BRANDWOOD:BIOMEDICAL NZ
securing your compliance

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Nancy L. Yopp

Director and Senior Consultant – Brandwood Biomedical New Zealand

With 25+ years of technical manufacturing, operations and regulatory senior management experience in the US and NZ medical device industries, Nancy Yopp provides expertise in regulatory compliance and implementation and commercialization of medical devices, including in-vitro diagnostics. Nancy has worked extensively with animal based products and the risk management associated with these products and has a proven track record working with the varied complexities of both start-ups and multi-national companies.

Business Profile

25+ years senior management experience in the Medical Device Industry inclusive of regulatory and quality and manufacturing operations; Extensive work with animal based products and risk assessment of these products; GMP and ISO 13485 Quality Management System expertise; Development of Quality systems from start-ups to US$100M+ organizations;

Achievement-oriented with advanced project and client management capabilities, problem solving, communication, and leadership skills

Nancy opened the NZ office of Brandwood Biomedical in 2014 and provides expertise in Medical Device regulatory, manufacturing operations and product development. She held the positions of Director of Operations and Director of Regulatory and Quality at Mesynthes Ltd, a NZ medical device company specializing in animal based products use in regenerative medicine. At Mesynthes she wrote and implemented a Quality System meeting ISO 13485 and US FDA GMP regulatory compliance, successfully scaled-up manufacturing and prepared 510k, CE and EDQM applications.

In the US, Nancy was Director of Manufacturing for Ventana Medical Systems, and in-vitro Diagnostic company. She managed both reagent and instrument production and Quality Control, as well as coordinated the relocation and validation of several plants into a single locale. She has also held the position of Vice President of Operations at Chemicon International and International Enzymes managing both of these companies successfully through change and growth strategies. She has developed and managed operations, product development and regulatory/quality teams during her successful career.

Nancy has served on the Board of the Medical Technology Association of New Zealand (MTANZ) and participates on the industry Regulatory Special Interest Group. She has been active in representing industry in the Australia New Zealand Therapeutic Products Act (ANZTPA) development.

Qualifications

MBA, Pepperdine University

BS (Biology), Northern Illinois University

Nancy holds an MBA from Pepperdine University and a BS in Biology from Northern Illinois University.