

Pharma Middle East

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International harmonisation of medicines' regulatory affairs

Regulatory affairs started to get organised over 50 years ago following unfortunate incidents such as the thalidomide tragedy. The quality of medicines was established in different countries through the development of pharmacopoeias, such as the British and the United States pharmacopoeia. Pharmacopoeias were harmonised in regions such as the European Pharmacopoeia and on an international basis, the international pharmacopoeia. The regulation of production and the authority to market medicines were also harmonised in regions, such as the Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in Europe. The authorisation of third countries to be able to produce and market their medicines in other regions is carried out by the regional bodies independently and with restricted cooperation. Attempts to harmonise the regulatory affairs internationally were made such as the use of ISO standards and ICH guidelines. If the regulatory forces are developed into a scientifically-based status and thus, the nomenclature from regulatory affairs to regulatory sciences could be rightly undertaken, then, the internationalisation and hence the harmonisation of regulatory sciences should follow with relative ease in the same way that the laws of science have been accepted internationally. If the rules of innovation, research and education were followed, using today's technology and communication, the harmonisation process should become achievable. This is especially essential today where the science of pharmacovigilance is developing at a great pace. If pharmacovigilance is tackled on an international basis, then the benefits to the world community cannot be overestimated.

Biography

Anthony Serracino-Inglott studied at University of Malta and University of Cincinnati. He carried out research in clinical pharmacy with a completion of a residency programme under the supervision of the eminent Professor Don E Francke. He has started taking lectures and started his research work at the University of Malta where he established the Institute of Health Care now called as the Faculty of Health Sciences. He has been elected as a Chairman of the Medicines Authority.

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