DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

IMDRF International Medical Device Regulators Forum

IMDRF/DITTA Joint Virtual Workshop

Monday 16 March 2021

What to learn from COVID 19?

An industry experience and perspective

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DITTA Members

DITTA Overview

1. Pandemic: the start
2. Impact on MedTech supply chains
3. Pressure from governments: DPA & other pressures
4. Scaling up production: Innovations & partnerships
5. Planning for the next pandemic: Stockpiling
6. Lessons learned from a regulatory perspective
7. How can we be better prepared for the next time

DITTA Regulatory Lessons Learned

IMDRF

- Quickly identify and communicate what devices are critical to the public health emergency
- Develop expedited Emergency Use Pathways
  - Rapid regulatory review & approval
- Leverage regulatory decisions from other regulators to avoid duplication and delay of patient access; reliance
  - Premarket authorizations
  - Remote audits in place of onsite audits
  - Use of alternate sources of data
- Define process to maintain devices on the market or disposition post-emergency

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Thank you!