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## Where Are We Lacking? : A Comparative Review of Pharmacy Practice Profession between Two Nations - India versus USA



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### ABSTRACT

The Clinical Pharmacy Profession an important part of the healthcare system in the world. The Doctor of Pharmacy (Pharm D) is a professional doctoral degree in pharmacy that was initially introduced in the United States of America in 1950. In India, Pharm D was introduced in 2008 with the main objective of increasing the scope of pharmacy to fulfill healthcare needs. In USA, Pharm D is an Undergraduate program while in India, Pharm D is considered as a postgraduate program. This review mainly focuses on comparing the role of Pharm D in public health between two countries, India and USA. In this review we thoroughly describe and compare the scope of Doctor of Pharmacy program, its role & responsibilities of a Pharm D professional and the regulatory environment of both the countries. Through this review, we have tried to highlight the reason, why Pharmacy practice is lagging behind in India.



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## INTRODUCTION-

Pharm D is a “*Pre PhD Clinical doctoral program*” - a title used in health profession, initially introduced in USC School of pharmacy, USA. In 1950, After 58 years in 2008, Pharm D program introduced in India by pharmacy council of India under ministry of health & family welfare, govt. of India. In India Pharm D program is a postgraduate program which is divided into two programs such as first one is Pharm D (Regular) course and second is Pharm D (Post baccalaureate) course. Pharm D regular program can be pursued by 12th standard pass out with PCB/PCM or with Diploma in pharmacy. Pharm D (PB) can be pursued by B Pharm graduates. Pharm D (Regular) is a 6 years program consisting of 5 years of academics and 1 year of rotational residency /internship. Pharm D (Post Baccalaureate) is a 3 years program consisting of 2 years of academics and 1 year of rotational residency\ internship [1, 18]. The Pharm D program was introduced in India to create practicing pharmacists which is similar to the program in the United State of America [13]. The main goal behind introducing Pharm D program is to equip the country with trained pharmacy practitioners and to upgrade the pharmacy profession with respect to the developed nations. According to new guidelines of the National Association of Boards of Pharmacy (NABP) that a foreign pharmacy graduate have 5 years of pharmacy education before applying to take the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) in order to have the North American Pharmacist Licensure Examination (NAPLEX) and finally get a license to practice pharmacy in the United States[14,19]. This program is similar to Doctor of Medicine (MD) to become a registered medical practitioner doctor and Doctor of Dental Surgery (DDS) to become a dentists.[1] The Pharm D syllabus focuses on course such as Pharmacology, Pathophysiology, Pharmacotherapeutics, Clinical Pharmacy, Community Pharmacy , Hospital Pharmacy , Biochemistry , Microbiology , Therapeutic Drug Monitoring, Pharmacoepidemiology & Pharmacoeconomics , Clinical Pharmacokinetics , Clinical Research , Clinical Toxicology , Human Anatomy & Physiology with laboratory practical in which pursuer learns BP Monitoring and Blood test also. These subjects are taught with practical training. In 2nd year onwards, Pharm D candidate joins hospital round with clinicians and preceptor and after completion of academics session, candidate perform 1 year of internship ,in which, 6 months compulsory in general medicines & 2 month each in different specialties.[2,13,19]. Pharm D is different from Ph.D Programme in various aspect such as 1st a PhD students focuses on the models and methodology used to evaluate the usefulness of data, while Pharm D candidates try to consolidated results into the “big

picture,” for example how data might modify patient care. 2<sup>nd</sup>, PhD candidates provides assisted correlation to the critical assessment of research results that use advanced quantitative methods while Pharm D candidate help in providing clinical illustrations. Other difference is in knowledge and training between disciplines bridged the gap between research and practice. During their training in hospital and community pharmacy practice, Pharm D candidates are trained to apply proper research findings to get better patient care. Whereas PhD candidate are trained to develop these research findings by answering research questions applying population-based real-world data. To conduct and apply research findings developed by PhD candidates meanwhile Pharm D candidates, gains the potentiality to improve innovative patient care during their curriculum. [11]

### **Registration Procedure of an Indian pharmacist to become a US pharmacist:-**

#### **Recognition of equivalence**



[Submit an application to Education Credential Evaluators (ECE) to check qualification (Pharm D or any other Equivalent Exam with study period not less than 5 years) .If ECE approve qualification documents then candidate can sit in the equivalency exam.]



