WHO compendium of innovative health technologies for low-resource settings

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Glossary of terms

Term	Definition
Biocompatibility	Biocompatibility is a general term describing the property of a material being compatible with living tissue. Biocompatible materials do not produce a toxic or immunological response when exposed to the body or bodily fluids. The internationally recognized standard for general medical device biocompatibility is ISO 10993. There are many other standards that cover various aspects of biocompatibility testing and/or biocompatibility issues specific to particular types of medical devices.
510(k) Boundary Conditions	The elements of an FDA cleared 510(k) that characterize the device and demonstrate substantial equivalence, such as descriptions, predicate comparisons, labeling, performance characteristic data, and evaluation criteria.
510(k) Clearance	A 510(k) is a notification submitted to the FDA to demonstrate that a medical device to be marketed in the USA is "substantially equivalent" to a legally marketed device. There are different types of 510(k) submissions (traditional, abbreviated, or special),depending on whether the device is new or already on the market and has been modified. Clearance is granted to devices that receive marketing permission from the FDA through the 510(k) process. The 510(k) process is not an approval process.
Certificate to Foreign Government	An FDA certificate that is required by some countries to prove that an exported medical device from the USA is legally marketed in the USA and in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act).
Certificate of Free Sale (CFS)	Many countries require a CFS, sometimes called a Certificate for Export. It is evidence that goods, such as medical devices, are legally sold or distributed in the open market, freely without restriction, and approved by the regulatory authorities in the country of origin.
Clinical engineer	A trained professional who supports and advances patient care outcomes by applying engineering, life sciences, and managerial skills to optimize healthcare technology life cycles.
Clinical engineering	An application of engineering, life sciences, and management attributes to optimally deploy and safely manage technological tools, risk management techniques, and system challenges associated with the provision of healthcare services, especially in the clinical environment.
Clinical Evaluation Report (CER)	This documents the conclusions of a clinical evaluation of a medical device. A CER consists of analyzed clinical data that was collected from a clinical investigation of a device or the results of other studies on substantially equivalent devices. A CER demonstrates that a device achieves its intended purpose without exposing users and patients to further risk. The European Union's MEDical DEVices documents (MEDDEV), 2.7.1 Rev. 3 guidelines and the Medical Device Regulation provide manufacturers with guidance regarding how to evaluate the clinical safety and performance of their devices properly.
Clinical outcomes	Measurable changes in health or quality of life as result of specific healthcare delivery interventions.
CE marking	European Conformity (Conformité Européenne) mark. A mandatory European mark for products (including medical devices) to indicate conformity with essential health and safety requirements set out in the EU directives and regulations.

Term	Definition
Design control	Design control is an interrelated set of practices and procedures that are incorporated into the design and development process, i.e., a system of checks and balances. Design controls make systematic assessment of the design an integral part of development. As a result, deficiencies in design input requirements and discrepancies between proposed designs and requirements are made evident and corrected earlier in the development process. Design controls increase the likelihood that a design transferred to production will translate into a device that is appropriate for its intended use.
Design validation	Testing that aims to ensure that a product or system fulfills the defined user needs and requirements under specified operating conditions and establishing by objective evidence that device specifications conform to user needs and intended uses.
Design verification	Testing that aims to ensure that a product as designed is the same product as intended. Design verification is confirmation by examination and provision of objective evidence that specified requirements have been fulfilled, i.e., the design output meets the design input requirements.
Global Clinical Engineering Alliance (GCEA)	An international not-for-profit organization of national and regional clinical engineering associations and groups of other collaborating stakeholders within the healthcare field.
Good Manufacturing Practices (GMP)	The quality system requirements for FDA regulated products. Medical device GMPs are found in 21 CFR (Code of Federal Regulations) 820 (see QSR below).
Health innovation	Health innovation aims to develop and deliver new or enhanced health policies, systems, products, technologies, services, and delivery methods to improve people's health.
Health technology	The WHO definition is the application of organized knowledge and skills in the form of (medical) devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of care and/or life.
Health Technology Assessment (HTA)	A multidisciplinary process that uses explicit methods to determine the value of a health technology in comparison to others at different points in its lifecycle. The purpose is to inform decision-making to promote an equitable, efficient, and high-quality health system.[1]
Health Technology Management (HTM)	A process focusing on health-related devices and their usage within clinical procedures and systems.