The Swiss Medical Technology Industry 2018

Sector Study

SWISS MEDTECH

helbling

Introduction

With 421 companies represented in the Swiss Medical Technology Industry (SMTI) Sector Study 2018, participation is higher than ever before. We have been able to follow many changes in the industry in the ten years that we have been publishing this study series. Thankfully, the sector continues to be healthy today - contrary to earlier concerns regarding the negative effects of increasingly fierce international competition, price and regulatory pressures and the overvalued Swiss franc. Significant growth in sales has continued over the past two years; at levels well above the overall Swiss GDP. Exports have also increased considerably, resulting in above-average numbers of newly created jobs compared to other areas of the medtech industry.

Fitness program successfully completed

The Swiss medical technology industry is agile, innovative and internationally competitive. Over the past few years, companies have actively responded to the increasing collapse in margins and the overvalued Swiss franc by implementing programmes that they can profit from today. The Swiss medtech industry has strengthened its international competitiveness and is well prepared for the future.

With its high density of manufacturers, industry-specialised suppliers and service providers, Switzerland represents a unique medtech cluster and continues to provide an important site for production. Advantages include the presence of specialised medtech know-how, highly skilled professionals and strong research centres. Given the favourable conditions, the positive exchange between government, public authorities and industry, as well as the high innovative strength of companies, our country still provides the best conditions needed to occupy an important position in the worldwide supply of medical devices.

The new EU regulations are weighing heavily on the industry

For the first time this year, the focus of the SMTI survey is on the introduction of the new EU regulations MDR and IVDR, which are currently absorbing the attention of most of the Swiss medtech sector. Our survey shows that three-quarters of the companies are already dealing actively with the changes. The biggest challenge is the availability of the required internal resources. The recruitment of suitable specialist personnel and the associated additional financial burden presents a particular problem for SMEs. Attempts are being made to cushion the impact with countermeasures such as reducing costs or increasing product prices. Cuts in spending on research and development have also been cited as a consequence of the new regulations. In the future, one of the goals for the Swiss medtech industry will be to maintain its high level of innovative strength and, among other things, make even greater use of the untapped potential that digitalisation offers.

This sixth edition of the Swiss Medical Technology Industry (SMTI) Sector Study was once again made possible thanks to the close collaboration between Swiss Medtech and the Helbling Group, and the support of an expert advisory board. The industry report has been produced every two years since 2008 and is based on the results of a wide-ranging survey of manufacturers, suppliers, specialised service providers and retailers throughout the country.

Bern and Zurich, September 2018

Laura Murer Mecattaf[1], Jonas Frey[2], Tobias Pieper[1] and Peter Biedermann[2],
Authors and publishers of the SMTI 2018 Sector Study

1) Helbling; 2) Swiss Medtech

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Management Summary

Management Summary (I/II)

Key data of the Swiss Medtech Industry

- In 2017, the Swiss medtech industry employed around 58,500 individuals, representing 1.1% of the total Swiss workforce
- The 1,400 companies (manufacturers, suppliers, service providers and trade & distribution) achieved sales of 15.8 billion CHF. This represents 2.3% of the total Swiss GDP
- In 2017, exports totalled 11.3 billion CHF, with USA and Germany as the main export destinations
- With its 5.1% share of total national exports, the medtech industry plays an important role for the entire Swiss economy
- The export surplus is 5.9 billion CHF; representing 13.5% of the total for Switzerland

Attained growth

- Compared to other industries, the medtech industry has created more jobs than the average of other sectors. Over the past two years, the number of employees has increased by 4,000
- The sector has increased its sales by 1.7 billion CHF since 2015
- The attained sales growth of 6.4% in 2017 significantly exceeded the nationwide GDP growth of 1.1%
- Medtech exports have risen by 0.7 billion CHF since 2015

Switzerland as a production site

- Swiss medtech companies often produce globally and continue to rely on Switzerland as a production location
- Switzerland provides a unique medtech cluster thanks to its high density of manufacturers, industry-specialised suppliers and service providers
- Significant medtech know-how and specialised experts are further advantages of the Swiss production site
  - Capable research centres provide important research partners for the medtech industry
  - The dual education system supplies the Swiss medtech industry with highly qualified specialists

Management Summary (II/II)

Challenges

The common challenges for Swiss medtech companies are:

- Increasing quality and documentation requirements aggravated (among other things) by the introduction of MDR/IVDR
- Constantly rising pressure on costs and margins
- Recruiting suitable personnel; particularly in the areas of marketing & sales, research & development and regulation
- Digitalisation and the effective management of data

MDR/IVDR

- ¾ of companies have already begun implementing MDR/IVDR
- Ensuring the availability of internal capacity is a key challenge in the introduction of MDR/IVDR
- Foreseeable difficulties include the timely implementation of the MDR/IVDR and the availability of reliable information
- Companies are recruiting additional staff due to the introduction of MDR/IVDR,
- Cost reductions and price increases are planned to help cope with the additional burden

Outlook for medtech industry in Switzerland

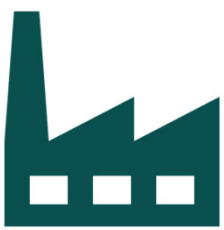
- The Swiss medtech industry forecasts an annual sales growth of 6% for 2018 and 2019
- ⅔ of medtech companies surveyed are planning investments in Switzerland over the next two years
- Swiss medtech companies see a need for action in terms of access to skilled workers and national funding of research and innovation

An overview of the Swiss Medical Technology Industry (SMTI)

- Sales, employees and Top 10 companies
- Swiss medtech manufacturers – according to areas of specialty
- Medtech industry imports and exports

Switzerland showcases a strong medtech industry

1,400



Companies

58,500

Employees

15.8 billion

Sales

11.3 billion

Exports

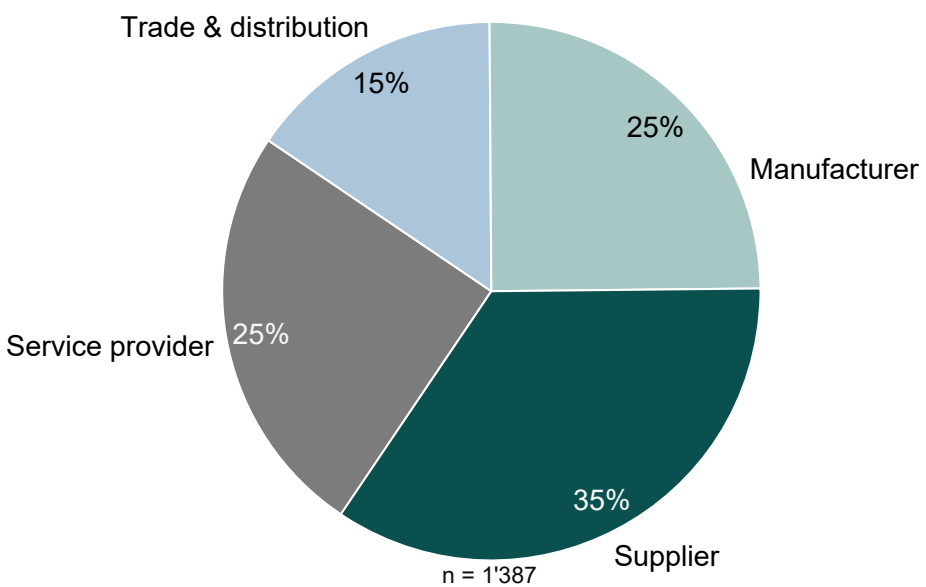
Comments

- In 2017, the Swiss medtech industry employed around 58,500 individuals, or 1.1% of the total Swiss workforce
- The 1,400 companies (manufacturers, suppliers, service providers and trade & distribution) generated sales of 15.8 billion CHF, which corresponds to 2.3% of the Swiss gross domestic product
- The Swiss medtech industry exported a volume of 11.3 billion in 2017 which represents 5.1% of total Swiss exports

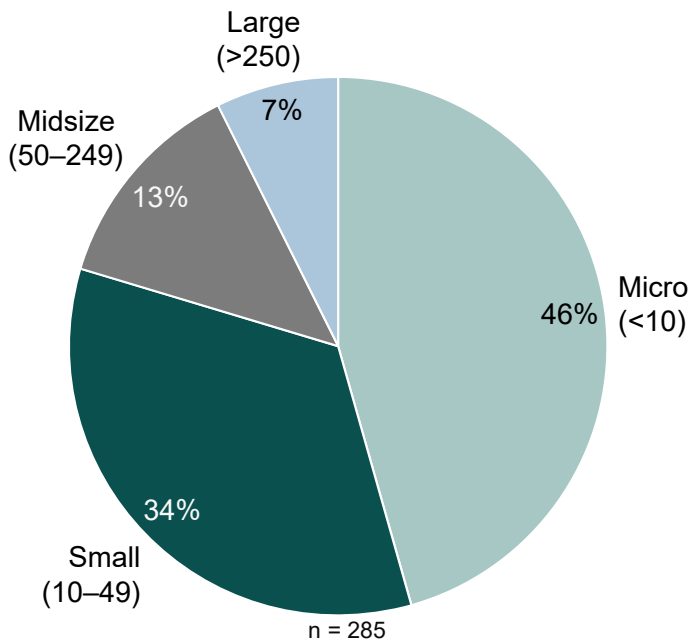
Source: Swiss Medtech databank; SMTI 2018; Federal Department of Statistics(BfS); Swiss Federal Customs (FCA); State Secretariat for Economics (SECO);

Approx. 1,400 companies are active in the Swiss Medtech Industry

Companies by category[1)]
(in %)



Company size by number of employees[2)]
(in %)



Comments

- The Swiss medtech sector is comprised of 1,400 companies:
  - ¼ are manufacturers (including start-ups) who produce their own products
  - ⅓ are suppliers and represent the largest business category

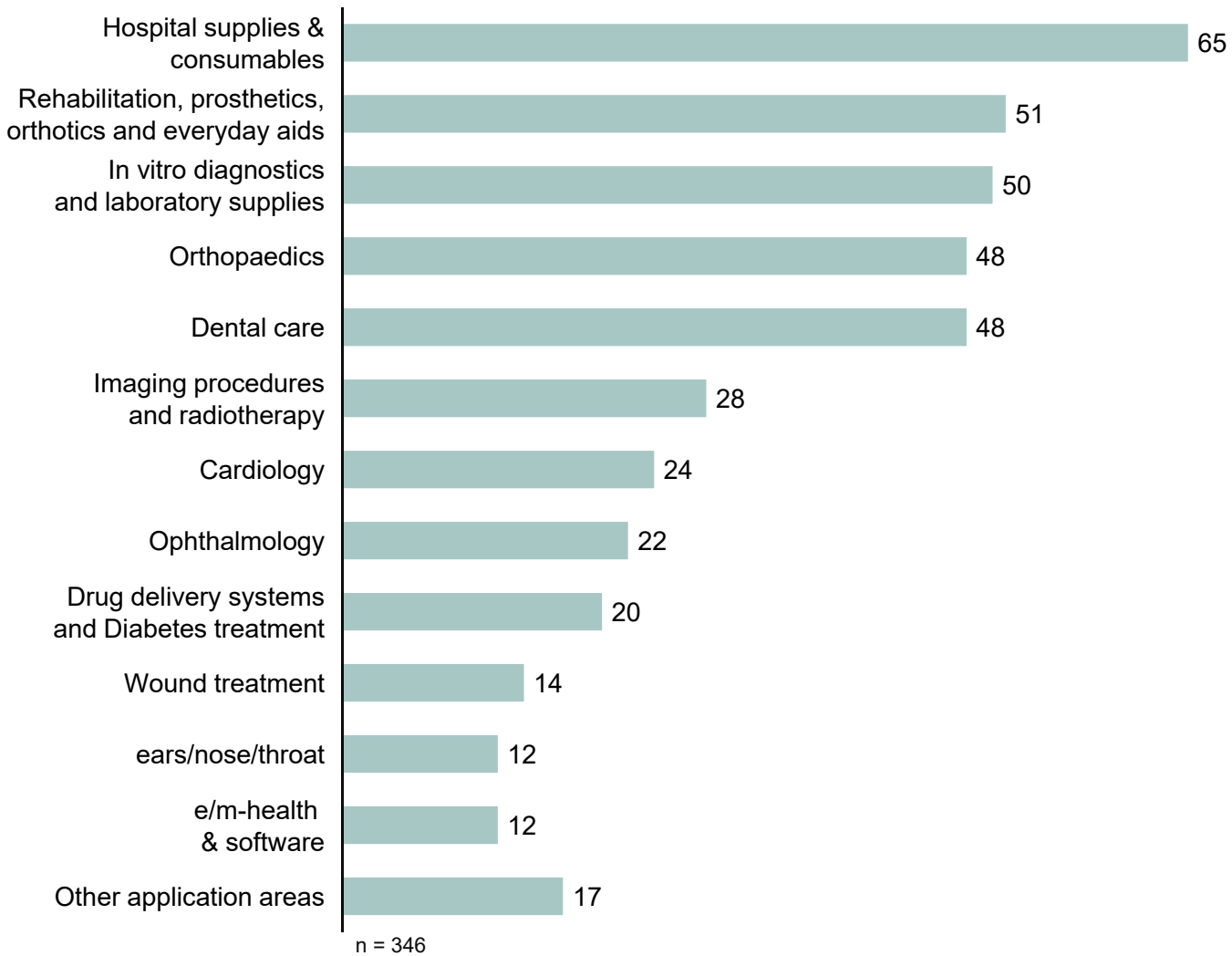
Comments

- The SMTI consists mainly of SMEs; 93% of companies employ fewer than 250 employees and 4 of 5 companies have less than 50 employees
- Micro enterprises (less than 10 employees) represent the largest group
- The majority of large companies are manufacturers

Source: 1) Swiss Medtech databank
2) SMTI survey results 2018

The Swiss medtech industry is made up of 12 major application areas

Swiss medtech manufacturers according to application areas
(# of responses)



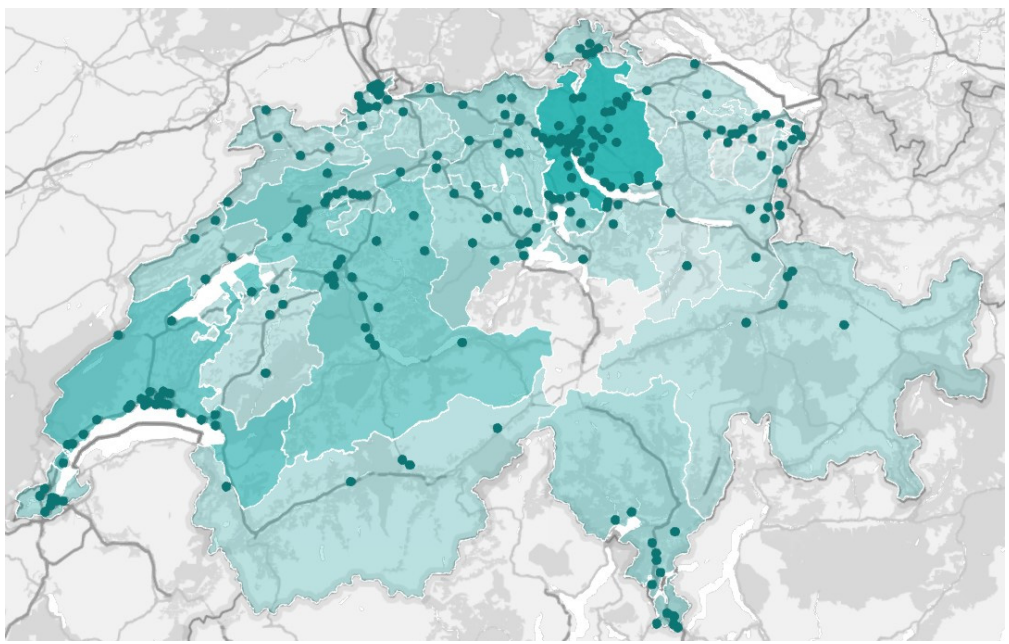
Comments

- Most Swiss manufacturers produce hospital equipment and consumables
- Other well-represented fields of application in Switzerland are:
  - Rehabilitation, prosthetics, orthotics and everyday aids
  - In vitro diagnostics & laboratory supplies
  - Orthopaedics
  - Dental care
- Fields of application with low representation are:
  - Wound treatment
  - ears/nose/throat
  - e/m-health & software
- Sales and employment figures were not included in the analysis

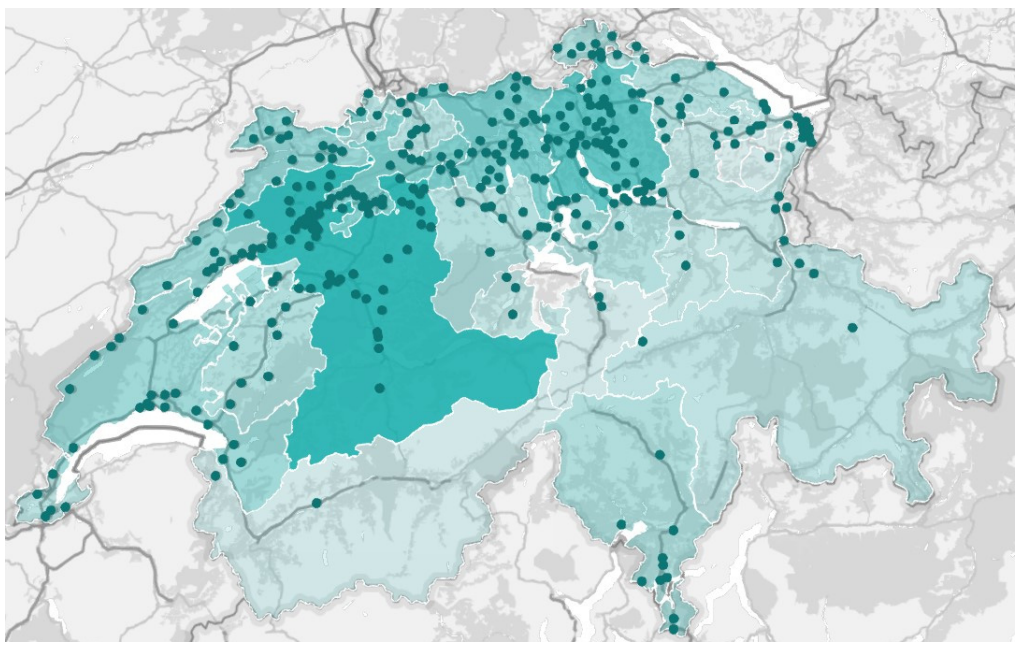
Note: multiple responses possible; see Appendix for explanation of application fields
Source: Swiss Medtech databank, SMTI survey results 2018

