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Review Article

Transformation of Pharma Curriculum as Per the Anticipation of Pharma Industries-Need to Empower Fresh Breeds with Globally Accepted Pharma Syllabus, Soft Skills, AI and Hands-on Training

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ABSTRACT

In this domain of specialty and globalization the pharmacy teaching and learning in India is suffering from serious backdrops and flaws. In India, in present-day need of pharmacy is to physique and shape strategies for a renovated innovative future for affordable and effective healthcare system. There is a crucial necessity to begin an academic exercise aimed at renewing of prospectus, focusing recent and evolving learnings in the field of pharmacy. The current youth of pharmacy graduate sought to have technical expertise of sophisticated instrument functioning, trouble shooting, product and process development, IPR, innovative rational based thinking, quality by design, regulatory aspects of global level to match the anticipation of industrial revolution of pharma 4.0. Certainly, they are short age of expertise in new generation instruments, latest development in Pharma Industry, Intellectual Property Rights and Regulatory needs of Industries and profound exposure of Process Analytical Technology (PAT). The numerous factors which should be well-known are Environmental Health and Safety (EHS), Investigation like 6 sigma's, Ishikawa Fish bone skills and CAPA, Parameters Efficiency including OEE, SMED, 5S, OPE, Lean production, Latest Development of Pharma Industries, Regulatory knowledge about Internal and External Audits, Self-Inspections, technology Transfer, Change Management emphasizing on Control on changes and Risk management: FMECA, Risk Evaluation and Mitigation. Artificial intelligence (AI) has the potential to bring about a paradigm shift in the way drug are researched, developed and marketed. AI is changing the pharmaceutical industry by looking at 5 key areas of AI in pharma: data science, drug discovery, clinical trials, marketing and R&D. The article emphasizes on raising the current standards of knowledge, skills and domain of scholars of Diploma, Bachelors, Masters and Doctorate of Pharmacy course. The necessity of an hour is to work on enhancing the concept of innovation and quality management. Solicitation of technical expertise to the educational system improves the present situation. The admission procedures should be brought underneath the scanner as these are the opening of the students for entrance in the profession. Gaining expertise at bachelor's level will lead to proficiency and brilliance.

Keywords: Pharmacy Education, Pharma Industries, Latest Development, Pharma 4.0, Artificial Intelligence.

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INTRODUCTION

The new breed of young budding pharmacist is not much aware about Data management procedures like electronic data management, 21 CFR Part 11, Documentation of SOP, Specification, BMR, BPR, Qualification and Calibration of Equipment and Instruments. The various Engineering procedures like HVACs and ISO/ Grading of Air, PPM and Predictive maintenance (21 CFR Part 210, 2005, ISO 14001, 2004, ISO 15189, 2007, ISO/IEC 17025, 2005). The Utilities viz PW, WFI, Pure steam and equipment, their role and importance. The study of QMS with its Deviation, Investigation and CAPA, Complain Management. The Quality control its Method Development, Validation, RS, WS and Stability, Sustainability with Energy and Environmental conversation, Citations like FDA 483s, Human errors and its implications, ALCOA+: Data reliability and Integrity. Details about Regulatory bodies WHO, TGA, MHRA, ANVISA, USFDA etc.

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The Pharmaceutical Industries has diverse sections and divisions like API-R&D, Formulation R&D, Clinical Research, Analytical, Quality Assurance, Industry Regulatory Affairs, Intellectual Property and soft skill development. These sections have their individual necessities of proficiency and expertise. In order to cater those needs the pharmacist should be acquainted with necessary cognitive domains.[1]

Pharmaceuticals industry –Recent trends and future prospective

As previously well-known that Pharmaceutical drugs are intended for human or veterinary use, therefore, they are subjected to numerous guidelines and regulations which are associated with patenting, testing, safety, efficacy and marketing (Figure 1).

The global pharmaceutical industry revenue is forecasted to reach an estimated $1,226.0 billion by 2018, with good growth over the next five years (2013-2018).[2]

On the whole the industry is anticipated to growth which is led by aging, lifestyle and its changes, Daily Activities, Unhealthy eating habits, various chronic diseases these all disorders are providing global opportunities for Industrials.

