# HNP Brief #8

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## An Overview of Medical Device Policy and Regulation[1]

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*This brief addresses key policy issues to be considered by World Bank staff and their country counterparts when designing and supervising projects that support the procurement and utilization of medical devices commonly deployed in developing health programs*.

### Introduction

Medical devices include a wide range of instruments from a simple wooden tongue depressor to the most sophisticated implants or medical imaging systems. Like drugs and other inputs to patient care, medical devices play an essential role for modern health care – at the bedside, at the rural health clinic or in a large, specialized hospital.

The provision of medical devices is frequently an important component of Bank health projects. Good planning for medical devices results in good monetary investment and, more significantly, in appropriate distribution of devices over different levels to ensure quality of care and across the country to ensure equity of access by the population. Furthermore, durable medical devices require careful planning of recurrent operating budgets for sustainable operation.

From 1997 to 2001, the Bank invested some $1.5 billion in medical devices. However, recent Bank reviews of the results have not been satisfactory. There were cases where "about 30 % of sophisticated equipment remained unused, while those in operation have 25 to 35 % equipment downtime because of weak capacity to maintain equipment. A root cause has been identified as ineffective management including planning, acquisition and subsequent operations"[1].

"Many ECA countries continue to face significant problems in terms of: the inappropriate selection and poor distribution of technology; the inability to maintain and operate safely and efficiently; and ultimately, the inability to obtain the desirable health outcomes as a result of these technology investments. Furthermore, the Bank projects have done relatively little to assess investments in medical technology in terms of cost-effectiveness, affordability and quality of health care" [2].

The abundance of existing literature and guidelines on medical device management are written in different contexts by different medical device groups employing diverse terminologies. For a policy maker or a health care manager, it could be a difficult task to digest the large amount of information. This Brief will introduce a big-picture framework [3] to facilitate the understanding of the different aspects and stages in the management of medical devices. This is the first in a series of briefs; subsequent briefs will provide more details on the components in each of the three levels in the framework on the medical device policy: 1) medical devices on the national market complying with essential safety and performance principles; 2) appropriate selection by healthcare providers from the vast device market; and 3) safe, appropriate use, and good management including disposal practices.

### What Is a Medical Device?[2]

While drugs have a limited number of physical forms, a medical device can be an instrument, apparatus, implement, machine contrivance, implant, in vitro reagent, or a component that provides a diagnosis, cure, mitigation, treatment, or prevention of a disease or condition, which does not achieve its intended use by being metabolized or through a chemical reaction.

Examples of medical devices can include: walking stick, surgical instruments, contact lens lubricants, condoms, stethoscopes, pregnancy test kits, insulin syringes and needles, wheelchairs, hearing aids, centrifuges, dental chairs and drills, various implantable devices, Magnetic Resonance Imaging (MRI), and Computed Tomography Imaging (CT). The living blood sucking leech is recently classified by the US FDA as a medical device because of its function as an aid to blood-letting in healthcare.

Therefore, medical devices include an enormous variety of existing healthcare items, and many new forms are being constantly invented. The Global Medical Device Nomenclature (GMDN) system [4] designates 12 categories of medical devices consisting more than 10,000 generic groups that can be linked to more than 500,000 device types.

[1] The term Policy refers to an overall direction or course of action. In a policy, some elements may need legislative regulatory interventions. Whether certain policy element needs legislations depends on the local social and government systems.

[2] The terms "device", "equipment" and "instrument" are synonymous and used interchangeably in this Brief.

**The 12 GMDN designated categories**

01 Active implantable devices
02 Anesthetic and respiratory devices
03 Dental devices
04 Electro mechanical medical devices
05 Hospital hardware
06 In vitro diagnostic devices (IVD)
07 Non-active implantable devices
08 Ophthalmic and optical devices
09 Reusable instruments
10 Single use devices
11 Technical aids for disabled persons
12 Diagnostic and therapeutic radiation devices

These categories include distant patient monitors and home-care devices. An important task in establishing national policies on medical devices is to define precisely what medical devices are to be included in the definition. For regulatory purposes, a globally harmonized definition of medical device [5] has been developed for reference by the Global Harmonization Task Force (GHTF).

The purpose of the GHTF is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness / performance and quality of medical devices, promoting technological innovation and facilitating international trade, and the primary way in which this is accomplished is via the publication and dissemination of harmonized guidance documents on basic regulatory practices (see www.ghtf.org).

