Medical Devices Industry versus Aerospace Industry

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Abstract *— Manufacturing or production has been characterized as one of the biggest growth areas of economic sector. It is a very wide field, around about 13 categories of different manufacturing such as: Construction, Electronics, Transport, etc. Within the diversity of categories that exist in the Manufacturing Industry, we could talk about the two most outstanding subdivisions in these times that are the Medical Devices and Aerospace industries. Although both industries work in different concepts, we can find some similarity within their criteria, since they could be equally rigorous because each of them is of utmost importance for the human being. This paper is created to have a certain idea of how the operation of both industries is. It will be taking a separate assessment of both industries and then be making a comparison of both.*

Key Terms *— AS9100, FAI, ISO, Risk.*

INTRODUCTION

Why is so important the Medical Devices and Aerospace industries in these times? We know that the field of medicine is a field that is always in constant movement and is in high demand. The Medical Devices industry in which it manages or generates equipment that are related to the medical field such as pacemakers, artificial heart valves, diagnostic, synthetic skin, surgical tools, infusion pumps, life support machines, catheters, bandages, etc. The complexity of medical device products continues to increase with the inclusion of multiple technologies into a given product. Technologies such as advanced materials, etc. are now routine technologies featured in medical devices. [1] The question is that we would be if the Medical Devices industry did not exist, since many of the components that today save lives or improve the health of patients come out of it.

On the other hand, what is the Aerospace Industry in which provide different components both the hardware (aircraft, component, spare, etc.) and software (design, service, logistics, etc.) to their customers to have the proper transportation. Due to the aerospace manufacturing suppliers provide the products to satisfy the demand of main aerospace manufacturing companies, so the customer satisfaction is the fundamental requirement of suppliers to keep long-term relationship and obtain stable, enough business from main aerospace manufacturing companies. [2] Both Industries are continually growing, being two of the largest industries at the socio-economic level.

There are several projects that evaluate certain criteria separately from what are the Aerospace Industries and Medical Devices. For which there is no kind of complete analysis that tells us what processes are carried out in each of the industries mentioned and the specifications of these. Which of the Industries, whether Aerospace or Medical Devices, has greater criteria? What are the similarities and differences of both Industries based on the requests of governments or federal agencies? What are the steps that each industry takes to ensure the integrity of the product? What are the best practices of each industry and the improvements that each one is making?

Based on these questions, my idea for this research is to validate the criteria of the two most import industries on these days, which are Medical Devices and Aerospace. Also validate the similarity and the difference between these industries.

BACKGROUND

To have clear understanding of the most important aspect of Medical Devices and Aerospace Industries, the following section we will discussing in detail the terminology for both industries. In the methodology section we will cover how these terminologies are integrated on both industries and the different between each other. When someone start talking about anything related to the Medical Devices, the first thing that many people come to mind, are the acronym FDA or FDC. But what is the difference between the FDA and the FDC? The Federal Food, Drug, and Cosmetic Act (FD&C Act) is a federal law enacted by Congress. It and other federal laws establish the legal framework within which FDA operates. The FD&C Act can be found in the United States Code, which contains all general and permanent U.S. laws, beginning at 21 U.S.C. 301. FDA develops regulations based on the laws set forth in the FD&C Act or other laws under which FDA operates. FDA follows the procedures required by the Administrative Procedure Act, another federal law, to issue FDA regulations. FDA regulations are also federal laws, but they are not part of the FD&C Act. FDA follows the procedures required by its "Good Guidance Practice" regulation to issue FDA guidance. FDA guidance describes the agency's current thinking on a regulatory issue. Guidance is not legally binding on the public or FDA. The Good Guidance Practice regulation can be found at 21 CFR 10.115. [3]

Other technical terms that we need to have in mind when we talk about Medical Devices are PMA, section 510(k) documentation, Federal Register, Code of Federal Regulations, ISO, Process Validation, CGMP, Data Integrity and GAMP.

