Ken Geskes

Managing Consultant

kge@granitegrcconsulting.com

484.929.3880

Experience

An experienced life sciences executive and consultant, Ken Geskes brings more than 40 years of skill and insight into quality system design, operations and compliance across the US, Canada, Europe, the Middle East, Latin America and Asia. In this regard Ken teams with clients to define, enhance or remediate quality management systems, quality assurance activities and regulatory compliance activities with a focus on prevention, efficiency and sustainability. Ken helps clients navigate all aspects of U.S. Food and Drug Administration (FDA) and Notified Body audit management, audit response definition and remediation management, including consulting on corrective and preventive action (CAPA).

Working at plant, division and corporate level, Ken's experience includes handling regulatory compliance for multiple types of medical devices ranging in complexity from simple FDA class I (e.g. suction tubing, surgical instruments) to FDA class II (e.g. orthopedic implants, Software as Medical Device - SaMD) to FDA class III (e.g. bone cements, cardiac catheters) as well as device and pharma combination products (e.g. pre-filled syringes). A number of these devices are associated with in vitro diagnostics such as software that collates, assesses and recommends treatment regimens to clinical staff.

His responsibilities have ranged in scope from a single site to global responsibility for up to 30 sites in multiple countries in Europe, Asia, Central and South America, the Middle East, the U.S. and in Canada. He brings firsthand knowledge of frontline aspects of manufacturing to handling international and domestic regulatory compliance. Ken has also held multiple senior leadership positions in management at DePuy Synthes, a division of Johnson & Johnson. In his most recent in-house leadership role, Ken oversaw the global remediation quality plan focused on the enhancement and harmonization of multiple quality management systems and the elimination of ineffective and inefficient quality system elements.

Education

- Fairleigh Dickinson University, B.S. in Biology, 1975

GRANITE GRC

280 Granite Run Drive,
Lancaster, PA 17601

granitegrcconsulting.com

Optimize resources.
Manage risk.