## Comparison of Medical Devices and Drugs

The emergence of medical devices as an important healthcare product is relatively recent compared with drugs. There are important distinctions between these groups of health care inputs that are worth noting for policy formulation. Table 1 lists some distinguishing features with implications for the subject matters of this paper.

**Table 1: Some contrasts between medical devices and drugs**

| Policy Element | Medical Devices | Drugs |
|---|---|---|
| Regulation | Recent development. Regulations are explicitly based on risk classification of new devices. Regulatory scrutiny increases with higher risk-class devices. | Long established regulations based on extensive review and testing of all new drugs. |
| Technology assessment | Randomized Clinical Trials are difficult, costly and done only in some high risk devices (e.g. active implantable devices). Placebo is impractical for the majority of medical devices. | Randomized Clinical Trials are mandatory. |
| Interface in use | Device-*operator*-patient or specimen<br>*Operator* skill is a critical element (see more in text) | Drug-patient<br>No operator interface[3] |
| Maintenance | Needs proper care and maintenance for durable or reusable devices | No maintenance needed other than proper storage |
| Recurrent operating cost | Essential for durable devices (see Figure 1) | Not applicable |
| Counterfeit | Relatively uncommon (e.g. difficult to imitate a device, easy to visually detect frauds) except for certain vulnerable types such as condoms; intra-ocular lenses and in-vitro diagnostic medical devices. However, many sub-standard devices such as surgical instruments, surgical gloves, masks and others, usually with low bulk price as sales pitch, are reported in developing countries. | Common problems (e.g. easy to imitate a pill or fluid, difficult to visually detect frauds), particularly in developing countries without effective regulatory control [6]. |

[3] Here we exclude drugs with delivery devices or combination products such as a drug eluting stent.

## Salient Implications for Medical Device Policy

- The risk-based regulatory approach mandates post-market monitoring on device performance as key in ensuring the continued safety and effectiveness of devices in use.
- The large variety of designs implies the need for technology assessment and selection to ensure the proposed devices are appropriate (e.g. compatible with the local human and environmental factors, qualified operators, clean water, adequate electricity - see Table 2)
- Medical device is like a tool that requires not only knowledge but also skills to operate. The operator interface stresses the importance of proper education and training before using any medical devices. In addition, implantation of active devices often requires effective coordination of a team of specialists and supporting professionals.
- Durable medical devices are an asset that needs adequate recurrent budgeting for proper management and maintenance in operation (see "Budgeting for Durable Medical Devices", p.4 and Figure 1, p.5).

## Evolving medical device issues in the industrialized countries

There has been accelerated growth in the field of medical devices since the 1950s. Invasive interventions such as cardiac pacing, blood pressure and other physiological parameter monitoring by electrodes and catheters entering the heart or great vessels were increasingly used with good healthcare outcome. The major concern in 1960-70's was the hazard of micro-shock, a tiny electrical current not perceptible by normal human contact that could be channeled via the invasive devices to cause cardiac fibrillations. Intense research by scientists led to improved design of devices and education on users to minimize this concern.

As medical equipment began to spread beyond major health facilities, the issue of maintenance came into attention. This issue was generally resolved in industrialized countries by the availability of technical personnel from the vendors, and the emergence of hospital in-house clinical engineers and technologists. These technical professionals are also tackling another emerging issue caused by the interactions among an increased number of devices used in the clinical environment including electro-magnetic interference from non-healthcare devices.

With the emergence of expensive diagnostic imaging devices such as the CT scanners, laboratory auto-analyzers, life support or sustaining devices, the issues of cost-effectiveness, distribution, accessibility and re-imbursement became priority concerns. A new interdisciplinary function emerged to conduct "Health Technology Assessment (HTA)" along with the Evidence Based Healthcare Movement. National governments and health care professionals are establishing HTA capacities in order to assist the health policy makers and managers in the health care system cope with the difficult decisions associated with containing spiraling healthcare costs and rapid proliferation of medical technologies.

More recently, the attention has been extended to reducing the occurrence of general iatrogenic errors[4] that occur in healthcare facilities affecting patient safety [7, 8]. Medical devices, with an operator interface that is vulnerable to "use errors"[5] as a result of human factor conditions, are prime targets for prevention of human as well as mechanical errors.