The Swiss medtech cluster is unique

Medtech manufacturers in Switzerland



Medtech suppliers in Switzerland



Comments

- Switzerland has a high density of medtech companies covering the entire value chain. This makes Switzerland a unique medtech cluster
- The producing medtech companies are distributed all over Switzerland and reach into the Alpine valleys
- Switzerland is characterised by a cluster of technology companies – suppliers and service providers that possess specialised know-how

Note: The colour intensity is based on the number of companies per Canton.
The points on the map correspond to postal codes; one point may represent more than one company
Source: Swiss Medtech databank

Many global players are active in Switzerland

Top 10 medtech employers in Switzerland by number of employees (2015 data)

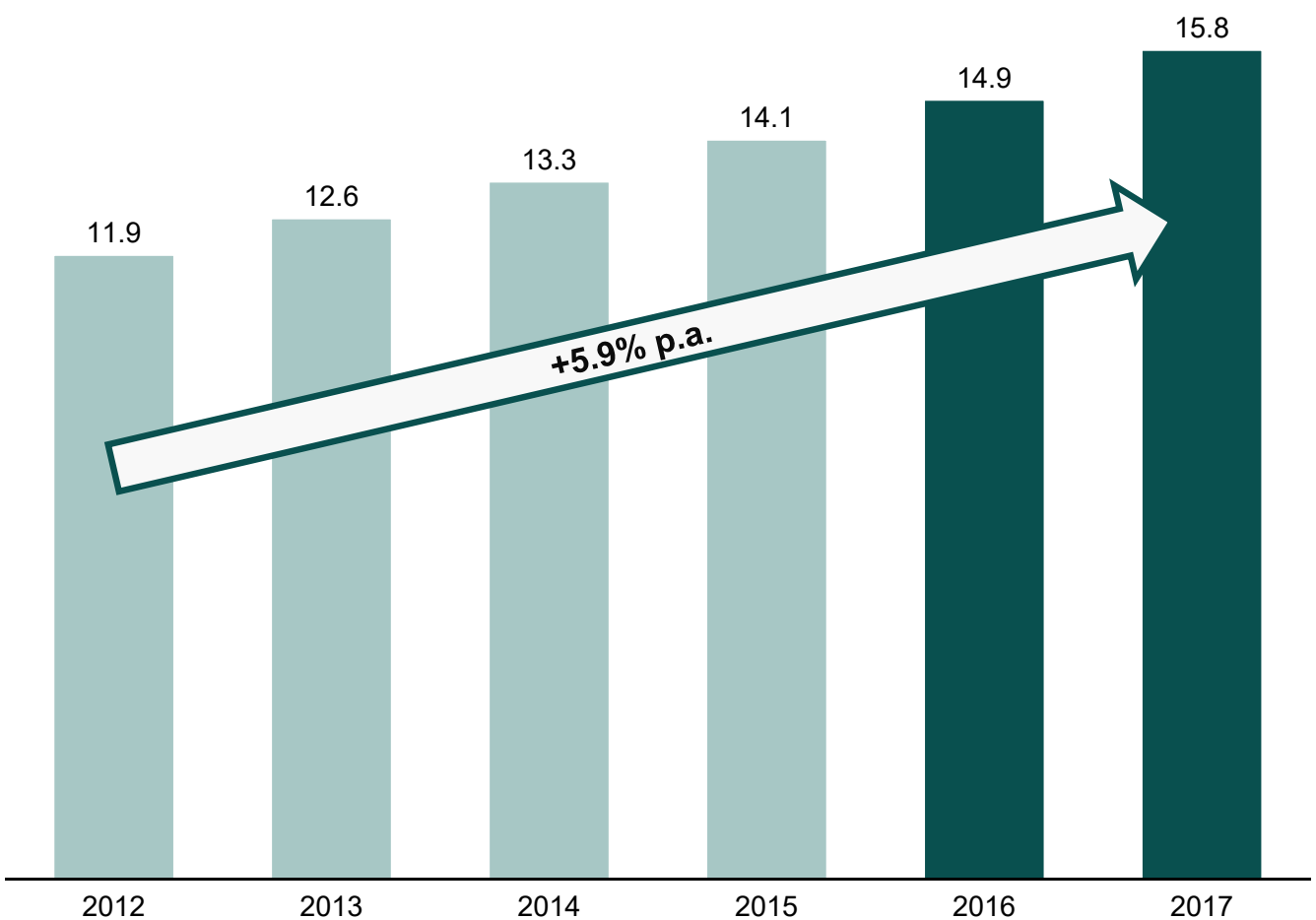
No.	Company	Core activities in Switzerland	Headquarters	# employees in Switzerland	Global growth in sales (in %)	Global R&D / sales (in %)
1	J&J Medical	Cardiology, orthopaedics, ophthalmology, wound treatment, ears/nose/throat, hospital equipment and consumables, e/m-health and software	USA	3,800	8.7%	6.4%
2	Roche Diagnostics	In vitro diagnostics and laboratory equipment	CH	2,800	5.0%	11.0%
3	Biotronik[1)]	Cardiology	D	1,245	n.a.	n.a.
4	Sonova	ears/nose/throat	CH	1,219	15.6%	5.7%
5	Medtronic	Drug delivery systems and diabetes therapy, cardiology, ears/nose/throat, hospital equipment and consumables	IRL	1,100	3.0%	7.4%
6	Zimmer Biomet	Dental care, orthopaedics	USA	1,050	2.0%	5.0%
7	Straumann	Dental care	CH	1,025	21.2%	6.0%
8	B. Braun	Wound treatment, hospital equipment and consumables	D	1,023	4.9%	5.2%
9	Ypsomed	Drug delivery systems and diabetes therapy	CH	955	20.0%	9.0%
10	Dentsply Sirona	Dental care	USA	900	6.6%	3.8%
				Σ 15,117	**Ø 9.7%**	**Ø 6.6%**

1) Not a listed company; no further information available

Sources: Annual reports and information provided by the companies

SMTI has shown constant revenue growth over the years

Medtech sales performance (in billion CHF)



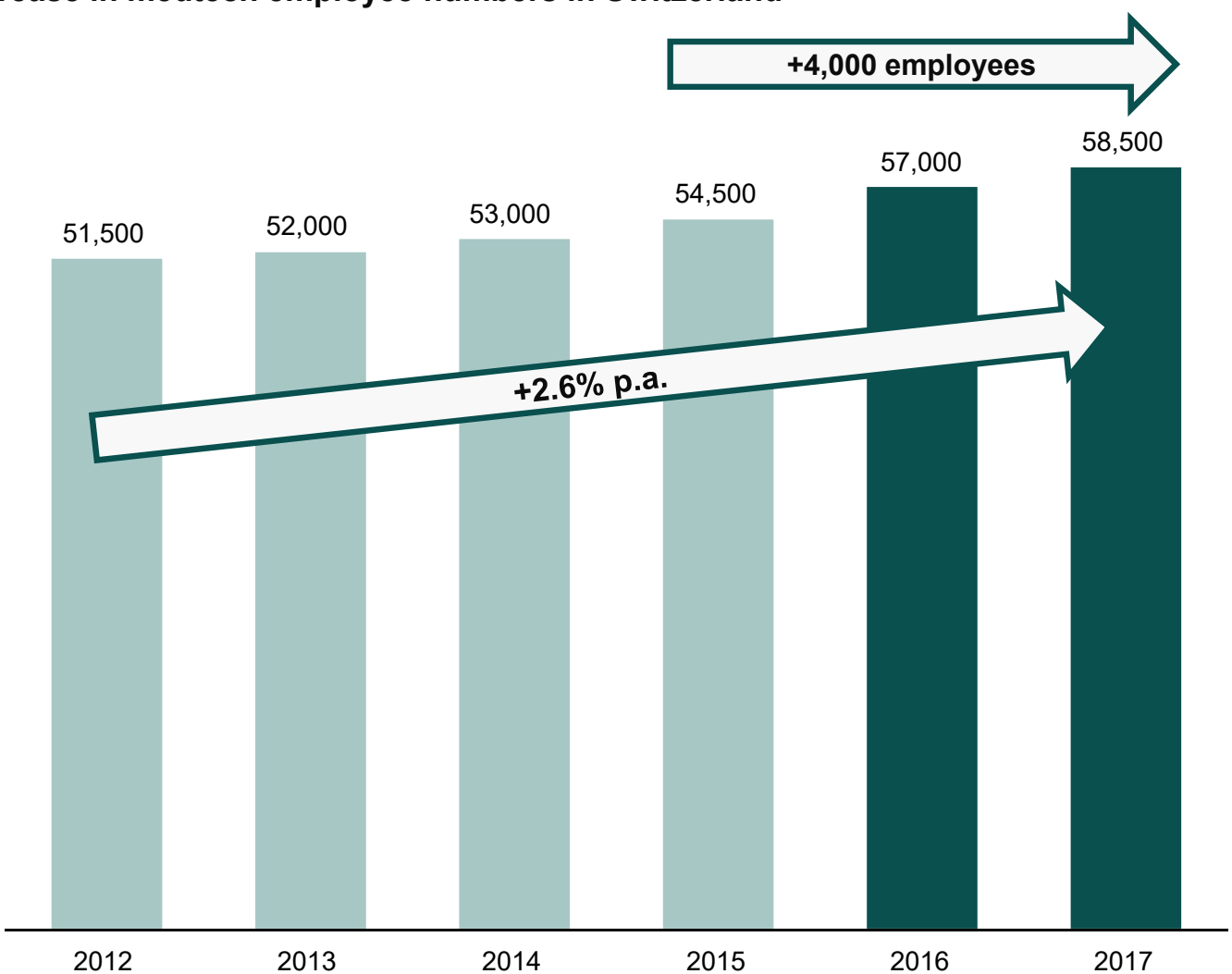
Comments

- In 2017, medtech industry players (manufacturers, suppliers, trade & distribution and service providers) generated estimated sales of CHF 15.8 billion.
  - Growth 2016: 5.4%
  - Growth 2017: 6.4%
- Since 2015, sales growth has been equivalent to an annual increase 0.85 billion CHF.
- The trend of recent years has continued. Over the past six years, the SMTI has shown a constant sales increase of 6% per annum
- The achieved growth has exceeded that of the Swiss GDP in recent years (1.4% in 2016 and 1.1% in 2017)

Sources: Own analyses; SMTI survey results 2018; SMTI industry reports; State Secretariat for Economic Affairs (SECO)

The SMTI has created around 4,000 new jobs in Switzerland since 2015

Increase in medtech employee numbers in Switzerland



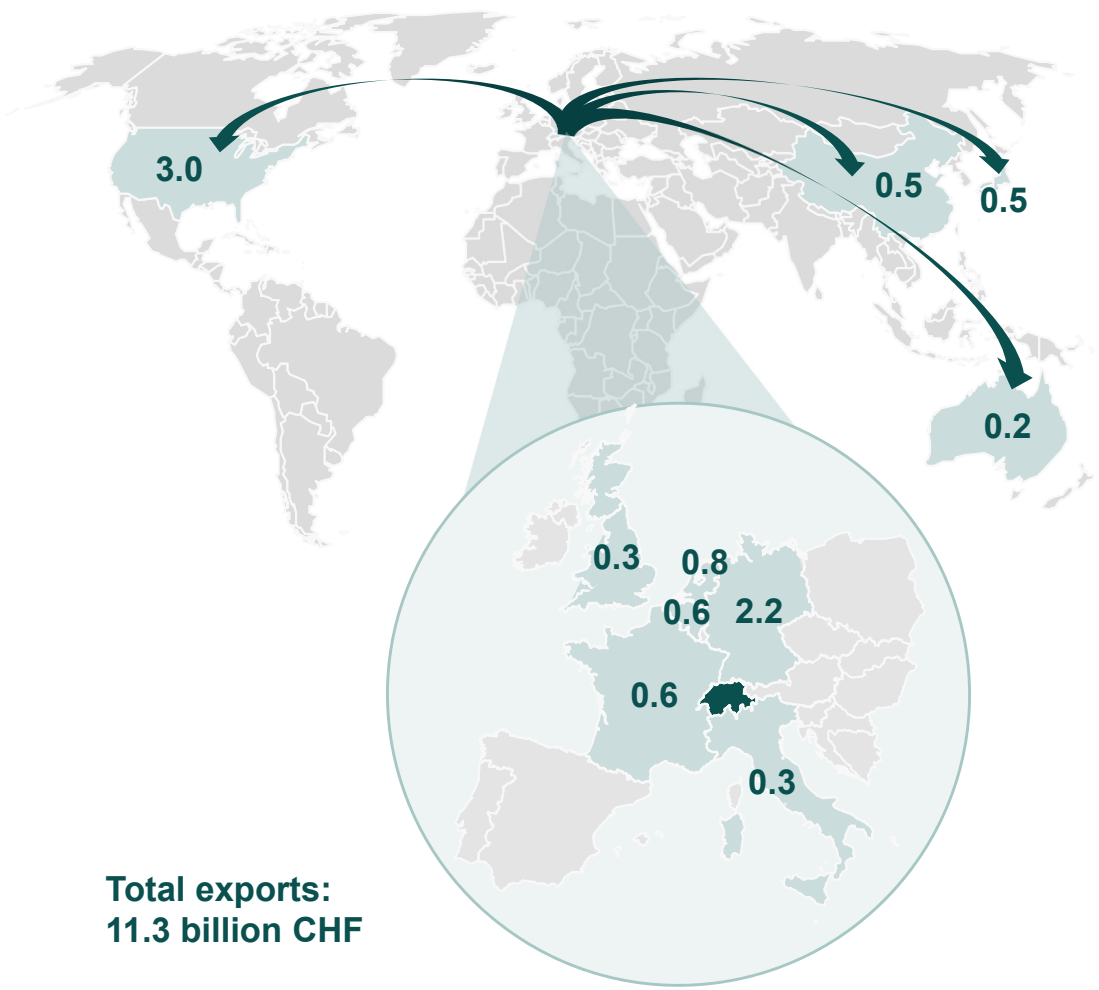
Comments

- Approx. 58,500 people worked in the medtech industry in 2017
- Around 4,000 additional jobs have been created in the Swiss medtech industry in the last two years
- With industry sales of CHF 15.8 billion, labour productivity was CHF 270,000 per employee in 2017
- The number of employees has increased by an average of 2.6% per year since 2012
- The increase in employment was 4.6% in 2017 and 2.6% in 2016. This is above average compared to most other manufacturing industries (2016/2017):
  - Watch industry: –3.4%/–3.3%
  - MEM industry: –2.0%/+1.4%
  - Pharma. industry: –1.0%/+3.9%

Sources: Own analyses SMTI survey results 2018; SMTI sector reports; Swissmem; Swiss watch industry Employer Association; science industries

The most important export destinations remain the USA and Germany

Swiss medtech exports 2017 (in billion CHF)



Total exports: 11.3 billion CHF

Top 10 export destinations

Rank	Country	Volume BCHF
1.	USA	3.0
2.	Germany	2.2
3.	Netherlands	0.8
4.	Belgium	0.6
5.	France	0.6
6.	China	0.5
7.	Japan	0.5
8.	Great Britain	0.3
9.	Italy	0.3
10.	Australia	0.2
Top 10 total		**9.0 (80%)**

