

JSK Consulting Services
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J. Scott Kemp, Principal

EXPERIENCE:

Mr. Kemp began his career in manufacturing and associated operations support functions with Johnson & Johnson (J&J). In his position as Executive Director, Operations, for the (then) McNeil Pharmaceutical Division of J&J, Mr. Kemp was responsible for the design, construction, validation and the FDA's Pre-approval Inspection (PAI) of McNeil's new prescription pharmaceutical manufacturing facility in Pennsylvania. The facility was approved by the FDA in a record 2 ½ day inspection that resulted in no 483 (non-compliance) deficiencies by the inspectors.

After nearly 21 years with J&J, Mr. Kemp was subsequently recruited as Vice President, Operations for a start-up biotechnology company where he oversaw the design, construction, validation and the FDA's PAI of that company's new manufacturing facility. Again, the site was approved by the FDA without a single 483 observation.

Subsequently, Mr. Kemp founded Certified Facilities Corporation (CF) where he headed the firm's validation and regulatory compliance consulting services for FDA regulated manufacturing clients. Successful projects included validation of the new Novavax manufacturing facility, utilities, equipment and process in Philadelphia. Mr. Kemp was subsequently retained by Novavax to assist in the FDA's PAI which was passed without as single 483 deficiency.

Although many of his projects with CF were for new, emerging companies, Mr. Kemp also consulted with several major multinational companies, including Bristol Myers Squibb, where he was retained to evaluate construction drawings and documentation for compliance to ISO and CGMP requirements; 3M Pharmaceuticals, where he managed the design of a multi-product pilot manufacturing facility and Novartis, where he managed the development of a Basis of Design for a multi-product formulation and sterile filling facility. Other clients included: Amgen, Biogen-Idec, Chiron, Genzyme and Wyeth-Ayerst.

PRE-APPROVAL INSPECTION CONSULTING SERVICES

Mr. Kemp currently assists clients preparing for a PAI by reviewing and providing recommendations, where appropriate, of the following:

1. validation documentation of HVAC and Building Automation Systems (BAS) systems, including IQs, OQs, and SOPs;
2. validation documentation of process utilities' systems, including IQs, OQs, SOPs and PQs (where required) of USP and WFI water systems, clean steam systems and process gas(es) distribution systems;
3. validation documentation of process equipment, including IQs, OQs and SOPs;
4. preventative maintenance programs and SOPs for facility and utility systems;
5. materials receiving, sampling, quarantine and warehousing, flows and segregation/labeling procedures.

PROFESSIONAL EXPERIENCE:

2008 - JSK Consulting Services
1989 - 2008 CERTIFIED FACILITIES CORPORATION, Seattle, WA
1986 - 1989 IMRÉ Corporation, Seattle, WA
1980 - 1986 Johnson & Johnson, McNeil Pharmaceutical Division, PA
1965 - 1980 Johnson & Johnson, Consumer and Hospital Products, IL and NJ

EDUCATION:

B.S., Industrial Management, Georgia Institute of Technology, Atlanta, GA