

GMP, GCP & QUALITY CONTROL

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Roadmap to pharmaceutical regulatory harmonization in Pakistan

Muhammad Naeem

Indus Pharma (Pvt.) Ltd., Pakistan

Introduction: Provision of affordable quality pharmaceuticals is an integral part of every national health policy. Attaining optimal quality standards for pharmaceutical products is impossible without an effective pharmaceutical regulation regime that protects public health by ensuring safe, effective and quality pharmaceuticals and detecting illegal manufacturing and trade. Pakistan, despite having a large Pharmaceutical sector (over 600 manufacturing units; market size of around 3 billion dollars) has not realized its true potential in the area due to non-adherence to globally accepted quality standards. There is a huge unexploited potential for export of the country's pharmaceutical products especially in the context of the GSP Plus status granted to Pakistan by the European Union.

History & Challenges: In Pakistan, the ministry of health (MoH) used to regulate drug manufacturing and pricing at the federal level. After the decentralization of the Health Ministry (2011), Drug Regulatory Authority of Pakistan (DRAP) came into being (December 2012). DRAP has been continuously evolving and advancing in its vision and procedures; there is still a long way to go in order to overcome its current challenges like premarket evaluation and registration, post-market surveillance, cost recovery, price control, international harmonization, access to regulated markets and capturing the scientific advancements for modernization of act and regulations etc.

Recommendations: Promote harmonization of regulatory processes by adopting globally harmonized standards; establish targeted capacity-building for quality APIs; introduce an online submission system for dossiers/query responses etc., train the regulators; hire more staff and set transparent pricing rules.

Conclusion & Significance: Pharma regulatory authorities all over the world are rapidly advancing. Likewise, DRAP is already on its way for reformation and improvement. The recommendations in this presentation may prove helpful for DRAP in its journey towards excellence.

Biography

Muhammad Naeem has more than 19 years diversified experience in quality operations, regulatory affairs, research and development. He has done certificate courses on cGMP, GLP, Process Validation, ISO/IEC 17025:2005, 14001:2004, OHSAS 18001:2007, SA 8000 and 9001:2008. He is a Member of International Society for Pharmaceutical Engineering (ISPE) and Regulatory Affairs Professional Society (RAPS), USA. He has extensive knowledge of ICH, USP, BP, ASTM, and HACCP and has led several investigational/developmental and technical/analytical projects at CMOs in USA, Europe and Pakistan. Some of the major pharmaceuticals he served are Pfizer & Takeda (USA), CCL Pharmaceuticals and INDUS Pharma, Pakistan. He has strong scientific, analytical, planning, managerial and training skills.

mnparco@gmail.com

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