According to recent facts and Figures North America pharmaceutical drugs market is worth $341.1 billion, and is the largest in the world. It currently has about 36.5% share of the global pharmaceutical drugs market.[3]

The main reason behind is the availability of major industries of Pharmaceuticals, increasing healthcare and Patent expiration. According to recent studies second largest pharmaceutical drugs market of the world is in Asia-Pacific. It covers 21.5% of global pharmaceutical drugs market. The main trends in Industries are shift from prescription to non-prescription drugs due to increasing demand of personalized medicine that divert them from Ethical Methods of Animal testing that leads towards development of personalized medicine.[4]

Pharma industry ethics of quality: Essential and impartial subject

The quality in the pharmaceutical industry is foremost precedence of pharmaceutical Industry. In 21st century; People are more aware about importance of the quality of the pharmaceutical products by the launching of the FDA current good manufacturing practices–the cGMP. The Pharmaceutical Industry is following guidelines WHO GMP: main principles for pharmaceutical products, good manufacturing practices for starting materials and specific pharmaceutical products, Quality system requirements for national GMP inspectorates and Guidelines for GMP Inspections. Pharmaceutical manufacturers have just commenced to comprehend and apply the FDA's cGMPs for the 21st century.[5]

The Food and Drug Administration have precisely stated three notions that will monitor reevaluation procedures like Advances in Risk management, quality Management, Pharmaceutical and manufacturing Technology. Industries check product lifecycle and implement approaches of risk management which assess, communicate, control and review risks to quality of the drug. The concept of quality is designed by Corrective and Preventive actions leads to ICH Q8 which is defined as design space. Identifying trends allows the manufacturer to anticipate and prevent future problems. The organization should focus on correcting and preventing problems. Preventing problems is generally cheaper than fixing them after they occur. The organization should also start thinking about problems as opportunities to improve "Root cause analysis" is a process by which the manufacturer can identify causes and preventive actions Process capability is the comparison of the "Voice of the Customer" (VOC) with the "Voice of the Process" (VOP). VOC, which is built on customer requirements, is defined by the specification limits of the process, which are fixed, while VOP is defined by control limits, which are based on performance data and vary over time six Sigma as "…a business process that enables companies to increase profits dramatically by streamlining operations, improving quality, and eliminating defects or mistakes in everything a company does…." It can help an organization reduce defects and improve profitability using several basic tenets.[6]

Lean manufacturing is about eliminating waste across an entire company and focusing on the big picture through learning how to do more with less. Lean means putting the right things in the right place at the right time the first time while minimizing waste and being open to change.[7]

Pharmaceutical industry self assesment for authentication and growth

The Necessities of Industries associated to infrastructure is altering as a consequence the expenses of Research and development is increasing in each and every sector. With the current innovations, R&D investment are fetching additional sensitive to price controls or other cost containment measures. Drug development under today's new institutional arrangements could turn out to be faster and better, but not cheaper. Furthermore, the pharmaceutical industry is also under going crisis in productivity. The scientific achievements related to human genome, its sequencing and generation of new products is decreasing.[8]

Strengths

The Strength of Pharmaceutical Industry is that they are strategically well placed and Entrepreneurs are well qualified. In Madhya Pradesh Region Especially Indore which is the commercial capital of Madhya Pradesh there is easy availability of labor, good number of financial institutions/ banks available, Indore City is well connected to all major cities like Mumbai,

