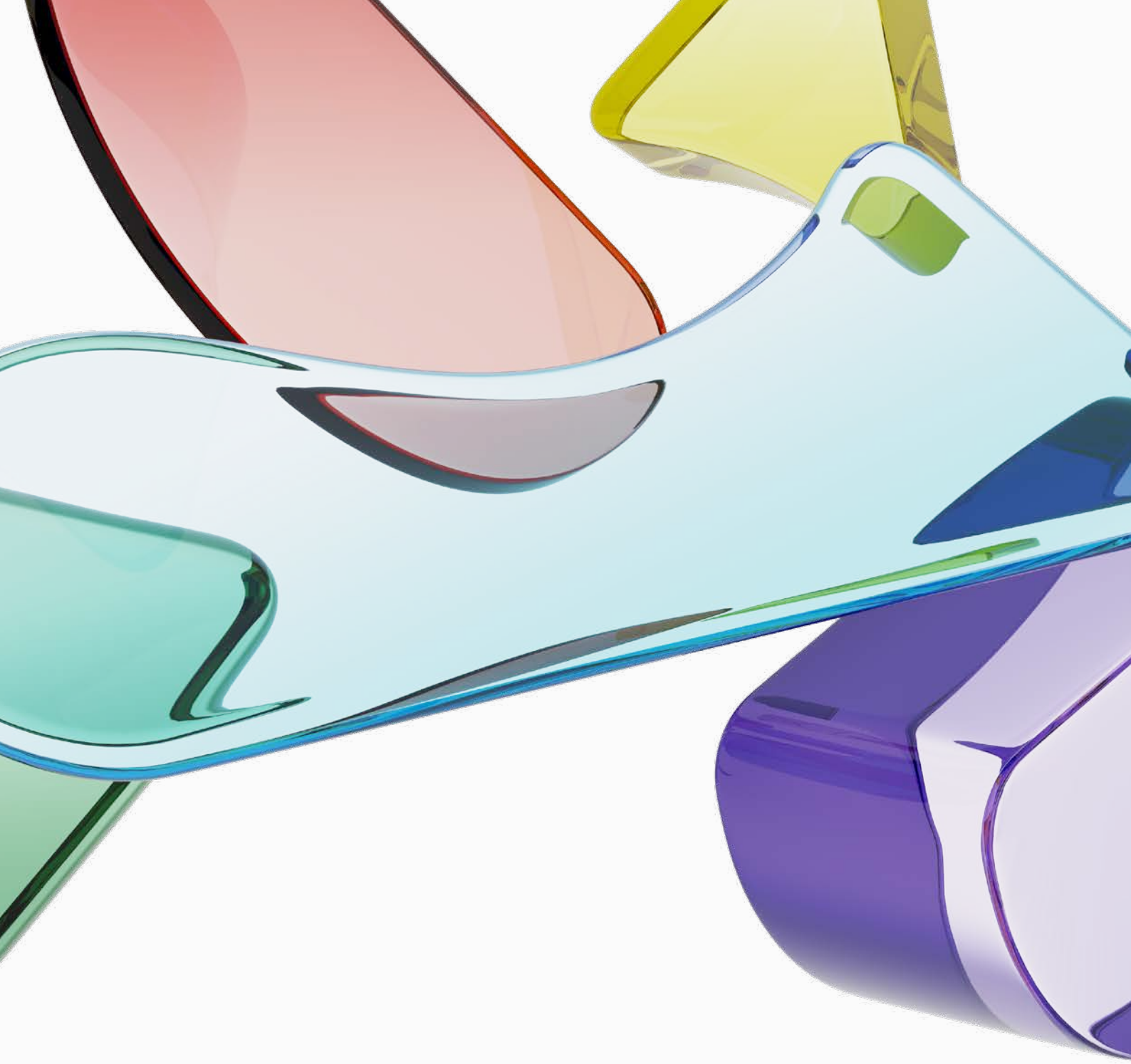


The Medical Device Single Audit Program

Your partner
in progress

What is MDSAP?

The Medical Device Single Audit Program (MDSAP) allows a single audit of a medical device manufacturer's Quality Management System (QMS), which satisfies the requirements of multiple regulatory jurisdictions.

Audits are conducted by Auditing Organizations (AO), such as BSI, authorized by MDSAP member Regulatory Authorities (RA). Through MDSAP medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets.

MDSAP Audit Cycle

MDSAP is based on a three year audit cycle.

