



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

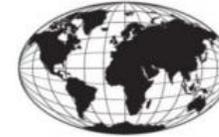


IMDRF

- 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



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



IMDRF International Medical
Device Regulators Forum

Thank you!