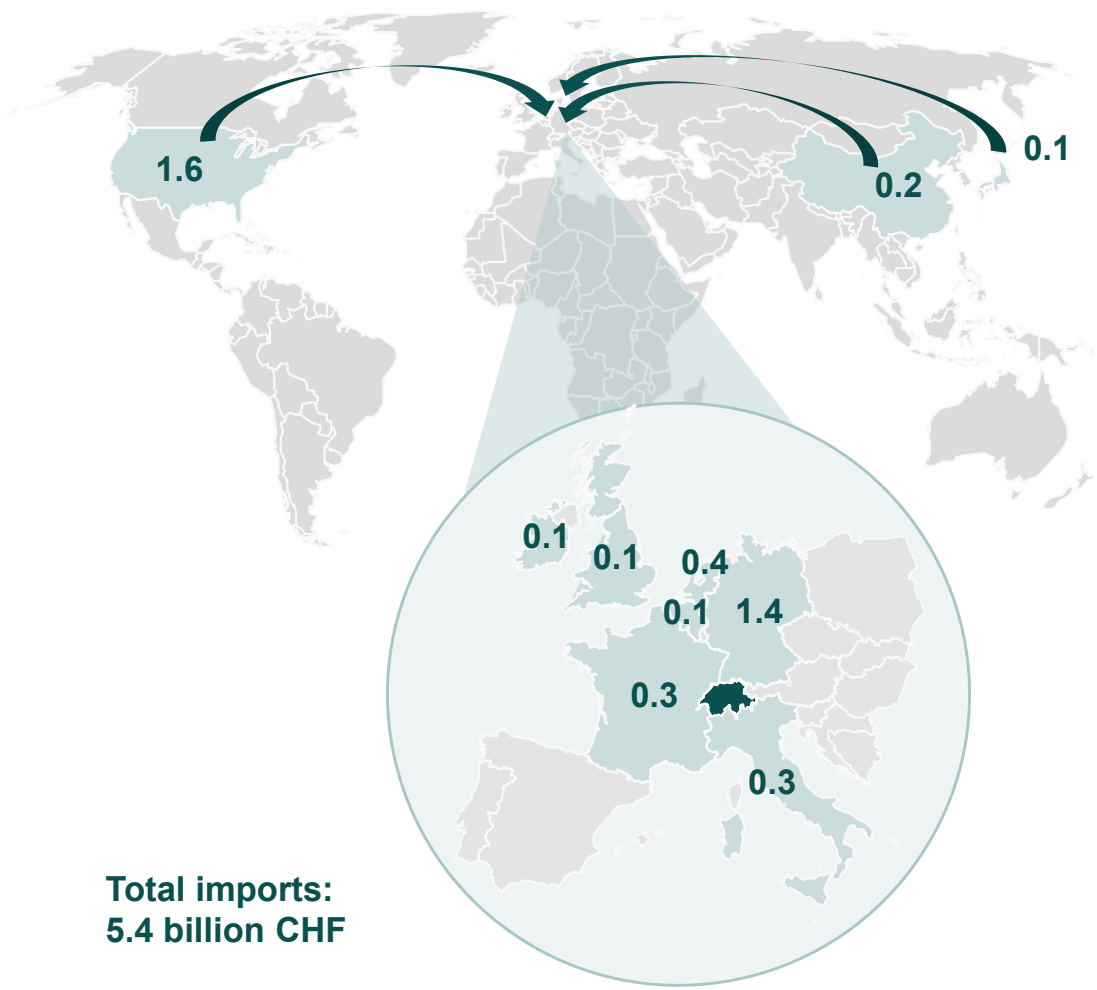
Comments

- In 2017, the Swiss medtech industry exported products worth 11.3 billion CHF. This represents an increase of 0.7 billion CHF since 2015
- As in previous years, the most important export destinations were the USA and Germany
- Exports to the US have risen especially sharply
- Six of the top 10 export destinations are in Europe
- 80% of medtech exports are achieved with the top 10 customer countries

Note: Trade figures (exports & imports) reflect finished products only; trade/sales of semi-finished products are not included
Source: Swiss Federal Customs (FCA)

Switzerland imported 5.4 billion CHF in medtech products in 2017

Swiss medtech imports in 2017 (in billion CHF)



Top 10 importing countries

Rank	Country	Volume BCHF
1.	USA	1.6
2.	Germany	1.4
3.	Netherlands	0.4
4.	France	0.3
5.	Italy	0.3
6.	China	0.2
7.	Ireland	0.1
8.	Great Britain	0.1
9.	Belgium	0.1
10.	Japan	0.1
Top 10 total		**4.6 (85%)**

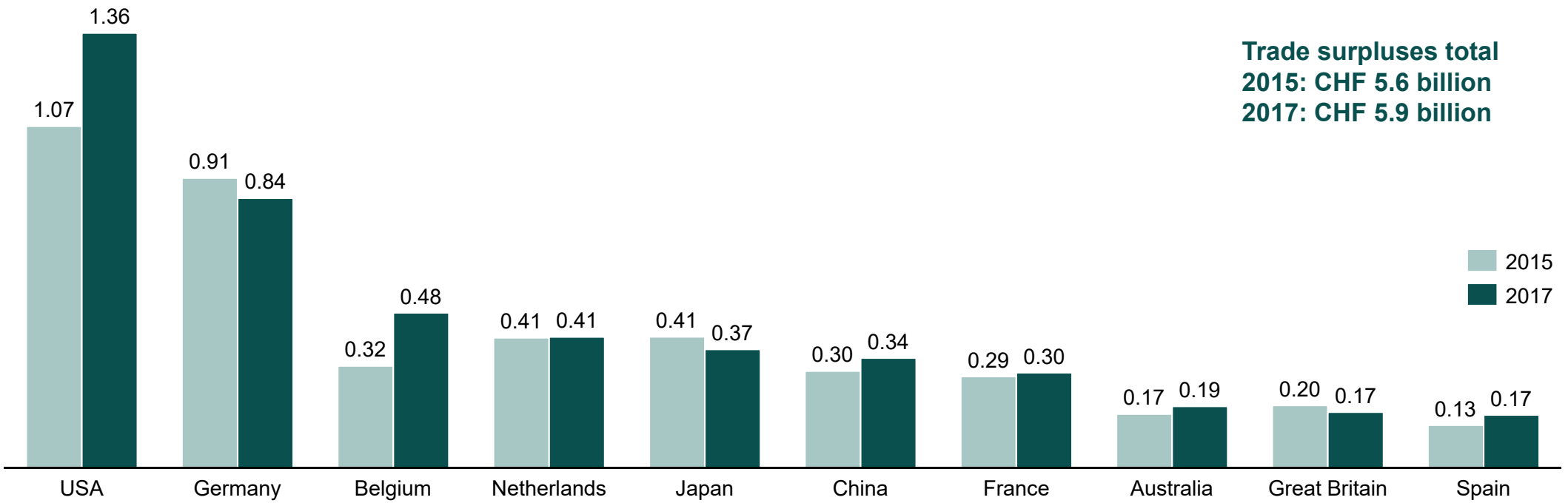
Comments

- Switzerland imported medtech products valued at 5.4 billion CHF in 2017. This represents an increase of 0.4 billion CHF since 2015
- The top 10 import countries represent 85% of all medtech imports
- More than half (55%) of all Swiss medtech products are imported from the USA and Germany
- The top 3 import countries are also the top 3 export destinations for medtech products

Note: Trade figures (exports & imports) reflect finished products only; trade/sales of semi-finished products are not included
Source: Swiss Federal Customs (FCA)

In recent years Switzerland has confirmed its position as a medtech exporter

Top 10 Swiss medtech trade surpluses (in billion CHF)



Comments

- A trade surplus of 5.9 billion CHF was generated in 2017 and a 5.6 billion CHF surplus was seen in 2015
- The top 10 trade surplus nations are responsible for 90% of the total Swiss medtech trade surplus in 2017
- The two largest trading partners together represent 37% of the total trade surplus (USA: 23%, Germany: 14%)
- See page 42 of the appendix for further analysis

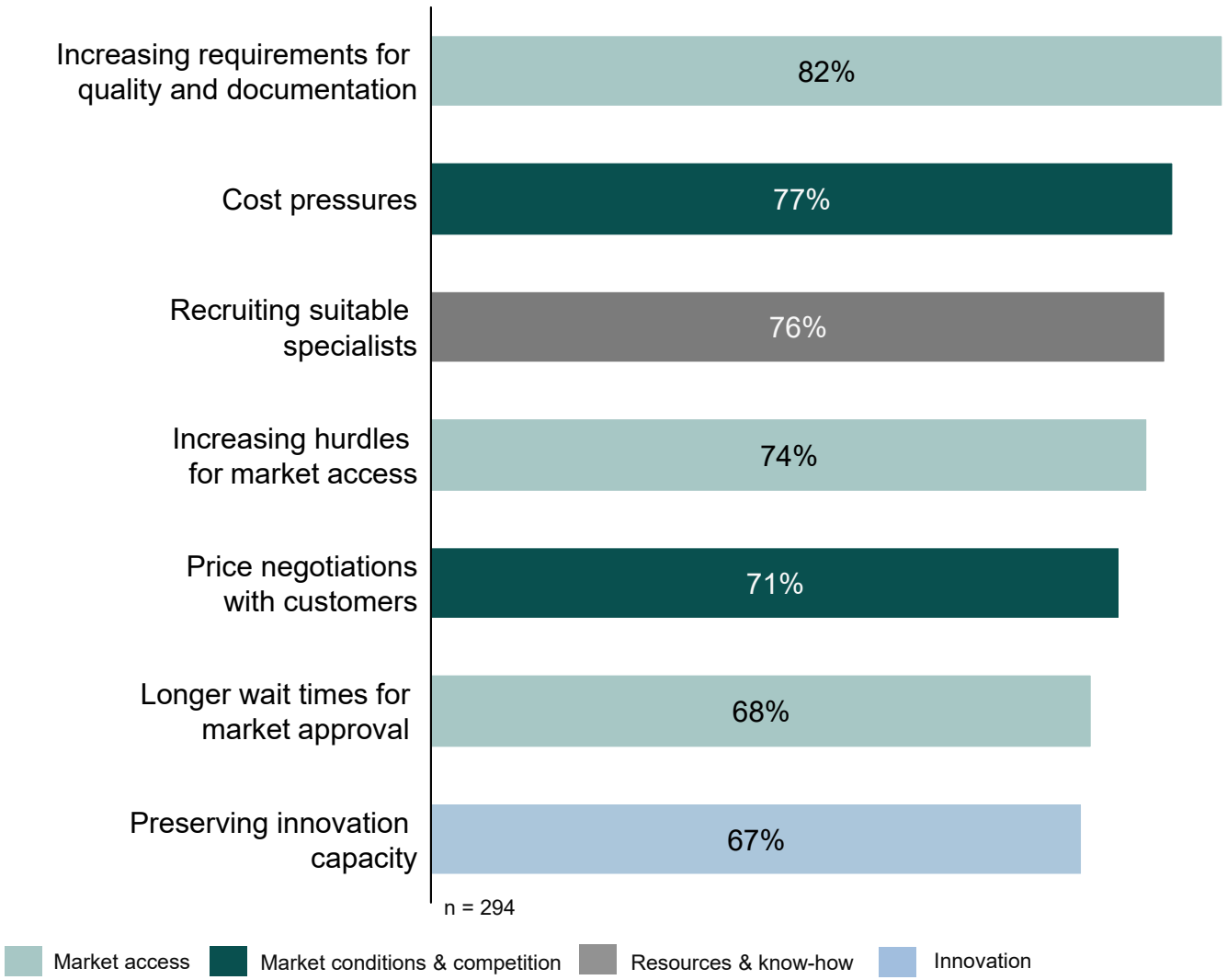
Note: The European central warehouses of several global players are located in The Netherlands and Belgium
Trade figures (exports & imports) reflect finished products only; trade/sales of semi-finished products are not included
Source: Swiss Federal Customs (FCA) 2017

Challenges

- Top 7 challenges for medtech companies
- Selected focus topics: recruitment, R&D and digitalisation

Market access presents the biggest challenge for Swiss medtech companies

Top 7 challenges for medtech companies
(% of all reponses; all categories)



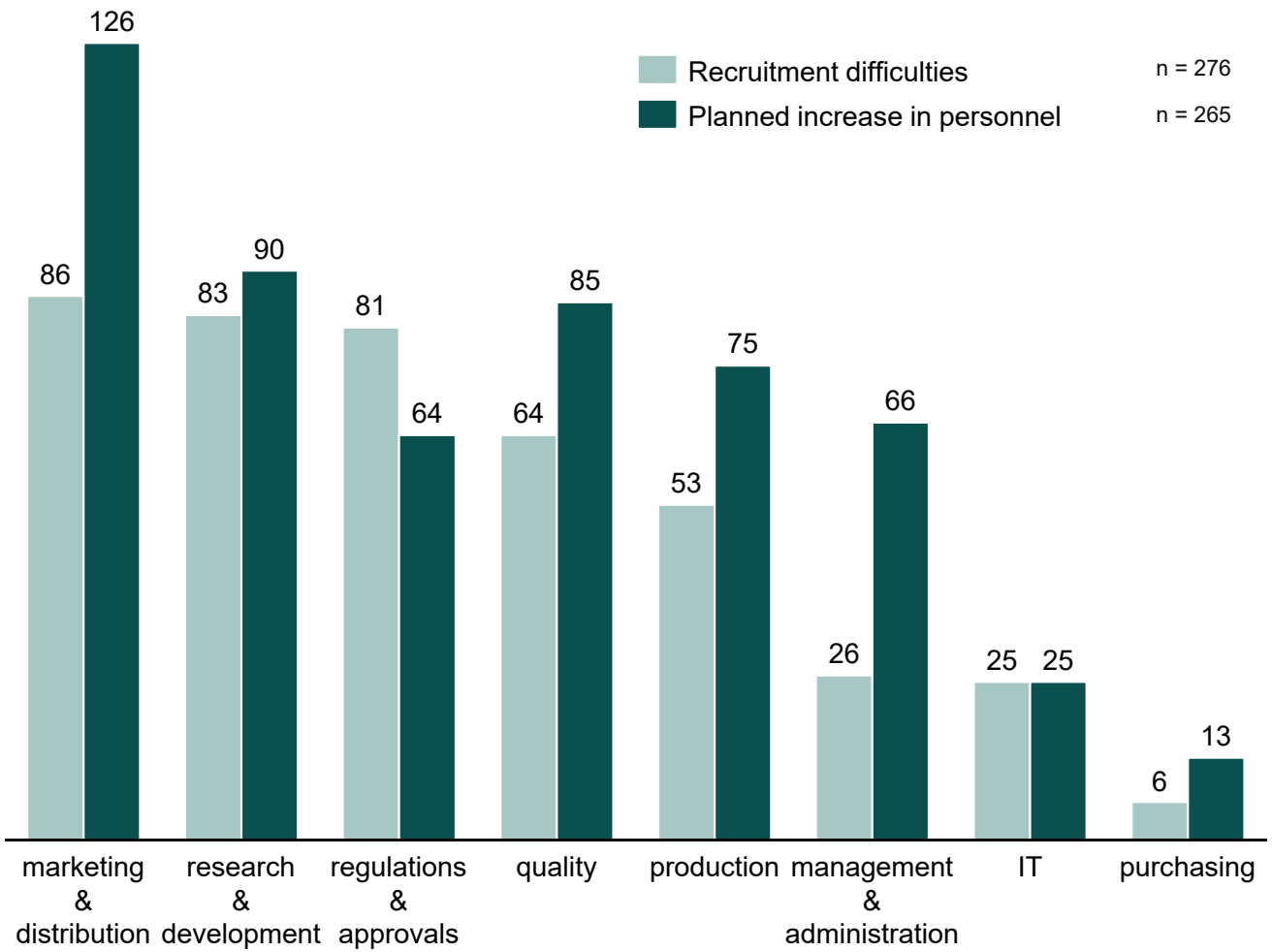
Source: SMTI survey results 2018

Comments

- The biggest challenges are the increasing requirements for quality and documentation, which are partly due to the ongoing introduction of MDR/IVDR
- Challenges with market access have become a higher priority compared to SMTI 2016
- Increasing challenges are forcing companies to invest even more resources for market access
- Consistent challenges include cost pressures and the recruitment of medtech-specific specialists
- Maintaining innovative capability remains a key challenge, as in the past, but has lost priority since SMTI 2016 (Top 1)
- See page 48/49 of the appendix for further analysis

Difficulties finding specialist personnel – especially in the areas of marketing & distribution, research & development and regulation

Recruitment difficulties and planned increase in personnel in the next two years
(# of reponses; all categories)



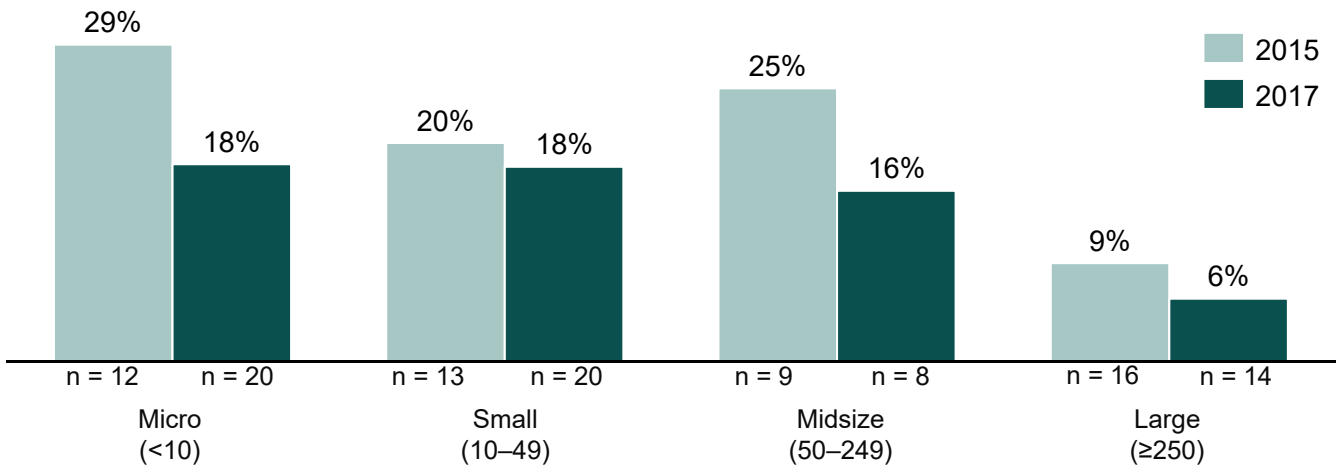
Note: multiple responses possible
Source: SMTI survey results 2018