Initial Audit

Initial Audit (Initial Certification Audit): a complete audit of a medical device manufacturere's Quality Management System (QMS)

Surveillance Audit – Year 1

Surveillance Audit – Year 2

Re-audit (Recertification audit) – Year 3

Which markets do MDSAP cover?

MDSAP is indicated for globally based manufacturers keen to export medical devices into the countries participating to the MSDAP program. Regulatory Authorities included:

Australia

The Therapeutics Goods Administration (TGA) uses an MDSAP audit report as part of the evidence that it has assessed for compliance with medical device market authorization requirements, unless the medical device is otherwise excluded or exempt from these requirements or if current policies restrict the use of MDSAP audit reports.

The Therapeutics Goods Administration

Brazil

The Brazilian National Health Surveillance Agency ANVISA utilizes the outcomes of the program, including the reports, to constitute an important input on ANVISA's pre-market and post market assessment procedures. It provides, when applicable, key information that is expected to support regulatory technical evaluation on these issues.

The Brazilian National Health Surveillance Agency

Canada

Health Canada Health Canada (HC) will only accept MDSAP for manufacturers who market their devices in Canada. Therefore, manufacturers wishing to place a product on the market in Canada need to have MDSAP Certification issued by an Auditing Organization.

Health Canada

Japan

The Ministry of Health, Labour and Welfare (MHLW) and Pharmaceutical and Medical Devices Agency (PMDA) utilize these audit reports in both pre-market and periodical post-market audits under regulations in Japan.

