Pharma Life

MET IMS wins scientific paper presentation at 60th IPC 2008

Page 108

Making the right choice

The clinical research industry in India is growing exponentially and a number of institutes have flourished to produce candidates to meet this heavy demand for trained people. **Usha Sharma** tracks the career options available

As per ancient Indian philosophy, there were four stages in a man's life—the student, the householder, the retired person, and the ascetic. learning was deemed to end as soon as a student left his teacher's gurukul, married and took up family responsibilities. Today, however, increasing competition and the speed at which knowledge is updated and outdated, has ensured that 'continuous learning' and re-training are the norm than the exception. Thanks to technology, time and distance are today no constraints and learning has moved from the traditional classroom-chalk-and-talk routine to options like online courses, distance learning and e-learning

The pharmaceutical industry is no different. As industry dynamics change, new career options open up and professionals need to re-train to meet evolving industry demands. In India, the evolution from the pre-GATT era to a global level playing field has subsequently opened up new avenues like Contract Research and Manufacturing Services (CRAMS) and clinical research (CR), to name but two of the options.

Indian pharma companies hold a very strong advantage over Western pharma companies in terms of cost of production and reverse engineering skills. India is becoming one of the most favoured destinations for pharma exports with the country exporting drugs worth of $7.2 billion in 2007-08, according to RNCOS, a market research agency. The report also states that the pharma industry will grow at a rate of nearly 18.5 percent by 2008-12.

Today, as many molecules lose patent protection and pharma companies test new molecules to replace these in their product portfolios, there is increasing concern about the safety profile of these new medicines. The pharma companies find themselves having to meet increasing tougher regulatory standards across the world. At present, the average timeline for development of a new drug is approximately 15-20 years and costs nearly $800 million. Therefore, this is seeing more work in branches of CR (like clinical trial management, clinical data management and drug development) move towards India.

As per a McKinsey & Co report, by 2012 when Indian pharma industry size is expected to be $2 billion and during the same time professional's manpower requirement would be approximately 50,000 professionals.

Considering that as per estimates, there are only 10,000 Indian CR professionals are available today, there could be a massive talent shortage facing the industry four years hence.

Sensing this skills gap and future demand, many CR education institutes have mushroomed across Indian metros over the past few years. Commenting on overall market scenario, Medha A Joshi, Principal, Bilcare Research Academy, says, "Even if we put together all the institutes in India, the number of students will come, well short of the actual demand. This is one industry where the difference between the demand and the supply is still huge. The CR industry is poised to grow at a rate of nearly 31 percent to reach $2 billion by 2012. This will create a heavy demand for trained and certified professionals who can expect to be paid six-figure salaries at even the entry-level."

Cliniminds, a Delhi-based CR education and training academy, estimates that at present, industry needs about 10,000 new professionals in a year. There are 150-170 companies involved in CR. There are over 1,500 sites including independent investigators and hospitals where trials are being conducted at present.

Dr Shamsher Dwivedi, Program me Director, RNIS College of Clinical Research and Allied Sciences, says, "As far as teaching and training industry is concerned, I feel it would see a boom for another five years after which it would plateau off. Those players who would run specialised and advanced training modules would stay in the race."

"In US, the programmes are run by both Universities and private institutions. However, Indian courses definitely follow the International Conference on Harmonisation and Good clinical practice (ICH GCP) principles as the foundation for programmes. And it also covers the Schedule Y; ICMR guidelines; US Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Par 21 and other international guidelines / regulations in our programmes

Kamal Shahani
CEO
Cliniminds

CR education can be broadly divided into two basic types

1) Full time courses conducted by standalone institutes like Institute of CR India (ICRI), Clinical Research Education and Management Academy (CREMA), Bilcare Research Academy Cliniminds, Mpower Institute of Clinical Research, RNIS etc. These are generally targeted at entry level professionals, ie fresh graduates and are full time courses. Some like Bilcare Research Academy and CREMA are residential courses while others are run over the week end, while the students train at CROs during the week, as in International Center for Training in Clinical Research (ICTCR), course based out of Khalsa college in Mumbai. For the students these institutes make them 'industry ready', equipping them with the right skill set required for CR jobs and enabling them to tap new career opportunities in this burgeoning field. Clinical research courses are also being conducted in graduate colleges at the MSc level.