Comments

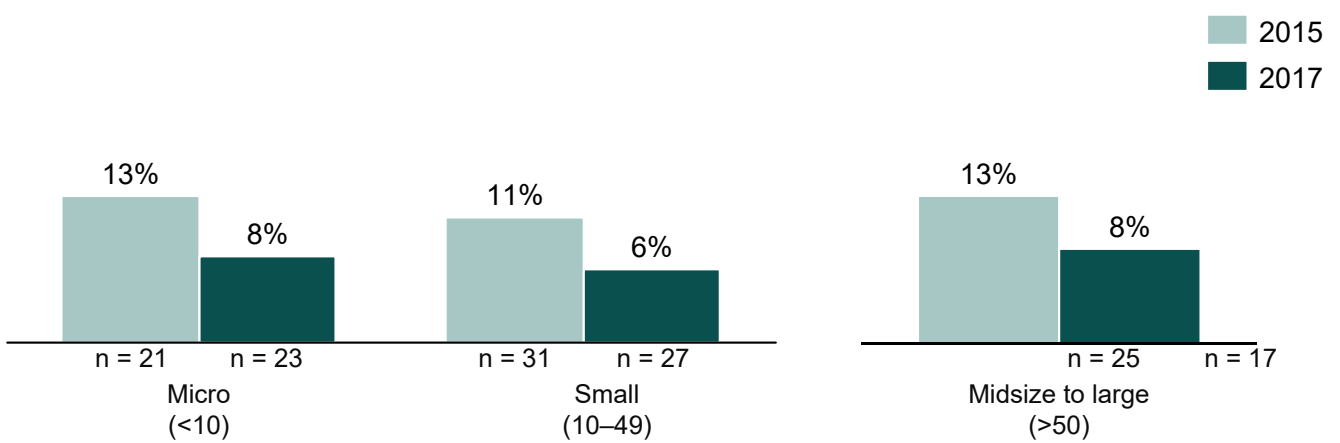
- Finding suitable personnel is one of the major challenges for Swiss medtech companies
- The recruitment of marketing and sales staff poses the greatest difficulty
- In addition, recruiting is difficult for areas with medtech-specific know-how:
  - research & development
  - regulations & approvals
- Specialised technicians, experts and qualified scientists are also difficult to find

Swiss medtech companies spend a lower percentage of sales on R&D

Manufacturers' spending share of medtech sales on R&D according to company size
(in %)



Suppliers' spending share of medtech sales on R&D according to company size
(in %)



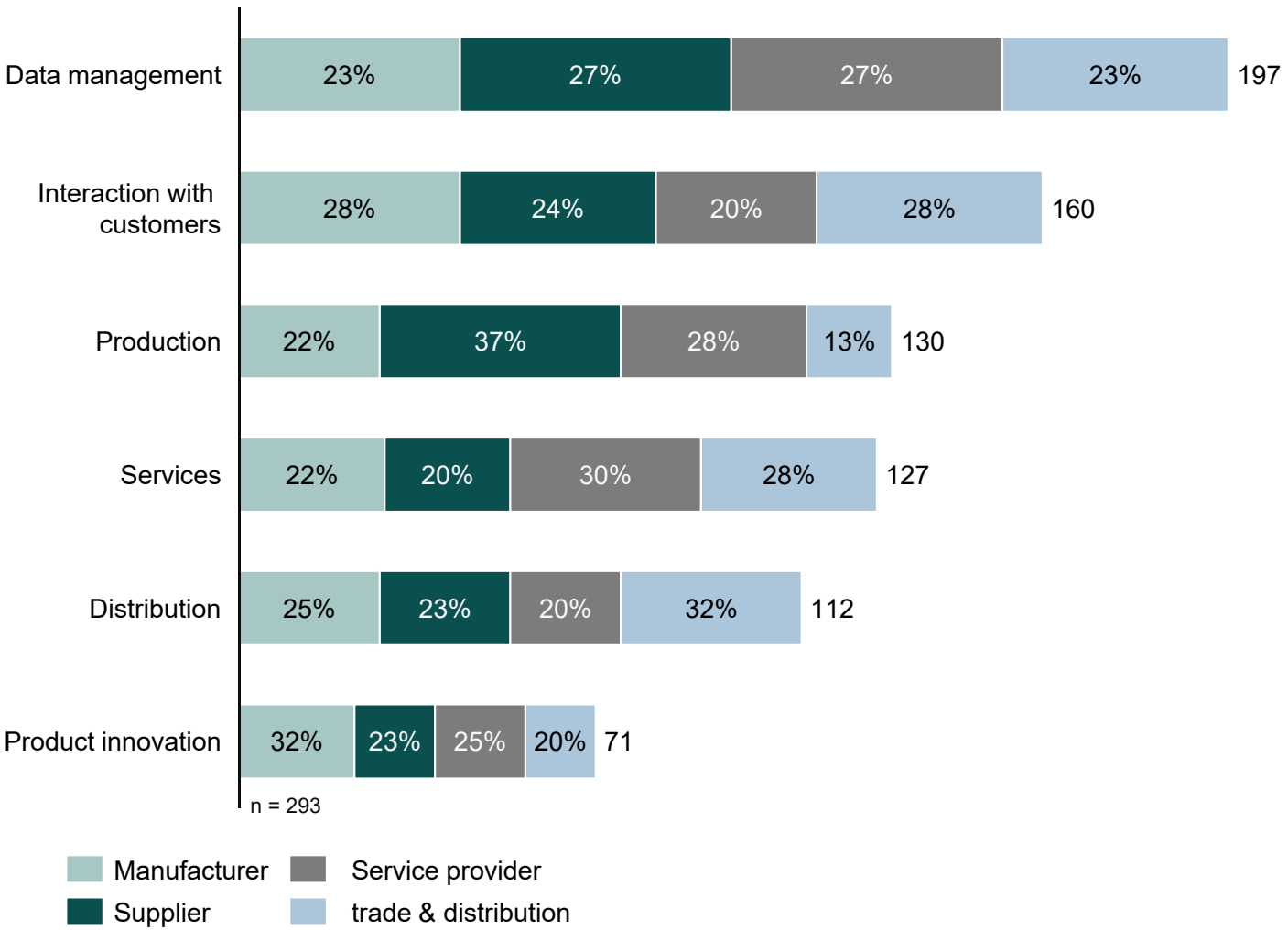
Source: SMTI survey results 2018

Comments

- Compared to 2015, companies have cut their R&D spending.
- Possible reasons are:
  - Increased competition
  - Cost-cutting measure in public health care
  - Uncertainty regarding regulatory requirements
  - Changes in the innovation process
- Medtech manufacturers spend a higher proportion of their turnover on R&D:
  - Manufacturers spend on average between 6% and 18% on R&D
  - Suppliers spend on average between 6% and 8% on R&D

Potential for digitalisation in Swiss medtech companies has not yet been exhausted

Reason for digitalisation
(# of responses; all categories)



Note: Multiple responses possible
Source: SMTI survey results 2018

Comments

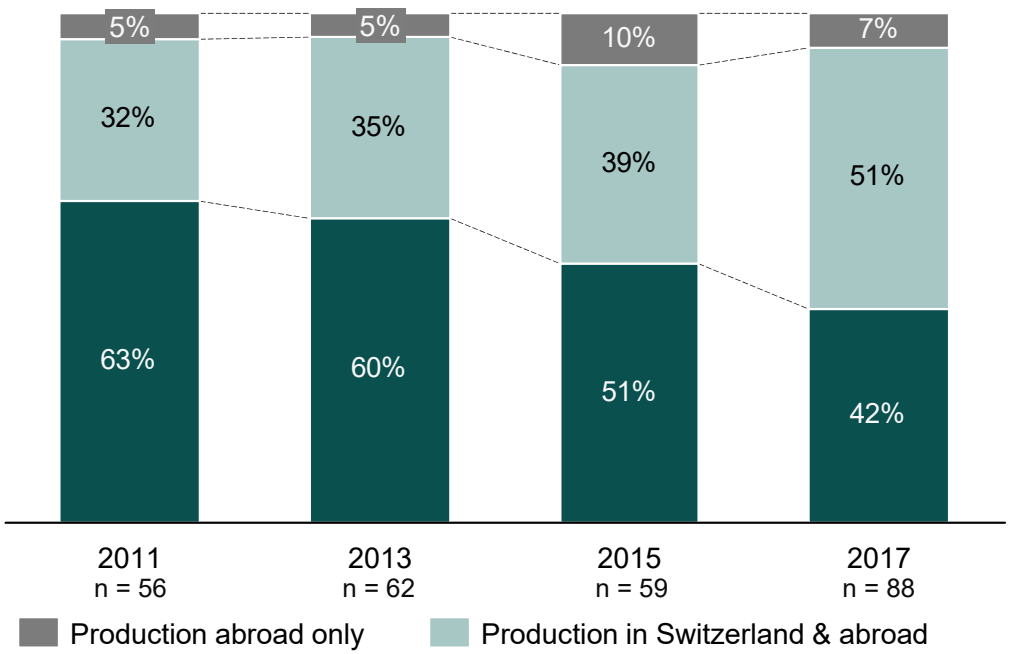
- The surveyed medtech companies generally see a very high need for action with regard to digitalisation in their company
- The effective management of data is the most common need for action
- Digital interaction with customers and supporting production with digitalisation are also key
- Data security and regulatory requirements are important success factors for the future

Future of the Swiss Medtech Industry

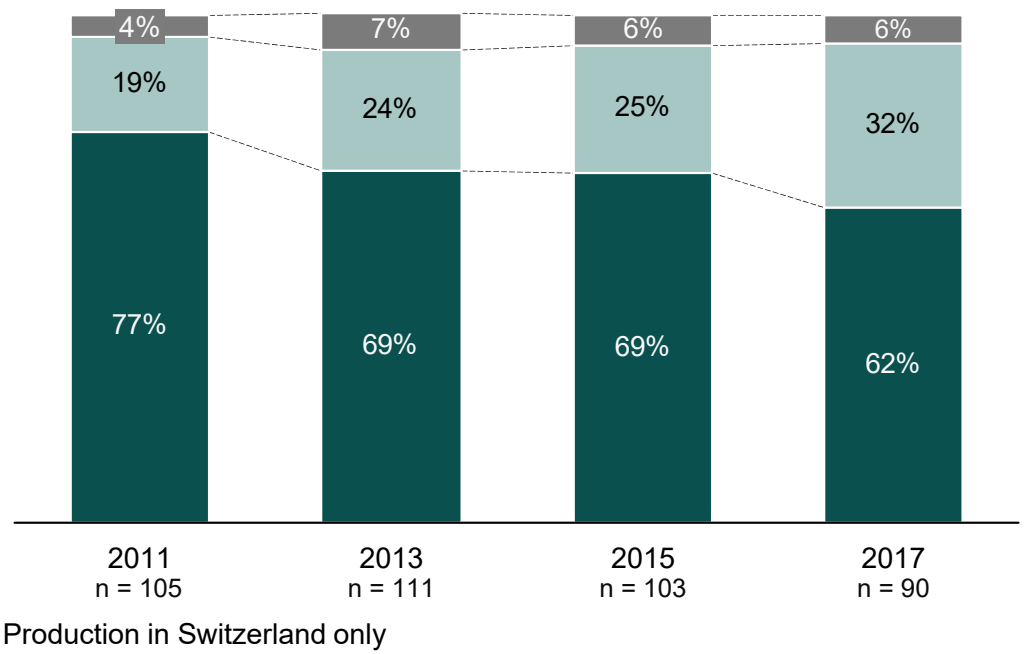
- Medtech production sites, investments and attractiveness of sales markets
- Expected growth
- Switzerland as a business location & priorities for action

Medtech companies continue to rely on Switzerland as a production location – but are increasingly producing abroad

Manufacturers' production location (in %)



Suppliers' production location (in %)



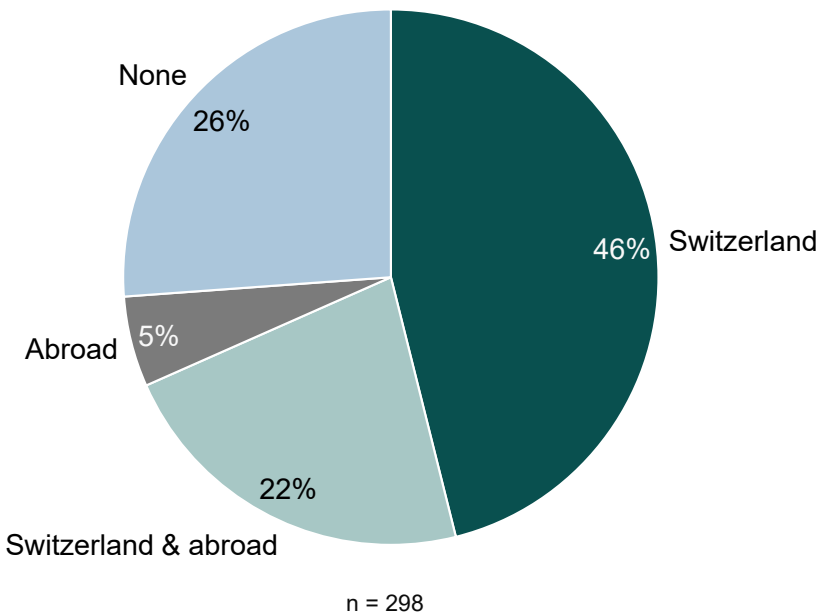
Comments

- Swiss medtech manufacturers are increasingly producing abroad in order to be able to profit optimally from local conditions and the proximity to customers. In 2017, more than half of the manufacturers surveyed in produce both in Switzerland and abroad.
- The share of manufacturers producing exclusively in Switzerland is sinking.
- The majority of suppliers produce exclusively in Switzerland

Source: SMTI survey results 2018; SMTI sector studies

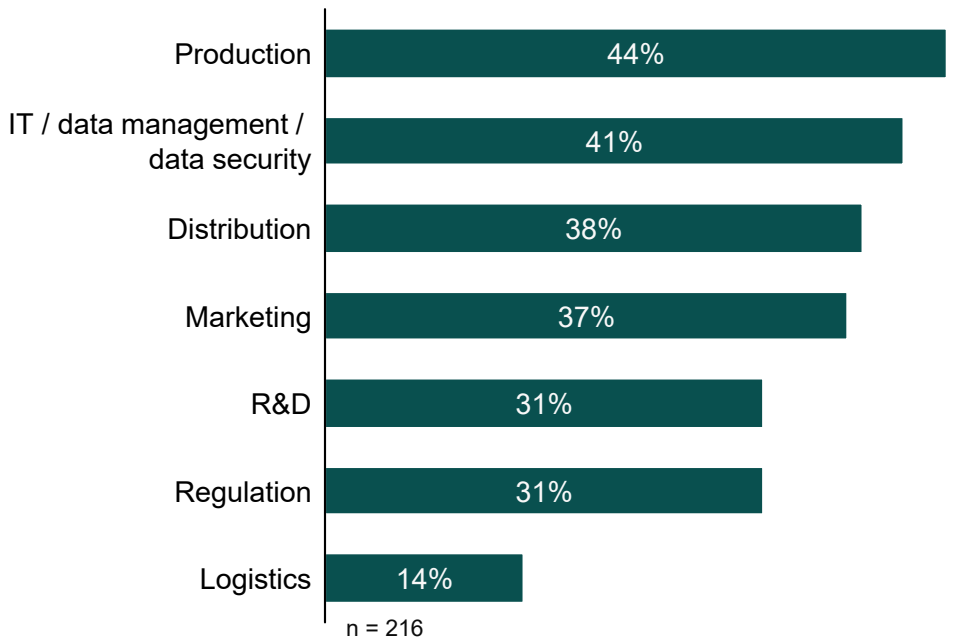
⅔ of the medtech companies surveyed plan investments in Switzerland in the next two years

Planned investments in the next two years
(in %; all categories)



n = 298

Planned inestments by category
(% of all reponses; manufacturers and suppliers)



n = 216

Comments

- Two thirds of medtech companies surveyed plan investments in Switzerland in the next two years
- Investments in Switzerland are amongst other reason made due to the existing locations and facilities

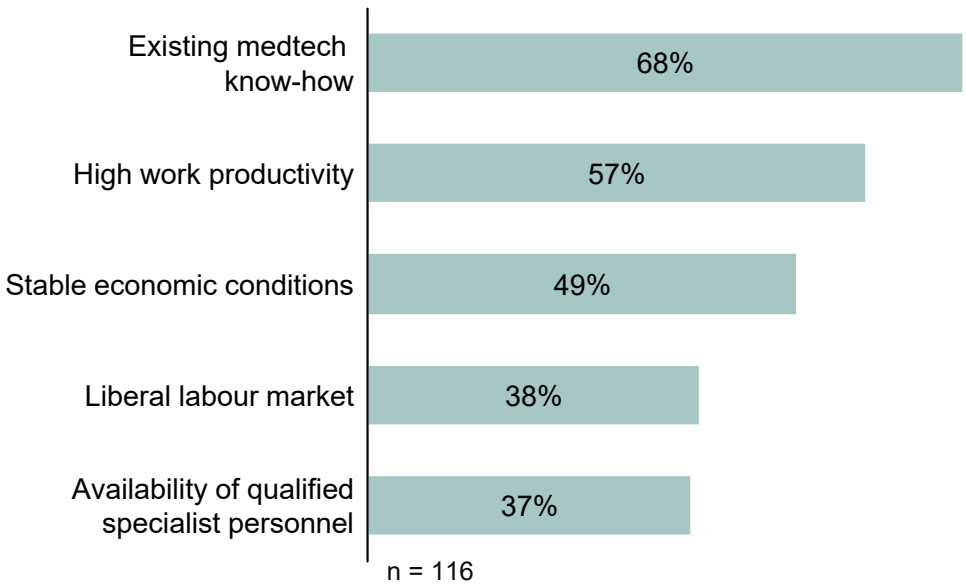
Comments

- Important areas for investment are: optimising production, improving data management and increasing data security
- Other major investment areas are sales, marketing, research & development and regulation

