

In vitro diagnostics growth to spearhead future of medtech



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In vitro diagnostics (IVDs) is not only the largest segment within medtech, with forecast worldwide sales of \$58.8bn in 2018, it is also one of the fastest growing, [EvaluateMedTech's World Preview 2013](#) shows. The analysis of the top 20 sectors of the worldwide medical device market reveals that the IVD sector is expanding at a CAGR of 5.1%, outpacing the overall medtech market growth rate of 4.5% (see table).

This expansion, fuelled by the increasing demand for companion diagnostics and interlinked innovations in molecular testing, is a contrast to much of the rest of the medical technology world. The diagnostic imaging and orthopaedics sectors, for example, have below-average growth, with higher regulatory bars and decreased investment working against the development of fewer transformative new technologies.

Device area	WW sales (\$bn)		
	2012	2018	CAGR
In vitro diagnostics (IVDs)	43.6	58.8	5.1%
Cardiology	38.1	48.7	4.2%
Diagnostic imaging	36.1	45.1	3.8%
Orthopaedics	32.7	40.0	3.4%
Ophthalmics	23.6	32.9	5.7%

Regulatory changes are afoot on both sides of the Atlantic, with the FDA finally issuing its long-awaited rule on device identification numbers late last week. The Unique Device Identifier (UDI) will have to be printed on each product's label, along with a scannable barcode to allow physicians and regulators and even the public to track the devices and monitor safety, as the resulting data will be stored in a publicly accessible database.

A similar initiative is likely to be brought in in Europe, too ([Vantage Point - Europe set to tighten device regulation but reject central authority, September 11, 2013](#)).

While this new rule will not be excessively expensive - it is estimated that compliance with it will cost the US medtech industry less than \$100m million a year - it is all part and parcel of the increasing stringency at the FDA.

In 2012, 5,606 medical devices were approved by the US FDA through one of its various pathways, a slight increase on the previous year. But so far in 2013, the number of first-time PMA approvals - the pathway used for the most innovative or dangerous devices - has fallen dramatically. The first eight months of the year have seen a 42% decline compared with the 24 new PMAs that had been approved by August 31st last year.

FDA approval count (1st PMAs/HDEs/supplementary PMAs/510(k)s)										
	2008	% change	2009	% change	2010	% change	2011	% change	2012	% change
1st Time PMA/HDE/PDP	30	-6.3%	18	-40.0%	22	22.2%	43	95.5%	41	-4.7%
Supplementary PMA/PDP	1,488	33.2%	1,498	0.7%	1,841	22.9%	2,192	19.1%	2,380	8.6%
510(k)	3,102	2.2%	3,044	-1.9%	2,850	-6.4%	3,150	10.5%	3,185	1.1%
Total	4,620	10.4%	4,560	-1.3%	4,713	3.4%	5,385	14.3%	5,606	4.1%

The FDA's aim of improving patient safety is laudable, naturally, but it must ensure that in tightening regulatory standards it does not deny patients life-saving therapies.

There is a squeeze on R&D, too. *EvaluateMedTech* consensus forecasts show that, while worldwide medtech R&D is expected to grow at a healthy 3.9% CAGR between 2012 and 2018, reaching \$26.7bn, the share of revenues that medtech firms are investing in innovation is in fact falling.

The overall R&D investment rate is expected to be around 5.9% of sales in 2018, slightly down from the 6.1% observed in 2012, perhaps owing to companies husbanding their cash, fearing longer times to market.

Within the top 20 companies the reinvestment rate is higher at a forecast 7.6% in 2018, but still down on the 8.0% seen in 2012.

WW medtech R&D spend (2012-18)							
	WW medtech R&D & medtech sales (\$bn)						
Year	2012	2013	2014	2015	2016	2017	2018
Medtech R&D spend	21.3	21.9	22.7	23.7	24.7	25.7	26.7
Growth per year	1.5%	2.9%	4.0%	4.3%	4.2%	4.1%	3.9%
WW medtech sales	349	357	374	394	414	434	455
R&D as % of medtech sales	6.1%	6.1%	6.1%	6.0%	6.0%	5.9%	5.9%
R&D as % of medtech sales (top 20 in 2018)	8.0%	-	-	-	-	-	7.6%

There are signs that the medtech market overall is maturing from a period of fast expansion to one of slower growth. Nonetheless the future of medtech is solid, and its forecast 4.5% CAGR overall means it is growing faster than the prescription drugs market, which is expected to see just 3.8% CAGR to 2018.

Medtech companies could find themselves having to clear ever-higher regulatory hurdles, but they seem to be relishing the challenge.

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