Global Medical Technology Alliance
Innovating for a Healthier World

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Subject: Exploring the Benefits of Reliance and the Medical Device Single Audit Program (MDSAP) for Manufacturing Site Audits Requirements

The medical technology industry strongly supports a robust regulatory system that ensures the safety and performance of devices and promotes timely access of patients to lifesaving and life-enhancing medical devices.

In our continuous efforts to streamline access to medical devices, we advocate for the adoption of global convergence and regulatory reliance strategies to advance "smart regulation" which will help:

- Conserve and optimize the use of limited regulatory resources, elevate regulation to one high standard and accelerate access to safe, high-quality, effective, and innovative medical technologies to benefit patients, caregivers, and healthcare providers.
- Facilitate an environment conducive to the growth of the medical technology sector, enhancing innovation, facilitating trade, and providing knowledge-based jobs.
- Enhance global health equity through the acceleration of global access to safe, high-performing and innovative medical technologies.
- Reduce unintended consequences associated with increased product site inspections that contribute to potential barriers to trade and entry into markets, which can have negative impact for healthcare and patient access.

Convergence to international best practices and regulatory reliance[1] provides an opportunity for both industry and regulatory bodies to **reduce redundant audits where appropriate, improve resource allocation/utilization and enhance efficiency** of regulatory processes by enabling both to focus on those activities that are appropriately conducted at the local level by National Health Authorities. This helps enhance the regulatory capacity of National Health Authorities and the compliance activity of industry while enabling timely response to both local and global health needs and emergencies. Moreover, convergence and reliance facilitate patients' uninterrupted access to innovative, high-quality, safe, and high-performing devices while supporting sustained innovation and responsiveness to public health needs.

[1] Regulatory reliance is the act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others. - WHO, Technical Report Series, No. 1033, 2021, Annex 10: *Good reliance practices in the regulation of medical products: high level principles and considerations*. https://www.who.int/publications/m/item/annex-10-trs-1033 (last retrieved 03/09/2024)

MDSAP as a Model of Inspection Reliance

Overview of MDSAP

The Medical Device Single Audit Program (MDSAP), established on the foundation of ISO 13485:2016, enables a single regulatory audit of a medical device manufacturer's Quality Management System (QMS) to meet the requirements of multiple regulatory jurisdictions. Audits are conducted by Auditing Organizations (AO) that are qualified and authorized by the MDSAP Regulatory Authority Council (RAC). Launched initially in 2014 as a pilot program, MDSAP became fully operational in 2017 and has seen increasing international implementation year after year, contributing to global regulatory convergence.

ISO 13485 is an international standard that outlines the requirements for a Quality Management System of medical devices manufacturers. This standard is specific to medical devices and covers the entire life cycle of a device, from design and development to production, installation, and servicing. ISO 13485 focuses on creating a robust quality management system that ensures the safety and effectiveness of medical devices and is recognized globally.

The medical technology industry encourages reliance on MDSAP audits and their eventual MDSAP Certificates. Non-MDSAP members may leverage the MDSAP framework to streamline regulatory compliance and quality management processes, aligning with international standards and best practices, allowing manufacturers to demonstrate a robust quality system with a single audit that can be recognized across multiple markets. By leveraging MDSAP audits as a replacement for local audits or a replacement for additional on-site audits, a more efficient use of regulatory resources can be enabled, fostering a common understanding of safety and effectiveness. The adoption of MDSAP should not delay access or slow innovation; flexibility should be exercised to allow continuity of access. This strengthens the consistency, predictability, and transparency of regulatory programs, without compromising audit standards, in line with the program's primary mission: "...jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers." For a list of Regulatory Authorities that members of the MDSAP, please refer to Annex 1.

How does it work in a nutshell?

The MDSAP audit model was developed to assess the compliance of a manufacturer's quality management system to the international standard ISO 13485 and additional regulatory requirements of the participating Authorities, depending on the markets where the devices are intended to be sold. Regulatory authorities continuously oversee the competence and performance of auditing organizations as part of an ongoing 3- year recognition cycle. this structured recognition cycle includes periodic surveillance and re-recognition activities to ensure consistent application of MDSAP requirements.

Conclusion

The medical technology industry welcomes additional conversations to share MDSAP case studies and provide additional insights to support consideration and implementation of these best practices. In addition, regulatory authorities participating in MDSAP make available extensive training materials and procedural documents through their official websites, which can help non-participating regulators in gaining a comprehensive understanding of the MDSAP audit process (see References).

Annex 1

- **MDSAP Regulatory Authority Council (RAC) Members**
  - Therapeutic Goods Administration of Australia
  - Brazil's Agência Nacional de Vigilância Sanitária
  - Health Canada
  - Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency
  - U.S. Food and Drug Administration

- **MDSAP Official Observers**
  - European Union (EU)
  - United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA)
  - The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme
  - Singapore's Health Sciences Authority (HSA)

- **MDSAP Affiliate Members**
  - Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT)
  - Ministry of Health of Israel
  - Kenya's Pharmacy and Poisons Board
  - Republic of Korea's Ministry of Food and Drug Safety
  - Federal Commission for Protection from Sanitary Risks (COFEPRIS) of Mexico
  - South African Health Products Regulatory Authority (SAHPRA)
  - TFDA - Taiwan Food and Drug Administration

List of international partners participating in the MDSAP as of May 6, 2025

References:

- Global Medical Technology Alliance position paper "The Need to Advance Global Convergence and Regulatory Reliance to Accelerate Access to Medical Technology"
- US FDA MDSAP webpage
- Australia's TGA MDSAP webpage
- Japan's PMDA MDSAP webpage
- Health Canada MDSAP webpage
- Brazil's ANVISA MDSAP webpage
- MDSAP Q&A
- List of Auditing Organization availability to conduct MDSAP Audits
- MDSAP Roles and Responsibilities