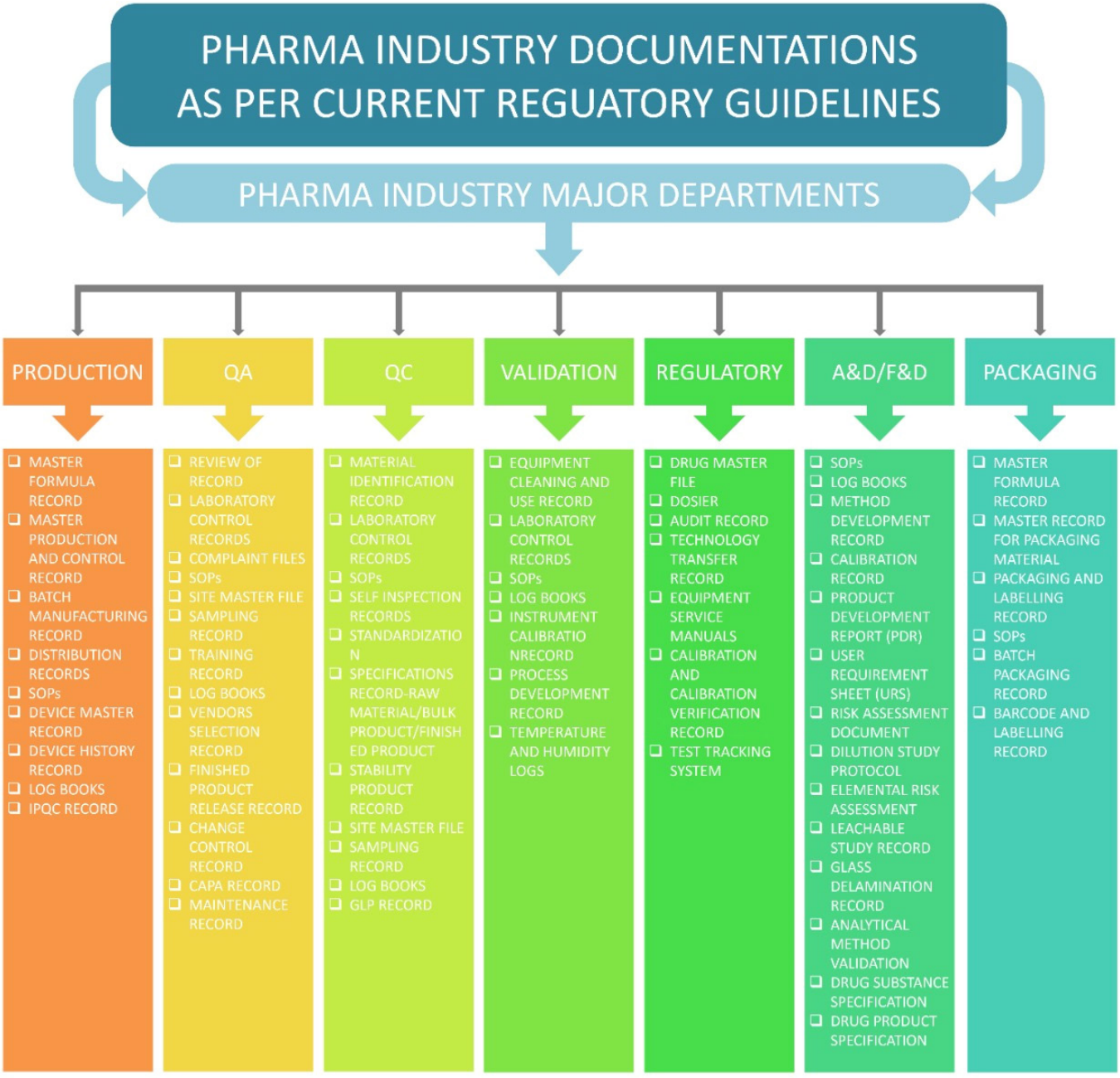

Figure 1: Pharma industry documentations as per current regulatory guidelines.

Delhi and Ahmedabad wherein an established Trade house known as "Dawa Bazaar", where 200 traders are having their offices under one roof. Here raw materials suppliers and machine manufactures are easily available with availability of Pharmacy, medical and dental colleges.

Opportunities

The opportunity in Pharmaceuticals units in Indore are that there is huge scope for a more effective utilization of local Dawa Bazaar, Loan licensing for multination companies, More scope of exports because of availability of dry port at Indore with availability of Good number of hospitals and doctors in the city.

Weaknesses

In Pharmaceutical Units Majority are old and not technologically upgraded with poor testing and R&D facilities. Most of the units are in residential area without any scope to shift to a nearby industrial estate, Underutilization of local trade house i.e., Dawa bazaar, under financing of working capital, Poor coordination between the Government organizations and Pharma industries,

Slow production because of old machinery, Labor and technical staff are not properly trained.