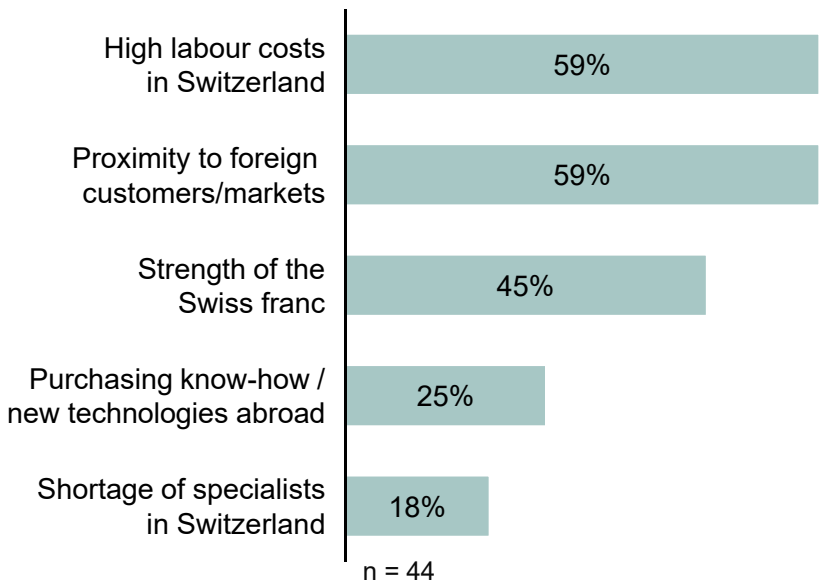
Source: SMTI survey results 2018

Presence of medtech know-how encourages investments in Switzerland

Top 5 reasons to invest in Switzerland
(% of all reponses; manufacturers and suppliers)



Top 5 reasons to invest abroad
(% of all reponses; manufacturers and suppliers)



Comments

- The most important reason for investment is the existing medtech know-how
- Further advantages of Switzerland are labour productivity, the stable economic environment and the liberal labour market with qualified specialists

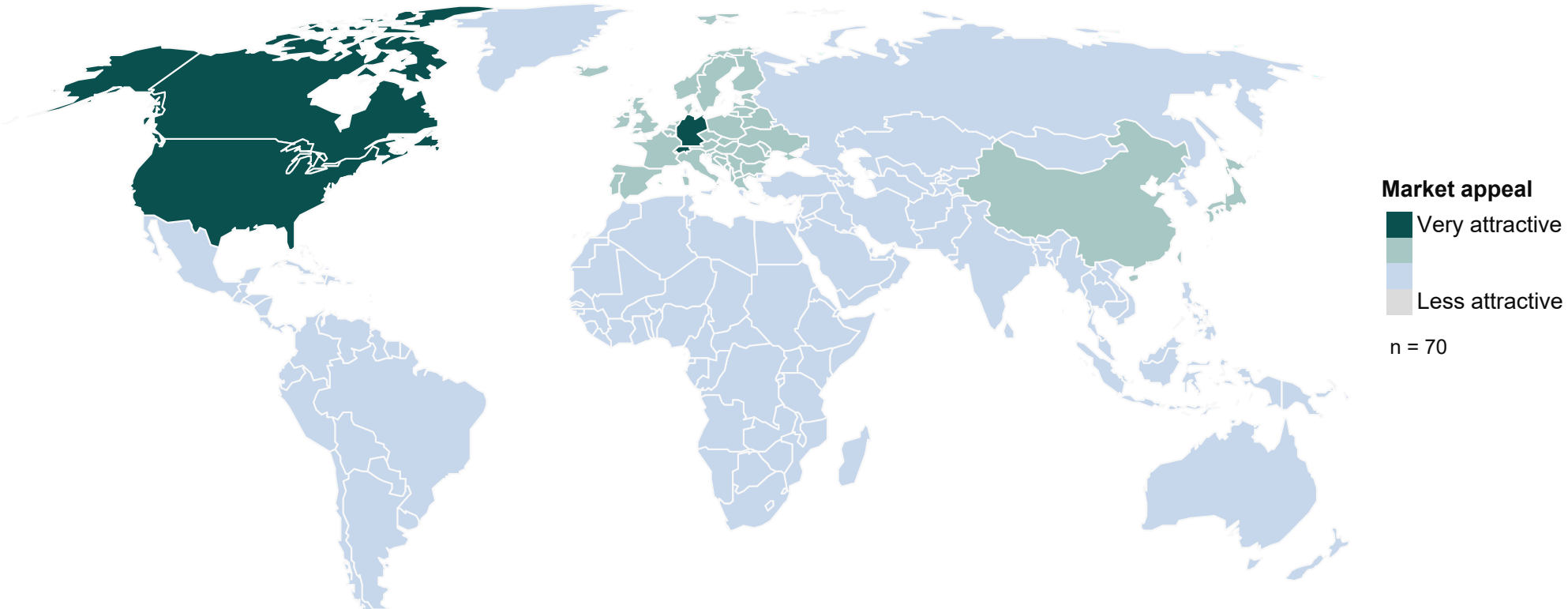
Comments

- The main disadvantages of the Swiss workplace are the high personnel costs, the strength of the Swiss franc and the shortage of skilled professionals
- Other key reasons for investing abroad include proximity to customers and purchasing know-how and new technologies

Source: SMTI survey results 2018

Switzerland, Germany and USA/Canada remain the most attractive markets for Swiss medtech manufacturers

Market appeal from a Swiss medtech manufacturer's point of view (# responses, manufacturers)



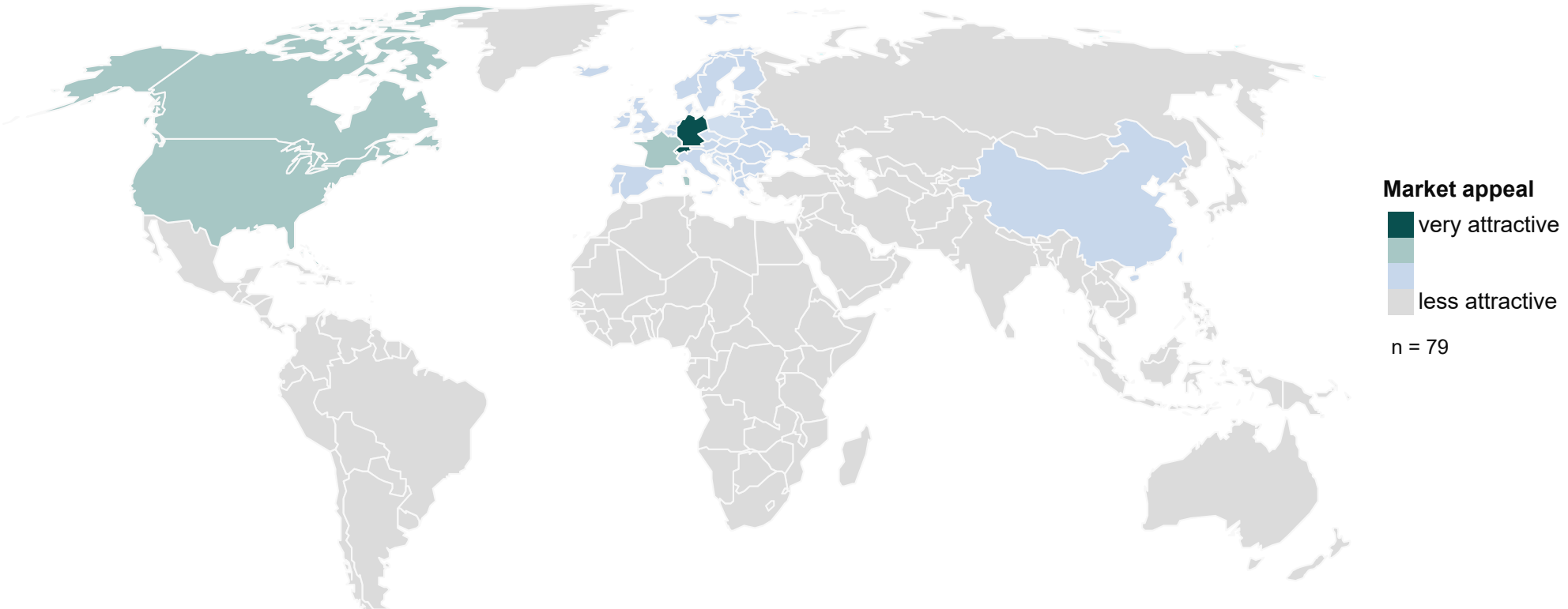
Comments

- Swiss medtech manufacturers sell their products globally
- Switzerland, Germany and USA/Canada are the most attractive markets
- The rest of Europe, as well as China and Japan are also attractive from a manufacturer's point of view

Source: SMTI survey results 2018

Switzerland and Germany remain the most attractive markets for suppliers

Market appeal from a Swiss medtech supplier's point of view (# responses, suppliers)



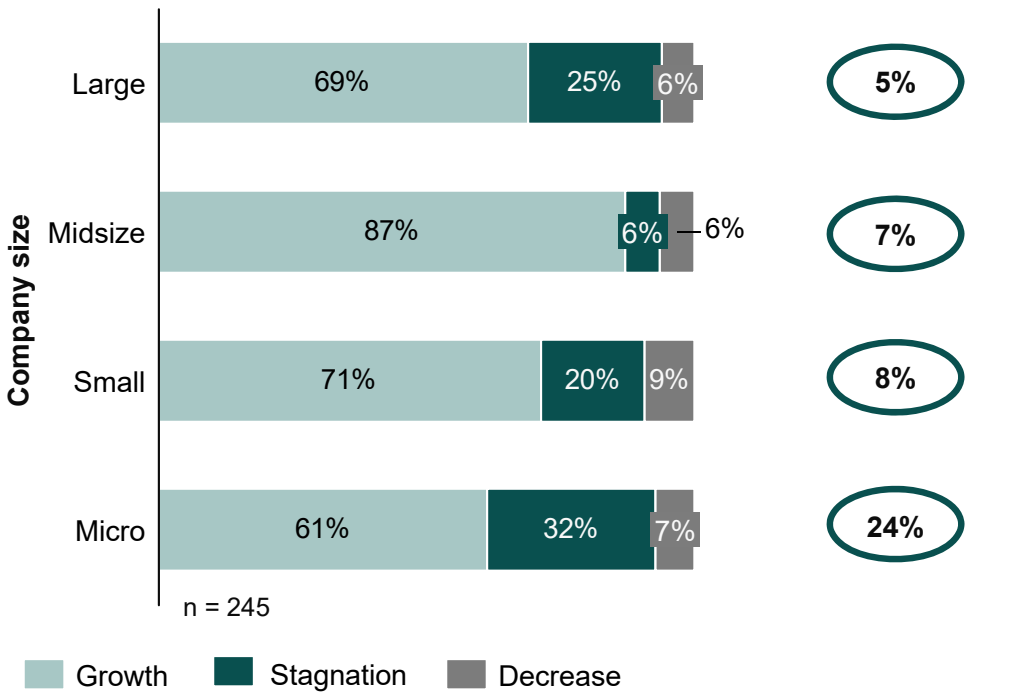
Comments

- Suppliers find nearby markets especially attractive. Switzerland and Germany are the most attractive markets for Swiss medtech suppliers
- USA/Canada and China are the only attractive markets outside of Europe

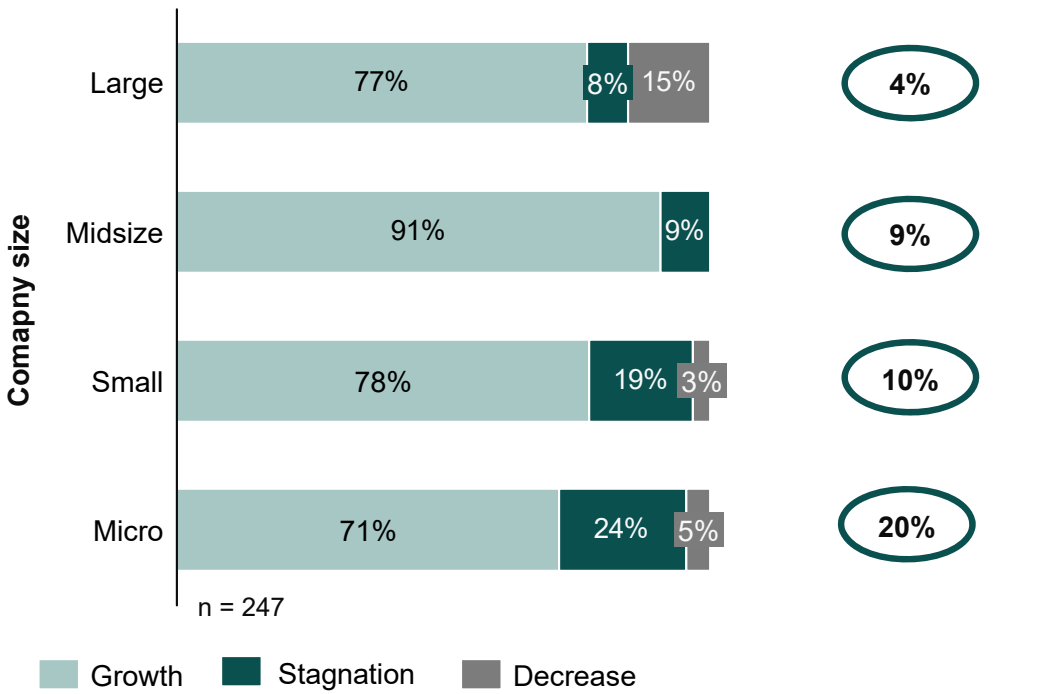
Source: SMTI survey results 2018

Majority of Swiss medtech companies expect increased sales for 2018 and 2019

Expected sales 2018
(% of all reponses; all categories)



Expected sales 2019
(% of all reponses; all categories)



Comments

- The majority of Swiss medtech companies expect sales to increase in 2018, with smaller companies forecasting faster growth
- Average expected growth ranges from 5% to 24% according to company size

Comments

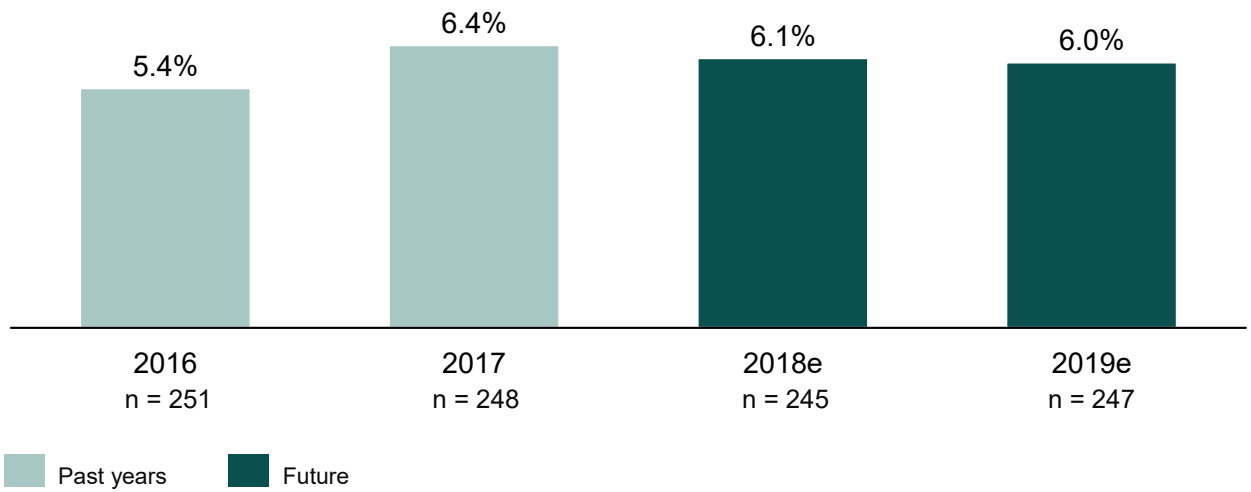
- The majority of Swiss medtech companies expect a growth in sales for 2019 as well
- Average expected sales growth for 2019 is comparable to 2018 and ranges from 4% to 20% according to company size

Note: 1) Weighted according to # of employees
Source: SMTI survey results 2018

6% increase in sales is expected for both 2018 and 2019

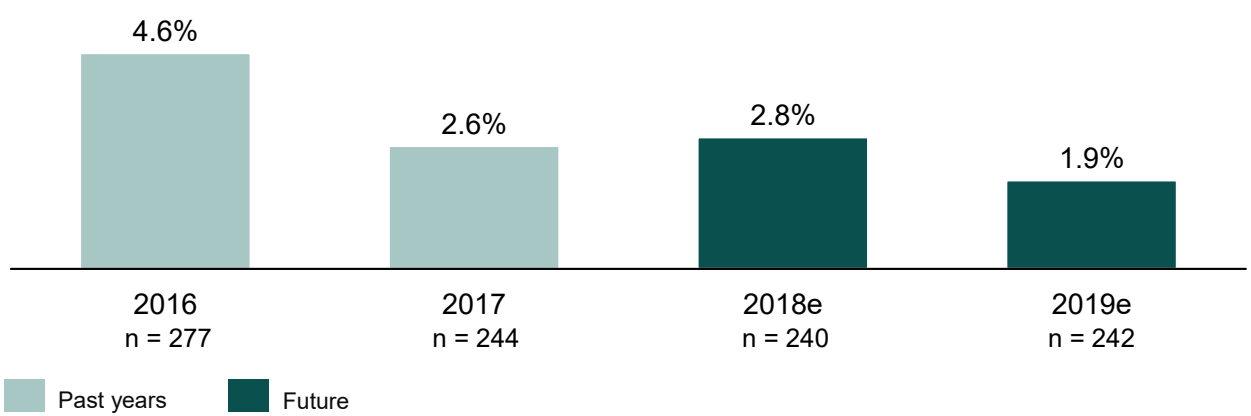
Ø Sales growth

(in %, weighted according to sales trends in Switzerland; all categories)



Ø Employee numbers

(in %, weighted by # of employees in Switzerland; all categories)



