



# WHITE PAPER

## Medical Device Product Development for Emerging Markets

Insights for Developing Tailored Products for Asian Markets

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Large multi-national firms, once reliant primarily on the US market for growth and innovation, are increasingly turning their attention toward Asian markets as a way to not only decrease R & D costs but to also capture new growth opportunities. And to accomplish this, they are increasingly looking to develop custom products designed for specific off-shore markets like India and China.

Regardless of the market, product effectiveness depends on the culture, market needs, market acceptance of products, appreciation of resources and facilities available to use the products.

Interesting challenges lie ahead when considering each of the points noted as the developing and developed markets are significantly different and each market has its own nuances.

And while everything noted above needs to be considered in the context of a complete ecosystem, the amount of resources available to pay for healthcare is a key differentiator between the developing and developed nations.

In developing nations the major emphasis is on saving cost because of the economic constraints of the general population. Many people in developing countries come from a mid socio-economic background and lack the insurance structure and disposable income required to access expensive medical solutions.

In developed countries OR time is valuable and time saved in an operation is often the most important cost parameter. Specific product cost, while becoming more important as the health care market changes and evolves, is often viewed as a secondary factor.

This causes a major shift in the way products are designed for the developing or developed markets.

In developed countries, surgeons cannot afford to spend time learning to use the device or assemble the device and hence the product should have a low learning curve, should be easy to use, and should be more automated and less manual, ultimately saving time which translates into significant amounts of money saved.

However, in developing nations the products can be simplified, modular designs can be made and devices can be made less automated so that the user may need to spend more time in assembling the products than their counter parts in developed countries. This is because surgeons do not mind spending extra time in learning to use a product and preparing the device for use as long as it is less expensive but equally effective.

Thus products developed for developing nations need not be simple to use, they can be complex but will still be appreciated. As an example, the Advant 55 linear stapler by Ethicon Endo is a

reusable stapler which is difficult to use but that is not considered a major drawback in a developing market.

Culture is another factor that affects the way products are designed for different markets. In developing nations, because of the economy constraints and conservative outlook of doctors, the tendency is more towards conserving resources and preventing waste. Many disposable devices are reused not just because of the cost factor but also because doctors feel bad about throwing plastic and metal into the garbage, creating huge amounts of medical waste.

One the reasons why disposable staplers are reused may be attributed to this type of thinking. As another example, Doctors will typically want to reuse the needles of disposable SUI tape and it is not only to save cost but to reduce waste. It may not be wrong to hypothesize that a product which has reusable needles will sell more than a product with disposable needles though the price is the same.

Designing a medical device should also consider whether the market has the right infrastructure and facilities available for supporting it. For example if a device is so complex that it can be sterilized only by Plasma sterilization and cannot be autoclaved, fewer doctors may prefer such a device because most hospitals and doctors have access to autoclaves for device sterilization purposes. In such a case, product development should take into consideration that the device should be both autoclavable and EtO sterilizable.

Speaking of infrastructure, many regions in developing countries experience frequent power failures. Hence a device that has an in-built battery system can prove to be a crucial feature. In case of a diagnostic device for one of the middle level diagnostic companies, the main game changer proved to be the incorporation of a battery in the device. This particular test needed costly reagents and each test wasted resulted in wastage of a substantial amount of reagents which was not cost-effective. Incorporating a battery in the device changed the entire paradigm and increased the user reach and profitability.

Similarly a device having a built-in memory system is not as important to the developing market as it is to the developed market. In the case of a blood glucose monitor, a device having memory to store readings and data is not of utmost importance to the developing market because the users can spend extra time in noting down the readings and maintaining a log of all the patient data. Not giving a provision for memory in such simple devices helped cut down product development costs and did not affect the device functioning and ultimately its effectiveness in any way. Horizon blood glucose monitors by Johnson and Johnson did away with memory of their blood glucose meters, which reduced their costs significantly and went on to become a huge success across the world.

Regulatory hurdles are another important aspect of product development. Knowing for which regions the device is being developed and being acquainted with the regulatory requirements for the device can help ease of regulatory approvals. For instance, if you are developing a device for India and China, it is better to design the device in India and manufacture the device in China for ease of regulatory approvals. Since medical devices are not currently regulated in India, medical device manufacturers follow the drug-based pathway for regulatory submissions. Hence the device has to qualify for a drug based approach rather than a device based approach. This can be

achieved with the assistance of local expertise that may be proficient and well versed with the directives.

Therefore it may be a significant competitive advantage to develop devices in target regions to gain a heads up in local markets.

It is critical for the development team to have foot on the ground and gain from expertise available. Understanding the economic drivers, the users in their setting, knowing the nuances of the region and developing strategies to develop products which sync with the needs will be the cutting edge in the rapidly changing market patterns.

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