Threats

The major threats are competition from multinational firms, Implementation of WHO GMP, Commencement of Product Patent law in the near future, Dependency on Government Supply Shortage of water because of poor rain fail, a serious problem of electricity is expected because of division of MP, expecting big goods-dumping from China at low rates.[9]

Pharmaceutical industry regulatory compliance: Degree of quality system and reproducibilty

As API (Active Pharmaceutical Ingredients) R&D (Research and Development) Department requires Pharmacy students to have all necessary information about Synthetic Chemistry, Chromatographic Techniques, Spectroscopy, Diversity Analysis, Quantitative Structure Activity Relationship (QSAR) and Applications of instruments like Nuclear magnetic resonance.

The Formulation R&D section requires sufficient knowledge on Drug Discovery, Novel Drug Delivery Systems, Formulation Development, Bioequivalence and Stability Studies, Quality Management, Regulatory Management, Disease management and Therapy.

The Clinical Research section personnel should be detailed about of Phase I, II, III, IV studies and GCP Guidelines. Preparation and Execution of study Protocols, CRF and ICF, Designing, Conducting and Analysis of Clinical Research, Monitoring of Studies, Review and Reporting Safety data, Evaluation of Toxicity Studies, BE and PMS studies and Maintenance of Source Documents and Report Publishing.

In analytical Method Development department required sufficient knowledge about NCE (New Chemical Entity), NDA (New Drug Application) and ANDA (Abbreviated New Drug Application) Method Analysis for scale up techniques, Method Validation for product quality, Calibration and maintenance of Laboratory Instruments, Records/Documents complying with GMP and Knowledge and Implication of GLP.

The Expectations from Quality Assurance departments inculdes regulatory requirments like cGMP, WHO, GMP, MCA, TGA, USFDA. It inculdes knowledge of different type of validation Prospective, Concurrent, Retrospective, Revalidation. The knowledge of batch Manufacturing and Packing Records, SOP, STP, Specification and Documentation. Validation and Calibration of QC Instruments like HPLC, QC, TLC, Titrametric Anaytical Methods, pH METERS, Dissoution and Disintegration apparatus.

The Intellectual Property Rights expectations include knowledge of Patents, Copyright, trademarks, Geographical Indications, Design, Integrated Circuits, trade secrets.[10]

Human resource skills development: Continuous training to upgrade

The soft skills developments should cover Personality Development and Positive Attitude, Communication Skills and Shop floor relations, Command over English Language, Commitment, Sincerity, Dedication, Ownership Feeling and Effective planning.

The prospectus and curriculum charted by nearly all Universities in India are not at all up to the world standards. Every student must be proficient of evaluating themselves for continuously enlightening their excellence and expertise. Teacher mainly focus on training and learning part but indeed they should mainly emphasis on utilization of smart techniques. Need of an hour is the Restoration of pharmacy education in India, which will lead to upliftment of status of Profession of Pharmacy in India. Need is to train faculty fraternity on latest techniques, should visit industries, perform assignments and consultancy projects in industries wherein students can be beneficiaries. Training the students on human errors prevention, data reliability and basics of regulatory bodies the industries require employees who are equipped with both domain, technical skills and non-technical skills (Figure 2). The major needs are flexibility, adaptability, creativity, grit, team building capacities, advise to faculty introduce reforms in teaching Methodology, Pedagogy, Methods of Evaluation, Training to the faculty on latest technologies, Industrial training, Effective and Meaningful Projects and Workshops. Acquire Awareness about advances in pharmaceutical industry and R and D through Workshops, Seminars, Guest Lectures, Visits to the Industry.[11]

Leadership and decision maker in pharma industry: Soft skills vital for administrative positions

India is poised for a steady industrial growth, although at a relatively gentle pace, which would have positive hiring environment. In the Indian pharmaceutical sector, CAGR is estimated to be about 15% in next five years. In line with that, there will be talent requirements across various domains. The need is in major areas of operations such as process development, distribution network and R&D. The increasing demand of professionals in sector of pharmaceuticals is to compete with the global pharmaceutical needs with compliance to global regulatory requirements.

