

Only for Pharma People

Volume 3, Issue 3

March 2020, 30/-

QualPharma

The Learning and Development Journal

Future Ignorant Drug Inspectors

Medical devices
Under the drug law

Quality Culture and CAPA

Know Yourself

*When Should Formal Quality
By Design Documentation
Begin?*

CANCER VACCINE

Khan Omar, AIR 1
(GPAT)-2020

Dangal with
CORONAVIRUS

A portrait of Dr. Rajesh Jain, a middle-aged man with grey hair and glasses, wearing a white shirt and a patterned tie, sitting in a black office chair. The background is a plain, light-colored wall.

DR. RAJESH JAIN

**MANAGING DIRECTOR
PANACEA BIOTECH**

Future Ignorant Drug Inspectors

A notice has been published by Ministry of Health and Family Welfare dated 16.01.2020, wherein draft recruitment rules for Drug Inspector (Medical Devices), Assistant Drugs Controller (I) (Medical devices) & Deputy Drug Controller (I) (Medical devices) has been circulated in which Engineers and Biotechnologist were allowed to apply. Surprisingly Pharmacist has been given the last priority in specifying qualification. From time to time requirement has been raised to allow pharmacist to prescribe and medicate. The new notification has not only insulted the profession of pharmacist but also proved that pharmacist are overlooked by the government.

Recently the union health ministry have appointed Drugs inspector (around 23) and Assistant Drugs controllers (02 Numbers) who all are from mechanical engineering background. They do not have any knowledge of Human Anatomy, Human Physiology, Pathophysiology, Biochemistry, Pharmacology,

Toxicology, Drugs Pharmacokinetics and Pharmacodynamics, Drugs Safety, Clinical studies, clinical performance, preclinical safety and toxicity studies, Quantitative Structure activity relationship of drugs, Medicinal chemistry, Impurities, stability studies, process validation studies, technology transfer, scale-up and post approval changes, Good manufacturing practices, good clinical practices, Pharmaceutical analysis, good laboratory practices and many such specific knowledge of drugs and devices. Engineering disciplines never have these subjects in their curriculum and hence they won't be able to understand the drugs actions, adverse effects, drug abuse and misuses etc. These people will not only make the drug regulatory process cumbersome but due to absence of pharmacy professionals the drugs regulations becomes handicapped. This will affect the lives of the citizens, we can't afford to allow these engineers to play with the health and lives of the people.



Dr Sanjay Agrawal

Dr Agrawal founded PHARMA CONSULTANTS and INVENTOR to fulfill his passion, capabilities and desire to assist pharmaceutical companies around the globe. He has actively worked in pharmaceutical and related industries for more than 28 years and started this firm in 2005. He is **Editor-in-Chief** of renowned IJM Today and honorable member of the editorial board of **The Antiseptic**.

The draft recruitment rules are against the provisions of Drugs and Cosmetics Act, 1940 and Rules, thereunder.

1. Rules 18 of the Medical Device Rules, 2017 gives provisions for designating the Medical Device testing officer and Medical Device officer. **It does not give the power to appoint the said officers but gives power to designate such officers.**
2. Under Rule 18 (1) of the Medical Device Rules, 2017; the central government may designate a Government Analyst appointed under section 20 of the Act as Medical Device Testing officer.
3. The Government Analyst under section 20 of the Drugs and Cosmetics Act, 1940 is appointed by the government in compliance to the Rule 44 of Drugs and Cosmetics Rules, 1945.
4. Under Rule 18 (2) of the Medical Device Rules, 2017; the central government, or as the case may be, the state government, may designate an Inspector appointed under section 21 of the Act as Medical Device Officer.

An Inspector under section 21 of the Drugs and Cosmetics Act, 1940 is appointed by the government in compliance to the Rule 49 of Drugs and Cosmetics Rules, 1945.

“Rule 49. Qualifications of Inspectors.

—A person who is appointed as an Inspector under the act shall be a person who has a degree in Pharmacy or Pharmaceutical Sciences or Medicine with specialization in Clinical Pharmacology or Microbiology from a University established in India by law:

Provided that only those Inspectors: –

- i. Who have not less than 18 months experience in the manufacture of at least one of the substances specified in Schedule C, or
- ii. Who have not less than 18 months experience in testing of at least one of the substances in Schedule C in a laboratory approved for this purpose by the licensing authority, or
- iii. Who have gained experiences of not less than three years in the inspection of firms manufacturing any of the substances specified in Schedule C during the tenure of their services as Drugs Inspectors; shall be authorised to inspect the manufacture of the substances mentioned in Schedule

From the Rule 49 it is clear that only a person who is appointed as an Inspector under the Act shall be a person who has a **degree in Pharmacy or Pharmaceutical Sciences or Medicine with specialisation in Clinical Pharmacology or Microbiology** from a University estab-

lished in India by law. And such person who has been appointed under section 21 of the Drugs and Cosmetics Act, 1940 possessing the qualifications as per Rule 49, shall be designated by the central or state government, as the case may be to the post of Medical Device Officer.

Also, the post Drugs Inspector (medical devices) is nowhere mentioned in the Act or Rules thereunder. The prescribed qualifications in the medical device rules have to be as per the provisions of The Drugs and Cosmetics Act, 1940 and Rules thereunder. This makes the draft recruitment rules ultra vires and violates the provisions of Article 309 of the constitution of India.

By recruiting the persons with knowledge in Engineering does not serve the entire purpose of Medical Device Regulation which comprises the very diverse in nature. Due to the dynamic nature of Medical Device field, the persons with the engineering background shall not be suitable for performing his duties.

The draft regulation is very partial decision and not benefitting the society in any way. The author strongly believe that the said draft regulation shall be revoked and the pharmacist must not be behaved as step child.

~ Dr Sanjay Agrawal