## Considerations for Developing Countries

Developing countries face a number of challenges in adopting technologies for healthcare. The majority of medical devices are designed for use in the industrialized countries. This has a number of implications on the appropriateness of many devices in a developing country context:

- Healthcare priorities in most industrialized countries are different from those in developing countries, with greater focus on ageing and management of chronic diseases;
- Deriving maximum benefits from the medical devices requires technical knowledge, skills and resources in operation and maintenance that are geared towards industrialized countries and may not be readily available in a developing country context; and
- The devices may not be adapted to the environmental and operating conditions, including climate, access to water and electrical supplies, and transportation conditions.

Upon these preconditions of developing countries, the following should be considered in the implementation of medical devices.

a) Compliance with international safety and performance standards at the pre-market stage

World Health Organization (WHO) [9] recommends that countries establish medical device regulations to ensure public safety by preventing the marketing of substandard, repackaged or counterfeit devices. Furthermore, such regulations will protect citizens from inadvertently becoming clinical trial subjects of unproven medical devices. A comprehensive local pre-market assessment program for medical devices requires extensive expertise and financial resources.

[4] This term refers to errors induced inadvertently by a healthcare professional or by treatment or diagnostic procedures.

[5] Act, or omission of an act, that has a different result to that intended by the manufacturer, or expected by the operator.

Fortunately, developing countries can benefit from leveraging on global harmonization of medical device standards and regulatory practices.

b) Need for Health Technology Assessment (HTA) [10]
Expensive technologies are often adopted and devices purchased before there is clear evidence of their contributions to the priority health problems of the nation. Cost effectiveness/ benefit have become important concerns. HTA is an attempt by the industrialized countries to address technology assessment issues in a more systematic manner. In many emerging economies, the increase of mortality due to chronic versus infectious diseases adds another important factor for the healthcare decisions, and timely preventive strategies are urgent [11]. Recently, international and regional associations of HTA have been forming that include an increasing number of developing countries. These associations provide a forum for sharing information across borders and could help to reduce the time and cost of technology assessment [12]. Developing countries could benefit by building on the available literature and knowledge being accumulated by the growing number of HTA groups around the world. It is important, however, to examine the international information in light of local contextual considerations such as socio-economic, cultural, ethical and political factors before making a decision.

Inappropriate use of established technologies
Not only expensive new technologies should be subject to careful assessment but making established low cost technology widely available should also be carefully considered with respect to appropriate use. For example, ultrasound units for fetal scan are now available at cost comparable to high end television sets. In one developing country visited by the author in 1998, fetal scan ultrasound units were made available to all community clinics below the district hospital level. It was revealed that most of the time the ultrasound scan was used to allow the mother to view the fetus or to detect the sex of the fetus before birth. In such cases, client payment was a factor for service.

Two other examples are indiscriminate use of x-ray and unnecessary use of injection. More than 16 billion injections are given yearly worldwide but a substantial number was deemed medically unnecessary [13]. Such practices represent a waste of resources and could bring harm instead of benefit to healthcare. Inappropriate use can be minimized by introducing clinical practice guidelines at a policy level (level 2, figure 2) and implementing the guidelines at the operation level (level 3, Figure 2) as a component of Good Management Practice (Figure 3, Education and Training of users) in the proposed three-level policy and regulatory framework.

The Concept of Essential Health Technologies (EHT)
This is used by WHO to describe technologies with proven health benefits. WHO is taking the lead in developing norms and standards, guidelines, training materials, reference materials and estimation of burden of disease, with the focus on diseases of the poor (see recommendations by WHO [14]). A comprehensive set of guidelines on managing Blood Cold Chain Equipment is also available on the same WHO's EHT web site.

c) Patient Safety
As mentioned earlier, this is a current focus of the healthcare communities in industrialized countries [7, 8]. With respect to medical devices, it is proposed that before a medical device is released for clinical use, a sample checklist be run through to ensure that:

- The device complies with regulatory requirements;
- The device will be used by a qualified operator with education and training for that device;
- The device will be properly maintained and calibrated;
- There are measures to prevent cross infection and electromagnetic interference hazards;
- The device meets local human factor and environmental conditions;
- There are strict rules and procedures for operating radiation devices including safe dosage settings;
- There is a program in place for continued surveillance of safety and potential problems; and
- A Technology Management program (below) is in place to coordinate and support the above activities.

