Medical Device Single Audit Program (MDSAP)

Global market access through MDSAP

BSI: an experienced Auditing Organization

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, which are authorized by the participating Regulatory Authorities (RA) to audit under MDSAP requirements.

MDSAP is a way that medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States.

A BSI MDSAP audit can also be combined with assessment for CE and ISO 13485.

"The Medical Device Single Audit Program offers an excellent opportunity for manufacturers to gain access to multiple geographies through an efficient audit process. BSI is proud to have been involved in this program from the beginning, and we have built up a robust level of expertise."

Patricia Murphy, Global MDSAP Manager

bsi.

...making excellence a habit.™

MDSAP audits can be performed by a recognized MDSAP AO, such as BSI. We have been active from the inception of the MDSAP pilot phase and have now completed significant numbers of MDSAP audits, predominantly from world-leading medical device manufacturers.

Which geographies and Regulatory Authorities are included in MDSAP?

MDSAP should be considered for companies based globally, if they wish to export products into the countries participating, as described below.

The five RAs involved with MDSAP have made the following statements on how they will utilize MDSAP reports:

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.

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.

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 AO.

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.

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

MDSAP Official Observers

A member of the World Health Organization (WHO) or a non-participating RA who observes and/or contributes to Regulatory Authority Council (RAC) activities.

- WHO
- European Union (EU)

MDSAP Affiliate Members

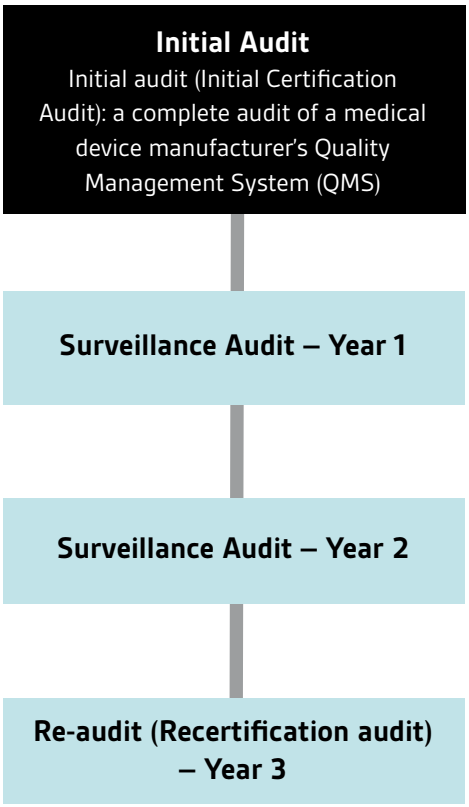
An MDSAP Affiliate Member demonstrates understanding of MDSAP and utilizes MDSAP audit reports and/or MDSAP certificates for evaluating a medical device manufacturer's QMS. Their national requirements do not feed into the MDSAP requirements.

- Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT)
- Republic of Korea's Ministry of Food and Drug Safety

It is the manufacturer's responsibility to supply the Affiliate Members with the relevant MDSAP audit report.

Medical Device Single Audit Program process:

MDSAP is based on a three year audit cycle.



What are the benefits of MDSAP

A Single Audit by Auditing Organizations would:

- minimize medical device manufacturer disruptions due to multiple regulatory audits
- provide reliable audit schedules (agenda with opening and completion dates)
- benefit patient health and patient access with ease of entry to multiple markets
- leverage regulatory resources
- incorporate ISO 13485 assessment
- meet regulatory requirements of Australia, Brazil, Canada, Japan and the US
- reduce time and resources dealing with findings from multiple audits
- reduce the cost of audits in comparison to independent audits
- improve transparencies in the industry

Where can I find more information on MDSAP to allow me to make the best decision?

- BSI has a dedicated website for your MDSAP Transition
- BSI Training Course: Medical Device Single Audit Program (MDSAP): Fundamentals and Readiness.
- Read the excellent information available free online through the FDA website

BSI and MDSAP: our commitment to excellence

BSI is a fully recognized AO. We supported the MDSAP pilot and have been conducting audits since September 2014. We've experienced increased interest and applications by manufacturers. Feedback about the benefits of MDSAP has been overwhelmingly positive.

BSI understands the specific challenges medical device manufacturers face and the importance of bringing innovative and safe products to global markets. Ensuring the resilience and transparency of regulatory clearance is key to maintaining a competitive edge.

We demonstrate this commitment through:

- over 200 MDSAP assessors worldwide
- over 240 QMS ISO 13485 assessors globally
- internal Product Experts and Auditors
- direct access to a team of technical and clinical specialists

How do I apply for MDSAP?

For clients holding ISO 13485, BSI can roll the MDSAP audit into the existing certification cycle.

Contact us for more information on how to apply for MDSAP.

Call BSI today: **+91 11 2692 9000**
or visit: **bsigroup.com/MDSAP**

Note: *For current clients, we can start the audit in the current visit cycle, i.e. surveillance or recertification. BSI can discuss the available options with you depending on your business needs.*

Special audits, audits conducted by Regulatory Authorities, and unannounced audits are extraordinary audits that may occur at any time within the audit cycle.

Five reasons to make BSI your Notified Body

Experience and product expertise

The benefits of having experienced, professional and well-qualified technical specialists cannot be overstated in the complex and ever-changing medical device industry. BSI Medical Devices has a team of over 700; within that team are our technical experts with experience encompassing the full range of medical devices and management system standards.

BSI Group is a global network of over:

Focus on service

Clients work with us because we understand the challenges medical device manufacturers face in bringing compliant products to market efficiently and safely. We offer a range of flexible product review services providing you with efficient pathways to bring your product to market.

Global market access

We are a global organization, trusted and recognized around the world. BSI has two Notified Bodies, one in the UK (0086) and one in the Netherlands (2797), both of which have full scope designations to the IVDR and MDR.

Confidence and robust reviews

Our comprehensive review process combined with our world-leading experience as a Notified Body will ensure that your conformity assessment process is both efficient and robust.

Passion for patient safety

Our mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to set the global standard in thorough, responsive, robust conformity assessments, evaluations and certifications.

How can BSI support your product launch?

Be prepared

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.

Worldwide access

We offer a wide range of proven regulatory and quality management programs that work together for full international compliance. Our Quality Management System (QMS) solutions include ISO 13485, ISO 9001, ISO 14001 and many more.

We are a recognized Certification Body in Hong Kong, Japan, Malaysia, Singapore and Taiwan, and a recognized MDSAP Auditing Organization for all participating Regulatory Authorities.

Seamless transfer to BSI

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

Certification support and additional services

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, either in-house or through our public training courses
- **regulatory updates** and a newsletter service focusing on industry changes, helping you to plan for the future
- **webinars** delivered by our experts on complex regulatory issues
- **comprehensive whitepapers** providing the latest insights on key industry topics

Talk to our MDSAP experts today
Call: **+91 11 4762 9000**
Visit: **bsigroup.com/mdsap**

bsi.

bsigroup.co.in

BSI/IN/084/MD/0820/en/BLD