Growth of Employees within the organization and positioning them to higher post in order to enhance their leadership skills in due course of time in seen majorly in Reliance Life Sciences. These systems require establishment of roles and responsibility plans as well as regular training and development of prospective internal employees through continuous competency development programs. This is beneficial for career development of an individual as well as from retention stand point. With scale-up and growth of businesses there arise requirements for niche profiles at senior

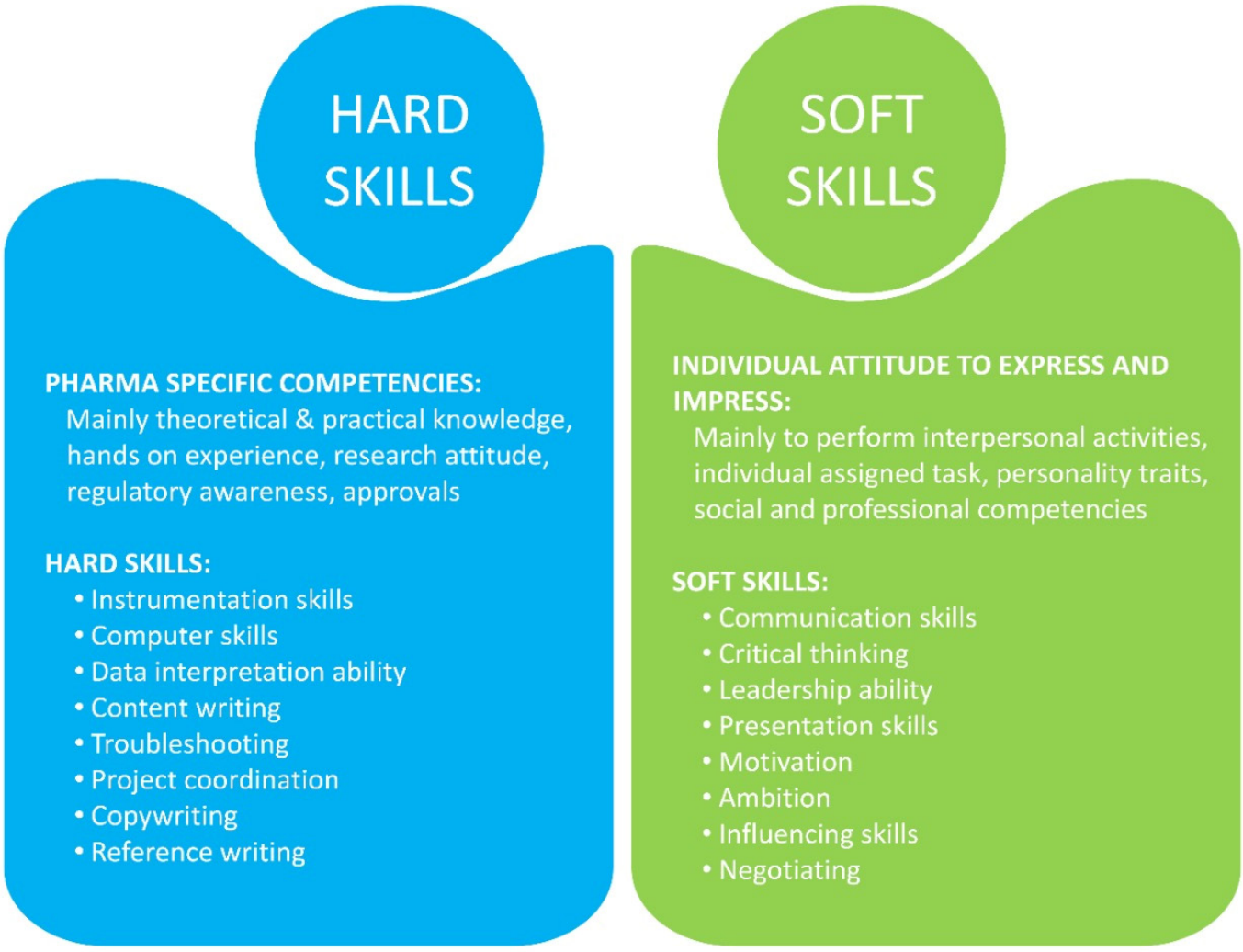

Figure 2: Hard Skills Vs Hard Skills.

levels. In the backdrop of businesses our company is into, such talent is rarely available in domestic market. Thus, the HR team scouts for such talent outside India if a suitable candidate is not found in the country. Team selection can also depend on sourcing of talent by internal references too. A structured selection process evaluates the candidature and fit in the organization, especially from cultural stand point. Reference checks are also conducted on case-to-case basis for senior profiles.