2) Selected courses and workshops conducted by CROs like the UK-based Symogen and the Ahmedabad-based Synchron or Associations like Indian Society for CR (ISCR). These tend to be more advanced, in terms of course/workshop content, in specialised modules like pharmacovigilance, quality assurance, etc and target the mid and senior level CR professional, who see it as a re-training/skills upgradation opportunity. These programmes assist pharma companies and CROs in continuously upgrading the skills of their teams by keeping their employees in touch with the recent trends, regulations and skill set required to perform their roles.

For instance, Bilcare Research Academy offers all-rounded training through specific modules in different fields such as clinical data management and pharmacovigilance. This comprehensive programme trains the candidate to meet the exact criteria which the industry is looking for. Courses are designed in such a way that it will take care of production and safety matters in the pharma as well clinical research organisation (CRO) activity. Various courses are being offered in different fields and specialisations such as clinical trial management, pharmacovigilance and clinical data management. "Our course which integrates all of these together and is certified would be ideal as it would cater to all the demands from the industry. These courses create professionals who are domain experts in their respective fields. This would be advantageous as the industry will not need to waste time and money in training these professionals," Joshi comments.

"Even if we put together all the institutes in India, the number of students will come well short of the actual demand. This is one industry where the difference between the demand and the supply is still huge

Medha A Joshi
Principal
Bilcare Research Academy Bilcare

Practice while you learn

Institutes are aware that 'theory' will not suffice in a CR setting, and therefore, go to lengths to insure that courses are industry-oriented, by inviting lecturers from industry. Courses are designed in consultation with the industry to meet current challenges.

"Many institutes are conducting courses on CR. As we know about the global requirement of trained professionals in various branches of clinical research viz, regulatory, pharmacovigilance, clinical data management, medical and scientific writing etc the industry is in demand of these professionals to take the challenging responsibilities to meet the Indian trials to global standards, avers, Dr S Malini, Chief Course Coordinator, Mpower Institute of Clinical Research.

Also as the cost of an average one year full time course in CR costs Rs one lakh and is substantially more expensive than other courses, students and their parents are looking to recover this investment as fast as possible. Hence, placement guarantees have proved a big draw.

CR institutes like CREMA Cliniminds ➤

and Bilcare Research Academy offer to place successful students in pharma and CRO firm. "Successful placement of students at CREMA in companies is a testimony to the fact that our courses create industry ready professionals," asserts Vijay Moza, Chairman, CREMA.

"We are also the one CR institute in the industry which give assurance to their students while entering the institute campus. We are the only institute in the industry who provide online training to students. Over here student can pay online and study the course online; give exam online and get online certificate. At present we cater to the students not only from India, but also from United States, UK, Canada, Africa and Middle East," Sahani added.

> "Many institutes are conducting courses on clinical research. As we know, about the global requirement of trained professionals in various branches of clinical research viz., regulatory, pharmacovigilance, clinical data management, medical and scientific writing etc the industry is in demand of these professionals to take the challenging responsibilities to meet the Indian trials to global standards
>
> **Dr S Malini**
> *Chief Course Coordinator*
> **Mpower Institute of Clinical Research**

Types of Jobs	Number of New Positions in the next 4 years
Clinical Monitors / CRAs	7000
Clinical Research Coordinators / Site Coordinators	20000
Drug Safety Personnel	2000
Project Personnel	2000
Medical Monitors	3000
Regulatory Affairs Personnel	3000
Medical Writers	1000
Quality Control / Assurance Personnel	2000
Data Management Personnel	7000
Bio Statisticians	500
Research Scientists	2000
Lab Personnel	1500
Management & Administrative Personnel	2000

(Source: Cliniminds Market Research - Interviews with HR & Clinical Research Heads)

New career opportunities

Going ahead, there will be tremendous career opportunities in the emerging areas like pharmacovigilance, clinical data management, medical writing, and medical monitoring. Currently, there is a dearth of professionals in these areas.