Premarket Approval (PMA) are Class III devices are high risk devices that pose a significant risk for human or animal. The PMA process need to have a submission of clinical data to support claims made for these devices. The approval process for PMA devices is like that for prescription drugs, meaning that the FDA requires the manufacturers of PMA devices to prove efficacy and safety by providing data showing the device's performance in humans. The FDA also has the authority to regulate the promotion of PMA devices. [4] Unlike 510 (k) that does not require clinical data or human trials to demonstrate the efficacy and safety of the devices. With the 510(k) the manufactures demonstrate that the medical devices have the same intended use and are equivalent to similar legally products. On December 2017 the FDA approved approximately 254 medical devices versus PMA which was 206 medical devices [5] [6].

The Federal Register (FR) is a daily publication that contains rules, proposed rules and notices from the Federal agencies. Proposed rules are initially published in the Federal Register for public comment and subsequently published in the Code of Federal Regulations after the rule is final. Final regulations published in the FR are subsequently placed or codified into the printed edition of the Code of Federal Regulations (CFR) on an annual basis. The CFR is a codification of the general and permanent rules that were published in the FR by the Executive departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to Federal regulation [7].

The acronym ISO represents the International Organization for Standardization; organization responsible for regulating a set of standards for manufacturing, commerce and communication in all industries and businesses around the world. For medical device, the standard more use is the ISO 13485 that is related to medical equipment that is an internationally recognized quality management system for manufacturers of medical equipment and related services. The ISO 13485 standard is a world benchmark for good practices in medical equipment quality management systems. The principal objective for this standard is to be harmonized regulatory requirements for quality management systems within the sector of medical devices. This ISO is update each time when new requirements come out.

The FDA define the Process Validation as establishing documented evidence which provides a high degree of assurance that a specific process will

consistently produce a product meeting its predetermined specifications and quality attributes [8].

The CGMP refers to Current Good Manufacturing Practice regulations enforced by the FDA. CGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the CGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. The CGMP requirements were established to be flexible to allow each manufacturer to decide individually how to best implement the necessary controls by using scientifically sound design, processing methods, and testing procedures [9].

The guidance on data integrity takes that notion a bit further. FDA expects data to be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA) [10]. Which mean that the FDA that all the companies must implement meaningful and effective strategies to manage their data integrity risks.

Good automated manufacturing practice (GAMP) is both a technical subcommittee of the International Society for Pharmaceutical Engineering (ISPE) and a set of guidelines for manufacturers and users of automated systems in the pharmaceutical industry.

In Aerospace industry there are various key standard that need to be consider/explain to have clear understanding of the process of this industry. They need to be certified to the AS9100 to be able to conduct business. AS9100 is quality management system which every manufacturer or supplier must comply/register to this standard and this replace the earlier AS9000 and incorporated the current version of the ISO 9000, also include the need for producing quality product and safety measure. The current revision of the AS9100 is rev D it was release in September 20, 2016 which include the ISO 9001:2015 and focus the structure of the aviation, space and defense to the new structure from ISO 9001:2015 and this are the latest change [11].

- 10 Elements
- Context of the Organization
- Interests of External Parties
- Objective Programs
- Risk-Based Thinking
- Product Safety
- Ethics Training
- Management Review
- Organizational Knowledge
- Counterfeit Parts Prevention
- Supplier Monitoring
- Purchasing
- Communication
- Change Management
- Human Factors

The ISO 10006 is reference in the AS9100 and is a guide for quality management in project, therefore this standard can't be use as a guide for project management. In ISO 10006:2017 addresses the concepts of both "quality management in projects" and "quality management systems in projects". These are distinguished by being addressed separately by the following topics and clauses [12]:

1) Quality management in projects includes:
   - Quality management systems in projects (Clause 4);
   - Management responsibility in projects (Clause 5);
   - Resource management in projects (Clause 6);
   - Product/service realization in projects (Clause 7);
   - Measurement, analysis and improvement in projects (Clause 8)
2) Quality management systems in projects includes:
   - project characteristics (4.1);
   - quality management principles in projects (4.2);
   - project quality management processes (4.3);
   - quality plan for the project (4.4).