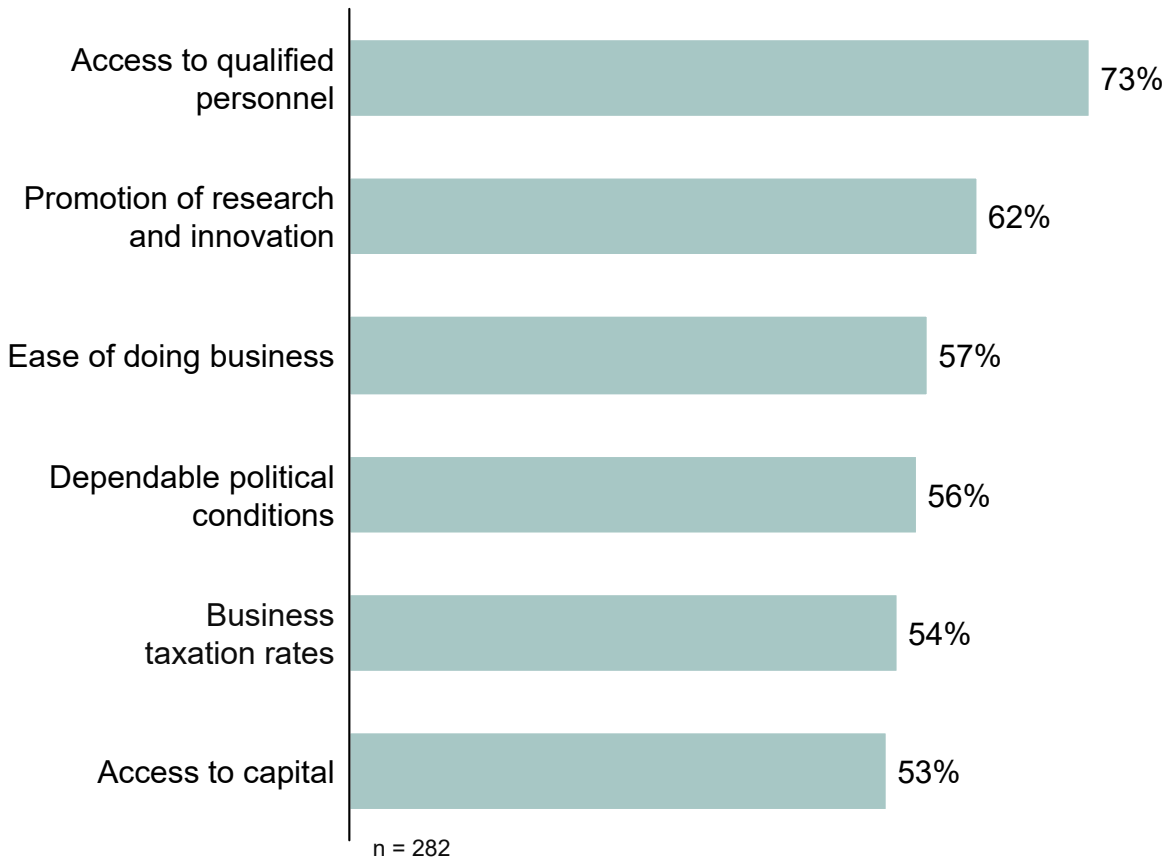
Source: SMTI survey results 2018

Comments

- Sales growth
  - Swiss medtech sales increased by 5.4% in 2016, and by 6.4% in 2017
  - The effective growth remained below expectation compared to SMTI 2016 sales estimates for 2016/2017
  - Medtech companies are positive about the future; stable growth of 6% per annum is expected
- Employment growth
  - Employee numbers rose by 4.6% in 2016, and by 2.6% in 2017
  - Reduced growth in additional employees is forecast for the future

Swiss medtech companies need better access to specialist personnel and more support for research and innovation programmes

Actions required for the Swiss medtech workplace
(% of all reponses; all categories)



Comments

- Medtech companies see the greatest need for action regarding access to qualified personnel. In addition, the companies see room for improvement in the expansion of specific medtech training
- Action is also required to improve and increase the targeted promotion of research and innovation
- In addition, companies see room for improvement in support received from the competent authorities, including (amongst others) Swissmedic

Note: Ease of Doing Business includes (amongst others) founding of company, building permits, electricity supply, infrastructure
Source: SMTI survey results 2018

Focus MDR/IVDR

- Implementation of MDR/IVDR
- Expected effects
- Priorities for action

Swiss medtech companies are effected by MDR and IVDR

MDR and IVDR, the new EU regulations for medical devices

The EU regulations for medical devices (MDR) and in-vitro diagnostics (IVDR) have been in force since 26 May 2017. They aim to significantly improve patient safety by improving risk assessment, market surveillance and increased transparency.

The two new regulations will become mandatory in EU member states starting from May 2020 and May 2022, respectively. Among other things, higher classifications for specific products as well as risk classes for in-vitro diagnostics are being introduced. High-risk products are subject to stricter controls before a EU certificate is issued. Furthermore, processes for market access are more demanding and the requirements for clinical evidence have been increased. Additional provisions also apply regarding the monitoring of products placed on the market. A new European database "Eudamed" and the introduction of the Unique Device Identification UDI will also improve market and product transparency.

Regulatory equivalence as a basis for trade with the EU

The Swiss regulatory provisions for medical devices have been aligned with EU directives since April 1996. This regulatory equivalence forms the basis for simplified marketability, with the free exchange of goods throughout Europe. The introduction of MDR and IVDR, however, requires appropriate adjustments to national legislation within the European transitional time periods. One example: the revised Swiss Medical Devices Law will enter into force early in 2020.

Significant consequences for business operators

The new regulations affect all industry players – from medtech manufacturers to traders. Small companies will be especially affected. In some cases, the extensively expanded regulations require significant adjustments regarding both processes and products. Increased requirements for the provision of technical and clinical evidence will also generate more work and more qualified specialists must be recruited.

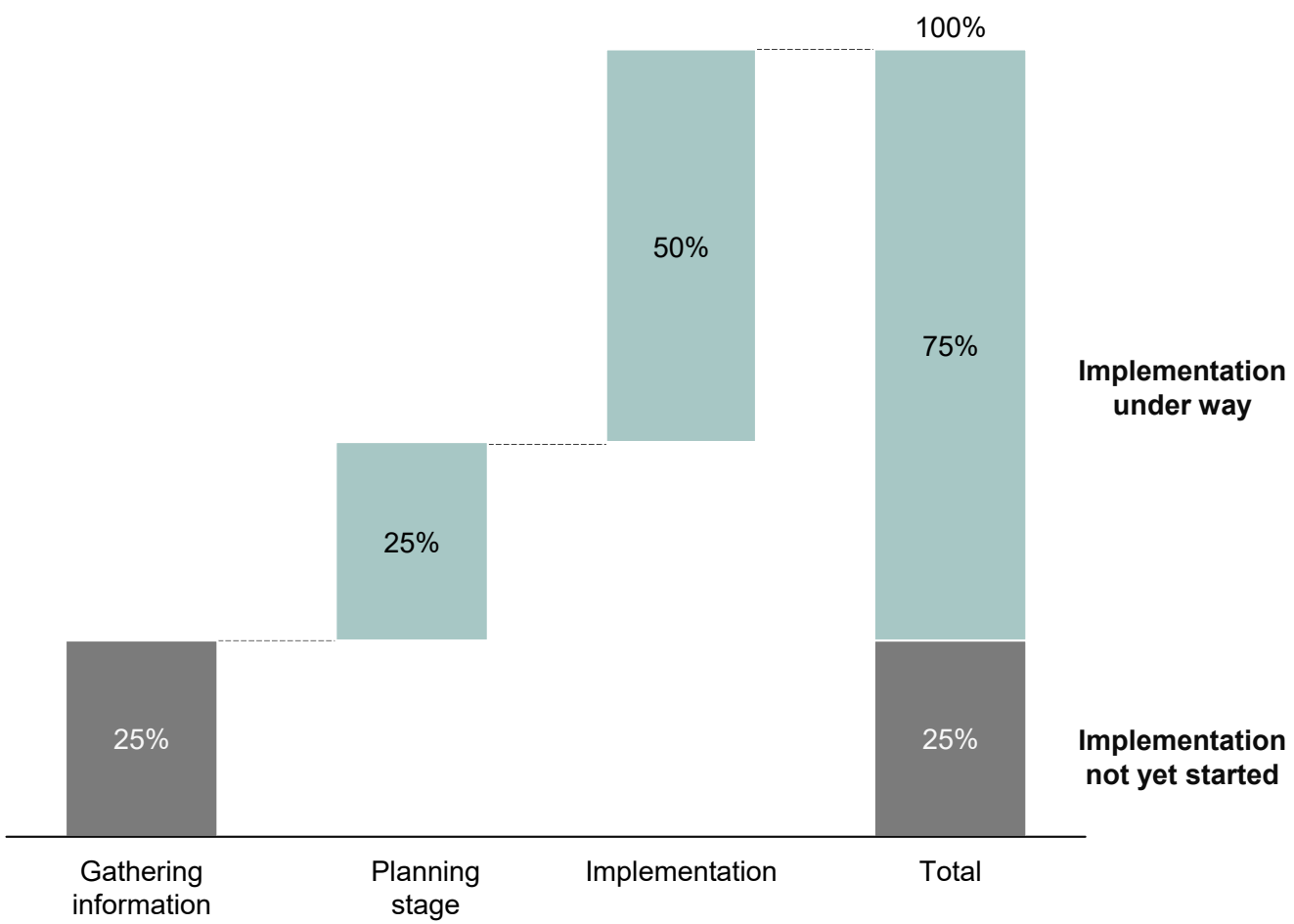
In this context, economic operators will in particular have questions concerning:

- Personnel and financial consequences
- The effect on the innovative strength of the individual companies
- The influence on product portfolios and sales markets
- How to manage the transitional phase

The participants of this year's SMTI survey were asked to assess the expected consequences in a special MDR/IVDR section of the questionnaire. In many respects, the regulatory effects were only partially known at the time of the survey, and these results should therefore be understood as the first rough estimates during an early phase of the transitional period.

¾ of companies have started implementing MDR/IVDR

Status of MDR/IVDR implementation
(% of all reponses; all categories)



n = 223

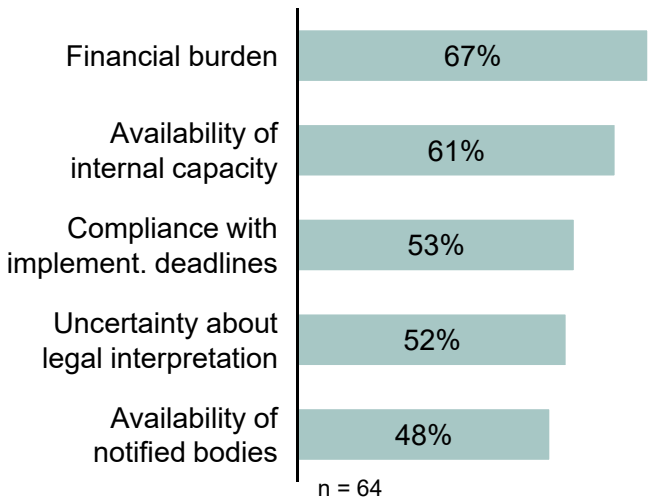
Source: SMTI survey results 2018

Comments

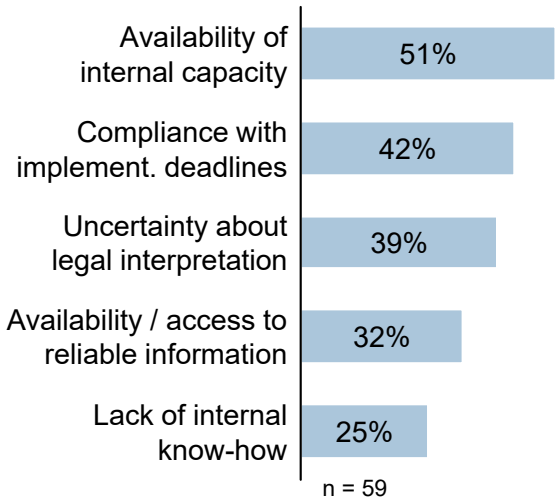
- 75% of the companies are actively implementing the MDR/IVDR specifications (planning, implementation)
- 25% of the companies surveyed are still in the information gathering phase
- In cross-comparison, manufacturers have made the most progress with implementation to-date

One major difficulty related to the implementation of MDR/IVDR is the lack of internal capacity

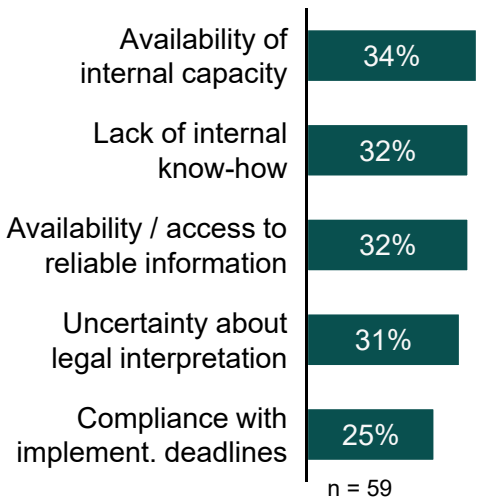
Manufacturers top 5 difficulties
(% of all reponses)



Trade & distribution top 5 difficulties
(% of all reponses)



Suppliers top 5 difficulties
(% of all reponses)



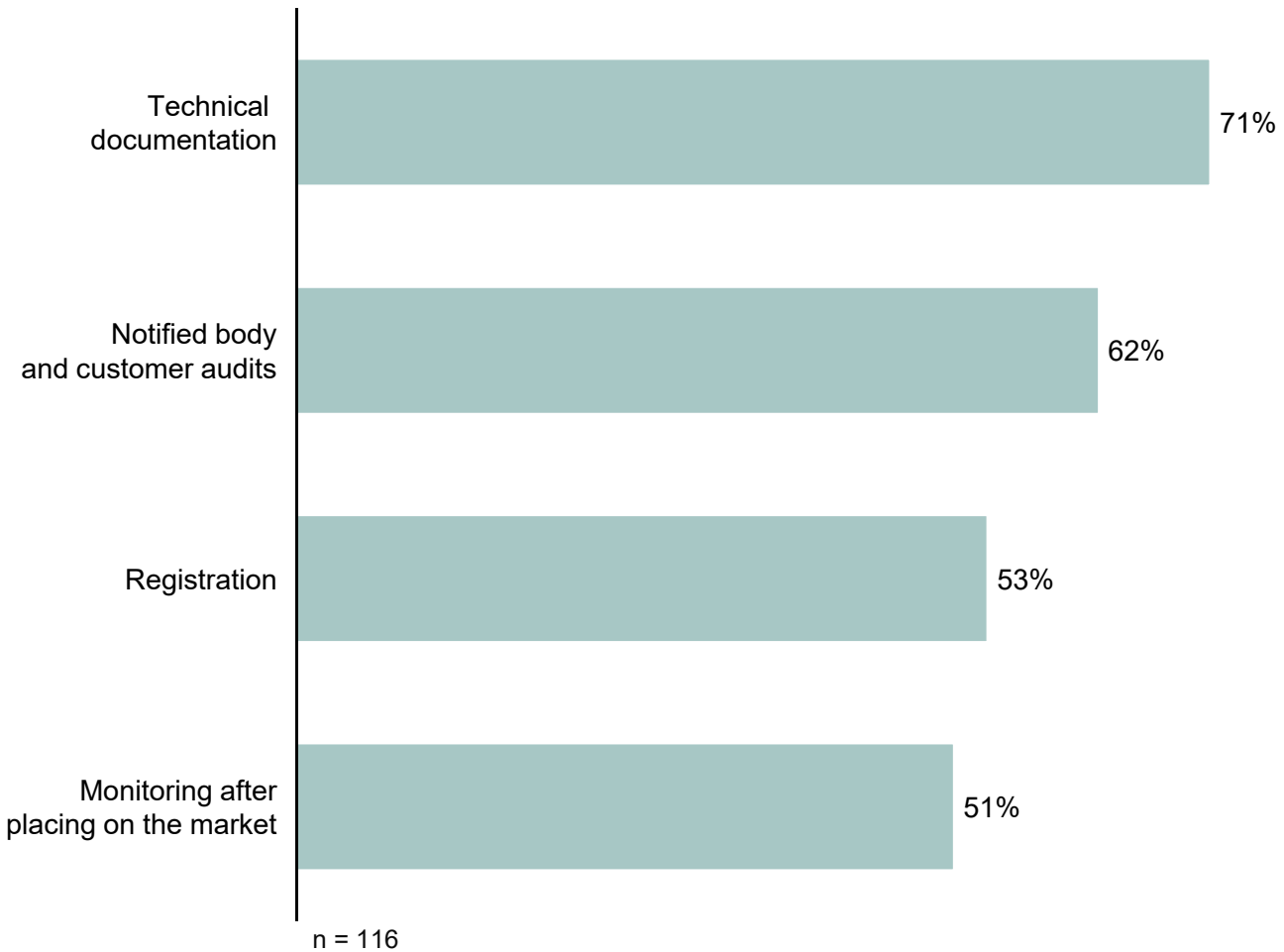
Comments

- Medtech companies cite the additionally required internal capacities for the implementation of the MDR/IVDR as the the greatest difficulty
- Manufacturers see the financial burden as the biggest challenge
- The significant changes in the new regulations lead to uncertainties in legal interpretation and the appropriate implementation
- Foreseeable difficulties include the timely implementation of the MDR/IVDR and the availability of reliable information

Source: SMTI survey results 2018

The introduction of MDR/IVDR is primarily expected to increase overhead costs for technical documentation and audits

Additional expenses for distributers
(% of all reponses; manufacturers and trade & distribution)



Comments

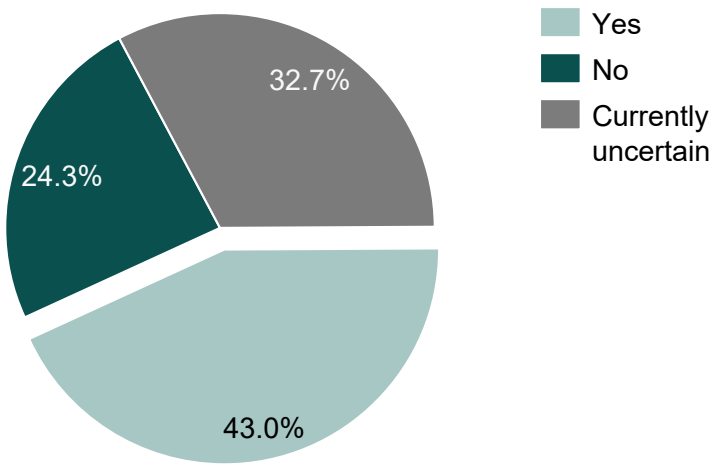
- With the introduction of the MDR/IVDR, most manufacturers and trade & distribution actors expect additional work for the required technical documentation as well as for audits by notified bodies and clients
- Manufacturers estimate the additional effort to be much higher than those involved in trade & distribution