#### **Obtain a work visa**

(If candidate have a spouse in the US then he/she can skip this section. Granted by the UK section of the US embassy, in most cases, a job offer from a U.S. based employer is required so as to qualify for a visa, so first step here would be to find a pharmacy that is willing to employ in the US. Within this visa application time limit, the candidate should qualify the following exam.)



#### **Test of English as a foreign language (TOEFL) Exam**

(This exam is an English aptitude exam in which candidates will need to take to prove that they are competent in speaking technical English.)



**Foreign Pharmacy Graduate Equivalency (FPGEE) Exam**

(Apply to the National Association of Boards of Pharmacy (NABP) to start the Foreign Pharmacy Graduates Equivalency Committee certification process)



**Start Internship**

[Register as a pharmacy intern with the state board of pharmacy and start recording hours. (Up to 1500 hours depends on the different state laws) After that submit the records of internship hours to the state board of pharmacy/PCS once completed.]



**The North American Pharmacist Licensure Examination (NAPLEX) Exam**

(Once internship is approved then the candidate will need to take this national clinical competency exam which will cover you for all states.)



**Multistate Jurisprudence (MJP) Exam**

(Many states require to take the Multi-State Jurisprudence exam however some, more popular destinations, such as California require to take a state-specific exam such as the California Practice Standards and Jurisprudence Examination for Pharmacist (CPJE) Exam. Each pharmacist which takes the exam gets 5 attempts.)



**Obtain professional liability insurance**

(One of the most commonly used is the Healthcare Providers Service Organization (HPSO) which has links to the American Pharmacist Association (APhA).)



**Registered Pharmacist**

**Registration procedure of a Pharmacist in India:-**

**D.Pharm/B.Pharm/M.Pharm/Pharm.D**

(From Pharmacy Council of India approved Institution)



**Documents required for pharmacist registration**

- Educational Qualification certificates (12th, all years mark sheet of D. Pharma,/B. Pharma or Pharma D)
- Proof of Identification and Proof of residence in state applying for registration
- Date of Birth Proof
- Training certificate
- Prescribed fee
- Photographs
- Affidavit if required
- Original character certificate / College Leaving Certificate/Migration /transfer certificate
- Letter from pharmacy institution/college showing its approval from PCI for the year in which candidate qualifies for its diploma/degree
- Diploma Degree certificate



**Registration of Pharmacist is done by the State Pharmacy Council**

(Registration of Pharmacist is done by the State Pharmacy Council Constituted by the state governments. Under the section 19 of the pharmacy act. The registration is done under section 33 read with 32(2) of the Pharmacy act, according to which minimum statutory

requirements are as applicant should have attained the age of 18 years and application should resided or carry on the business or profession of Pharmacy, in the state.)



### **Registered Pharmacist**

#### **ROLE OF PHARM. D IN INDIA:-**

Role of Pharm D doctors are:

