Global Medical Technology Alliance
Innovating for a Healthier World

Differences between medical devices and drugs

Medical Devices	***In Vitro* Diagnostic Medical Devices**	**Drugs**
In vivo and/or ex vivo use	*In vitro* use	*In vivo* use
Diagnostic **or** therapeutic intended uses	Diagnostic intended use	Therapeutic intended use
Outcomes of use often depend directly on skill or experience of user	Outcomes generally not dependent on skill or experience of user	Outcomes generally not dependent on skill or experience of user
Industry Composition Over 80% small and medium-sized companies		Very large multinationals dominate
Active Components Generally based on mechanical, electrical, and materials engineering. Many medical devices incorporate and are driven by software.	IVD components have no therapeutic effect – only used for diagnosis. Key components are those essential for detection of the analyte of interest. Biological core reagents (e.g. antibodies) Performance of tests (e.g. sensitivity, specificity) depends on design of test, geographic variations of the infective agent, populations, and the setting of use Variable batch sizes for a given reagent, individual batches of the same reagent may use different starting materials. Stability varies between products and may vary between batches. Generally stored at 4°-8°C Generally short shelf lives (< 12 months)	Based on pharmacology and chemistry; now encompassing biotechnology, genetic engineering, etc. Pharmacologic properties and action of active ingredients are known, based on pre-clinical and clinical studies Standardized batch sizes, manufacturing processes and starting materials. Products stable. Generally stored at room temperature Generally long shelf lives

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	Some IVDMD incorporate and are driven by software.	Software is not incorporated
Product Development Wide variety of products and applications – from thermometers and bandages to pacemakers to x-rays Designed to perform specific functions and approved on the basis of safety and performance Many products developed by doctors or nurses	Products are usually in the form of reagents (solutions, coated microwells, strips). Wide variety of IVDs designed for different indications (e.g. screening, confirmation, monitoring of treatment) Product development by discovery, evaluation, and approved on basis of performance Products developed in laboratories by chemists and biologists.	Products are usually in the form of pills, solutions, aerosols, or ointments Product development by discovery, trial, and approved on basis of safety and efficacy Products developed in laboratories by chemists and pharmacologists.
Most act through physical interaction with the body or body part.	Tests performed on samples (e.g. blood, tissues, saliva, faeces or urine) taken from the body No direct contact with human body - No need for “clinical trials” with patients => “performance evaluations” of IVDs with samples	Products are administered by mouth, skin, eyes, inhalation, or injection and are biologically active; effective when absorbed into the human body. Often act systemically on the entire body.
Intellectual Property Concerns Continuous innovation and iterative improvements based on new science, new technology, and new materials	Continuous innovation and iterative improvements based on new science, new technology, and new materials	Extensive research and development of a specific compound or molecule; takes several years for a new drug to enter the product pipeline
Short product life cycle and investment recovery period (typically 18 months on market). Little patent linkage possible. Data exclusivity is important.	Rapid innovation, short product life cycle (3-5 years) and investment recovery period	Intensive patent protection, including data exclusivity and patent linkage, needed due to extensive product life cycle and long investment recovery period.

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Majority of new products bring added functions and clinical value based on incremental improvements; often results in range of related "models" for user to choose among based on patient needs.	Majority of new products bring added clinical value based on improvements of performance	Usually large step innovation
Support Provided Large investment in manufacturing, distribution, and training/education (and retraining); plus need to provide service and maintenance (for many high tech devices)	Large investment in manufacturing, distribution, and training/education (and retraining); plus need to provide service and maintenance (for many high tech devices)	Low manufacturing and distribution cost, and, in most cases, little or no training, service or maintenance costs.