Clinical trial activities involve a lot of data of the patient, thus there is constant demand for quality data management professionals, who are familiar with the latest data management systems. Clinical Trial Management (CTM) forms the major part of any form of CR education. It is the management of drug candidate trial in humans for obtaining safety and efficacy data regarding the drug candidate and is the anchor-sheet of the CR industry as it is the actual process of collating, recording and analysing the safety and efficacy data of the potential drug candidate. A thorough knowledge of CTM is essential for any candidate who wants a break in the CR industry.

Pharmacovigilance is another area where there is a dearth of qualified personnel. "Pharmacovigilance deals with the safety monitoring of drug, especially after the drugs have been marketed. We have seen in the recent past that some of the drugs even after being in the market for five years have been withdrawn because of the advice effects, says, Dr S K Gupta, Dean and Director General, Institute of CR, India, ICRI.

Today CROs and pharma companies have become doubly serious on equipping themselves with the best pharmacovigilance infrastructure. Considering that pharmacovigilance relates to the detection, assessment, understanding and prevention of long-term and short-term adverse effects in medications, and involves collecting, monitoring, researching and evaluating reports on adverse effects information received from healthcare providers and patients. Pharmacovigilance plays a very crucial role in identifying hazards associated with medicines and protecting patients from harm.

It is a burgeoning field as India is a member of the World Health Organisation (WHO) Pharmacovigilance plan. Because pharmacovigilance stands for a safety reporting of various drugs, periodic safety from multiple adverse. Drug reactions are a very crucial aspect in any clinical trials. It is a vital part of CR as the drug candidates are being tested for the first time in humans and they need to be carefully monitored for any adverse effects they can cause in subjects of clinical trials. The pharmacovigilance planning in clinical trials is highly robust and ensures adequate protection of the subjects. It forms an integral part of the training offered in CR as the candidate needs to be fully aware of the regulations and procedures involved in the pharmacovigilance process.

Commenting on Symogen's certificate course in pharmacovigilance and pharmacoepidemiology, Dr Pipisha Biswas, Managing Director, Symogen says, "The certificate course run by Symogen is to bring awareness on pharmacovigilance and pharmacoepidemiology as this field is still in its infancy and there are hardly any full trained and skilled people available in India."

> "Pharmacovigilance deals with the safety monitoring of drug specially after the drugs have been marketed. We have seen in the recent past that some of the drugs even after being in the market for five years have been withdrawn because of the advice effects
>
> **Dr S K Gupta**
> *Dean and Director General*
> **Institute of Clinical Research India, ICRI**

Considering the huge demand from industry end, large number of multinational pharma companies and CROs are establishing pharmacovigilance outsourcing operations in India, and that is opening up an excellent opportunity for the Indian pharmacovigilance professionals. This field offers excellent opportunities for medical and pharmacy or pharmacology professionals. "Companies like CliniRx, Novartis, Quintiles and number of other players are doing quality work in this field. All CR professionals must understand the need of pharmacovigilance; reporting of adverse events and adverse reactions; processes of reporting; documentation involved; correct time frames and regulatory guidelines both during the clinical trials and for authorised products during post marketing trials," Shahani, comments.

Accreditation by association

All these institutes claim that their courses are at par with the some of the best programmes available in Asia. India is also innovating in terms of the availability of variety of programmes, eg some of the programmes currently offered (pharmacovigilance, BA/BE studies; quality assurance) are unique in nature. However, at present, there are no government or international guidelines for judging the standards of these courses. Most of these courses have been

initiated and designed by private sector industry experts in India.

In today's competitive environment, any course in any field has to meet international criteria for the course to be a true value-add and this stamp of approval is most often conferred by global organisations like Association of Clinical Research Professionals (ACRP) or Institute of Clinical Research India (ICRI). "There are a number of Indian institutes which offer courses in CR but there is a question mark over the fact as to how many of them reach to international standards. Generally speaking, pharma companies and CROs would prefer to employ persons who are certified by global organisations," Joshi points out.

