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A Review on Medical Device Single Audit Program (Mdsap) It's Pros, Cons and Challenges

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ABSTRACT: The Medical Device Single Audit Program (MDSAP) is a program that was created for single harmonized procedure that can accepted globally toallowthe conduct of a single regulatory audit of a medical device manufacturer's quality management system that satisfies the stringent requirements. The main aim of MDSAP is to provide a procedure that is more effective, efficient, and less burdensome regulatory oversight of the quality management systems of medical device manufacturers. This work gives an overview of the history, procedure , pros(advantages)and cons (disadvantages) challenges one has to face while adapting to the MDSAP program.And whether the program is a replacement to the ISO 13485 or not. Currently,five different jurisdictions have adapted to this program,they are namely the USA, Canada, Brazil, Australia, and Japan.

KEYWORDS:MDSAP,ISO13485,QMS,regulator y authority, IMDRF.

I. INTRODUCTION

As far as accepted around the world "Medical devices are any instruments the help in the diagnosis,prevention, elevation of disease / condition of the patient" these range from very small instrument such as a scalpel or gloves to large and heavy instruments such as MRI, CT and many more. These instruments are used to ease the work of physician while diagnosing as well as in the treatment of patient & provide life support to patients in some cases.so the manufacturing facility should take stringent measures set by the regulatory bodies of their respective countries or the regulatory bodies of the country in which they are selling their product. In order to ensure this the regulatory bodies conducts audit on some specific process and standards which could give assurance to the authorities that the medical device manufacturersare adhering to the standards. these audits are conducted as many times as the regulatory bodies want and when they wish. Although these processes are very useful to ensure adherence,they become a hassle to manufacturers and authorities.

In order to counter this the IMDRF came up with a approach that is globally harmonized. They named this approach as Medical Device Single Audit Program (MDSAP) in the year 2012 and have drafted its regulations. As the name itself indicates this allows the authorities to conduct a single audit that satisfies them.

This has been launched as a pilot program from January 1, 2014, to December 31, 2016, for this WHO and European union and United kingdom's MHRA are the official observers of the program, and five countries have joined this program as participants they are as follows.

- 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 devises Agency
- U.S. Food and Drug Administration

In 2014, when the program was launched as a pilot program more than 100 manufacturers who sell internationally &especially in Canada registered themselves as participants and the result generated by the program was more than satisfactory. This led to determine the program as a success by the MDSAP regulatory authority council. the newest affiliate members are

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

One of the misconception about MDSAP program by most of the manufacturers of the participating countries is that, they think can avoid the regular inspections by the authorities if their country is one of the participating one.

The manufacturerdecision to go for the MDSAP certification ismainly due to the markets the manufacture would like to sell in. for this they have to comply with the country-specificregulations that they intend to sell in, and ISO 13485 since ISO 13485 remains one ofthe key standard for quality management systems .[1]

AUDIT PROCESS

The MDSAP has a sequence-specific approach that the auditor is expected to follow while conducting the audit,this specific approach ensures a more efficient and logically focused manner of auditing.there are two kinds of processes involved one is a primary process and another is a supporting process followed by the primary.

The primary process involves the following steps/actions:

1. Management,
2. Measurement, analysis, and improvement,
3. Design and development,
4. Production and service controls,
5. Purchasing.

The supporting process involves the following steps/actions

1. Device marketing authorization and facility registration,
2. Medical device adverse events and advisory notices reporting.

The supporting process fulfills the regulatory requirements of the jurisdictionsof the facility involved.

The sequences are fixed and are risk-based hence carrying more importance in the audit. All the above-mentioned procedures cover both the relevant ISO 13485:2016 clauses and the specific regulatory requirements of the participating five different countries. the audit model has detailed linkages interconnecting the different processes which make the auditing process precise and clear.one does not get the MDSAP certification through a single audit, 3 successive audits must be qualified by the manufacturer in a time span of 3 years in order to get the MDSAP certification.[2]

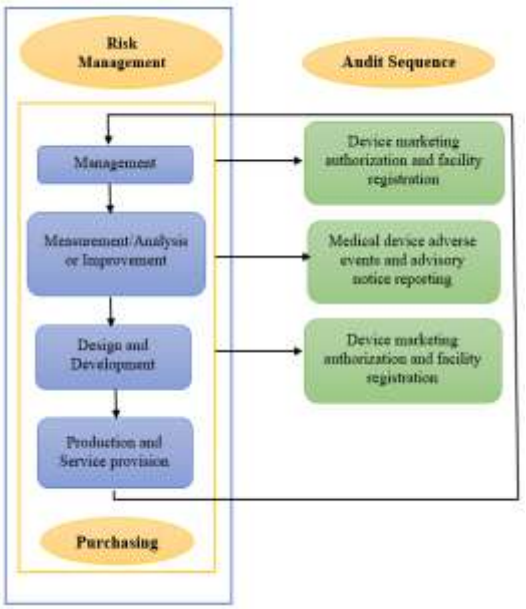

FIGURE 1:MDSAP audit sequence

THE GRADING SYSTEM OF THE MDSAP SYSTEM

A quantitative grading system has been introduced for this program;the grading system is called a nonconformity grading system. As the name suggests firstly nonconformities are graded using a grading matrix that is based on QMS impact which can be either direct or indirect, however, the impact of safety is of prime importance. Secondly, the nonconformance frequency of occurrence is taken into account.The recurrence of nonconformity indicates ineffective corrective actions. Thirdly, the escalation criteria are applied and aspects like non-conforming devices on the market and documented procedures for the medical device are taken into account.