Source: SMTI survey results 2018

Introduction of MDR/IVDR: Increasing human resources and reduction of product portfolios

Increase in personnel

(# of responses in %; all categories)



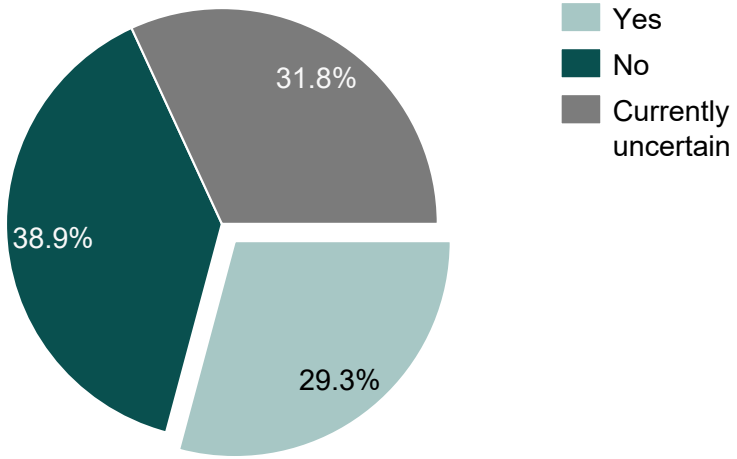
n = 272

Comments

- 43% of companies expect a need to increase human resources due to new regulations MDR/IVDR
- ¼ of medtech companies expect to manage the changeover without additional personnel
- See page 51 of the Appendix for further analysis

Reduction of product portfolio

(# of responses in %; manufacturers, suppliers, trade & distribution)



n = 198

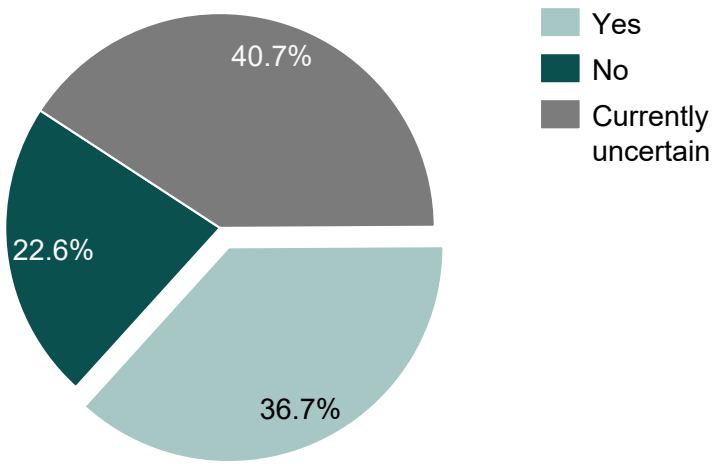
Comments

- Approximately 40% currently plan to maintain the entire product portfolio
- About 30% of the companies are sure they must reduce the product portfolio
- See page 51 of the Appendix for further analysis

Source: SMTI survey results 2018

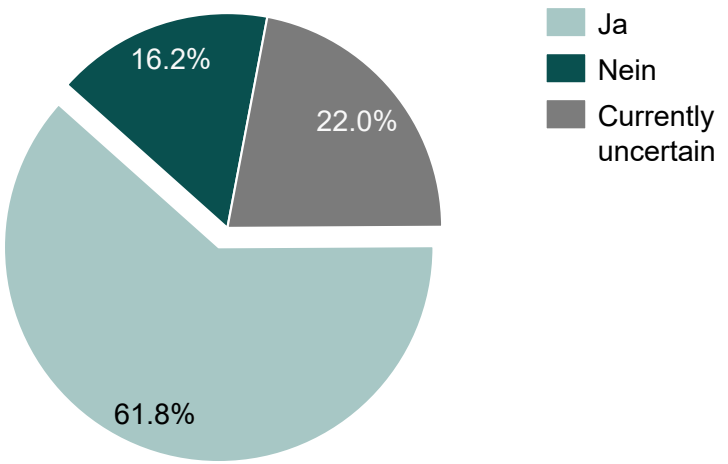
Introduction of MDR/IVDR: Increasing product and development costs

Increase in cost of products
(# of responses in %; manufacturers, suppliers, trade & distribution)



n = 199

Increase in development costs
(# of responses in %; manufacturers)



n = 68

Comments

- 37% of companies expect higher product costs due to the implementation of MDR/IVDR
- 40% were unable to estimate changes in product costs at the time of the survey
- See page 52 of the appendix for further analysis

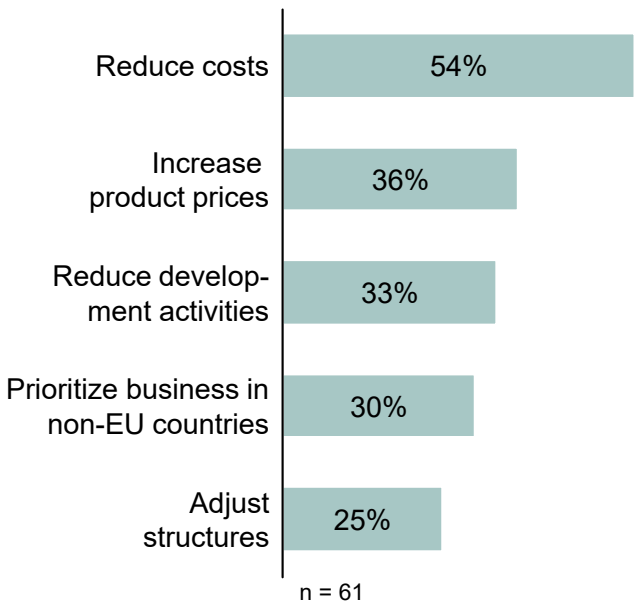
Comments

- The majority of manufacturers (62%) assume that MDR/IVDR will increase development costs
- Only 16% of the manufacturers expect no changes in development costs
- See page 52 of the appendix for further analysis

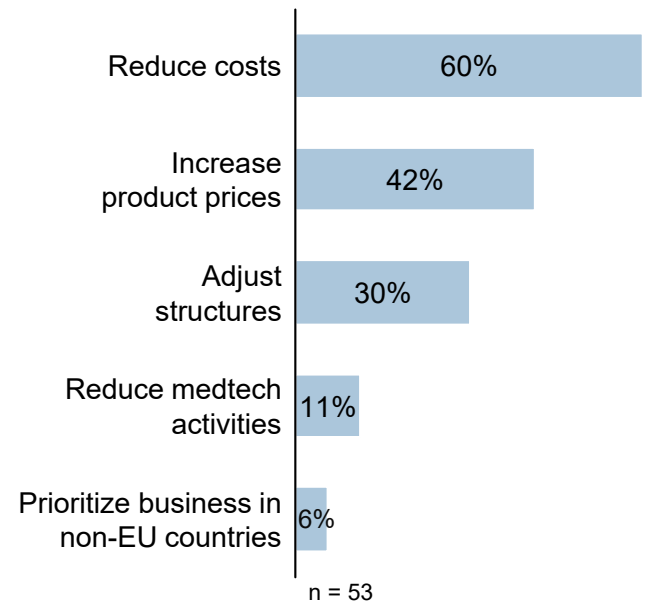
Source: SMTI survey results 2018

The main priorities for action are cost reduction measures and price increases

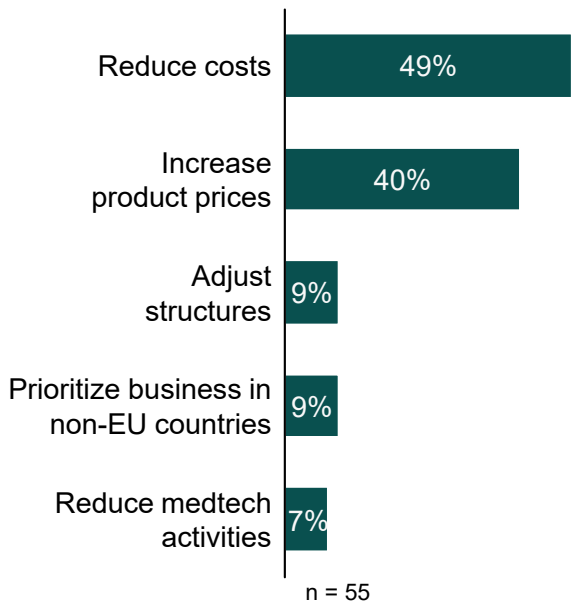
Top 5 priorities for action manufacturers
(% of all reponses)



Top 5 priorities for action trade & distribution
(% of all reponses)



Top 5 priorities for action suppliers
(% of all reponses)



Comments

- Cost reduction measures and price increases for products are the primary priorities for action
- Structural measures and focusing business activities on non-EU countries are also being considered
- Another priority for action for manufacturers is to focus on innovation and development activities

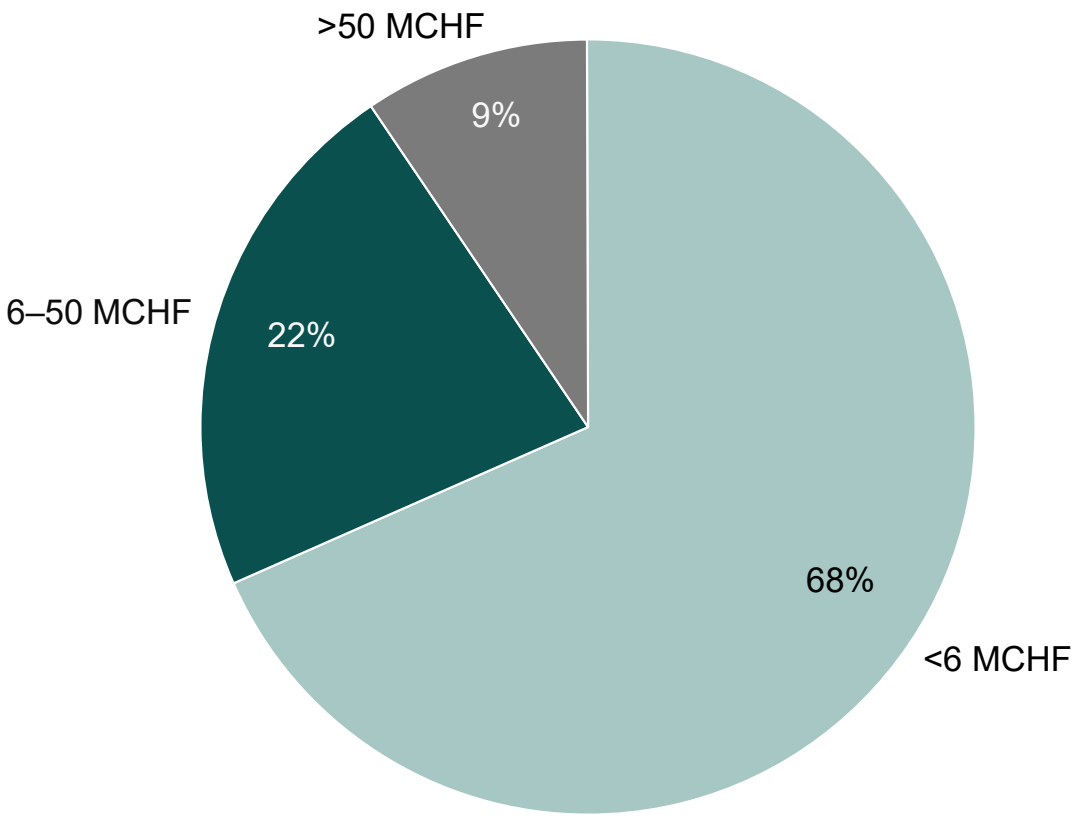
Note: multiple responses possible
Source: SMTI survey results 2018

Appendix

- Further analysis
- Methods
- Partners and authors
- Abbreviations

More than 2/3 of companies surveyed report sales lower than 6 million CHF in 2017

Companies surveyed – according to turnover of medtech products and services manufactured in Switzerland in 2017
(in %)

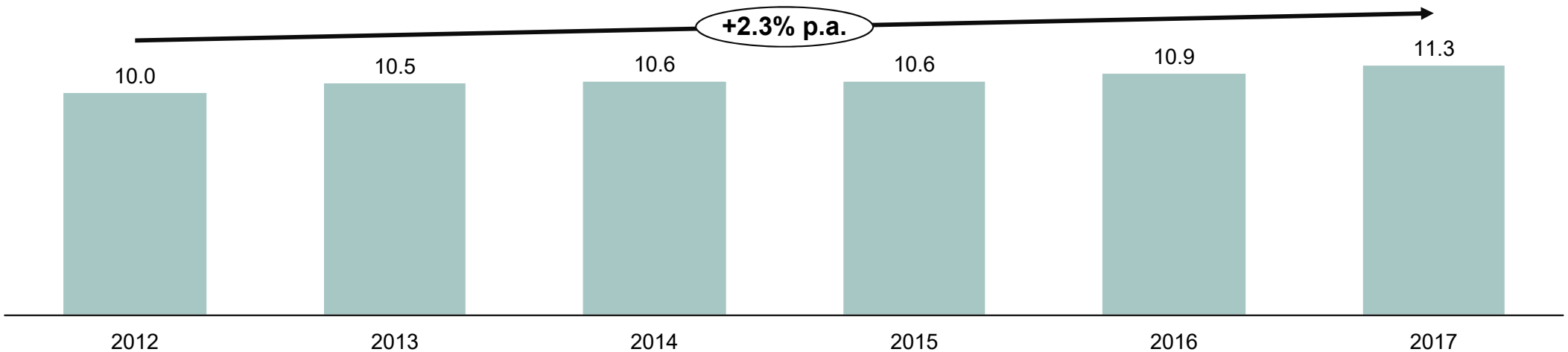


n = 358

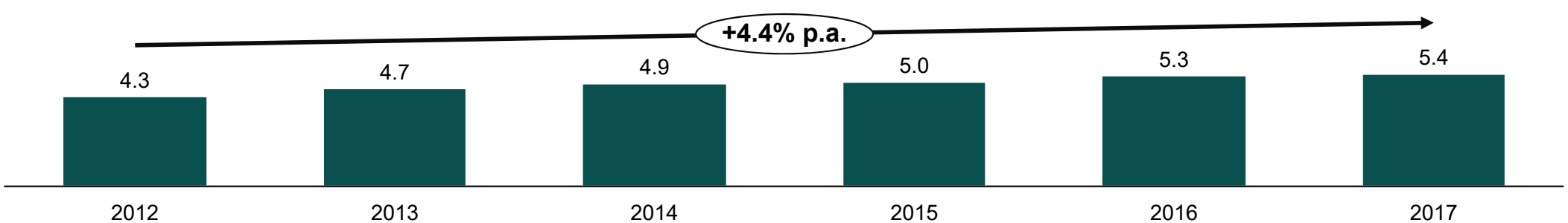
Source: SMTI survey results 2018

Swiss medtech industry import and export performance

Swiss medtech industry export trends (in billion CHF)



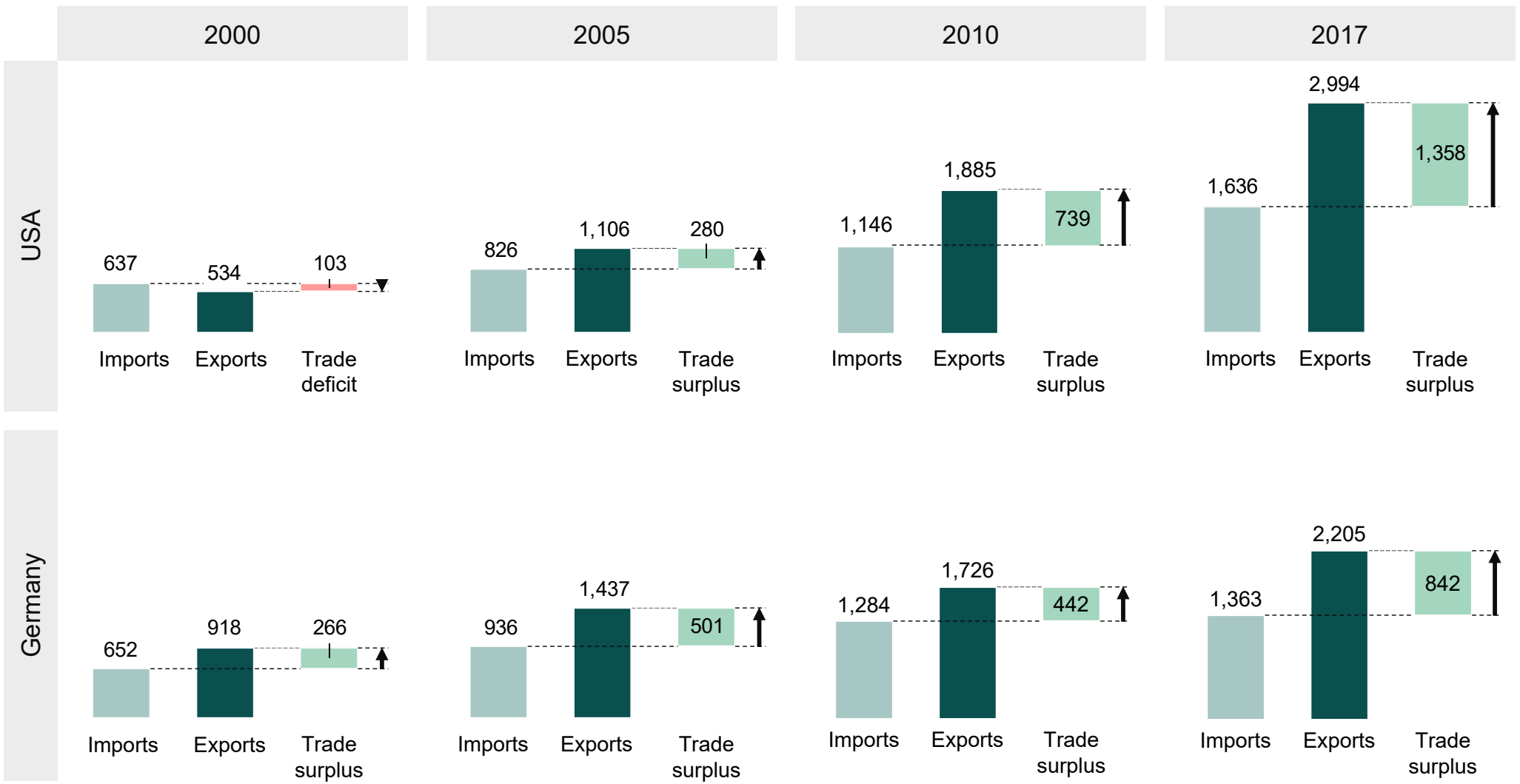
Swiss medtech industry import trends (in billion CHF)



