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Skill development in the pharmaceutical sector in India

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In the recent past, the Indian pharmaceutical industry has been changing rapidly, as a result of globalization and the large dependence on the Indian industry for the supply of quality pharmaceutical products. To ensure its continued success, Indian pharmaceutical corporations will need to introduce quality specialty products, for which they will require more skilled and qualified man power. The emphasis of the current Indian government on the development of skills across all industry sectors is well thought and is a logical extension of its “Make in India” program. We are all well aware that there exists a gap between academia and industry and the Human Resource Department of every industrial organization, including those in the pharmaceutical industry, desires graduates who are more knowledgeable about the needs of the industry and trained to serve these needs. Academia in India, as compared to the developed nations, lags behind the industry with regards to current manufacturing trends, innovation and research. We acknowledge that there exists a need to bridge this gap and numerous efforts have been made to reduce the differences between reality and that what is desired. In view of the multi-dimensional skills involved in the operation of a pharmaceutical company, a multi-faceted approach must be used to ensure skill up gradation of personnel involved in all functions of putting a product into the market.

Until 2015, eleven NIPERs were approved and in 2016 the Government of India has approved three more NIPERs in Chhattisgarh, Maharashtra

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and Rajasthan. Considering the large number of government and private pharmacy colleges in India, one of the approaches of bridging the gap, between academia and industry is by ensuring that the Bachelor of Pharmacy and Master of Pharmacy curriculums in these institutions are current and relevant. The role of the Pharmacy Council of India in updating the syllabus of the BPharm program is noteworthy. However, in view of the long interval between the previous revisions, it may be a good suggestion to have a core curriculum, which is uniform across the country and flexibility may be granted to progressive academic institutions to offer additional electives that are now required in the functional working of the pharmaceutical industry. Some of the developments that have provided opportunities for the introduction of new disciplines of study are enumerated here. New concepts in pharmaceutical production such as continuous manufacturing processes and process analytical technologies offer interesting new areas for specialization. In the area of Quality Assurance students must be exposed to systems, commonly used in pharmaceutical quality management, such as Deviation Management, Change Control Procedures, OOS etc., early in their careers, to enable them to adapt quickly once they start their careers in the industry. Apart from the knowledge of Schedule M, 21 CFR, ICH Q7 and other international regulatory requirements, students must be trained with language and interpersonal skills to prepare them to interact with international regulators and auditors. While traditional pharmaceutical jurisprudence has been a subject in the curriculum since long, students must be sensitized to Trademark and Patent laws, the Drug Price Control Order 2013 and the Uniform

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Code of Pharmaceutical Marketing Practice, which is currently a guideline and not enacted as law.

The Indian Pharmacopoeia Commission has been entrusted with implementing the Pharmacovigilance Program of India. With its formalisation since 2010, pharmaceutical companies are required to ensure compliance with the pharmacovigilance program, resulting in a need for trained personnel who are knowledgeable with the best pharmacovigilance practices.

Further, in the past new drug discovery research involved the chemical modification of small molecules, while, current drug discovery programs primarily involve development of complex large molecules commonly called biosimilars. Hence, with the rapid changes in the industry it is desirable that curriculum up gradation be perceived as a continuous process that must be done periodically.

The government has also established many large research institutions like the Council for Scientific and Industrial Research (CSIR) and Indian Council for Medical Research (ICMR) to create a culture of product development based on basic scientific research. There must be a purposeful mandate among these institutions to develop technologies that are of national importance. These government institutions must be coerced to license out these technologies to national pharmaceutical organizations for commercialization. This will ensure that the products are developed to a level of market readiness for immediate commercialization.

It may also be noted that these large government research institutions have also played a role in providing the pharmaceutical sector technical, trained scientists, some of whom have established companies and are today successful entrepreneurs. This again is another noteworthy initiative that provides the pharmaceutical sector with skilled professionals.

Industry associations such as the Indian Drug Manufacturers' Association (IDMA) have been facilitating workshops and training programs for the industry in collaboration with various international certification bodies such as UL and NSF International to upgrade the skill sets of personnel in the pharmaceutical industry involved with the Quality Unit. These workshops and programs bring international experts to India and allow greater number of personnel to interact with these experts.

Further, programs have been organized to showcase the facilities and the capabilities of faculty members at the various academic institutions encouraging industry members to utilize these facilities and to interact more with academia resulting in mutual benefit. With academia and industry busy with their own mandates to further expand their operations and garner more profit, the onus is now on industry associations to be the catalyst, to coax its industry members to shoulder greater responsibility and ensure that the pharmaceutical workforce for the future is qualified, well-trained and employable.