



Mediteq Forum Digital – Roads to US Market – Is product code the key?

Mediteq Forum is excited to welcome Michelle Lott from Lean RAQA as guest.

She will share her knowledge and experience on US medical device regulations from more than 20 years of supporting companies to reach US clearance for their medical devices.

Some key points from the presentation:

- Find a suitable product code for your medical device, and what to do when no code seems to fit.
- Selecting and using a predicate device in the best way?
- Exploring the different submission and review processes 510k and PMA. When and how to use De Novo?
- Pre-submission – When to use this feedback tool?
- Understanding the 510k third-party review process and benefits from it.
- Tips and tricks during interaction with FDA
- Essentials of device labelling (21 CFR Part 801).



Date: 21 November 2023, from 16.00 – 18.00

Digital: Zoom link will be available for participants

Sign up: [here](#)

16.00 Introduction to Mediteq Forum & Today's Guest

16.15 FDA's Medical device regulations

17.30 Questions and answers

18.00 Summary and end

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

Welcome!

Helen Sandelin & Nupur Sharma
Facilitators

Mediteq Forum



Presentation of today's' guest



Michelle Lott

20+ Year RAQA Master;
Founder/Grief Counselor

Since 2010, Michelle Lott has been on a mission, helping more than 100 smaller companies with all things regulatory – strategy and planning, regulatory submissions, audit preparation and remediation, due diligence, quality systems, compliance and more.

She served a term on the FDA's Device Good Manufacturing Practices (CGMP) Advisory Committee, providing strategy and guidance to the FDA on key healthcare industry topics.

She has served as a regulatory participant in the Global Enteral Device Supplier Association (GEDSA) and has been a member of The International Consortium on Systems Engineering (INCOSE), serving as sub-team lead for their Model Based System Engineering Healthcare Working Group.