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Report |Awareness Talk | FDA's Quality Management System Regulation (QMSR) - Final Rule. |Online Mode| 22nd April 2025 |

About The Talk

Awareness talk was organized with Akash Dhade in Online Mode, aimed to equip medical device manufacturers with insights into the QMSR for navigating the US FDA regulations. The talk covered key aspects of the ISO 13485 and FDA's QMSR. We received registrations from various audiences, including startups, academia, and industry professionals keen to gain an understanding requirements of QMSR for navigating the US FDA regulatory pathway.

Key Points Discussed in the Talk -

- Introduction to QMSR and its purpose
- Differences between 21 CFR Part 820 and ISO 13485
- Compliance timeline and transition strategy
- Impact on medical device manufacturers
- Best practices for QMS alignment
- Live Q&A with the expert

Attendees - 40+

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Overall Feedback: 6.2/7

"Overall the experience was engaging ones, hoping to have more such insightful sessions." - Chinmayee patil

"The session was good.' - Dr. Arati Deshmukh