d) Education and Training in Medical Devices

The safety and health outcome of the majority of medical devices is inextricably linked to how the devices are managed (including maintenance) and to operator skills. The traditional one-time training by the manufacturer / vendor as a condition of purchase is not enough. In developing countries, the turn-over of medical professionals are relatively high and new workers must be properly trained to manage and operate designated devices. The manufacturer's instruction manuals in local language might not be reliable training tools because accurate translation of the original technical language is very difficult; a local program should be established to ensure that every operator of medical devices is properly trained before the use of a medical device. A local well-trained trainer should serve as a buffer (as a component of Technology Management described below). Furthermore, implantation of medical devices may require assembling a team of experienced professionals including the manufacturer's representative. The capacity and cost must be carefully addressed.

Multiple usage of single use devices
With low cost plastic manufacturing, simple devices such as syringes, trocars and drainage catheters were introduced in industrialized countries to save labor and material costs in reprocessing. Caution must be exercised to guard against the temptation to reuse such devices. Considerations must also be given for their safe disposal to prevent infection, environmental pollution, or repackaged for re-sale by uniformed or unethical profiteers. In some industrialized countries, certain single use devices are reprocessed by specialists under strict government regulatory compliance requirements. However, single use injection syringes and needles cannot be properly re-sterilized, and should never be re-used since the risk for infection or physical injury is extremely high [15, 16].

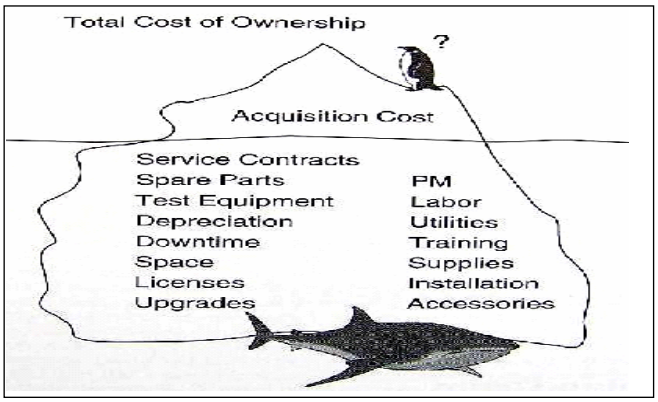
The single use injection syringes and needles are one of the most commonly used medical devices with multiple potential risks that demand top government attention to ensure safe injection practice. WHO has a website [17] that provides extensive guidance on this subject.

e) Technology Management
In healthcare facilities, personnel with technical knowledge are necessary to manage an ever increasing complexity and number of medical devices. It is estimated that over 50% of medical equipment in developing countries is not maintained and out of order. Developing countries could obtain greater returns on their investments in medical devices if they would pay greater attention to ensuring adequate recurrent budget, training of operators and staff and the introduction of Good Management Practices (Figure 3 provides and outline to be elaborated in future issues).

If a single healthcare facility cannot afford an in-house technology management service, a group of regional facilities could pool resources to support a shared service. The need for technology management services should deserve equal recognition to the need for pharmaceutical services in a healthcare facility.

f) Budgeting for Durable Medical Devices
In the developing countries, the operating and maintenance costs associated with the acquisition of medical devices are often severely underestimated. The cost of capital is only a tip of an iceberg: the recurrent cost of ownership has many cost elements (see Figure 1) that are often not taken into consideration at the time of acquisition. Some durable medical devices have accessories that are consumables; for example, an intra-venous (IV) infusion pump needs compatible IV sets that must be replaced for each patient. Often medical device suppliers will provide the infusion pumps at no cost, but the continued operation of the pumps using consumable IV sets will need a continuing operating budget.

**Figure 1: Hidden Cost of Durable Medical Device Ownership**




Most of the costs below the "water level" are recurrent and are essential to keep the "iceberg" afloat (i.e. operational)!

