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医疗器械单一审核方案(MDSAP)
MEDICAL DEVICE SINGLE AUDIT PROGRAM

什么是MDSAP?

MDSAP是IMDRF (International Medical Device Regulatory Forum) 创立并由其授权第三方认可的审核员开展对医疗器械制造商的单一审核，此审核覆盖了ISO13485和其它相关的法规要求，实现了一次审核，多国承认，优化和节省了时间与资源。

目前参与到MDSAP试行方案的法规组织有如下:

- 澳大利亚-TGA (Therapeutic Goods Administration)
- 巴西-ANVISA (National Health Surveillance Agency)
- 加拿大-Health Canada
- 美国-FDA
- 日本-MHLW(Ministry of Health, Labour and Welfare) 和PMDA (Pharmaceuticals and Medical Devices Agency)

注：欧盟、中国和俄罗斯也是IMDRF管理委员会的成员，但不在此次试行方案之列。

法规授权组织对MDSAP的认可

澳大利亚

TGA将使用MDSAP审核报告作为部分性证据来评价器械上市许可的符合性，除非医疗器械在其他方面被排除或豁免这些要求，或者当前的政策限制使用MDSAP审核报告。

巴西

ANVISA将使用包括审核报告在内的结果作为ANVISA上市前和上市后评估程序的重要输入，适用时提供关键信息以支持此类事项的法规技术评估。

加拿大

HC(Health Canada)将使用MDSAP审核作为CMDCAS认证方案的一部分。基于试行所取得的成功结论，HC期望通过实施MDSAP作为符合加拿大质量管理体系要求的审核机制。

日本

在日本的法规约束下，MHLW和PMDA将在上市前和上市后的定期审核中使用MDSAP审核报告。通过运行MDSAP试行审核来减轻日本法规流程的负担。

美国

美国FDA器械与放射健康中心(CDRH)–FDA将接受通过MDSAP审核报告来替代FDA的例行检查。FDA对"原因(For Cause)"或"符合性跟进(Compliance Follow-up)"的检查不受MDSAP的影响。另外，MDSAP不适用于上市前许可(PMA)申请的任何许可前或许可后的必要检查或根据该法案(21U.SC.360c(f)(5))第513(f)(5)章节有关器械的分类的决定。

您的挑战

制造商应执行适用的要求并利用FDA网站上可获取的MDSAP审核文件(审核模型和配套文件)进行内部审核。沟通、审核计划和策划将是成功的关键。应让您的策划人员尽快知道您将应用MDSAP的要求来审核。MDSAP审核可以在原定年度审核或特殊审核时开展。

Intertek可以帮助您

Intertek是首批获得MDSAP医疗器械单一审核资质的机构之一。基于多年质量管理体系认证、审核、ISO 13485认证、CDMCAS认证经验，Intertek可以为客户提供专业的审核，通过 MDSAP 多国单一审核项目，通过一次审核实现全球市场准入。

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MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP)

INTERTEK IS NOW AUTHORIZED TO PERFORM MDSAP AUDITS

What is MDSAP?

The Medical Device Single Audit Program was developed by a group of medical device regulators to allow recognized third-party auditors to conduct a single audit of a medical device manufacturer that will cover ISO 13485:2003 and their respective regulatory requirements. More information and documents about the International Medical Device Regulators Forum (IMDRF) and MDSAP are available on the IMDRF website and on the FDA's website.

What regulatory authorities are currently participating in the MDSAP pilot?

The regulatory authorities that are currently participating in the MDSAP Pilot Program are:

- Australia - TGA
- Brazil - ANVISA
- Canada - Health Canada
- U.S. - FDA
- Ministry of Health, Labour and Welfare (MHLW) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA)

Note: The European Union, China and Russia are members of the IMDRF Management Committee but are not participating in the pilot program at this time.

Timeline

The MDSAP Pilot Program started January 1, 2014 and is expected to run for three years.

As of December 31 2016, the list of MDSAP Auditing Organizations formally recognized under the MDSAP program were announced and the operational phase of the program began.

On December 4, 2015, Health Canada announced that it intends to implement

MDSAP as the sole mechanism for manufacturers to demonstrate compliance with the quality management system requirements of the Medical Devices Regulations. MDSAP will replace the current Canadian Medical Devices Conformity Assessment System (CMDCAS) program, even in situations when a manufacturer intends to sell only in Canada. The implementation began at theconclusion of the Pilot which was on January 1, 2017, and will span a period of two years. During this two year period, Health Canada will accept certificates issued under both CMDCAS and MDSAP. As of January 1, 2019, only MDSAP certificates will be accepted. Source: http://hc-sc.gc.ca/dhp-mps/md-im/activit/int/mdsap-trans-notice-avis-eng.php

How can manufacturers participate and prepare for an MDSAP audit?

Manufacturers should implement applicable requirements and may perform internal audits using the MDSAP audit documents (Audit Model and Companion document) available on the FDA website. Communication, audit planning and scheduling will be a key to success. Please let your scheduler know as soon as possible of your intent to be audited to MDSAP requirements. MDSAP audits may be performed during the scheduled annual visit or during a special visit.

FOR MORE INFORMATION

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