The Ministry of Health, Labour and Welfare

Pharmaceutical and Medical Devices Agency

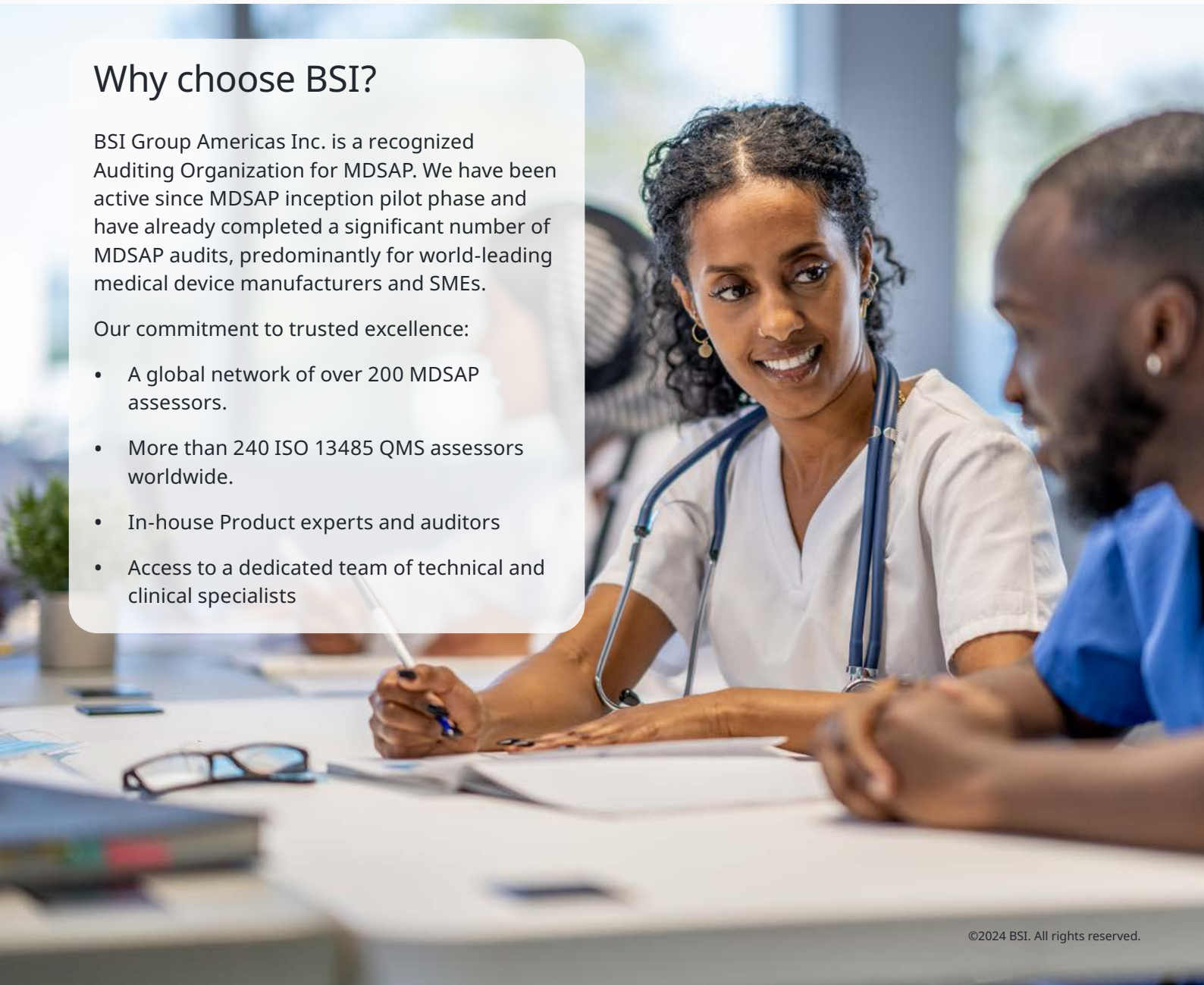
United States

U.S. Food and Drug Administration's Center for Devices and Radiological Health FDA will accept the MDSAP audit reports as a substitute for FDA routine inspections. Inspections conducted "For Cause" or "Compliance Follow-up" by FDA will not be affected by this program. Moreover, the MDSAP program would not apply to any necessary pre-approval or post-approval inspections for Pre-Market Approval (PMA) applications or to decisions under section 513(f)(5) of the Act (21 U.S.C. 360c(f)(5)) concerning the classification of a device.

U.S. Food and Drug Administration's Centre for Devices and Radiological Health

What are the benefits of a MDSAP?

- Streamlined Audits: consolidates multiple global regulatory audits into a single, efficient process, reducing audit-related costs and disruptions to operations.
- Global Market Access: BSI Group Americas inc. is a recognized Auditing Organization. In addition to the 5 MDSAP member countries, the MDSAP affiliate members utilize the reports and certificates for market entry.
  Find out more: Medical Device Single Audit Program (MDSAP)
- Continuous Improvement: encourages proactive identification and resolution of compliance gaps, enhancing product safety and minimizing the risk of costly recalls or regulatory sanctions.
- Risk Management: The program places a strong emphasis on risk management, aligning with modern quality standards and ensuring the safety and effectiveness of medical devices.
- Efficient Market Entry: Manufacturers can navigate the complexities of global market entry more efficiently.
- Reduced Regulatory Burden: eliminates the need for separate audits conducted by different regulatory authorities, simplifying compliance efforts for medical device manufacturers.
- Enhanced Reputation: bolster a manufacturer's reputation for quality and safety, instilling confidence in customers and regulatory authorities alike.



Why choose BSI?

BSI Group Americas Inc. is a recognized Auditing Organization for MDSAP. We have been active since MDSAP inception pilot phase and have already completed a significant number of MDSAP audits, predominantly for world-leading medical device manufacturers and SMEs.

Our commitment to trusted excellence:

- A global network of over 200 MDSAP assessors.
- More than 240 ISO 13485 QMS assessors worldwide.
- In-house Product experts and auditors
- Access to a dedicated team of technical and clinical specialists

How can BSI support you?

Preparation support

In the competitive medical device marketplace, ensuring that product development meets all regulatory requirements is essential. We provide guidance and training to support you through the application process.

Global Market Access

We are a global organization, trusted and recognized around the world. BSI The Netherlands (2797) is a leading Notified Body. We review medical devices to ensure that they conform to the requirements of the European Directives and Regulations. BSI UK (0086) is a UK Approved Body able to provide conformity assessments under the UKCA scheme.

BSI is a recognized Auditing Organization, providing Quality Management System certification through Medical Device Single Audit Program (MDSAP). BSI is a Conformity Assessment Body for EN ISO 17021-1 (EN-ISO 9001, ISO 14001, ISO 13485) as accredited by the Dutch Accreditation Council (RVA) and the UK Accreditation Service (UKAS).

Seamless transfer to BSI:

We can offer a seamless transfer service with comprehensive support and the absolute minimum level of disruption.

Additional resources to support you

We offer continual support throughout the certification process and beyond; we also offer:

- **Access to more than 34,000 standards** and related products, as well as online guidance documents
- **Expert training delivered online or face-to-face**, through BSI Training Academy courses portfolio.
- **Regulatory updates** through monthly newsletters
- **Webinars delivered by our experts** on complex regulatory key topics
- **Comprehensive whitepapers** providing the latest insights on key industry topics

Your partner in progress

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