Risk Based Classification of IVD

Summary statement
The construction of a 'risk based' classification system for medical devices to guide the regulatory review and approval process is considered one of the essential features of a regulatory system. It enables the degree of regulatory control to be proportionate to the risk of harm, where costs and delays can be moderated for low risk products. Adoption of harmonized rules for classifying IVDs will be critical in reducing barriers to market entry and improving access to IVD in the less developed countries.

In 2001 the World Health Organization, in collaboration with the Pan American Health Organization and the United States Food and Drug Administration published a set of guiding principles and essential features of a model regulatory authority[1]. This included a risk classification system for medical products where the stringency of premarket assessment and regulatory control should be proportionate to the potential of the product to harm individual or public health. Risk has been defined by the Global Harmonization Task Force (GHFT) as the combination of the probability of occurrence of harm, and the severity of that harm. In 2006 GHTF published their recommendation for a system of risk based classification of medical devices[2].

> An essential feature of a model authority includes "the construction of a regulatory system that is risk-based, i.e. a system that stratifies and applies premarket assessment controls based on the risk (or hazard) potential of a product, as well as the potential for misuse and the breadth of commercial distribution, known or projected."

Status quo

- A risk based strategy for guiding the degree of regulatory control for in vitro diagnostic medical devices allows the burden of regulation to be moderated for low risk products, reducing costs and the delay in these products reaching the market.
- Manufacturers are required to provide less substantial submission dossiers for products classed as low risk whereas high risk products require stringent conformity assessment including evidence of satisfactory performance in populations and settings representative of the target market.
- Most of the National Regulatory Authorities that regulate IVDs have adopted a risk classification system for regulating medical devices and IVDs. However, variations in classification rules mean a single product may be placed in different categories in different countries, where they are subject to different regulatory requirements.
- Lack of harmonization has led to confusion and added complexity in marketing IVD in different countries.

[1] A Model Regulatory Program for Medical Devices: An International Guide. WHO, 2001.
[2] GHTF/*SG1*/*N45*:*2008* Principles of In Vitro Diagnostic Medical Devices *Classification* http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf

Risk classification systems in current use

	Classes	1st tier	2nd tier	3rd tier	4th tier
GHTF/ AHWP/ WHO	A, B, C, D	Low individual risk and low public health risk	Moderate individual risk and/or low public health risk	High individual risk and/or moderate public health risk	High individual risk and high public health risk
Australia	1, 2, 3, 4	No public health risk and low personal risk	Low public health risk or moderate personal risk	Moderate public health risk or high personal risk	High public health risk
Canada	I, II, III, IV	Minimal risk	Low public health risk or moderate individual risk	Moderate public health risk or high individual risk	High public health risk
European Union	A, B, C, D	Low individual risk and low public health risk	Moderate individual risk and/or low public health risk	High individual risk and/or moderate public health risk	High individual risk and high public health risk
Japan	I General II Controlled III Highly controlled	Very low risk to human body (self declaration)	Low risk to human body (third party certification)	Medium and high risk to human body (requires Ministerial approval)	
USA	I, II, III	Low to moderate risk: test result does not support life or prevent impairment of health; does not present unreasonable risk of illness or injury.	Moderate to high risk: low public health risk or moderate individual risk. Probable benefit outweighs risk.	High risk: used in supporting or sustaining human life or preventing impairment of health, or that may present a potential unreasonable risk of illness or injury for which general controls and special controls are insufficient to provide reasonable assurance of the safety and effectiveness, or for which there is insufficient information to make such a determination. Test is critical in diagnosis of disease.	

Action going forward

Adoption of a harmonized risk based classification system for IVDs, either globally or regionally, will be critical in reducing barriers to market entry for products that are needed to protect public health and save lives.

Global Harmonization Task Force risk based classification of medical devices

Class	Risk level	Examples
A	Low Individual Risk and Low Public Health Risk	Stains, culture reagents
B	Moderate Individual Risk and/or Low Public Health Risk	Home use pregancy tests, Urine test strips
C	High Individual Risk and/or Moderate Public Health Risk	Rapid tests for rubella, malaria
D	High Individual Risk and High Public Health Risk	Blood screening tests: HIV, HBV, HCV, HTLV