- **Drug Information Services:** The Health care professionals involved in the medicine prescribed, dispensed, administered, require authentic drug information such as dose of the medication, route of the drug administered, frequency of drug prescribed to a patient, dosage form of the drug, indications, contraindications, drug-drug interactions, contraindications, drug-food interactions, adverse effects, side effects, dose adjustment in renal & hepatic failure patients, drug information to pregnant & lactating patients to provide these information to the patient Pharm D Professionals are well trained in adequate manner by using various sources and software E.g. Medscape, Micromedex, DMS etc.(1)
- **Patient Counseling Services:-** Better Disease outcomes depend on the how patient take their medication in an appropriate manner or not due to heavy load of diseases in India Physicians have no sufficient time to counsel the patients, so Pharm D Professionals are well trained to counsel the patients so these gap are filled by Pharm. D Professionals.[3,12]
- **Pharmaceutical Care Services:-** It is the care need for the patient to convince rational and appropriate drug use. Pharm D Professionals interacting directly to the patient and give pharmaceutical care to the patient.[3]
- **Ward Round Participation:-** Pharm D professionals are involved in ward rounds, By involving in ward round, a Pharm D Professional directly interact with patient and give the rationalize therapy to the patient and provide drug information to the medical staff.[3]
- **Pharmacovigilance Program:-** Pharm D professionals are involved in Pharmacovigilance Program by monitoring the adverse drug affects and detection, assessment, reporting & prevention of adverse effects.(1)

- **Poison Information Services:-** Pharm D have knowledge of clinical toxicology so Pharm D plays a major role in providing a poison information to a health care professionals which reduce the morbidity & mortality caused by the poisoning.[3]
- **Medication Chart Review:-** It involves the checking of the drug therapy of the patient , it helps to ensure the safe , effective & appropriate medicine to the patient . Pharm D have the knowledge of therapeutics which help to manage the disease condition of the patient which is beneficial for the health care teams and patients.[3]
- **Medication Errors Monitoring:-** A medication error is an episode associated with the use of medicine that should be preventable through effective control systems. Pharm D Professionals reduce medication error by applying the clinical knowledge thus, improve the medication therapy received by the patient and reduce medication error. [3]
- **Medication History Interview:-** Sometimes patient received medications from various pharmacy commonly known as polypharmacy , which cause harmful effects in patients and leading to therapeutic failure , by taking the history of patients Pharm D help to reduce this therapeutic failure and promotes rationalize therapy.[3,12]

#### **Actual Condition of Pharm D in India:-**

There are many barriers for Pharm D Professionals in India such as there is no specific board or cadre for Pharm D Professionals. Pharm D is treated as plain pharmacist without just like a Diploma in Pharmacy or B Pharm. The level of knowledge among medicos, about this degree is so less that they pronounce Pharm D as “D Pharm”. There are no other specific jobs for Pharm D professionals and there is a lack of trained Pharmacy practice faculties in Pharmacy colleges due to very low pay scale. The condition of pharmacy colleges in India is such pathetic, that management of the college depute faculties of pharmaceutics/pharmacology/chemistry to teach pharm D graduates. One reason that why the pharmacy profession is suffering a setback is no implementation of Pharmacy Practice Regulation 2015(PPR-2015). As like corporate hospitals, there should be a mandatory creation of clinical pharmacist post in Government hospitals. [4] In India, pharmacy practice implementation still faces a number of challenges including the carelessness of regulatory bodies and lack of recognized system. [6]

**The reason why, Pharmacy Practice/Pharm D is not developed in India.**

In Pharmacy council of India there is not even a single member from clinical pharmacy practice/Pharm D/M Pharm (Pharmacy Practice) degree holder/background. Due to this drawback, the profession of Pharmacy practice is not developed in India, due to which, are no jobs for Pharmacy Practice/Pharm D. The Pharm D program is running since 2008, since then, almost 12 years had been passed but no developments have taken place. There is no amendment done or regulations introduced exclusively for Pharm D program. Even no specific cadre for Pharm D professionals have been generated up till now. On 07-Feb-2018, an YSRCP member of parliament, Mr. Vijay Sai Reddy requested the government to recognize Pharm D graduates as clinical pharmacist. He addressed in Parliament that Doctor of Pharmacy popularly known as Pharm D is a Six years doctoral program introduced in India in 2008 by the Pharmacy council of India. 10 years are over, since introducing the program. The objective of the Doctor of Pharmacy is to provide rationalize therapy to the patient and improve the quality of therapy and patient life, this particular program has got the three phases first phase is academic in the academic they study Anatomy, Physiology, Pathology, Pharmacology, Pharmacotherapeutics, Medical chemistry and Biochemistry of human body. In the second phase it is one year internship where student undergo training relating to clinical pharmacy services and critical evaluation in the third phase the student are trained in the general medicine for six months and other six month trained in three specialty departments. The objective behind framing of this kind of syllabus is that Pharm D graduate learn to how to treat many basic illness. He requested to the honorable minister for health and family welfare to recognize Pharm D graduate as clinical Pharmacist and he also requested that since many MBBS doctors are not willing to go rural areas and serve the patients. These Pharm D doctors can work in the rural areas.