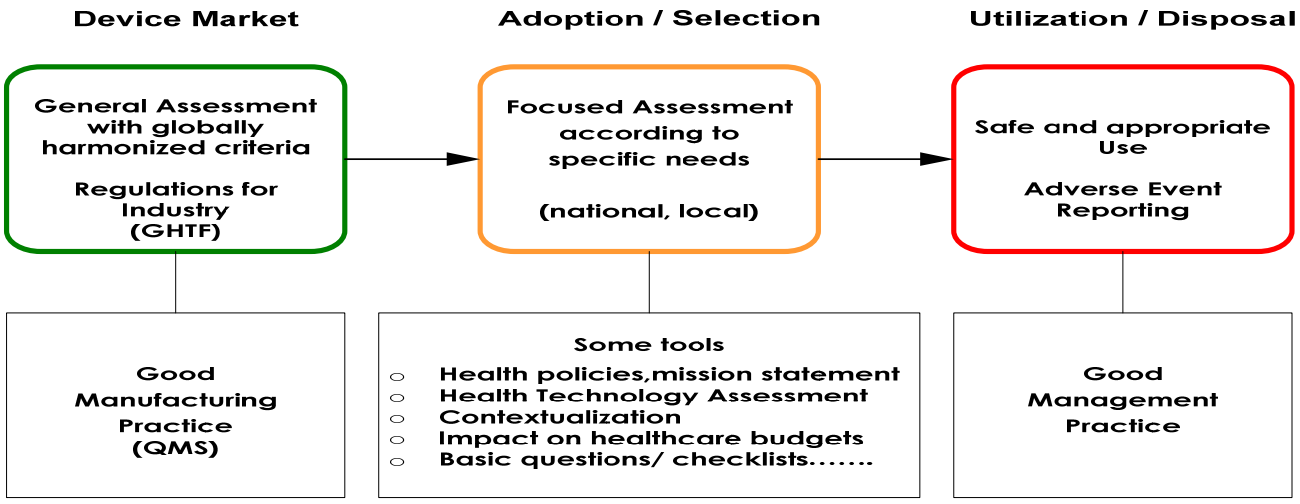
A Bank staff member has observed the following examples of poor practice resulting in failure to take all costs into account: donors granting devices but leaving all recurrent costs to the recipient, which may be impossible to bear by the specific recipient and leads to bad quality performance of services delivery, to devices standing idle in basements or to pressure by hospitals and patients on governments to provide for the running costs.

## A Framework for Developing a National Policy on Medical Devices

The rapid evolution and the complexity of issues in the medical device field have made technology adoption and administrative decisions a very challenging task for health policy makers and health care managers alike. While literature and guidelines on medical device management are abundant, they were written in different contexts by different medical device groups employing diverse terminologies. For a policy maker or a health care manager, the task becomes very difficult to navigate and digest the enormous amount of information.

A three-level scheme, drawing an analogy with the consumer market behavior, was conceived to identify the key functions for the professionals who work within the life-span of medical devices. These key functions are: (1) to ensure that medical devices comply with regulatory standards and requirements before their clearance for the market; (2) to study and contribute to the decision on the adoption, selection and utilization policies on devices; (3) to ensure safe and appropriate use, as well as good management including appropriate disposal after use. Such a scheme could facilitate national policy formulation. Figure 2 illustrates the three-level functions of a medical device policy [3].

**Figure 2: Three Levels of Medical Device Policy**




This framework provides an overview of the key components linked to specific responsibilities or technical activities at different stages in the life span of a given medical device. The three levels should function as a continuum with co-operative interactions for optimal results. Because of the familiar consumer market analogy, the use of this simple framework could facilitate common understanding among all stakeholders, including the public. On the other hand, the basic framework can be expanded for various technical applications to be described in future HNP Briefs. Proposed policy and regulatory interventions at each level are outlined in Table 2.

