**SECTION II**

1. Identify , invent, and implement defines Biodesign process
2. Regulatory measures in manufacturing medical device

**Device attributes**

* Safety and Performance: Performance is closely related to safety. For example: a blood collection syringe with blend needle would perform badly for collecting blood and could inflict injury.

**Manufacturing**

* Inspection and enforcement ensuring that

1. A predicate exists that the FDA will accept
2. There’s a solid risk management plan in place
3. FDA guidance documents for testing are adhered to;

* Clinical trial based on the risk level of medical device
* Quality system: A preventive approach to assuring medical device quality versus the previous reactive approach by inspection and rejection at the end of manufacturing line.

**Labelling**

* Accurate description of product
* Instruction for use

Classification of Medical devices in USA

Regulatory pathway: 510(K) application, Premarket Approval(PMA)

|  |  |
| --- | --- |
| Classification categories | Medical Devices and risk level |
| Class I | Non-life sustaining, least complicated, minimal or no risk |
| Class II | More complicated and present more risk than class I. General control to prove safety and efficacy and pass through 510(k) |
| Class III | Life sustaining, most stringent regulatory control, requires pre-market approval |

Classification of Medical devices in Europe

|  |  |
| --- | --- |
| Classification categories | Medical Devices and risk level |
| Class I | Blood Pressure cuff, Hospital bed |
| Class IIa | Hearing aid, X ray diagnostic equipment |
| Class IIb | Ventilator, Blood bags |
| Class III | Drug eluting coronary stent, PTCA balloon |

Classification of Medical devices in China

|  |  |
| --- | --- |
| Classification categories | Medical Devices and risk level |
| Class I | Safety can be ensured through routine administration. |
| Class II | Further control is required to ensure their safety of use |
| Class III | Life supportive and implanted devices, and require strict safety surveillance |

Classification of Medical devices in India

|  |  |
| --- | --- |
| Classification categories | Medical Devices and risk level |
| Class A | Devices involving low risk. Example: Thermometer, tongue depressor |
| Class B | Low to moderate risk. Example: suction equipment, hypodermic needle |
| Class C | Moderate to high risk. Example: Bone fixation pate, Lung Ventilator |
| Class D | Highest risk. Example: Heart valves, implantable defibrillator |

1. Suggestion to improve healthcare system in India
2. The health care system in India is primarily administered by the states. Quality of care is not same in urban and rural area. Rural areas are in need of healthcare services at anytime and anywhere.

Thus, telehealth and telemedicine services need to be improved.

1. To bridge the gap between quality of patient care and medical systems, increase use of electronic health records (EHR) need to be improved. This can reduce the filing system difficulties.
2. Measuring Health related Quality of Life (HRQOL) will help monitor progresses in achieving patient specific outcomes.
3. Providing affordable, portable, reliable healthcare system can improve easy availability of health service to all rations.

Health Insurance Portability and Accountability Act (HIPAA) helps to protect the patient information in order to protect the patient privacy, security and confidentiality of patient information.

**HIPAA Awareness**

|  |  |  |  |
| --- | --- | --- | --- |
| S. No. | Awareness | Number of laboratories | Percentage |
| 1. | Aware | 14 | 28 |
| 2. | Unaware | 36 | 72 |
|  | TOTAL | 50 | 00 |

Source: Primary data.

In India, HIPAA is not popular and recognised and hence the laboratory is not aware even though it is established in the year 1996. Some of them have not heard of the term ‘HIPAA’; some of them are aware of HIPAA, and doesn't know the purpose why it is established and used for. Totally there is no public awareness.

Governance of Health Insurance Coverage in India

|  |  |  |  |
| --- | --- | --- | --- |
| S. No. | Health insurance coverage is governed well | Number of laboratories | Percentage |
| 1. | Yes | 29 | 58 |
| 2. | No | 21 | 42 |
|  | TOTAL | 50 | 100 |

Source: Primary data.

It is observed that still further improvement is needed to fasten up the claim settlement process especially the bills coming from lay persons individually (as reimbursement) and not through the hospitals for cashless treatment.