**Recommendations:-**

India has a second largest population in the World, this leaves India with a heavy burden of diseases with 37% of deaths from communicable diseases[17]. The appearing load of communicable and non-communicable diseases has led to a shortage of primary care clinicians in rural India. Presently, according to the data provided by the World Health Organization (WHO), India has a very low ratio of doctors 0.69 for every 1000 people living in its rural communities and 1.33 for every 1000 people living in its urban areas. For 70% of the Indian rural population, the patient-doctor ratio is exceedingly low and amounts to an



only 0.39 per1000 people. This data provides indicate of the severe shortage of trained health care professionals such as physicians, pharmacists, dentists, nurses, etc. Here, Pharm D can play a major role in providing a good standard health care by working accompanying with physicians. In rural areas a group of 5–6 pharmacists should be appointed in Primary Health Centers at Nagar panchayat level and in Community Health Centers at the Tehsil level. There should be presence of a pharmacy officer who has Pharm D degree working under a medical officer at the CHC and PHC level and uniformly in each district, there should be the presence of a chief pharmacy officer (CPO) also who has Pharm D degree working under a chief medical officer (CMO).[4]

Awareness of Pharm D program among health care professionals require to be established. [16]

### **PHARMD SCENARIO IN USA:-**

Pharm D was first started in USA in 1950[18]. The American society of health system pharmacists, (ASHP) defined pharmacist as “pharmacists are responsible for providing of safe, effective& accountable medication enhance care for hospitals and health system patients.”[5]. Attaining highest level of pharmacy practice demand that U.S. Pharmacists are wisely educated via Doctor of Pharmacy, residency, and certification programs.

### **Education & Training:**

Pharmacist qualification, training, teaching, & Professional practice version closely mirror those of physicians in the U.S. In akin to the physicians’ Clinical Doctor of Medicine (M.D) degree. Pharmacists completes a clinical practice program at the Doctor of Pharmacy (Pharm D) level. In U.S., Pharm D is 4 year professional degree completed after a 2-4 years of pre pharmacy.[5] Pharmacist in USA provides clinical pharmacy practice services at a distinct levels of implementation, e.g. Pharm D in USA have several supporting systems for the implementation of pharmacy practice[6]. In the USA, clinical pharmacist performs ambulatory care i.e. outpatient departments, highlights their practice in chronic illness and progression of care. Being a primary care health provider, they provide therapy management and vaccination. [7]

### **Curriculum of Pharm D in USA:-**

In 1 year, the Pharm D curriculum focus on following subjects (Biochemistry, Pharmacokinetics, Pharmaceutics, Pharmacodynamics, Anatomy, pharmacy calculation and drug information). Additionally, in-class studying students have to complete 120 hours service learning. Clinical pharmacy education starts in the 2 year students participate in social and behavioral Pharmacy too, and communication skills. In the second semester students attend the lectures of therapeutics and nonprescription therapies. Also, students need to finish a 120-hour internship in community pharmacy practice. In the 3 years, the focus is more on clinical Pharmacy services Students have nine credits in therapeutics and are required to finish one group poster presentation. They practice prescription reading and patient counseling in patient care management classes. Students enroll for 240 hours hospital rotation in this year. The 4 year is exclusively for students to earn clinical practice experience. Students have 9-month rotations, and each month they are assigned to different settings, depending on the school's request and personal preference. [7]

