Global Medical Technology Alliance

Innovating for a Healthier World

GMTA

Reliance White Paper

May 17, 2023

Global Medical Technology Alliance
Innovating for a Healthier World

Presentation Outline

- Background
- Foundational Principles
- Core Tenets
- Next steps

Global Medical Technology Alliance
Innovating for a Healthier World

Background

- Regulators and manufacturers are committed to timely patient access to safe, effective, and quality medical devices
- Small differences in standards, guidance and regulations can cause major differences in the regulatory path (e.g., MD/IVD classification)
- These differences are amplified during a pandemic and seen in countless emergency use pathways

Global Medical Technology Alliance
Innovating for a Healthier World

Foundational Principles

- Implement convergent regulatory frameworks based on internationally recognized best practices and standards.
- Implement Regulatory Reliance, including recognition
- Implement core tenets of medical device regulations

Global Medical Technology Alliance
Innovating for a Healthier World

10 Core Tenets

- Ensure predictability and adequate resources
- Support innovation and apply equal regulation to both domestic and international companies
- Adopt Good Regulatory Practices (GRP)
- Avoid requirements that lack a patient safety benefit

Global Medical Technology Alliance
Innovating for a Healthier World

10 Core Tenets

- Accept global clinical trial data and leverage Real World Evidence
- Implement a risk-based approach to product changes.
- Avoid unnecessary barriers to access based on product country of origin

Global Medical Technology Alliance
Innovating for a Healthier World

10 Core Tenets

- Implement a single dossier
- Adopt electronic instructions for use
- Accept digital labels

Global Medical Technology Alliance
Innovating for a Healthier World

Next Steps

- Communicate at international events
- Leverage in partnership with global regulators