The candidate is expected to possess technical information, apart from that HR team concentrates on soft skills of the person to be hired for managerial position (Figure 3). In addition, the decision-making strength is also evaluated as they will be holding positions to take business related decisions. Other capabilities like willingness to learn new things, techniques and technology, possessing agility to adjust to change and positivity and attitude for development of organization.

In what manner do you evaluate a candidate's soft skills in an interview? In today's context, soft skills play acromioplasty in development of career. It is the individual's attitude and proficiency of working in a team-based culture, possessing flair for leadership and effective communication skills, which make a difference. For example, companies like Reliance Life Sciences adopt proficiency-based selection process including presentation on technical skills, interactions, questionnaire, stimulation of a situation. If the reasons for such gaps are genuine and convincing, the management takes cognizance of that. However, at no point in time, should the candidate hide actual facts. For instance, if the employee has been asked to leave the job due to any type of slowdown in business or recession faced by company. In case of Women's they need of break in duration of maternity, In such circumstances, such breaks in the employment history would not create any problem as an when she wants to rejoin. Fresher's need to be clear about their career objectives and choose something close to their heart. It is always important to build a career in an area of interest rather than taking up fashionable options.[12]

Figure 3: Soft Skills Impart.

Soft skills catalysing the work culture, individual growth and influence total qualty system

The development of soft skills is based on five set notions like self-control, self-concept, communication skills, thinking pattern including problem solving tendency, positivity and decision making and social skills. A focus on these skills for youth employment programming does not mean that they are the only soft skills that matter for all young people everywhere, nor that programs should cease conducting assessments to determine the needs of particular target groups. The positive employment outcome can be achieved by building soft skills talents in young budding pharmacist. Professional is successful due to his acquittance of soft skills, Industries and organization hire new employees considering their soft skills than hard skills. The need of the hour is to create good and effective teams for collaborative working atmosphere.

The quality of products provided by any industry then doesn't only base on the materials chosen and, on the technology, used, neither only on the expertise of workers who contribute to their fabrication, but also on the quality of the enterprise in its whole. Human resources and its positivity are major force that drive the company towards success. The Pharmaceutical Industry in India is uplifting employment status of the country by engaging millions and pro viding essential drugs are affordable prices. The medicines

Figure 4: Features of soft skill.

are accessible to the vast inhabitants of this sub-continent. But prerequisite of an hour is to accomplish the expectancy of Pharma Industries from academician. As Pharma academician can only inculcate and instill desired qualities, potential and abilities in new breeds in order to fulfil requirements of Industries.

It is an identified statistic that Pharmacists are mainly stimulated to cultivate their scientific expertise, adding worth and different profits to our lives.

A lesser amount of encouragement is provided to their individual development and less emphasis is given to the communication in the pharmacy However, it is needed to understand how to link and connect, form valued relationships with others and team management.

Indeed, Management and interpersonal skills are hardly ever included in the Pharmaceutical curriculum at universities and yet these abilities are essential when faced with the responsibility of managing teams (Figure 4). It can be challenging to lead a team effectively and implement Methods and procedures without an understanding of governance and communication skills. It is well known fact that "to be a good professional, a pharmacist should own "a blend of inclusive of therapeutic knowledge, experience, problem-solving expertise, and capability to give verdict". According to latest survey soft skills were valued and rated than the hard skills. Soft skills are non-technical, immaterial, persona specific skills which governs an individual's strength as a front-runner, listener and negotiator, or as a conflict mediator. These skills are attitude-based abilities of behavior and attitude of the knowledge. The Pharmacist is the personnel who requires skills to have good relations with customers as well as

