



Certification by I4.0

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In India, Medical Device Sector has market of **5.2 billion USD**. But total import of medical devices is more than **75%** of total medical device's sales.

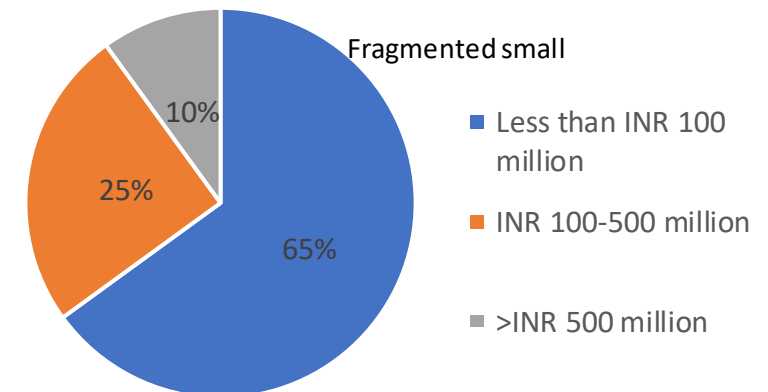
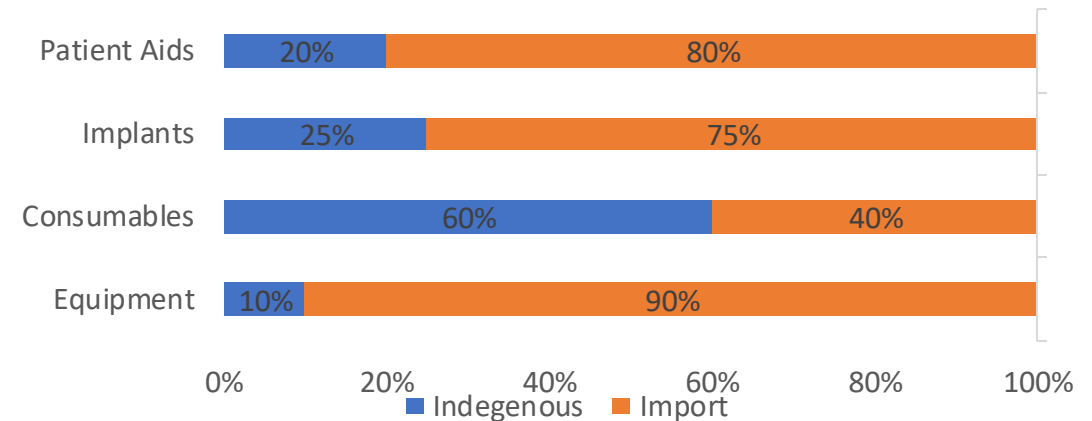
The reasons- **Certification regulations**, market competitiveness, unaffordable manufacturing technologies. **65%** of indigenous manufacturers falls under MSME category.

To get certification the manufacturer must follow Quality management system (QMS) as one of the requirement to sell his product.

The accepted QMS standard globally is **ISO 13485:2016**. In India, the **Medical Device Rule 2017 schedule V**

The literature and field survey shows following reasons for MSMEs, find **difficult to implement** QMS:

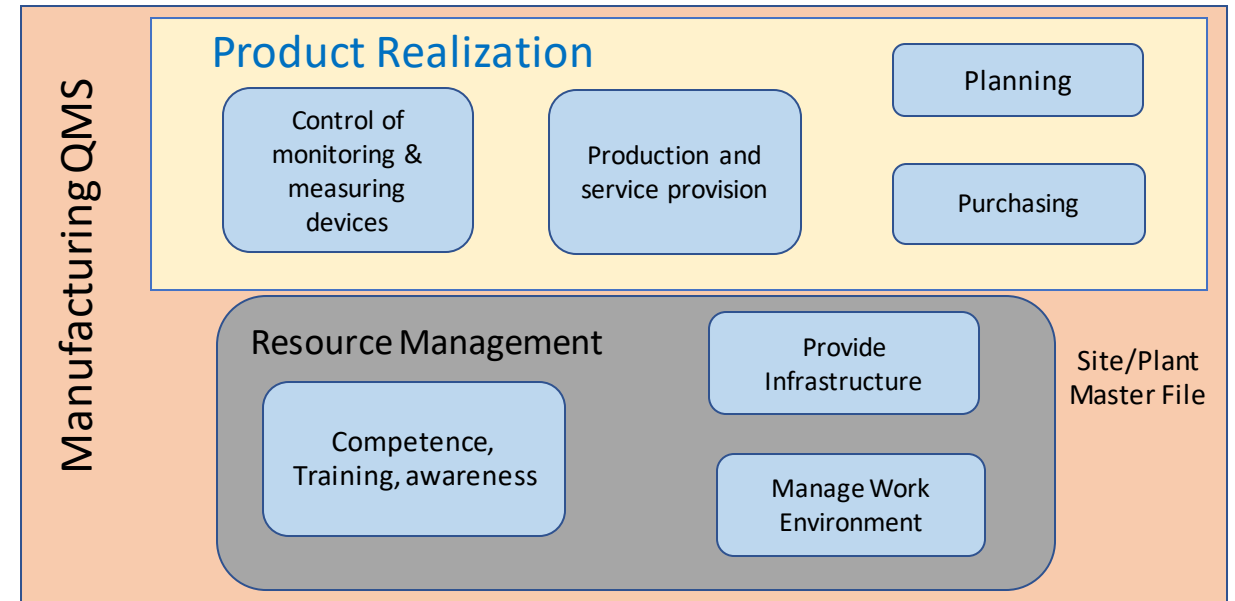
- Time for implementation
- Lack of Resources (Infrastructure, Manpower)
- Lack of Training and guidance



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The Research concentrates on the manufacturing part of QMS. The QMS elements in Manufacturing are:

- **Resource management**
- **Training**
- **Infrastructure**
- **Environment Monitoring**
- **Inspection/ Quality of process and product**
- **Testing / Performance Analysis/ Calibration**
- **Identification and Traceability**
- **Cleaning and Sterilization**



A **Framework** to support manufacturing QMS using I4.0 technologies and smart solutions.

The framework will support the **data collection** from critical manufacturing processes, **analyze** the collected data and **utilize** to useful information.

The information will then be used for the **documentation** of QMS, ERP, MES, PLM, SCM and vice versa.

The validated results are to be compared with the actual scenario.

This will help in reducing the burdens of QMS implementation and will make the device worthy for certification.



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Thanks!