In the AS9100 also incorporated the ISO 10007 which is a guideline to improve mutual understanding about configuration management, to promote its use and help organizations that apply it to improve their performance. Configuration management is a management activity that applies the technical and administrative direction to the entire life cycle of the product, its configuration elements and the information related to the configuration of the product [13]. See in figure 1 four procedure of CM and define as follow

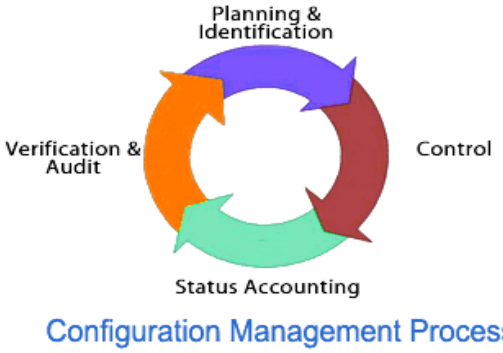

Figure 1
Configuration Management

In the following points will be a brief explanation of each procedure of the Configuration Management Process [14]:

1. Identification: process in which an attribute is identify in all aspect of the configuration item.
2. Control: is a set of processes and approval stages required to change a configuration item's attributes and to re-baseline them.
3. Status Accounting: is the ability to record and report on the configuration baselines associated with each configuration item at any moment of time. (Traceability).
4. Audits: are separated into functional and physical configuration audits:
   a) Functional configuration audits verify that the functional and performance attributes of a configuration item are achieved.
   b) Physical configuration audit ensures that a configuration item is installed in accordance with the requirements of its detailed design documentation.

One of the important aspect of the AS9100 is the Production Process Validation (section 7.5.1.1) which require testing of a production part from the first run, this way the manufacturer can provide evidence that they have the right setup to mass produce the part. Here come in play the AS9102 standard (First Article Inspection) which is a unique standard independent from the AS9100, its use due to the Production Process Validation which is invoke in the AS9100 which state the above mention which is basically the same as the AS9102. The FAI is used to document production method were acceptable as define in an Engineering drawing, Purchase order or any other applicable document. With this the manufacturer can provide evidence that all engineering design and specification were capture, understood, verified and documented. When an FAI is required?

1) Full FAI
   a) New part Introduction
   b) New Supplier or new location of manufacture
   c) Lapse in production for more than 2 years
   d) When required by the customer.
2) Partial (Delta) FAI
   a) Design Change
   b) Significant change in the method of manufacture (e.g. process, location change of process supplier, Engineering drawing updated, …)

To what specifically apply to?

- Engineering Drawing from an Aerospace industry
- Assemblies
- All detail part from an Assemblies
- Modified Electronic
- Modified Commercial Of The Shelves (COTS)

It doesn't apply to?

- Standard Parts: Evidence (CofC) that the part is obtain with a Specification such as MS, NAS, etc…
- Electronic Components: Only a datasheet is required
- COTS items

AS9102 is comprise of 3 forms and they are:

- Form 1: Part Number Accountability shall be used to identify the part that is being first article inspected (FAI part) and associated sub-assemblies or detail parts
- Form 2: Product Accountability – Raw Material, Specifications and Special Process(s), Test Verification shall be used if any material, special processes or functional testing are defined as a design requirement.
- Form 3: Characteristic Accountability, Verification and Compatibility Evaluation shall be used to record an actual measurement or inspection/verification of the FAI part for every design characteristic on the drawing, including notes.

Lastly the final reference standard is AS9103 (Key Characteristic) and this is invoked in the AS9100, section 4.9.1: The supplier shall identify and plan the production, installation and servicing processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following [15]:

…; monitoring and control of **key characteristics** where required by purchase order/contract;

What can be consider a Key characteristic?

- Dimensional features such as: thickness, diameter, length, etc.
- Chemical concentrations
- Pressure, speed, rates, temperature, etc.

In general, any feature or process whose variation will have a significant effect on the performance of the characteristic for its intended use may be a key characteristic [15].

PROBLEM

Which of this two (medical device vs Aerospace manufacturing) is stricter on the following criteria: material acquisition and acceptance, risk management, quality of product and process.

METHODOLOGY

In this section will be talking about the following criteria: material acquisition and acceptance, risk management, quality of product and process separately from each industry in order to have a better understanding when determining what are the results of our research.

