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The quality journey; from the Stone Age to modern times, and the lessons learned

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Abstract

The origin of the Quality concept is perhaps enshrined in the invention of the wheel itself, and in all probability the act of "replicating" the wheel was the dawn of the primitive principles of Quality Assurance. When we take a trip down the history of medicine, we do find documented records on materia medica dating as far back as four millennia. Much later in history, the entrepreneurial pharmacies of the medieval Europe started emerging as early pharmaceutical establishments, with commitment to product quality as the key to their success. Nevertheless, with progressively intensifying competition, greedy elements started channeling substandard or unsafe products into the market, thus putting the consumer at risk. Thus the Thalidomide tragedy of the early sixties triggered the 1962 Amendment to the US Federal FD&C Act of 1938, and coining of the term Good Manufacturing Practice. After lapse of over half a century, the world is still far from being free of the pharmaceuticals related tragedies and serious GMP violations. Scores of establishments continue to operate on a sub-compliance, or at best marginal compliance level. And the reason is simple. When maximization of profits becomes a priority in an organization, the upper management's attitude towards quality changes significantly. They start merely reacting to problems as they occur, rather than focusing on preventive medicine. And talking of attitude, there is no shortage of examples and the disseminated effect it has on quality operations. Right attitude is thus the key to furtherance of the quality concept, and so is the buy-in of the GMP as a philosophical approach rather than a mere set of regulations.

Biography

Mohammed Khan is a Quality Management Consultant and Principal, Synergex Consulting, Canada. He has earlier served as Director QA/QC and Regulatory Compliance with DuPont Pharmaceuticals Canada, and also as a Director of the Pharmaceutical Manufacturers Association of Canada, Plant Operations Section. As an active member of the Drug Information Association, he has served on the DIA Advisory Council of North America, Chaired the DIA Canadian Programming Steering Committee, and served as Program Coordinator, Program Committee Member, Session Chair and Speaker at a vast number of the DIA events in the US, Canada, Europe and South Asia. He is a recipient of the DIA Outstanding Service Award. He has also served as a Presenter for the PDA in Europe and Japan, IQPC in the US, PSG Canada, and IPC India.