**SECTION 2**

1. Identify, Invent, Implement.
2. Unlike other electronic devices, medical devices are directly in risk with life of a patient, so there is a need for regulating the manufacturing and distributing process of the medical device, in order to ensure safety of the patients, These were the steps in regulating the measures while manufacturing a medical device,
3. Following the design process-generation of detailed design which met the regulatory requirements(horizontal, vertical, product specific)
4. Verification and validation of design(e.g. Failure mode and effect analysis)
5. After prototyping- functional analysis
6. Quality assessment
7. Safety assessment

USA

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| Class I | Low risk |
| Class II | Moderate risk |
| Class III | High risk |

EUROPE

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| --- | --- |
| Risk based classification | Class I (low risk)  Class I (Low /medium risk reusable)  Class II a (medium risk)  Class II b (medium/ high risk)  Class III (High risk) |
| Functionality based classification | Non-invasive medical devices  Invasive medical devices  Active medical devices  Special rule (Contraceptives, disinfectants, radiological) |

CHINA

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| Risk based classification | Class I (low risk)  Class II (Medium risk)  Class III(High risk) | |
| Device categories | Active surgical device  Passive surgical device  Neuro & cardio surgical device  Ortho surgical device  Radiation device  Imaging device  Diagnostic device & Monitoring device  Anesthesia device  Physiotherapy device  Infusion& Dialysis device  Sterilization device | Active implantable device  Non-active implantable device  Nursing and protective device  Bed and transportation device  Ophthalmic device  Dental device  Gynecological & obstetric device  Rehabilitation device  Traditional Chinese medicine device  Healthcare Software  Laboratory devices |

INDIA

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| Risk based classification | Class A(low risk)  Class B(low moderate risk)  Class C(moderate high risk)  Class D(high risk) |
| Functionality based classification | Non-invasive medical device  Invasive medical devices  Surgically medical device  Miscellaneous medical device  In-vitro diagnostic devices |

1. India is rapidly growing medical market, it has been valued 3.5 billion U.S dollars in 2015 and can grow up to 4.8 billion U.S dollars by the end of 2019, currently our medical market relies heavily on imports, many radiological and in-vitro diagnostics devices are imported from other countries, so the first thing to improve our medical market is to boost the manufacturing sector in India. This can be done by providing subsidiaries and economical support to more medical start-ups and encouraging them to enter into the market. Many youth get employed and can economically progress. Our new medical devices rule 2017 opened up our market and improved the regulatory standards of the medical devices in India. Other than start-ups, single window clearance for big manufactures like Siemens, General electric and Philips could also ease our market from relies on import. Similar to encouraging enterprises, training our youth is very important, skill development programs specific to medical device design, manufacturing and regulatory standards are necessary. Along the industry of hospital were expected to grow at the rate CAGR of 16-17 percent reaching the value of 132.84 billion U.S dollars, besides the development of healthcare industry in India, still many lack adequate medical coverage, this was because of poor medical insurance system. While in western countries like U.S every citizen has covered with a medical insurance. In U.S the medical expenditure by government is 52% and that of private is 48% while in India the expenditure by government is 30% and by private is 70% respectively, our government should take steps to invest in healthcare sector. Recently our government initiated medical insurance scheme for low income people called “Jan Arogya Yojana” insurance plan which is a great thing. The government of Andhra Pradesh took an initiative to boost healthcare start-ups by creating a zone called Andhra Pradesh med-tech zone (AMTZ) where people can start their medical enterprise with lot of privileges, similar such zones should be created in every state of India which greatly increases the production of medical devices in India. Even though the new medical devices rule has brought some good deeds it still cannot be compared with FDA or EU medical device directives , it doesn’t discuss about medical software , by overcoming the all these flaws and improving standards of our rules India can lead the other nation in healthcare industry.