Medical Device

Medical Device defined in 1938 on the Section 201(h), as part of the Federal Food Drug and Cosmetic Act (FDC Act), where a medical device was defined in three parts:

- As an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes [16].

In other word, the Food, Drug and Cosmetic Act defines a medical device as any healthcare product that does not achieve its principal intended purposes by chemical action or by being metabolized. It's important to understand that to qualify a medical device must have a medical purpose and a primary physical mode action.

In Medical Devices exist three classes: Class I, Class II and Class III to determinate the risk of each device as can be observed on Figure 1. Each class has the specific requirements where depends on the intended and indications to/for use of the device.

Depends where the device is assigned can determinate the type of premarketing application required to the FDA clear this product perform the corresponding marketing. These three classes are based on the control level that is necessary to assure the safety and the effectiveness of each device. To determinate which class is categorize the medical device exist 18 rules which are: Rules 1-4 Noninvasive devices, Rules 5-8 Invasive devices, Rules 9-12 Active devices and Rules 13-18 Special rules. These rules consider the following points: Duration, Degree invasiveness, Anatomy, Active and Re-usable. The FDA has settled approximately more than 1,700 different generic types of devices. In the following points are the device classification division:

- Class I – General Controls
  Most exempt from premarket submission [510(k)]
- Class II – Special Controls
  Premarket Notification [510(k)]
- Class III – Premarket Approval Require Premarket Application [PMA]

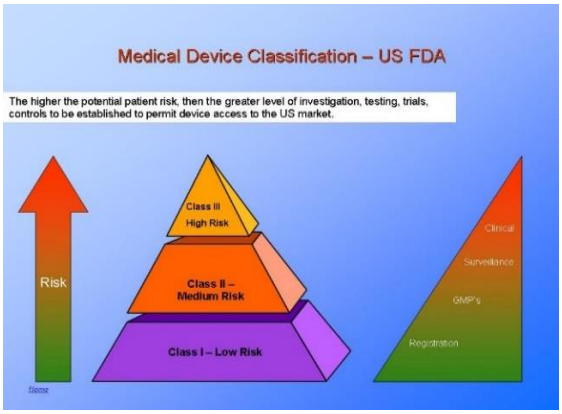

Figure 2
Medical Devices Classification

For the Class I, the devices are categorized to "General Control" and these devices are not intended to support or sustain life to human health and may not present any risk. In other words, the medical devices classified as Class I present minimal potential harm to the user. Examples of which device can be observed on the Class I will be the examination gloves or the elastic bandages. Class I Devices are subject to following requirements know as General Controls:

1. Register manufacturing and distribution locations
2. List device to be marketed with FDA
3. Manufacture the devices in accordance with Good Manufacturing Practices
4. Label medical devices in accordance with the labeling regulations, 21 CFR 801 or 21 CFR 809
5. Report adverse events of medical device as identified by the user, manufacturer and/or distributor"

For the Class II, the devices also are categorized as "General Control" but with special controls. This mean that the device need to include special label requirement, mandatory performance, etc since if the patient used the device incorrectly has a potential to pose a mild risk. Example of which device can be observed on the Class II will be: catheters, infusion pumps, air purifiers, etc. In the Class II can be also categorized as a IIa that will be as a Medium risk and IIb will be a Medium-High risk. Class II devices typically require pre-market notification by submission and FDA review of a 510(k) clearance to market submission. Special Controls applicable to Class II Devices are as follows.

1. Special labeling requirements,
2. Mandatory performance standards, both International and United States
3. Post-market surveillance
4. FDA medical device specific guidance"

For the Class III, is the top high-risk devices. These devices are usually those that support human life, therefore is the most stringent regulatory control. Example of which device can be observed on the Class III will be: heart pacemakers, intra-aortic balloons, etc. For Class III medical devices, sufficient information is not available to assure safety and effectiveness through the application of General Controls and Special Controls. Class III devices typically require pre-market approval (PMA). PMA application content includes:

1. Full reports of all information, published or which should reasonably be known to the

applicant, concerning investigations which have been made to show whether such device is safe and effective

2. Full statement of the components, properties and principles of operation for the device
3. Full description of the methods and the facilities used for the manufacturing, processing, packing and installation of the device
4. Reference to any existing performance standards and adequate information to show that the device fully meets each standard
5. Sample of the device or the location of one or more devices readily available for examination and testing in the instance that the device is burdensome to move;
6. The labeling proposed to be used for the device [17].