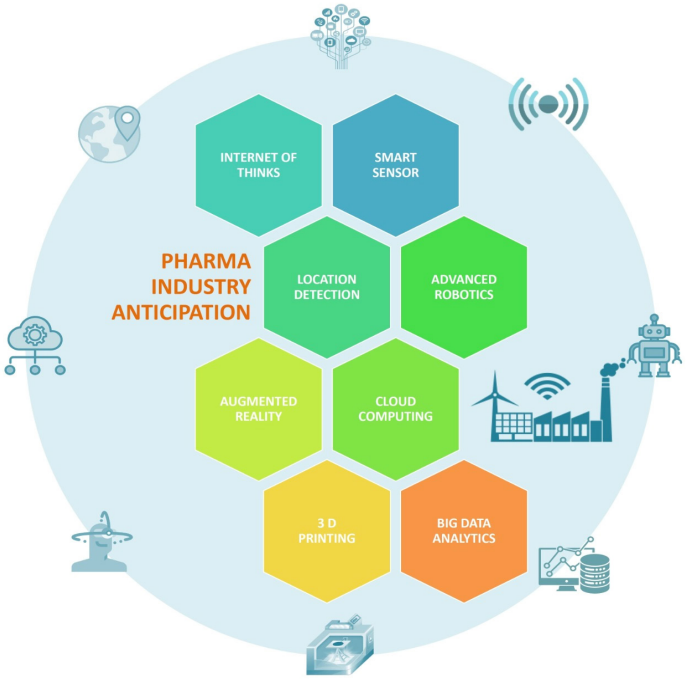

Figure 5: Pharma Industry Anticipation.

to explain and counsel patients for effects and side effects of the drugs, Efficient leadership qualities to form team, capabilities to supervise, ability to deliver well desired knowledge to employees and these set of knowledge are needed to updated for fruitful results.[13]

Transformation of pharma industry functioning in the era of ai and digital automation

Artificial intelligence is transforming the pharmaceutical industry and strengthening the collaboration with pharma academic institutions with aim to foster the research and innovation process[14] It has the potential to bring about a paradigm shift in the way drug are researched, developed and marketed (Figure 5). In this article, we'll explore how AI is changing the pharmaceutical industry by looking at 5 key areas of AI in pharma: data science, drug discovery, clinical trials, marketing and R&D.[15]

Artificial Intelligence (AI) allows humans to collect, process and analyze a large amount of data. When it comes to data science, AI can help identify pattern and trends that may have been missed or overlooked by human intervention. It's important to note that AI's capabilities in data science are different from those of conventional analytical models. In addition to helping companies generate insights and predication, it also helps develop drugs based on the latest scientific discoveries. How? By leveraging power algorithms, including machine learning and deep learning, it creates a seamless information exchange network between researchers, clinicians and pharmacists.[16]

Artificial intelligence is already been successful in the field of drug discoveries and have also received much attention in other

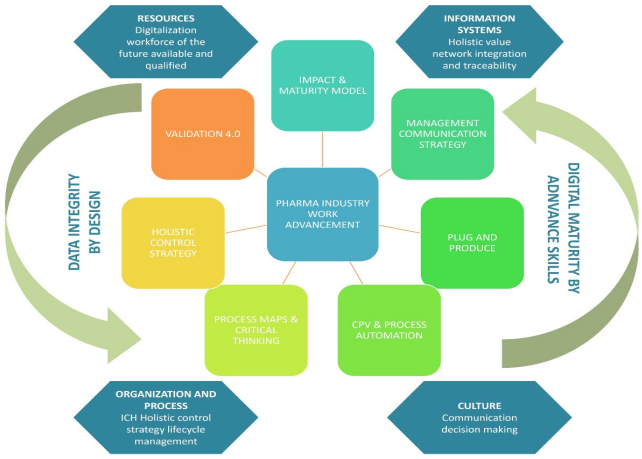

Figure 6: Pharma Industry Work Advancement.

