

Quality System Gap Assessment:

Why is it needed and what are the benefits?

April 19, 2021 - (SPARTA, NJ) - Gap Assessments are a standard in the Life Sciences Industry and are utilized by all size companies as a quality control and compliance mechanism. The results of the assessment and the recommendations it produces ensure that the Quality System program works in accordance with established rules and regulating body standards.

The Gap Assessment should be viewed as a tool to assess the company's in-house quality management system and current compliance level, according to Nick Andrews, Director of Operations at Medvacon. "A Quality System GAP Assessment is conducted to ascertain the status, validity, and reliability of quality information and provides an assessment of the internal controls of the Quality System," he explains. "In simple terms it is the inspection of the Quality System to ensure that it meets the requirements of its intended use and expectations/standards of regulating bodies, such as the US FDA."

A company that produces pharmaceutical products must be able to demonstrate that it does so with absolute reliability, in optimal conditions, and with extreme uniformity that allows accurate reproduction. "The GAP Assessment is a means for assessing compliance with the established objectives defined in the quality system and paves the way for a continuous improvement program by providing feedback to management," according to Andrews.

With Medvacon, some of the areas that will be reviewed during a GAP Assessment are derived from the FDA Guidance ICH Q10 - Effective Pharmaceutical Quality Systems. Andrews says they include pharmaceutical development, technology transfer, commercial manufacturing, distribution (excluding wholesaler activities), and product discontinuation.

Medvacon is a full-service Quality and Compliance consulting firm offering a suite of quality services such as: Quality Systems Implementation and Remediation; Computer System Validation; Process and Cleaning Validation; Equipment, Facility and Utility Qualification; Mock FDA Inspections and Audits; Project Management; and cGMP Training. These services help clients to ensure FDA Compliance and reduce compliance cost in the Life Sciences' industry. The company provides experienced project administration, trouble-shooting, and/or training services, on-site, with local resources and senior management involvement to optimize flow and collaboration. Headquartered in Sparta, NJ, Medvacon also has offices in San Diego California. More information can be found at www.Medvacon.com.