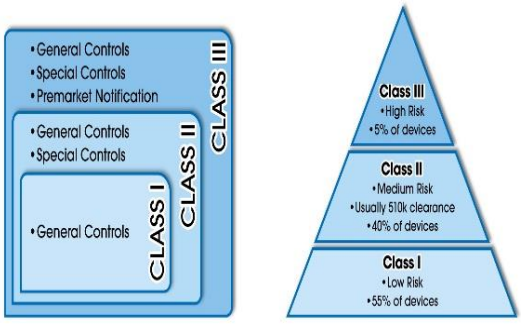

Figure 3
Summary Medical Device Classification

On Figure 3, can observed illustration of how the Medical Device Classes works and the percentage of medical devices that exist in these times divided by each class.

Exist several guidance for the Medical Device industry. In term of the standards in medical device are covered by the ISO which have more than 40 standard and/or projects related to medical devices. For the quality and risk management can be use the ISO 13485 and 14971. The first or the basic standard by the ISO will be 9001 since it signifies that a company engages in the creation of the new product and require an approval process with several rigorous quality standards and development records before the devices is distributed. The regulation is based on the FDA using the FR with the FDR that has the specific code of federal regulations for Medical devices which are the following:

- 21 CFR Parts 50, 56, 812: Clinical Studies
- 21 CFR Part 807– Establishment Registration and Listing, Premarket Notification [510(k)]
- 21 CFR Part 814: Premarket Approval (PMA)
- 21 CFR Part 812: Investigational Device Exemptions
- 21 CFR Parts 801, 809, 812, 820 – Medical Device Labeling
- 21 CFR Part 820: Quality System Regulation (Process Validation)
- 21 CFR Part 821: Tracking Requirements
- 21 CFR Part 803: Medical Device Reporting

Another requirement that is important in this time on the Medical Devices industry is the computer system validation since this will assure that critical processes are functioning correctly. In the ISA 13485:2003 was added the computer system validation. Exist several CS that are regulated by the FDA such as Control System, Automated laboratios equipment, Manufacturing execution system, etc. On the aspect of validation, the computer system verified the services, equipment, computer systems cleaning and processes. When a complex Medical Devices will be verifying the CSV become a critical process that must be completed and documented before the equipment hit the market. In the Figure 4 is a sample of a Good practice CSV [18]:

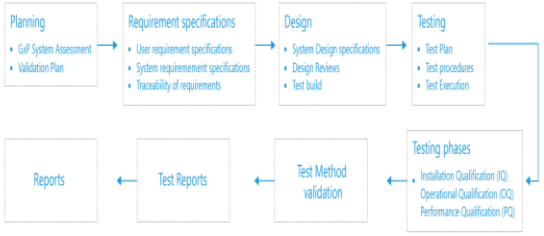

Figure 4
CSV Good Practice

To manage all this data is very important the Data Integrity that goes hand in hand with what is the CGMP and the GAMP. Process validation is an important part of the quality system for Medical

Device manufacturers. When on the Medical Device manufacturers complied with regulatory requirements is important to obtain the premarket approvals and premarket notifications for new and modified medical devices Process validation is a key element of the quality system regulation, which supports the main goal of a quality system: to consistently produce products suitable for their intended use. Process validation is required by 21 CFR part 820, section 820.75(a), which states, "Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures". [19]

Other important steps in Medical Devices is the integrity of the data that is generated by the equipment. This data is extremely important since a properly manage of the information recorded ensure the product identity, strength, purity and safety. The priority with data integrity on the manufacturers is to ensure that regardless of where information is stored, the system's data is never invalid, falsified, or adulterated. Non-compliance in the integrity of data can lead to warning letters and regulatory action from the FDA and other related agencies. Every year, there are new reports of manufacturing sites falsifying data to fast-track products to get them out the door and into the market. In fact, FDA sighted data integrity issues in 19 warning letters from the Center for Device and Radiological Health in 2016 [20].