fields too. A number of techniques based on artificial intelligence are being established including machine learning techniques, automation techniques, data mining, various software, etc. and utilized in the drug discovery processes.[17,18] All these techniques are at the same time playing a huge role in discovery of natural compounds that initiates the herbal medicine discovery and development. Further improvements in the property predictions of a compound are observed when compared deep learning techniques to the classical machine learning techniques as a result of neuronal network based novel algorithms such as deep neural network. Applications of techniques based on artificial intelligence in natural drug discovery are being demonstrated to predict the compound design, physicochemical properties of compound, biological activity, ADME properties etc. Along with this it is also helpful in mining the data in search of a compound with similar properties and biological activities as required when there is lack of the original compound. From an open-source implementation, artificial intelligence benefited the drug discovery strongly which provided access to software libraries allowing the implementation of complex neural networks. The extent of applications of artificial intelligence in drug discovery has been largely increased and may also increase its branches in the natural drug discovery and development.[19]

CONCLUSION

In view of the fact that during the last decades in society the apparent significance of soft skills has amplified significantly, it is of great prominence for the whole world to obtain satisfactory skills beyond academic or technical knowledge (Figure 6). As limitation in a definite area of soft skills has been recognized at oneself, there are plentiful ways of correcting such a deficit. Mentors have a special responsibility for the development of their student's soft skills. Moreover, raising awareness on the subject of soft skills and boosting students to expand their skills, professors should enthusiastically practice soft skills with their students. An

effective and efficient mode is to deliver soft skills training into the teaching of firm skills. These skills justify in giving proper shape to an individual's personality by complementing his/her hard skills. Modern humanity is progressively being coming forward for prosperous collaboration and the founding high class professional and personal associations.

Goals of AI is to make Research and Development (R&D) efficient. To achieve this goal, it helps bring together all the scientist data produced by researchers, clinicians, pharmacists and students across the globe. Constantly learning from the data, machine learning algorithms develop better predictions and solutions, which helps increase the number of accurate drug candidates for clinical trials.

Activities that raise spirits for effective communication soft skills in technical education is essential in building the budding pharmacists of the future. With ups and downs from somewhere need to start, the best of ourselves. The mentors and trainers are an example for future generations. The faculty fraternity always wish that students ultimately be more mature, more responsible, more self-aware, amicable and come out with flying colors after completion of their graduation. As a result, the main objective of the curriculum of technical education to prepare pharmacist for the 21st century, where except explicit specialized information, requires the possession of soft skills to be prepared for the tasks in a competitive global environment.[9]

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

R&D: Research and Development; **IPR:** Intellectual property rights; **PAT:** Process Analytical Technology; **EHS:** Environmental Health and Safety; **CAPA:** Corrective and Preventive Actions; **AI:** Artificial intelligence; **cGMP:** Current Good Manufacturing Practice; **RS:** Reference Standard; **WS:** Working Standard; **VOP:** Voice of the Process; **QSAR:** Quantitative Structure Activity Relationship; **NDA:** New Drug Application; **ANDA:** Abbreviated New Drug Application; **EHS:** Environmental Health and Safety.

SUMMARY

The present article summarizes the anticipation of pharma industries form pharma institutions to meet the requirement as per the industrial revolution of pharma 4.0. There is a crucial necessity to begin an academic exercise aimed at renewing of prospectus, focusing recent and evolving learnings in the field of pharmacy. The current youth of pharmacy graduate sought to have technical expertise of sophisticated instrument functioning, trouble shooting, product and and Process development, IPR, innovative rational based thinking, quality by design, regulatory aspects of global level to match the anticipation of industrial revolution of pharma 4.0. Certainly, they are short age of expertise in new generation instruments, latest development in Pharma Industry, and Intellectual Property Rights and Regulatory needs of Industries and profound exposure of Process Analytical Technology (PAT). The numerous factors which should be well-known are Environmental Health and Safety (EHS), Investigation like 6 sigma's, Ishikawa Fish bone skills and CAPA, Parameters Efficiency including OEE, SMED, 5S, OPE, Lean production, Latest Development of Pharma Industries, Regulatory knowledge about Internal and External Audits, Self-Inspections, technology Transfer, Change Management emphasizing on Control on changes and Risk management: FMECA, Risk Evaluation and Mitigation. Artificial Intelligence (AI) has the potential to bring about a paradigm shift in the way drug are researched, developed and marketed. To achieve this goal, it helps bring together all the scientist data produced by researchers, clinicians, pharmacists and students across the globe.

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