Quality, Regulatory Affairs, Medical Device & IT

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Mediteq Forum Digital – Take a walkabout Down Under

Mediteq Forum is excited to welcome Jane Shum from TGA and Gary Burgess consultant, former TGA employee, as guest speakers. During a morning webinar, Jane and Gary will share their knowledge and experience in Regulation and Pathways to supply in Australia' including:

- Pathways
- TGA Conformity assessment
- Classifications
- Comparable regulators (FDA/EU etc)
- Good Quality submissions
- Clinical evidence requirements

Date: 19 mars 2024, from 8.30 – 10.30

Digital: Webex will be available for participants

Sign up: here

Agenda:

08.30 Introduction to Mediteq Forum & today's Guests

08.40 Jane Shum TGA presentation

09.20 Gary Burgess presentation

10.00 Questions and answers

Please share your questions for Jane and Gary via the sign-up form, to ensure they get addressed during the session.

Welcome!

Line Vikingsson and Emilie Andersson
Facilitators Mediteq Forum

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Presentation of today's guests

Gary Burgess has over 18 years' experience in the medical device regulatory affairs industry, including with the Australian Therapeutic Goods Administration (TGA), Medical Technology Association of Australia (MTAA), hearing implant manufacturer Cochlear Limited, and as a consultant. Example of Garys experience: Australian and European medical device legislation, regulatory intelligence, regulatory strategy development, regulatory compliance, QMS requirements and auditing for medical devices (ISO13485 & MDSAP), as well as post-market vigilance and monitoring.

Gary is currently the Director and Principal Consultant at Hill Valley Regulatory Consulting, based in Canberra, Australia.

Jane Shum is an acting Director in the Medical Device Authorisation Branch at the Therapeutic Goods Administration (TGA). She leads a team of specialist evaluators who support conformity assessment, application audit, assessment of medicine delivery systems and provide expert advice to pre-market, post-market and policy teams. Jane has worked at the TGA for over 10 years with a focus on medical device regulation, including post market review, application approval, policy and reform. Prior to joining the TGA Jane worked as a Forensic Scientist as a member of the Australian Federal Police.