Quality, Regulatory Affairs, Medical Device & IT

Mediteq
Kämpegatan 6
SE-411 04 Göteborg, Sweden

+46 31 774 25 00
www.mediteq.se

Mediteq Forum Digital

What happens on the US market?

Mediteq Forum is excited to again welcome Michelle Lott from Lean RAQA as guest. We have had the privilege to listen to Michelles knowledge and experience on US medical device regulations before. In this session she will share insights and information on recent changes and possible impacts.



Some key points from the presentation:

- **How are FDA submissions affected by layoffs?**
- **Other effects of layoffs and leadership changes**
- **"US first" strategy – still valid?**
- **Transition from QSR to QMSR – impact on EU-based manufacturers:**
  Since ISO 13485 is already established in the EU, what practical implications does the shift to QMSR have for us?
- **What needs to be updated in our Quality Management System (QMS)?**
  We will review which updates may be necessary to maintain compliance when exporting to the U.S. under the new QMSR framework.

Date: 3rd September 2025, from 16.00 – 18.00

Digital: Zoom link will be available for participants

Sign up: click here: Link

16.00 Introduction to Mediteq Forum & Todays's Guest

16.15 Effect and possible effect to recent changes within the FDA. Recommendations on strategy and timelines. Upcoming QMSR in effect.

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.

Mediteq
Kämpegatan 6
SE-411 04 Göteborg, Sweden

+46 31 774 25 00
www.mediteq.se

Presentation of todays' 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.

Warm Welcome!

Ankie Sjöberg och Joshua Higby
Facilitators, Mediteq Forum