After notices that the integrity of the information is one of the priority points on Medical Devices, the GAMP will be the best practices to maintain the integrity since is automated. Also, Computer system validation following GAMP guidelines requires users and suppliers to work in concert so that responsibilities regarding the validation process are understood. The GAMP have 5 categorization that allows a flexibility when applying validation to the great variety of medical devices, processes and manufacturing facilities since it's not possible to state in one document all the specific validation elements that are applicable. In the Figure 5 demonstrate the 5 categories with the corresponding action of the validation [21].

GAMP Class	Category	Validation Action
1	Operating Systems	Record ID and Version.
2	Instruments and controllers	Record configuration and calibration.
3	Packages where existing code can be selected and set points imputed.	Audit supplier – validate any bespoke code – validate functionality
4	Systems that the code or part of the code are configurable.	Audit supplier and code, validate any bespoke configurations apply full life cycle requirements.
5	Systems utilizing custom or bespoke code which produce predicate rules information.	Audit supplier, validate all code, apply full life-cycle requirements

Figure 5
GAMP Categories Classes

Aerospace

Quality management system for aerospace was define in 1999 on the AS9100 which base it the ISO 9001. This standard provides the supplier the requirement to deliver a quality system to provide safe and reliable products to the aerospace industry. Any supplier must be certified to the AS9100 standard to distribute its product to the aerospace industry. This standard is use by companies that design, develop and/or produce aviation, space and defense products; and by organizations providing post-delivery support, including the provision of maintenance, spare parts, or materials, for their own products [22]. The AS9100 is approved by:

- Federal Aviation Administration (FAA)
- U.S. Department of Defense (DoD)
- National Aeronautics and Space Administration (NASA).

In this standard reference:

- ISO 10006 Project Management
- ISO 10007 Configuration Management
- ARP 9134 Risk Management
- AS9102 First Article Inspection (FAI)
- AS9103 Key Characteristics

This standard is well balance for the need of the aerospace industry. If we focused on why risk management is important to the aerospace industry and its application to it. Since this industry handle a large volume of people, material and ammunition

that are being transported to different location across the globe. It is in heavy-duty industries like this that a thorough risk management program must be established; as such heavy workload can result in many risks that can be both inherent and acquired. Risk management in the aerospace industry should be a description of the ways in which every organization in this sector employs means and ways for anticipating and mitigating risks. It should reflect the ways in which an organization in the aerospace industry approaches the various risks and ways by which it seeks to address them through risk mitigation techniques and mechanisms. The essential purpose of having a well thought out risk management process helps a player in the aerospace industry identify the various risks it is up against in the short and long terms of its business. It helps them size up the gravity of risk and put a mitigation process in place and create a process for aerospace risk management, while at the same time also enhancing customer perception in the product. Risk management in the aerospace industry is subject to two important standards -the AS9100, and the ISO 9001, which is the foundation for the AS9100. Till 1999, the ISO 9001 was the standard practice for risk management in the aerospace industry. The AS9100 evolved because of the observation that the ISO 9001 was not flexible and scalable enough to meet the unique needs required for meeting the risk-related aspects of the aerospace industry. That said, although the AS9100 goes a long way in satisfying DOD, NASA and FAA quality requirements and meets its primary purpose of establishing a single, pan-aerospace industry Quality Management System (QMS); it has not abnegated any of the primary requirements set out in ISO 9001. As a result, it complements its parent standard but addresses shortfalls in the generalized standard by adding necessary improvements tailored to the specific needs of risk management in the aerospace industry. This means that organizations which implement risk management in the aerospace industry must adapt these two standards together and suitably blend them to get consolidated, rather than piecemeal and patchy results. Since the aerospace industry is quite complex and highly technological; only a broad hint of the areas in which risk management is necessary can be given. The methods and extent to which risk management is to be implemented in each of these disciplines depends on the organization's business and products. These are the broad areas in which risk management is to be implemented in the aerospace industry: (a) Materials used in the build and manufacture of aircraft, (b) Management (c) Project management, relevant especially when aircraft are being built, (d) Supply chain [23].

