



## Executive Summary Gap Analysis Medtech/Biotech/Combitech in Flemish Brabant Geert Adriaens, Adrilenco & Frederik Horemans, DSP Valley, June 2015

In the context of its **internationalisation policy (inward invest)**, the Province of Flemish-Brabant in Flanders commissioned a gap analysis study of companies in the local region active in the fields of medical devices ("medtech"), biotechnology/biopharma applications ("biotech"), or a new combination of both (conveniently named "combitech"). The study was co-financed by the University of Leuven and Flanders Investment & Trade (FIT). In order to further develop the already strong ecosystem in the chosen fields, in-depth interviews were conducted with 25 companies to find out whether they have specific needs that could be addressed by bringing international players to the region with a local presence.

Flanders as a region in general, and Flemish-Brabant as a province in particular, have a **strong position** in medtech, biotech and the emerging combitech at the crossroads of both. Flanders has over 500 companies (mostly SMEs) active in these fields, employing over 30.000 experts, and representing nearly 10 billion EUR in combined revenues. A large proportion of these players have their offices in or near Leuven. As to R&D investments, the biotech industry is Flanders' third most important sector. World-renowned research institutes like VIB or imec, in collaboration with all Flemish universities (in particular the University of Leuven), are the firm foundation of this vibrant ecosystem. The recent creation of the new startup MiDiagnostics at imec in Leuven to develop a revolutionary lab-on-chip ("MiLab") bears witness to the smart specialisation of the region in the health sector.

In order to **further strengthen this unique ecosystem**, a representative group of 25 companies were interviewed on the basis of an extensive questionnaire to see what is still missing in their local environment to optimise their business and to further stimulate their growth. In preparation of this questionnaire, a thorough analysis was made of the markets, their value chains, and the possible gaps to be addressed. The focus of the interviews was on the potential role of international players (companies, investors) to fill the gaps in the ecosystem by establishing a local presence.

The study identified some 20 gaps, half of which can be seen as mostly local matters, and half of which relate to international needs.

As to the **local gaps**, the main challenge is the shortage of engineering profiles, in particular those that require multidisciplinary education (e.g. bio-ICT). As to education, the local universities do an excellent job, but industry and academy need to strengthen their cooperation to stay abreast of the rapid evolution in health-related sectors. Other issues are related to the complexity of regulatory matters in medtech & biotech, including the processes of application for reimbursement. Companies also do not always find the right contacts to all the stakeholders in the medtech/biotech landscape (medical practice, payors, disease experts, etc.). For high-growth companies, capital and (literally) "room to grow" (adequate and vibrant infrastructure) also remain issues to be addressed. Finally, there is a need for more biobanks and health-related databases.

As to the **international gaps**, several types of players across the medtech & biotech value chains were named whose presence would be a further reinforcement of the ecosystem.

The local companies would definitely welcome the presence of R&D centers of the “big medtech” and “big (bio)pharma” players, such as St-Jude Medical, Boston Scientific, Medtronic, Biotronik, GE, Siemens, Brooker, Pfizer, Roche/Genentech, Novartis, AstraZeneca, Amgen. After all, they will find an excellent environment here, with top-notch research institutes and SMEs, a strong tradition in the execution of clinical trials, and a favorable climate for approval of new products. They could complement the presence of world-class players that are already active in Flanders (and Belgium) with strong R&D: Cochlear, Janssen (J&J), GSK, UCB.

In relation to the need for capital, interviewees from all the subsectors (medtech/biotech/combitech) would also appreciate the presence of representatives of international VCs with a stronger commitment to understanding and addressing the local needs.

As to the **medtech value chain**, other categories of international players that would be most welcome here are companies with specific niche expertise in development, integration, assembly and production of cutting-edge medical devices (such as Cirtec, Valtronic, Decobar, or MST/Dyconex for production of class-3 PCBs). There is also a need for more test facilities for wafer and chip testing, for product sterilisation facilities, and for one-stop-shop manufacturers of medical devices, where our local companies now have to turn to players abroad for lack of a sufficient local offering.

As to the **biotech value chain**, players that would be welcome next to the big (bio)pharma to fill gaps are suppliers of CMC (Chemistry Manufacturing & Controls) like Fujifilm, companies specialised in automation of assay development, clinical contract manufacturing facilities for cell culture like Masthercell or Pharmacell, or facilities of type “biosafety level 3” to work with dangerous disease agents.

