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Subject: **S.R.O. 460(I)/2019**

This is with reference to S.R.O. 460(I)/2019 which has created a great deal of un-rest among a large number of employs with chemistry background, working in the pharmaceutical industries Under this S.R.O. 460(I)/2019 a large number of employs will lose job. The WHO guidelines don`t prevent chemists from working in Quality assurance department as their guidelines mentioned in **Quality Assurance of Pharmaceuticals Volume 2, second update edition** by WHO point **9.7** and article 49 in Directive 2001/83/EC European guidelines. Similarly, the European guidelines under article 49 in directive 2001/83/EC also don`t bare the chemists working in the quality control and quality assurance department of pharmaceutical industry. Other international guidelines are also not preventing employs with chemistry background from working in the quality assurance and quality control department of pharmaceutical industry. The requirement of working experience in quality control lab for a chemist is more than a pharmacist which is not justified as the job description of the personnel working in QC and QA labs are more relevant for chemists. Like the main functions of personnel in QA are the followings

1) Ensure that appropriate manufacturing process are implemented
2) Perform and verify laboratory testing of components, containers, in-process materials, packaging materials and drug product using validated methods.
3) Approve or reject drug products manufactured, processed and packed
4) Perform retests or reexamine approved components, drug product containers and closures after long storage or exposure to adverse conditions
5) Review and approve/reject reprocessing and rework procedures
6) Ensure investigation is conducted and root cause is eliminated for production and control record errors, discrepancies, and failure to meet specification, including quality attributes

The pharmaceutical industry would require a person with chemistry background to perform all the aforementioned tasks. Similarly, the main tasks of QC personnel in pharmaceutical industry are the following.

1) Quality control personnel utilizes chemistry lab skills to test and measure materials, generally in a manufacturing or pharmaceutical field

2) Ensures that experiments are completed according to established SOPs, GLP or Good Clinical Practices (GCP), as well as any applicable federal regulations or industry standards
3) Quality control personnel prepare and test samples from all phases of a manufacturing or other handling process, with the goal of determining if the substance meets the global standards.

The duty of QA and QC personnel slightly vary from industry to industry but generally require basic lab-work skills and thorough understanding of chemistry, chemical testing equipment and processes

On behalf of the chemical society we are requesting you to re-visit the S.R.O. 460(I)/2019 and align the qualification criteria for key personnel in S.R.O. 460(I)/2019 with WHO & European guidelines to meet the global. The implementation of S.R.O. 460(I)/2019 will not only reduce working force for pharmaceutical sector of Pakistan, but the pharmaceutical industry will also lose the rich experience of the pharmaceutical professionals gained over the years. The implementation of the subject S.R.O. will hampering the progress of the pharmaceutical industry and will drastically affect the production of quality medicines in the country on one hand and other hand a large number of peoples will lose the job.

Prof. Dr. M. Raza Shah *T.I.*