### **Pharmacist licensure in USA:-**

Pharmacist licensure and re-licensure is controlled at the state level by separate Boards of Pharmacy. Licensure stipulate that state needs to practice pharmacy are linked. Candidates for licensure in all states should pass the North American Pharmacist Licensure Examination. This capability-based examination applies knowledge obtained in pharmacy education to actual-life practice circumstances. All states also need a law examination integrating both federal and state laws. Most utilize the Multistate Pharmacy Jurisprudence Examination (MPJE) acclimate with state-particular laws, rules and regulations as they apply within that state's Pharmacy Practice Act. Re-licensure by state boards of pharmacy take place after pharmacists complete going on requirements, which generally incorporate a particular number of hours and type of ongoing education and attestation that in both controlled and actual-life circumstances.[5]

### **Postgraduate training:-**

Post-graduate residency training is mandatory to achieve certification for starting pharmacy practice. On other hand there are two specialization clinical practice certifications which necessary additional specialty residency training. After finalization of an accredited residency program is a certification that distinguish pharmacists from basic requirements for licensure.

A Post-Graduate Year One (PGY-1) residency program is the initial stage of residency training. PGY-1 is a directed, organized certification program which is of duration of 12 months that upgrade knowledge, skills and qualities learned from pharmacy institute. It is planned to improve basic abilities in governing rational use of medicines and manage optimal therapeutic result for patients with complicated disease condition. In other hand a Postgraduate year two (PGY-2) is also duration of 12 months this PGY-2 residency referred to as a specialty program as its focus a particular field of pharmacy practice example- Ambulatory care, Oncology and Pediatrics. Furthermore PGY-2 candidates prepared to pursue board certifications if it exist in that specialty. [8]

**Certifications:-**

Beside this, Pharmacist can become board certified in specific area. While licensure designed an essential competency for pharmacy practice certification establishes that practice and knowledge apart that level has been obtained. The board of pharmaceutical specialties (BPS) was formed in 1976 to approved specialties within pharmacy practice. To become certified Pharmacy practitioner a candidate must have a minimum level of practice experience in his/her area of specialty. After 7 years candidate must be recertified. [8]

An overview of Pharmacy Programs leading to registered pharmacist in India & USA:-

Country	Academic qualification	Duration of program	Duration of internship	Clerkship/Project	Regulatory authority	Exit test for Pharmacy Practice	Specialization
India	D.Pharm B.Pharm M.Pharm PharmD	2 Years 4 Years 2 Years 6 Years	3 Month 3 Month None 12 Month	Only in 5 year of Pharm.D First six months clerkship period in hospital and last six months Project /Thesis work	PCI PCI PCI PCI	None	None
USA	PharmD	4+ (2+3years pre	Varies from state to state(1200-	4-year School of Pharmacy, including clerkship 1,000-	NAB P/State	NAPLEX +MPJE (F	• Ambulatory care pharmacy

		pharmacy studies)	1500 hours)	1,800 practice hours -IPPEa 300 hours during first 3 years of course -APPEb 36 weeks in the fourth year	Board of pharmacy		<ul style="list-style-type: none"> <li>• Cardiology pharmacy</li> <li>• Critical care pharmacy</li> <li>• Geriatric pharmacy</li> <li>• Infectious Disease Pharmacy</li> <li>• Nuclear Pharmacy</li> <li>• Oncology Pharmacy</li> <li>• Pediatric Pharmacy</li> <li>• Psychiatric Pharmacy</li> <li>• Solid organ transplantation Pharmacy</li> <li>• Nutrition support Pharmacy</li> </ul>
<p>aIPPE=Introductory Pharmacy Practice Experience; bAPPE=Advanced Pharmacy Practice Experience</p>							

