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External QA audits: Ensuring compliance at the contract manufacturing sites

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As investors are getting smarter and demanding maximization of the return-on-investment, pharmaceutical industry is increasingly exploring horizontal integration by using contract manufacturers to produce the products as quickly and efficiently as possible. The industry is thus seeking departure from the 'traditional' way of doing the business that involves vertical integration.

Contracting out is not free of hurdles and challenges. The major one is ensuring that the products delivered by the CMO always meet the safety, efficacy, and quality standards as set out by the cGMP. Since this is the responsibility of the product marketing approval holder, an efficient system of ensuring ongoing compliance at the CMO level is indispensable. A thorough and effective annual QA audit of the CMO is highly desirable for the purpose, and the presentation effectively deals with this.

Biography

Mohammed R. 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. He is an active member of the Drug Information Association since 1996, and has served on the DIA Advisory Council of North America while concurrently chairing the DIA Canadian Programming Steering Committee from 2003 through 2007. He has also served on the Core Committees of the DIA GCP & QA SIAC and the NHP SIAC, and 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.

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