

II.

MDSAP PROGRAM

A. The Medical Device Single Audit Program allows an MDSAP recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program.

International partners that are participating in the MDSAP include:

- FDA medical device quality system regulation
- 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
- The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme and the European Union (EU) are Official Observers

References

- EN ISO 13485, U.S. FDA Quality System Regulations (21 CFR PART 820), Canadian SOR/98-282, Australian Therapeutic Goods Act 1989, Brazilian RDC ANVISA 67/2009, Japanese MHLW Ministerial Ordinance N° 136 "Ministerial Ordinance on Standards for Quality Assurance for Drugs, Quasi-drugs, Cosmetics and Medical Devices

Medical Device Single Audit Program (MDSAP) Fundamentals and Readiness Training Course

- MDSAP - Basic Terms and Concepts
- Back Ground Applicable Regulation & Guidance Standards
- Content of MDSAP program and audit
- Main differences in your current audits and audits conducted under MDSAP
- Prepare you to host a MDSAP audit

Our services:

A. MDSAP Training for Medical Device Companies

This training is conducted on-sites. The training session tailored to the needs of your organization regarding this sub-system.

B. MDSAP Auditing for Medical Device Companies

Full or partial internal PMS audit. We provide internal auditing services which allow for an independent review of this part of your quality system.

C. MDSAP - System Implementation Consulting and maintenance

Gap analysis, design solution (custom made system), standard operating procedures, implementation, training, verification of effectiveness, and follow up.