Total 250

There will be 2 sessions of 1.0 hour each for each subject and each elective per week.

The students will start with the research work in the laboratory in this semester under the supervision of a recognized research guide.

SEMESTER III

Every student will continue with his/her research project in this semester. Each students will give an exit seminar (Research colloquium) on the topic or his/her research project before submitting the thesis.

The candidates must submit their research synopsis at the end of the 16 (sixteen) months

from the date of registration.

Examination Scheme

Each paper in semester I and semester II will be of 50 marks. The duration of the paper will be 2 hours. The seminar in semester II shall carry 50 marks to be assigned as follows:

Scientific content	**Presentation, Communication, Slides etc.**	**Discussion**	**Report**
10	**10**	**10**	**20**

Successful candidate shall be awarded classes, as under jointly on the basis of the Semester I and Semester II examination and the thesis submitted by them:-

1) Those obtaining 65% marks or more of the grand total
   at both the Semester I and Semester II examination taken

together and grade A in the thesis - First class with distinction

2) Those obtaining 65% marks or more of the grand total at both the Semester I and Semester II examination taken together and grade B in the thesis - First class

3) Those obtaining 55% marks or more of the grand total at both the Semester I and Semester II examination taken together and grade A in the thesis - First class

All other cases - Second class

Pass the Semester I and Semester II examination, a candidate must obtain at least 50% of marks in each subject, each elective and seminar.

Campus News:

Campus interview TCS and Unichem

- **Unichem Laboratories Ltd** conducted a campus recruitment drive at HK Campus on 13 th March 2012 for the final year students of HKCP.
  38 students participated in interview and 9 were elected.
- **Tata Consultancy Service(**TCS) conducted a campus recruitment drive at HK Campus on 16th March 2012 for the final year students of HKCP.
  38 students participated and 5 students were selected.

Research Projects by HKCP-Faculties:

The following research projects have been published from the H.K.College of pharmacy under Mumbai university minor research project scheme-2011.

- **Dr. Anubha Khale-Principal and H.O.D.-Pharmaceutics "Design and evaluation of transdermal patch of antimigraine drug - sumatriptan succinate."**

- **Archana Bele-Assistant Professor- Dept of Pharm. Analysis "Antioxidant and antibacterial evaluation of a herbal formulation."**

- **Jaya Agnihotri- Assistant Professor- Dept of Pharmaceutics.: "Biodegradable cellular carrier based delivery of antimalarial drug"**.

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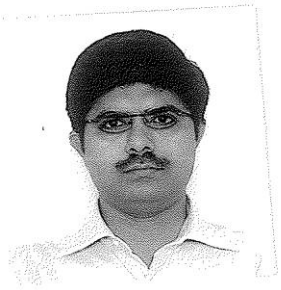
- **Parimal Kotkar- Assistant Professor- Dept of Pharmacognosy: "Standerdisation method for extraction of allicin from allium cepa and its phytochemical screening."**

Introduction of new faculty in Dept of Medicinal Chemistry:



Dr Kamlesh Soni

- Pursued M.Pharm. from Institute of Chemical Technology (ICT), Mumbai
- Pursued PhD from Central Drug Research Institute, HNB Garhwal University, Garhwal
- Published 8 research papers in reputed International journals

- **Research Interest**:- Synthetic carbohydrate chemistry, Heterocyclic chemistry, Microwave assisted organic synthesis
- **Teaching experience**:-

  S.V.B.'s College of Pharmacy, Dombivali, Mumbai University

  Institute of Pharmacy, Nirma University, Ahmedabad

  St. John Institute of Pharmacy and Research, Palghar, Mumbai University

- **Industrial experience**:-

  Worked as management trainee in Cadila Pharmaceuticals, Ahmedabad

Career in Drug Regulatory Affairs

Career in drug regulatory affair

#Meaning of drug regulatory affair

- It implies the confirmation regarding compliance of pharmaceutical product with respect to regulation governing industry.

- The initial application phase for a new or generic drug.

-In the licensing and marketing stages – making sure all operations and products meet required safety and efficacy standards.

#Task for Pharma regulatory affairs jobs

-Keeping on top of the latest developments within the industry.

-Writing product labels and patent information.

-Collecting and collating large amounts of information and preparing licensing submissions.

-Liaising with doctors and scientists, conducting clinical trials and negotiating with regulatory authorities.

-Undertaking and managing regulatory inspections within the company and reviewing practices when required to meet with new or updated regulatory requirements.

-Keeping of track of the ever-changing legislation in all the regions in which the company wishes to distribute its products.

-The presentation of registration documents to regulatory agencies, and carry out all the subsequent negotiations necessary to obtain and maintain marketing authorization for the products concerned.

-Take part in the development of the product marketing concepts and is usually required to approve packaging and advertising before it is used commercially.

