SECTION -2

1. Bio design innovation process means identify, invent and implement.
2. The regulatory measures in manufacturing a medical devices are medical device listing, establishment registration, premarket notification 510(K) , premarket approval, quality system regulation, labeling requirements and medical device reporting.

CLASSES OF MEDICAL DEVICE IN USA

|  |  |
| --- | --- |
| Class I(low to moderate risk) | General controls |
| Class II(moderate to high risk) | Special Controls |
| Class III (high risk) | General controls and Premarket Approval |

CLASSES OF MEDICAL DEVICE IN EUROPE

|  |  |
| --- | --- |
| Class I | Low risk |
| Class II a | Medium risk |
| Class II b | Medium risk |
| Class III | High risk |

CLASSES OF MEDICAL DEVICE IN CHINA

|  |  |
| --- | --- |
| Class I | Devices with lowest level of Risk- requiring only routine administration for their safety and efficacy |
| Class II | Devices with moderate level of risk – requiring greater control to ensure their safety and efficacy |
| Class III | Devices with the highest level of risk, subject to the strictest controls for their safety and efficacy |

MEDICAL DEVICE CLASSES IN INDIA

|  |  |
| --- | --- |
| Class A | LOW Risk |
| Class B | Low moderate Risk |
| Class C | Moderate High Risk |
| Class D | High Risk |

1. By providing services like management of mental illness, child health care etc.. we can improve the healthcare system.

National Health Protection Mission provides a defined benefit cover of 5 lakh per family per year . Likewise, we can improve this, by providing the health insurance scheme without considering the family size and age in the scheme. We should awareness about healthcare issues to the Indian population. Must regulate the distribution and sales of the drug. And should provide effective and efficient training to the healthcare professionals . Educate the professionals about the importance of quality of service than quantity. Jan Arogya Yojana – healthcare scheme aims to provide better healthcare services for the lowest strata of society. So by providing the healthcare scheme like this will allow the poor to benefit from case less secondary and tertiary healthcare.