**DISCUSSION:-**

In India Pharm D program is different from USA in wide range of aspects such as, in USA, Pharm D is an undergraduate program while in India Pharm D program is postgraduate. In USA, after completion of Pharm D there are so many specialization program i.e. Ambulatory

care pharmacy, Cardiology pharmacy, Critical care pharmacy, Geriatric pharmacy, Infectious Disease Pharmacy, Nuclear Pharmacy, Oncology Pharmacy, Pediatric Pharmacy, Psychiatric Pharmacy, Solid organ transplantation Pharmacy, Nutrition support Pharmacy. While in India, there are no such types of specializations available. In USA Pharm D candidate Practice as a physician for minor ailment, or in other words, Pharm D candidate have legal right for prescribing medicine in some states, but not all over USA. [8] While in India, there is no such type of permission or regulations. Even India is still struggling to meet Doctors shortage. According to the WHO report, for every 1000 patients India has a very low ratio such as doctor-patient ratio is 0.69 doctor for every 1000 people residing in its rural communities and a comparatively higher ratio of 1.33 doctors for every 1000 people residing in its urban areas. For 70% of the Indian rural population, the patient-physician ratio is extremely low and amounts to only 0.39 doctor per 1000 people. So to manage this shortage Pharm D are best option. Pharm D candidate can practice in rural areas where doctor don't want to go. Already study conducted by Akram et al.2014 (Can Pharmacy Doctors act as valuable assets in rural areas with a physician shortage).

#### **Reason of lagging behind of Pharmacy Practice in India:-**

To make a good pharmacy practitioner, good pharmacy academician, well organized institute and proper infrastructure are required. The success of any academic program depends on its regulatory authorities or council but there are no regulatory guidelines for having qualified clinical pharmacists in an Indian hospital. The reason of lagging behind Pharmacy practice profession in India is improper function or regulations implementation of Pharmacy council of India. In Pharmacy council of India regulations are governed but not properly implemented the reason behind this is, that its members have been elected from like pharmaceutical chemistry field. There is no member of Pharmacy practice field in PCI board of members. Such as a regulation PPR-2015 has been governed but not implemented yet. If this regulation may get implemented then there will be a great change for pharmacy practice field and Pharm D program may get recognized in health sector and Public sector [15].

#### **Constitution and Composition of Central Council of India:-**

The central council is constituted by the election of several types of members, in which six members among whom there shall be at least one teacher of each of the subjects, pharmaceutical chemistry, pharmacy, pharmacology and pharmacognosy elected by the University Grants Commission from among persons on the teaching staff of an Indian

University or a college affiliated thereto which grants a degree or diploma in pharmacy. Another six members of whom at least four shall be persons possessing a degree or diploma in, and Practicing community pharmacy or pharmaceutical chemistry, nominated by the Central Government and other one member elected from amongst themselves by the members of the Medical Council of India and a director general health services, drug controller, director of the central drug laboratory, representative of UGC and the representative of AICTE and one member from the state council should be a registered pharmacist one member nominated by state government who shall be a registered pharmacist.[9]

### **Constitution and Composition of Central Council of USA:-**





In USA there is a regulatory authority named National Association of Board of Pharmacy (NABP). The Executive Committee governs NABP and comprises four officers and eight members who work directly with the executive director/secretary, who acts as the chief executive officer and serves as secretary of the association. The executive committee members volunteer their time and skill to implement policy and oversee the association's programs and services. The officers and members are elected during the association's annual Meeting.

### **CONCLUSION:-**

In USA PGY1 and PGY2 training, specialization, certification, Licensure and training of Pharm D students makes the Pharm D program quite differ from Indian Pharm D program. To develop Pharm D program there should be specialization program after Pharm D to trained Pharm D professionals in different specialties, but In India, there are various challenges to develop Pharm D program. Pharmacy Council of India should think about to amend changes in Pharm D syllabus to improve the quality of Pharm D program like USA. In PCI there should be an elected member of Pharmacy practice specialization like Pharm.D/M.Pharm (Pharmacy Practice) like USA central council. There should be an exit test in India for practice in pharmacy to like USA. The advance implementation of Pharm D programs in India mandates evidence-based and gradual change that positively impact pharmacy education and practice.

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