RESULTS AND DISCUSSION

The concept of best practices is being observed on both industries, Medical Devices call the CGMP as the best practices which involve several steps that are stablished by the FDA unlike the Aerospace that does not have any specific name for the best practice, but this best practice involved several documents that are developed to provide timely information related to good operating practices identified within the aerospace community. The practices outlined in these documents are designed for voluntary use by anyone in the aviation community. These best practice documents have been developed and provided by the FAA and/or aerospace industry manufacturers, associations, organizations, and working groups. Each document was reviewed by the Aircraft Certification Service, Production and Airworthiness Division for content relevance, compatibility with regulatory requirements, and appropriateness to the broad range of aerospace manufacturers. Difference of Medical Devices that only the FDA inspector determinate any change on the CGMP documentation.

Data Integrity is fundamental in every job but when this term appears on Medical Devices and Aerospace, they contain certain faults. In Medical Device the data integrity was included not long ago and several companies they are not applying this concept in their processes but in Aerospace they are not so strict or do not surround what the data integrity process is. I supposed that each company

has the own criteria and security but at the level of required documentation is not the same as in Medical Device.

In both industries, the automated manufacturing is very important since this lowers the incidences that may occur when they are handled by humans and is more cost effective. The validation automatization will be more effective versus human validation. Both manufacturing has being improving each day with the Good Automated Manufacturing Practice although this terminology is not mentioned in aerospace, but it does have several automated processes for validation in different sectors.

If we compare the FDA with the FAA with all the documentation and the parameters that each one work. It is very clear that the FDA has a lot of weight in the FAA although it does not have to do directly but indirectly if it must depend on it, if we speak in general. For example, if a pilot during his preparation for the private pilot flight training is diagnosed with a medical condition, the FAA request the pilot a FAA medical certificate to allow this person to continue with the training. But in the meantime, FAA Doctor prescribes a medication that must be approval by the FDA. This type of issues passes several times and FAA personnel indicated that "We wait at least a year to let the FDA establish a more complete profile of benefits and side effects before we commit the resources required for aviation evaluation,". In general, the main of both agencies is to protect the human, but the FDA has more greater weight since it covers many fields for the protection of humans versus the FAA that is specific to what Aviation is. Some personnel mentioned that the FAA tactics is to promote aviation as well as regulate, while the FDA is strictly a regulatory agency.

The principal regulations of both industries are ISO13485 and the AS9100 which are based on the requirements of ISO 9001. The changes made it on the ISO13485 were for intended to also be requirements for regulatory purposes as well as non-statutory requirements for a quality management system. In the ISO13485, the quality management system requirements in the specific sections four through eight, were several small additions, mostly involved in the identification and application of pertinent legal requirements for the medical devices produced by the corporation. On the AS9100, takes also the complete ISO9001 standard requirements and added specification on several parts such as planning for product realization, design and development, Purchasing and purchased product, production and service provision, non-conforming process and product monitoring and measurement. For the process validation, well the Medical Devices need to get some tips from the Aerospace, since in aerospace, the exact location and movement history of high-value, fast-moving assets such as containers, tooling, equipment and consumable items are now being routinely tracked in real time using Radio Frequency Identification versus this process is not being manage on the medical devices how is it doing in aerospace.

CONCLUSION

It can be determined that the medical device industry is stricter in the procedures due to the strong regulations demanded by the FDA. However, Aerospace although it does contain regulations that are in some respects strict but when it refers to the processes of the equipment and materials that are used for the creation of the product are more efficient and more rigorous than what the FDA is. During this investigation, we have seen that the FDA handles strict regulations of Medical Devices, but this industry is one of the biggest industries that see errors that affect the human being in comparison with the FAA that are less the incidents that affect the human being. For logistics, the Medical Devices industry should be one of the least that should affect the human being but being such an ample industry could also think that this is something that can be seen coming, but this does not mean that the FDA should be more rigorous in what are the errors that occur in medical devices and be able to copy the way in which Aerospace handles these types of errors. Both industries have many opportunities for improvement in certain critical points that although

they can be seen in an aspect that is not very important but in the long run it can affect the product quality and affect how the client deliverable that it to produce a top-quality product to satisfy customer requirement and ensure the welfare of humans.

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