

Pharmacovigilance: Opportunity and Future Career Prospects for Fresh Graduates – A Report

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In India, surveillance of adverse drug reactions developed when most of the developed and some of the not so developed countries had established monitoring programme. Many of these had formed National Centers and joined hands with WHO collaborating Centre for International Drug Monitoring, being governed through Uppsala Monitoring Centre, Sweden. In 1989, Indian Council of Medical Research (ICMR) for the first time came forward to finance a multicentric ADR monitoring programme involving six medical colleges located at Aligarh, Delhi, Jhansi, Meerut and Vellore. In a span of three years, ADR data from 58,194 patients was collected and reported to ICMR. This programme was later on converted into a task force, wherein the centers were increased from 6 to 12 located at Aligarh, Delhi, Jammu, Bhopal, Baroda, Hyderabad, Vellore, Bangalore, Chennai, Kolkata, Mumbai and Guwahati. Both these multicentric studies were coordinated by Prof. K. C. Singhal.¹

Under the guidance of Prof. K. C. Singhal, the Society of Pharmacovigilance-India (SoPI) came into existence in 2001. This society now comprises of more than 500 life members and is a national non-profit scientific organisation, which aims mainly to foster Pharmacovigilance activities. In addition to organizing its own national conferences, seminars and CMEs, SoPI is engaged in supporting and providing academic expertise in other institutes.^{2,3} During the pandemic of covid-19, SoPI supported few events including the present webinar through 'Zoom' on the theme "Pharmacovigilance: Opportunity and Future Career Prospects for Fresh Graduates", which was organized by the


IES Institute of Pharmacy of the IES University, Bhopal on 10th July 2021.

IES University is a multidisciplinary university imparting quality education in engineering and technology, pharmaceutical sciences, management, nursing, paramedical science, basic science, teachers education program and also having its own IES Public Schools in Bhopal and Sehore. The campus is declared green and tobacco free by the IGBC, Hyderabad and by the State Government of Madhya Pradesh, respectively. Different institutes of the group have relevant accreditations by National Councils including NAAC for running various under-graduate and post-graduate degree programs.

The webinar had two guest speakers:

1. Prof. (Dr.) K.C. Singhal, Ex. Vice Chancellor, NIMS University, Jaipur, Rajasthan and Founder President, Society of Pharmacovigilance-India
2. Prof. Syed Ziaur Rahman, Department of Pharmacology, Jawaharlal Nehru Medical College Hospital, Aligarh Muslim University, Aligarh and National Secretary, Society of Pharmacovigilance-India.

Before the formal presentations by the speakers and invocation (Saraswati Vandana by Dr. Ankita Namdev), the registrar of the IES University, Dr. Jyotiram Sawale welcomed the guest speakers, participants and students. IES Students Ms. Kratiksha Arya and Ms. Alfiya Zahra were the masters of the ceremony.

Access this article online	
Website: www.journalofsopi.com	Quick Response code 
DOI: 10.21276/jpds.2020.18.01.04	

How to cite this article: Yadav R, Rahman SZ. Pharmacovigilance: Opportunity and Future Career Prospects for Fresh Graduates – A Report. J Pharmacovigilance & Drug Safety. 2021;18(1):10-11.

Source of Support: Nil, **Conflict of Interest:** None



Dr. K. C. Singhal enlightened with the detailed historical evolution of Pharmacovigilance in India. He mentioned the earlier contribution of scientists in the field of Pharmacovigilance. He clearly stated that all medicines and vaccines undergo rigorous testing for safety and efficacy through clinical trials before they are authorized for use. However, because of the limitations of clinical trials, the monitoring of drugs during the post-marketing surveillance is very important. He said that in post-marketing surveillance, we are not only concerned with the collecting, detection, assessment and monitoring of medicine but also make strategies on how to prevent and cure adverse effects with these pharmaceutical products. He also discussed various other drug safety specialisation like Haemovigilance (Blood and Blood Products), Materiovigilance (Medical Devices), AEFI (Immunization), Cosmetovigilance (PPCPs), Herbovigilance (AYUS) and Mineralovigilance (Micronutrients & Vitamins).

Prof. Syed Ziaur Rahman emphasized the need of pharmacovigilance and briefed why this discipline was important. He explained the pharmacovigilance processes, steps in pharmacovigilance safety data management, drug safety database collection and verification, coding of drugs and coding of adverse reactions description by the use of MedRA, causality assessment, timely reporting to authorities and pharmacovigilance services. While addressing the students particularly, he explained why fresh graduates should opt pharmacovigilance as a career option? He said, students of today's generation have more clarity on shaping up their own career. There are wide opportunities available across the globe. Pharmacovigilance could be considered to be one of the career benefited options. It's well defined structure eventually helps in constant growth in terms of both career and economy to future generations of life science and pharmacy graduates. He said, pharmacovigilance industry is growing exponentially because adverse reactions need to be checked in different drugs. Recent report suggests that pharmacovigilance market is expected to reach 6.1 billion US\$ by year 2020 and US\$ 8.33 billion by 2025. According to a market research report, pharmacovigilance market size is estimated to grow at a CAGR (compound annual growth rate) above 12.8% over the forecast time frame 2019-2026 and reach market value around 10.6 billion US\$ by year 2026. The key factors for expansion of the pharmacovigilance market are strict

drug safety regulations and policies by governments, increase of chronic disorders as well as the geriatric population base, increasing rate of ADRs leading to large number of deaths every year. Approximately 5-6% of total hospitalizations are due to these adverse reactions. The scope of pharmacovigilance is massive as countries have to come up with solutions to avoid these ADRs.

India ranks high in the list of largest producers and exporters of pharmaceuticals in the world. It is the fourth largest producer of pharmaceuticals in the world. More than 6,000 licensed drug manufacturers are present in India and over 60,000 branded formulations are made in India. It would thus create a great job opportunities for pharmacovigilance professionals. Pharmacovigilance career is high in demand all over the world including USA and many other European countries. India offers unique advantages for the growth of pharmacovigilance that include awareness on drug side effects among people, lakhs of formulation in domestic market, large number of licensed drug manufacturers in India and potentially large world scale ADR database.

There are many career prospects in India as drug development and safety processes are conducted on a timely basis in following sectors: Pharmaceutical Companies, Knowledge Process Outsourcing (KPO), Clinical Research Organizations (CROs), Medical Colleges & Reputed Hospitals, Regulatory Agencies like CDSCO and DCGI. To make brighter future in pharmacovigilance, a person can enroll in different pharmacovigilance courses to get training. There are wide range of courses and programmes provided in many cities for graduates and post-graduates of life sciences and medical background. To name a few, many full-time to part-time and distant learning courses like Certificate Courses in Clinical Research, Data Management, Pharmacovigilance and Drug Pharma Regulatory Affairs; Advanced Diploma Courses in Clinical Research, Clinical Trial Management, Clinical Data Management, Pharmacovigilance, Medical Writing, Bio informatics and various other corporate training programmes and M. Pharm degree in Pharmacovigilance.

During the deliberation, participants discussed safety review processes, risk management plan, and pharmacoepidemiology. In the end, Dr. Reenu Yadav, Principal, IES Institute of Pharmacy, presented the vote of thanks.

The webinar was covered live through FaceBook page: <https://fb.watch/6-O6OdEcwq/>

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