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Pharmaceutical regulatory environment with perspective on the International GMP's

Although the Thalidomide tragedy of the early sixties is regarded instrumental in the amendment to the US FD&C Act of 1938, and first appearance of the term Good Manufacturing Practice in 1962, but the GMP's were conceptually evolving for quite some time in the US as well as in Canada. Noticeable amongst such efforts was a paper on "Quality Control" by Dr Frank Taylor published in the *Journal of the American Pharmaceutical Association* in March 1947, but the first modern code that could be regarded as the first set of GMP's as we know them today, were the 1957 QUAD (Quality Assurance of Drugs) regulations dealing with the Manufacture, Control and Distribution of Drugs issued by the Canadian Specifications Board of the Supply and Services Department in order to ensure that drug products supplied to the Canadian Military were of the specified quality. Likewise, the term "Quality Assurance" was also first introduced to the Regulatory lexicon by Canada, which has since gained unparalleled international recognition. The success of the Canadian QUAD regulations led to accelerated issuance of the GMP's by Regulatory Agencies, with the US FDA issuing the first version in 1963 which underwent massive revision in 1973 and reissued in 1976. While the British drafted their GMP's in 1968 and issued those in 1973, more than 25 countries followed suit by the early 1980's. In the forefront are the US, Canadian, British, Japanese, WHO, PIC/S and the ICH Guidelines, and it is not uncommon for most countries to revise their GMP's usually every five years in order to maintain the currency status. The single exception has been the US FDA with the first revision in 2015 since issuance in 1976! Conversely, Canadian GMP's have undergone eight revisions thus far, and are harmonized with GMP standards from other countries and with those of WHO, PIC/S and ICH and take into account the implementation of the current MRA.

Biography

Mohammed Razdar Khan is a Quality Management Consultant and Principal for Synergex Consulting in Ontario, Canada. He has earlier served as Director QA, QC & Regulatory Compliance with DuPont Pharmaceuticals, Canada and also on the Board of the Pharmaceutical Manufacturers Association of Canada, Plant Operations Section. As an active member of the DIA, he has served on the DIA's Advisory Council of North America, chaired the DIA's Canadian Programming Steering Committee, and served as Program Coordinator, Program Committee Member, Session Chair and Speaker at numerous national and international DIA events. He is a recipient of the DIA Outstanding Service Award. He has also served as Presenter for the PDA, OMICS Group, IQPC, PSG Canada, UK based International Society of Ethno-pharmacology, and the Indian Pharmaceutical Congresses.

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