**Table 2: Policy and Regulatory Interventions**[6]

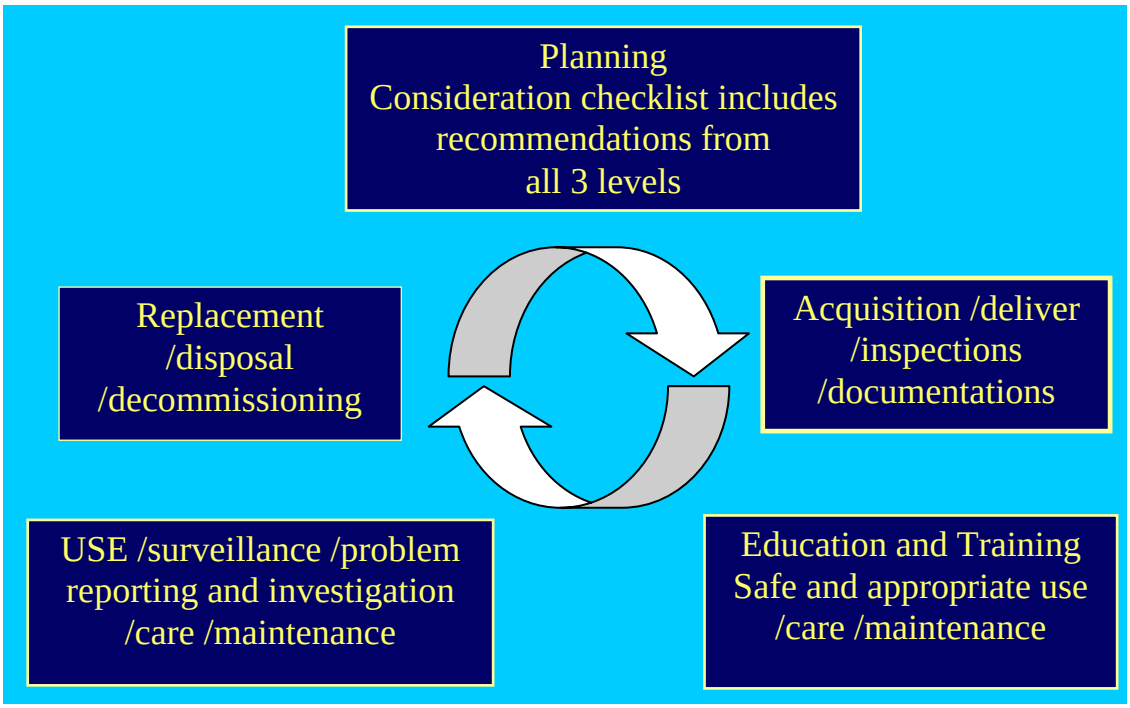
| Level of policy and regulatory intervention | Policy Element | Functions and Objectives | Typical Coverage |
|---|---|---|---|
| 1 | Device Market | • Device safety, performance and quality conformance with global standards<br>• Placing-on-Market device registration<br>• Post-market surveillance | Global<br>National |
| 2 | Adoption and Selection | • Local human factors (incl. skilled operators)/ environmental factors<br>• Cost effectiveness/ benefit Analysis<br>• Local cultural, political, equity considerations<br>• Impact on healthcare budgets<br>• Alternative care, preventive measures | National<br>Provincial/Regional<br>Healthcare facilities |
| 3 | Utilization and Disposal | • Safe, appropriate and effective Use<br>• Performance monitoring, problem identification and resolution<br>• Essential elements of good management practice (including user training, device performance monitoring, maintenance and disposal) | Healthcare facilities, Professional Associations, Individuals |

[6] See footnote 1.

All activities associated with medical devices can be assessed with respect to their ultimate impact on the key functions of each level. This framework can be used for situational analysis to determine resource allocations to strengthen these bottom-line functions, and for their subsequent outcome assessments. For levels 1 and 2, a country can benefit from the vast resources available globally. Level 3 is the local operation level where medical devices are put into use for patient care, and it is here that a country should give priority in resource allocation.

The need for Good Management Practice[7] for medical devices in use is at least as much as the need for Good Manufacturing Practice for medical device (or drug) production. The essential elements in the life cycle management of medical devices as outlined in Figure 3 are proposed, in general, as the essence of Good Management Practice for medical devices. Planning is the key element that incorporates information from all levels including technology and needs assessment recommendations from level 2, as well as any other necessary local facility considerations and assuring recurrent budget (Figure 1) for durable medical devices before making a decision on acquisition. Disposal is another important element that could be overlooked; proper disposal of single use injection equipment remains a problem in many developing countries. While Figure 3 presents an overview, the essential elements of life cycle management of medical devices will be discussed in more detail in the subsequent series of HNP Brief.

**Figure 3: Life Cycle Good Management Practice for Medical Devices**




[7] The term "Good Management Practice" is proposed by the author for the utilization of medical devices [18]. This has a parallel with the widely known "Good Manufacturing Practice" in the production of drugs and devices. For medical devices, Good Manufacturing Practice is now embedded as a requirement in a broader framework of Quality Management System (QMS).

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