"In US, the programmes are run by both universities and private institutions. However, Indian courses definitely follow the International Conference on Harmonisation and Good clinical practice (ICH GCP) principles as the foundation for programmes. And it also covers the Schedule Y; ICMR guidelines; US Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Par 21 and other international guidelines/regulations in our programmes," avers Shahani.

"The institutions would be happy to provide necessary inputs to the Indian government for setting up the standards. All Cliniminds, programmes have been accredited and certified by the industry body known as Pharmaceutical Society of India," Shahani added.

"Market is very huge and has got the space to accommodate a lot more institutes like us in the near future"

Vijay Moza
Chairman
CREMA

"The Indian government has not yet entered CR education sector for providing special training or education for the CR industry. Hence, whatever steps are being taken, are by the private sector alone"

Dr Mary Francis
Dean and Executive Director
International Centre for Training in Clinical Research

"The certificate course run by Symogen is to bring awareness on pharmacovigilance and pharmacoepidemiology as this field is still in its infancy and there are hardly any trained people available in India"

Dr Pipisha Biswas
Managing Director
Symogen

Courses offered at Indian clinical research education institutes
Post graduate programme in clinical trials management
Advanced post graduate programme in CR
Certificate programme in CR
Post graduate programme in pharmacovigilance
Post graduate programme in quality assurance in CR
Post graduate programme in conduct and management of BA/BE studies
Post graduate programme in conducting and managing cancer clinical research
Post graduate programme in regulatory affairs
Post graduate programme in clinical data management
Post graduate program in monitoring
Post graduate programme for investigators and other site personnel
Certificate program in CR for nurses
Post graduate program in biostatistics
Medical writing
Medical monitoring

Similarly, ICRI has international collaborations with (name of institute), Cranfield UK, ICR UK, FDA Smart USA, and has a 100 strong faculty and maximum specialised courses. CREMA recently announced collaboration with William Harvey Research Limited (WHRL), UK. As part of this collaboration, WHRL faculty visit the CREMA campus and there are also plans for student exchange programmes. Its partnerships with WHRL and Clinical Research International (CRI) make their courses globally recognisable. In addition it has also a tie-up with Clinical Research International, Canada for its online programme. Besides these, CREMA follows unique LIFSP (Learning by Industry, Faculty and Student Partnership) teaching model which involves industry leaders. Hence, all courses do have links to global institutes and industry associations.

CREMA has also partnered with Canada's CR International for online programmes. Besides offering the basic courses, Indian institutes are quick to identify new 'students'. Besides CREMA's full-time, one year integrated course, covering all aspects of CR called Advanced Post Graduate Diploma in CR (APGDCR), Moza says, "We also offer part-time diploma courses in the fields like clinical data management (CDM), pharmacovigilance, medical writing and medical monitoring. To assist medical doctors, who are looking at an alternative career in CR, we have introduced a unique course called diploma in CR and Medical Monitoring. Admission to the courses will take place on a time-to-time basis."

Quality over quantity

The demand will certainly drive up the pay packages of the candidates who can expect to obtain excellent remuneration. But far more important than the quantity, it is the quality of the professionals which will really matter.

Analysing world demand for Indian trained workforce Joshi says, "Indian CR industry will create an explosive demand for highly trained and certified professionals. A candidate who is properly qualified with practical training and certification from a global organisation can expect to be picked up by top multinational pharma companies. On the whole, for candidates in the healthcare field who is looking for a challenging career with excellent remuneration, the CR industry is the place to be in India."

"The Indian government has not yet entered CR education sector for providing special training or education for the CR industry. Hence, whatever steps are being taken, are by the private sector alone," says Dr Mary Francis, Dean and Executive Director, International Centre for Training in Clinical Research. Commenting on Indian trained workforce by 2012, Kamani adds, "India will definitely be able to provide trained workforce not only for India, but also for the other emerging CR markets." Moza comments that, "Market is very huge and has got the space to accommodate a lot more institutes like us in the near future."

u.sharma@expressindia.com