The QMS impact grade ranges from 1-to 3,the frequency of occurrence grade ranges from 2-to 4,

+1is added for scored grades for nonconforming devices on the market & another +1 is added if the procedure is undocumented in the escalation criteria section.

If the result of the audit is a single grade of 5/4/3 the nonconformities are considered serious and the auditing organization must report this to the RAs within 5 days and a correction action plan must be provided to the authorities within 15 days which must be implemented within 30 days. For the lower

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grades, the usual CAPA procedure takes place and closing is done at the next visit.[2][5]

ADVANTAGES OF MDSAP

The medical device manufacturer who has/chosen to participate in the MDSAP program is entitled to the following benefits.

1.Fewer regulatory audits
2.More predictable audits
3.More efficient marketing authorization applications
4.Access to multiple markets
5.Reduction of audit impacts on daily activities

These are the five most prominent benefits that a manufacturer of medical devices might ask for.

DISADVANTAGES OF MDSAP

From the manufacturer perspective one can be overwhelmed by the highly advantages features of the MDSAP, there are some issues which can be considered disadvantageous .one of the cases is if the manufacturer decides to drop out due to any issues, expecting an inspection from the regulatory bodiesat any time is best for them. The regulatory authorities can conduct the investigations based on the tips / any discrepancies found.Thus, the decision to pursue MDSAP certification or to drop out must be based on the manufacturer readiness of the QMS to comply with all the country-specific regulations, as well relevant ISOs such as ISO 13485.

The time provided by the regulatory authorities may not be enough to make the changes in the area where the irregularities have been observed, and the manufacturer may have to face the consequences.[12]

CHALLENGES FOR MANUFACTURERS TO PARTICIPATE IN MDSAP:

For the manufacturers of medical devices who have decided to go for MDSAP audit certification, the following aspects are set to become the greatest challenges.

1. Conduction of gap assessment of all SOPs and processes.
2.Developing and implementing a comprehensive risk assessment program.
3.Ensuring employees are competent in ISO 13485:2016

1. CONDUCTION OF GAP ASSESSMENT OF ALL SOPS AND PROCESS:

To ensure employees understand and correctly follow practices laid out in the SOPs manufacturers must create process maps and compare them with SOPs by doing so the manufacturer can identify where his employees are lacking and process,this allows revising the SOPs and process for better work functions.

2. DEVELOPING AND IMPLEMENTING ACOMPREHENSIVERISK ASSESSMENT PROGRAM:

MDSAP takes risk management and risk-based thinking to the next level as it is now considered to underlie every process. Manufacturers struggle to demonstrate how they link their interrelated processes as manufacturing is only a function of what's happened in design, and design transfer. "Risk Management has to weave its way through all of those processes into a risk management plan that helps the company and auditor see, where have they examined risk in their system.but developing this kind of program is a very challenging task, the easy way is to consult a third party which is able to develop and implement the program without any problems.

It is very important to know that no matter how many precautions one may take the concept of risk remains a pothole for the regulatory authorities on the road to compliance. Nowadays even the professional including the veterans of this field are struggling to know the exact point to expand the efforts to the entire quality systems.

3.Ensuring Employees Are Competent In Iso 13485:2016:

Even after conducting a gap assessment and developing acomprehensive risk assessment program the duty is not fulfilled. they have to train their personnel in the ISO 13485:2016,which is the most important part while preparing for the MDSAP or any other regu8latory audit. Every personnel involved should adequate knowledge on relevant ISO standards .it won't be a challenge for companies who already have FDA quality systems in place .in the recent time it highly anticipated that the next FDA QSR will be based on the risk management,so it would be best if manufacturers also make risk management their primary focus.[6]

IS MDSAP A REPLACEMENT FOR ISO 13485?

It is true both the programmes have more similarities between them than differences, but one has to understand that they are entirely two different programmes and cannot replace one another. it is seen that when a company that has already ISO certified goes for MDSAP certification the number of audit dates are increased, by this one

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can say that MDSAP has more stringent rules and requirementsthan ISO13485 but MDSAP is not a system but an audit whereas ISO 13485 is QMS that is mandatory for the quality of medical devices production. MDSAP has the ISO 13485 as it's structural framework,so it is no wonder both these programs are very similar to each other. basically ISO 13485 is a standard based on process approach on management systems. Until 2015 it was associated with ISO9001which was revised in that year did away with some of the requirements of ISO 13485 and it was no longer needed forISO 9001.In 2016 ISO 134845 was revised and the new form was more about risks than earlier prescriptive requirements.[13]

II. CONCLUSION

The Medical device single audit program which was started as a way to harmonize the audit of medical device manufacturers who are selling both locally and internationally has now transformed into a fully developed program and is currently being used united states FDA and the other participants of the program and had become mandatory Canada , and a lot of foreign countries and manufacturers are interested in the program as it provides benefits that has not been on the market never before, even though the program offers such benefits some manufacturer's might find it troublesome if they decide to drop out of the program ,as the authorities may decide to conduct unannounced audit if they find any issues. it is also true that ISO 13485 and MDSAP are similar to each other, but this is because MDSAP has ISO 13485 as it's framework and the program is not a replacement of the ISO 13485 standard.

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