It is clear that the gap analysis of 25 representative companies in the medtech/biotech/combitech value chains in the broad region around Leuven has yielded a lot of valuable material to further reinforce the local ecosystem. The study has formulated a number of recommendations for actions to follow up on its findings.

**Local gaps will be addressed** by concrete activities (such as events, roundtables, one-on-one consultation rounds, information and education initiatives) involving all stakeholders in the health business: industry, research&education, policy makers, regulatory/reimbursement bodies, infrastructure providers, capital providers, intermediaries, hospitals, medical service providers, insurers, payors.

**International gaps will be addressed** by approaching the identified international players with a strong story combining the local strengths with the international needs as expressed by the interviewees. Some 20 target companies have already been named, but further analysis is in order to find more potential targets with the specific expertise and offering sought for. As such, the gaps in the value chains can be filled by valuable international players in a win-win for the whole ecosystem.

Attached to this executive summary is a list of interviewed companies with their location on the map of Flanders, and a table summarising all gaps and recommendations.



*Map with the 25 interviewed companies in the broad region of Leuven, Flemish-Brabant (half of them concentrated around Leuven itself)  
med=medtech, bio=biotech, combi=combitech*



	GAP	Priority	Value chain(s)	Recommendations	Possible actors
<b>LOCAL</b>					
1	Finding the right personnel (engineers, multidisciplinary experts, regulatory profiles)	Very high	not specific	- Share findings with the academic world - Create a platform for dialog industry-academia	companies, universities/education
	Extra challenges for education (multidisciplinary, faster availability of talent on the market, longer internships at companies, keep up with latest developments)	Fair	medtech/biotech/combitech	- Continue stimulating STEM education (Science, Technology, Engineering, Maths) - Keep education offering up-to-date	
2	Problems with regulation (not sufficiently known, not clear, too many rules, too severe)	High	medtech/biotech/combitech	Organise event on regulatory matters	companies, regulatory bodies, government
3	Problems with reimbursement (who to talk to, what is the decision process)	Fair	medtech/biotech/combitech	Organise round table on reimbursement issues	companies, insurers, payors, advising experts, government (RIZIV)
4	Finding the necessary capital (especially for startups)	Fair	not specific	Look for creative low-threshold financial instruments (crash funds, tax shelter, crowdfunding,...)	commissioning organisations, government, financial players
5	Efficient planning/deployment of company resources	Fair	not specific	Internal matter for the companies	
6	Inadequate infrastructure or business parks ("just dull office buildings")	Fair	not specific	More vision when planning infrastructure, learn from good (foreign) examples	government, real estate players, city planners, companies themselves (timely inputs)
7	Lack of network in the medical world (who to talk to in the medical practice, where is which knowledge)	Fair	medtech/biotech/combitech	Build knowledge portal around medtech/biotech/combitech	intermediaries active in medtech/biotech/combitech
8	Insufficient cross-over from research to industry	Fair	medtech/biotech/combitech	Dialogue industry-academia (see 1)	companies, research institutions, universities/education
9	Space problems in case of expansion (2020)	Fair	medtech/biotech/combitech	See 6	
10	Too few biobanks and medical databases	Fair	medtech/biotech/combitech	Stimulate organisations like CMI (Center for Medical Information)	government, intermediaries, companies, hospitals
<b>INTERNATIONAL</b>					
1	Insufficient presence of big international players ("big medtech" and "big (bio)pharma"), see Cochlear, Janssen, GSK, UCB (who are already here)	Fair	medtech/biotech/combitech	Identification and approach of international players based on gap analysis	commissioning organisations, intermediaries
2	Not enough players with unique expertise in medtech (development, integration, assembly, production)	Fair	medtech	named parties medtech: Boston Scientific, St-Jude Medical, Medtronic, Biotronik, GE,	
3	Not enough test facilities for wafer and chip testing	Fair	medtech	Siemens, Brooker, Cirtec, Valtronic, Decobar, MST/Dyconex	
4	Not enough facilities for sterilisation	Fair	medtech		
5	Not enough "one-stop-shop" manufacturers	Fair	medtech		
6	Not enough players in Chemistry Manufacturing & Controls (CMC)	Fair	biotech	named parties biotech: Pfizer,	
7	Not enough players for automation of assay development	Fair	biotech	Roche/Genentech, Novartis, AstraZeneca,	
8	Not enough contract manufacturing facilities for cell cultures	Fair	biotech	Amgen, Masthercell, Pharmacell	
9	Not enough facilities of type "biosafety level 3"	Fair	biotech		
10	Finding capital: possible local presence of foreign VCs (US)	Fair	medtech/biotech/combitech		