#Importance of Drug regulatory affairs in Industry

The importance of the Regulatory Affairs function is such that senior Regulatory Affairs professionals are increasingly being appointed to boardroom positions, where they can advise upon and further influence the strategic decisions of their companies. The proper conduct of its Regulatory Affairs activities is of considerable economic importance for the company. A good Regulatory Affairs professional will have a 'right first time' approach and will play a very important part in coordinating scientific endeavor with regulatory demands throughout the life of the product, helping to maximize the cost-effective use of the company's resource. The attitudes and actions of the Regulatory Affairs professionals will condition the perceptions of the government officials to the company -for better, or for worse!

DRA is a dynamic, rewarding field that embraces both scientific and legal aspects of drug development. DRA professionals are dedicated individuals who take pride in their contribution to improving the health and quality of life of civilians.

#Qualities of good Regulatory Affairs professional

The regulatory specialist is central to the business and has the opportunity to interact with a wide range of specialities and extend his or her knowledge while doing so. Following are the some qualities of good regulatory professional.

-The ability to tackle data in a wide range of scientific areas

-Communication skills are very important.

-Analysis of issues and presenting both written and oral evidence before a panel of experts such as scientists, pharmacists, doctors and lawyers who run the government agencies require considerable understanding of both legal and scientific matters, Project management skills help to achieve the challenging goals they are set, Integrity and the ability to inspire trust and confidence are valuable attributes .

What you will need to become a RA professional :-

- A good background knowledge of the pharmaceuticals and medical environment.
- A meticulous approach to work .
- Attention to detail.
- Academic Qualification in Regulatory Affairs like degree or diploma in regulatory affairs from recognized institute.

We can expect to work in a multidisciplinary workplace where scientists and medics will come from very different backgrounds. Excellent written and verbal communication skills are a must as is the ability to work effectively under pressure.

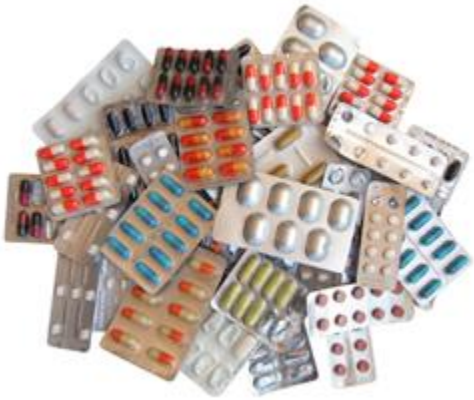
#Job Opportunities and Job Roles:

The jobs available are:

- In Federal Regulation of Drugs & Pharmacy
- Research Methods
- Ethics in Drug Production, Distribution
- Patient Safety Program Evaluation
- Pharmaceutical Health Economics
- Pharmaceutical Products
- Use and Abuse of Statistics
- Clinical research
- Health Care Risk Management
- Patient Responsibility in Health Care
- Health Care & Patient Safety

Research Updates

Top 10 Late-Stage Cancer Drugs – 2012



Thousands of experimental meds are winding their way through various stages of clinical trials today, and the largest category among the contenders is cancer drugs. Of the hundreds of cancer programs under surveillance at *FierceBiotech*, we've culled the most promising programs we could find.

We welcome contrary views about our picks, but we saw four of the 10 drugs we selected last year--Seattle Genetics' ($SGEN) Adcetris (brentuximab vedotin), Pfizer's ($PFE) Xalkori (crizotinib), Plexxikon's Zelboraf (vemurafenib, formerly code-named PLX4032) and Roche's ($RHHBY) Erivedge (vismodegib)--gain FDA approvals since last year. The others remain in the hunt for regulatory nods, and we've included many of them in this year's roundup.

Like in last year's edition of this report, we've emphasized drugs that are at the very least headed into late-stage development. Most of the programs featured have provided compelling safety and efficacy data, yet we also highlighted a lesser-known drug called BBI608 because it's an excellent example of how the field of new drugs targeting cancer stem cells has matured. Dainippon Sumitomo saw enough promise in the program to scoop up its developer, Boston Biomedical,in a deal that could be worth more than $2.6 billion.

Please alert us to what you think are glaring omissions and, importantly, tell us why those missing programs should have been included here. For instance, To be clear, we've only included drugs here that are new biologics or chemical entities that haven't been approved yet. -- Ryan McBride (Email | Twitter)

- BBI608 – Top 10 Late-Stage Cancer Drugs – 2012
- Cabozantinib – Top 10 Late-Stage Cancer Drugs – 2012
- Carfilzomib – Top 10 Late-Stage Cancer Drugs – 2012
- Enzalutamide (formerly MDV3100) – Top 10 Late-Stage Cancer Drugs – 2012
- Ponatinib – Top 10 Late-Stage Cancer Drugs – 2012
- Regorafenib – Top 10 Late-Stage Cancer Drugs – 2012
- Talimogene laherparepvec (OncoVex) – Top 10 Late-Stage Cancer Drugs – 2012
- T-DM1 (trastuzumab emtansine) – Top 10 Late-Stage Cancer Drugs – 2012
- Tivozanib – Top 10 Late-Stage Cancer Drugs – 2012
- Zaltrap (aflibercept concentrate) - Top 10 Late-Stage Cancer Drugs – 2012