Note: Trade figures (exports & imports) reflect finished products only; trade/sales of semi-finished products are not included
Source: Swiss Federal Customs (FCA)

Overview trade surplus: USA and Germany

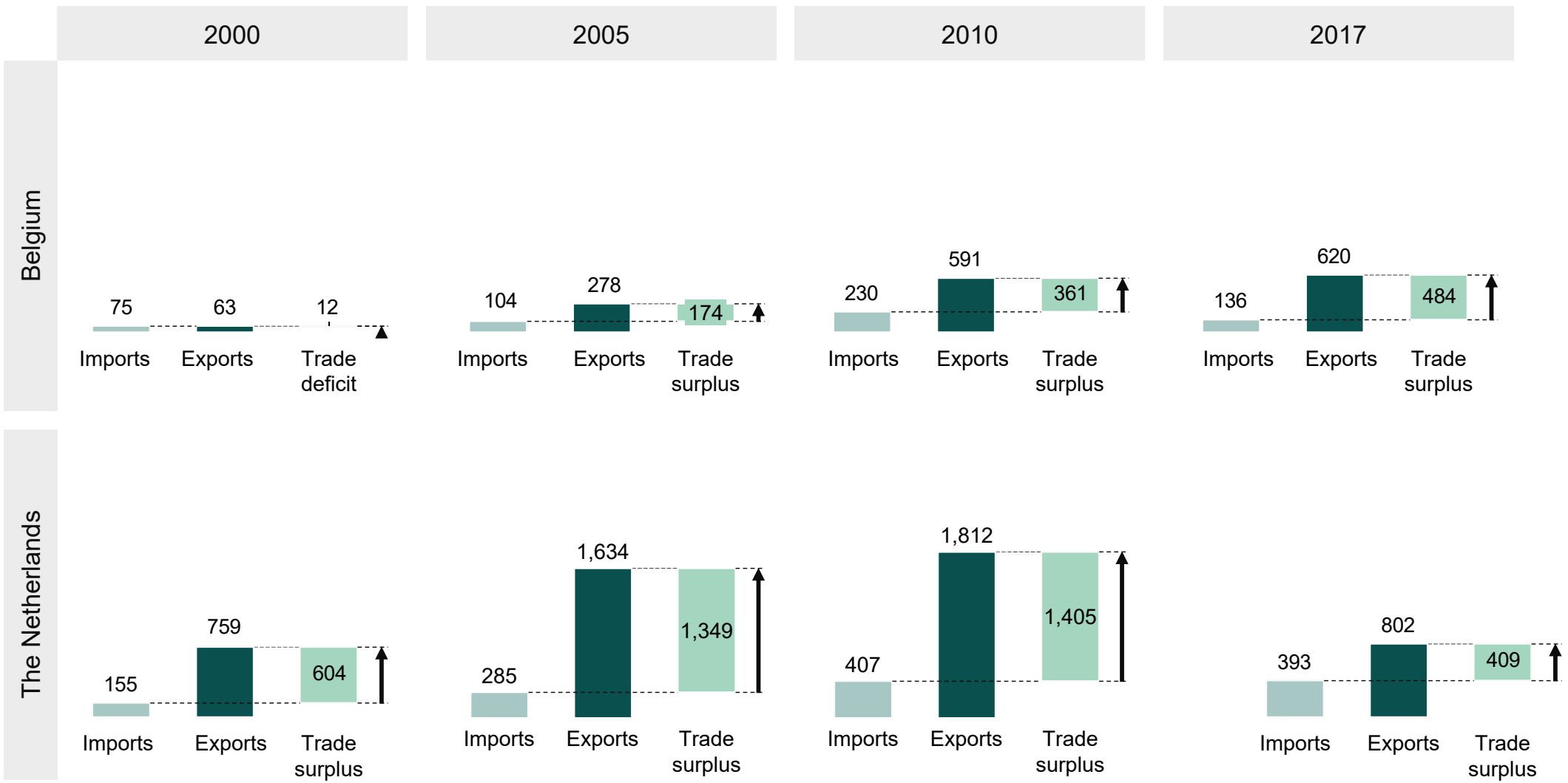
Key figures for USA and Germany from Switzerland's perspective (in million CHF)



Note: Trade figures (exports & imports) reflect finished products only; trade/sales of semi-finished products are not included
Source: Swiss Federal Customs (FCA)

Overview trade surplus: Belgium and the Netherlands

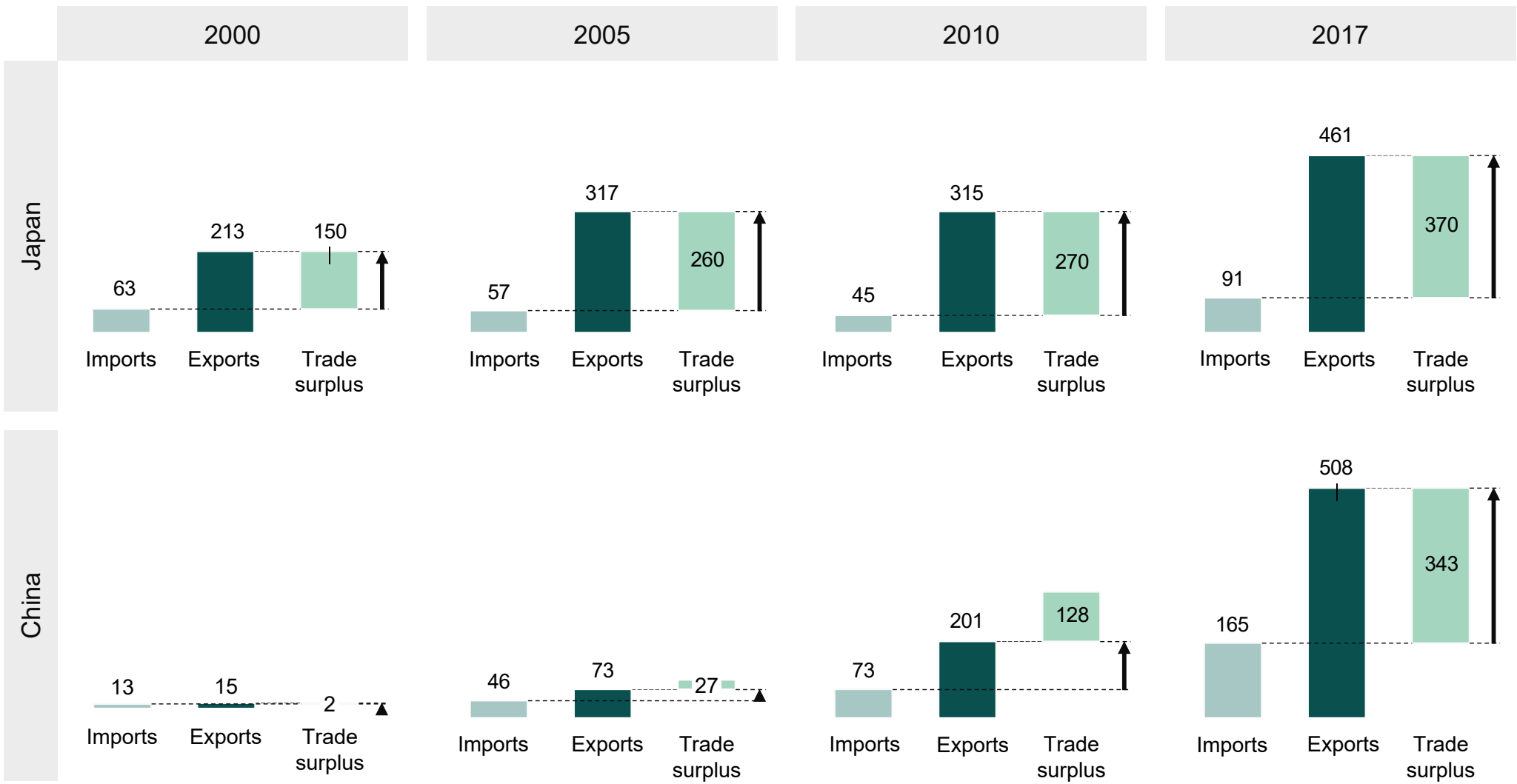
Key figures for Belgium and the Netherlands from Switzerland's perspective (in million CHF)



Note: European central warehouses in The Netherlands have lost importance for individual global players
Trade figures (exports & imports) reflect finished products only; trade/sales of semi-finished products are not included
Source: Swiss Federal Customs (FCA)

Overview trade surplus: Japan and China

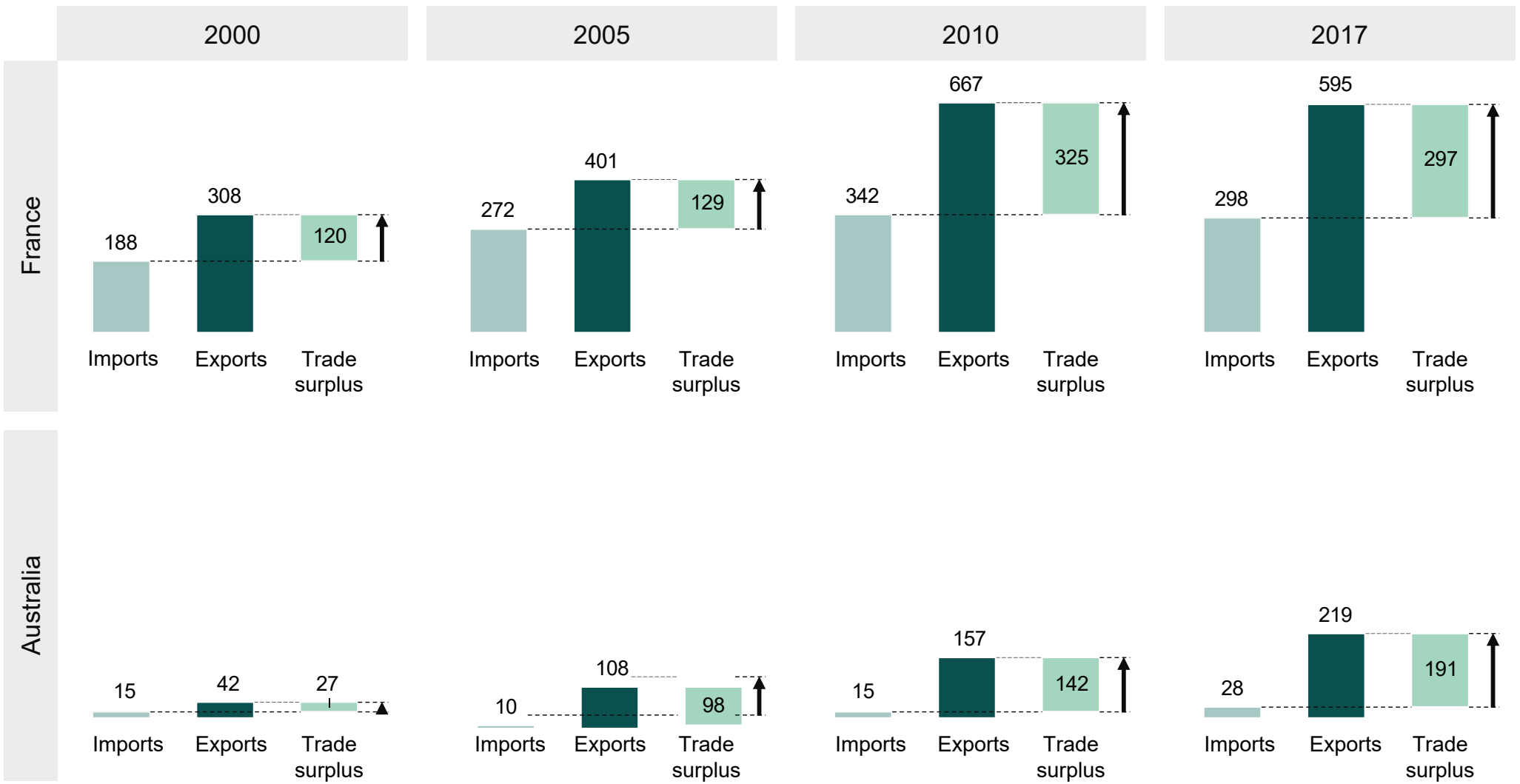
Key figures for Japan and China from Switzerland's perspective (in million CHF)



Note: Trade figures (exports & imports) reflect finished products only; trade/sales of semi-finished products are not included
Source: Swiss Federal Customs (FCA)

Overview trade surplus: France and Australia

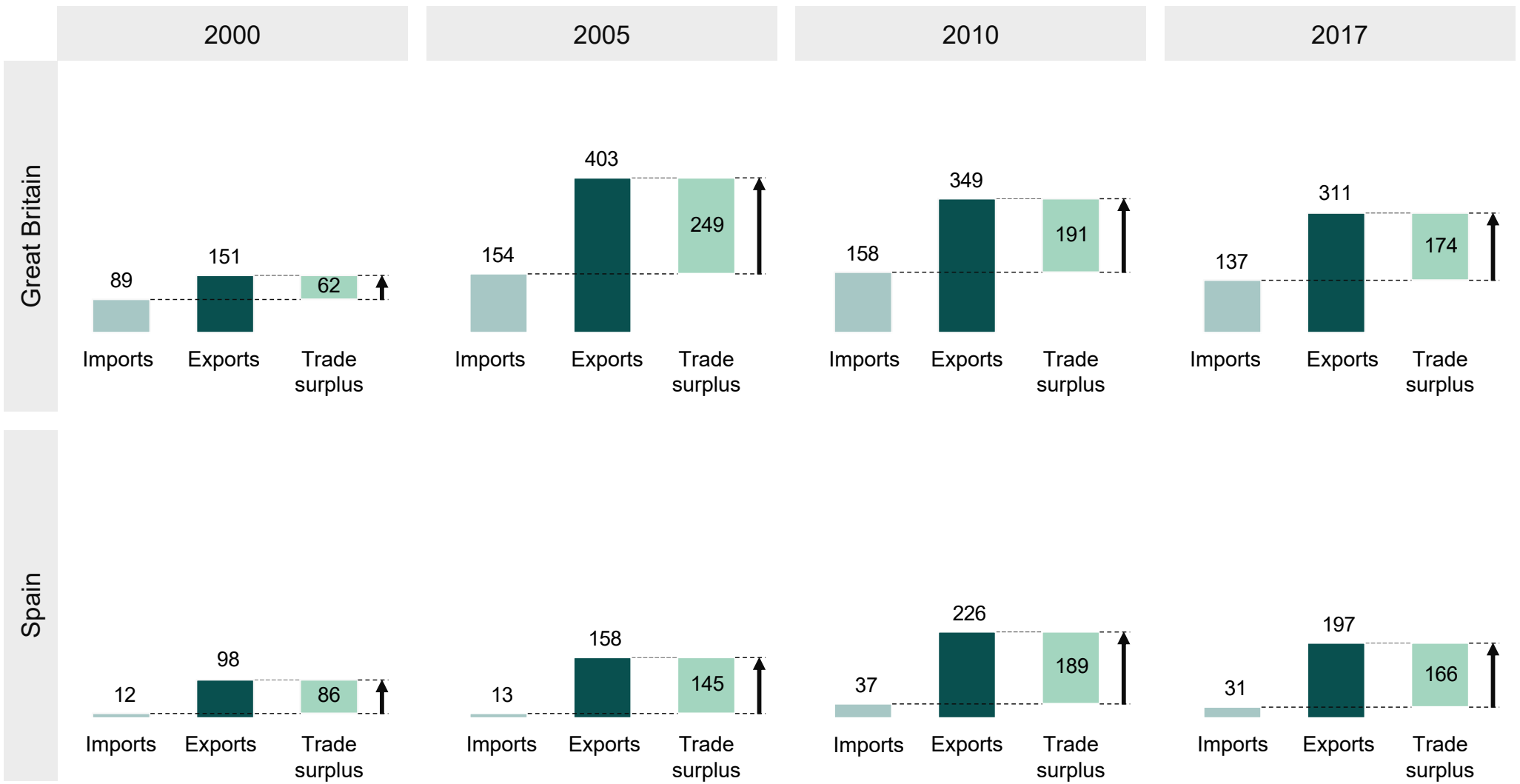
Key figures for France and Australia from Switzerland's perspective (in million CHF)



Note: Trade figures (exports & imports) reflect finished products only; trade/sales of semi-finished products are not included
Source: Swiss Federal Customs (FCA)

Overview trade surplus: Great Britain and Spain

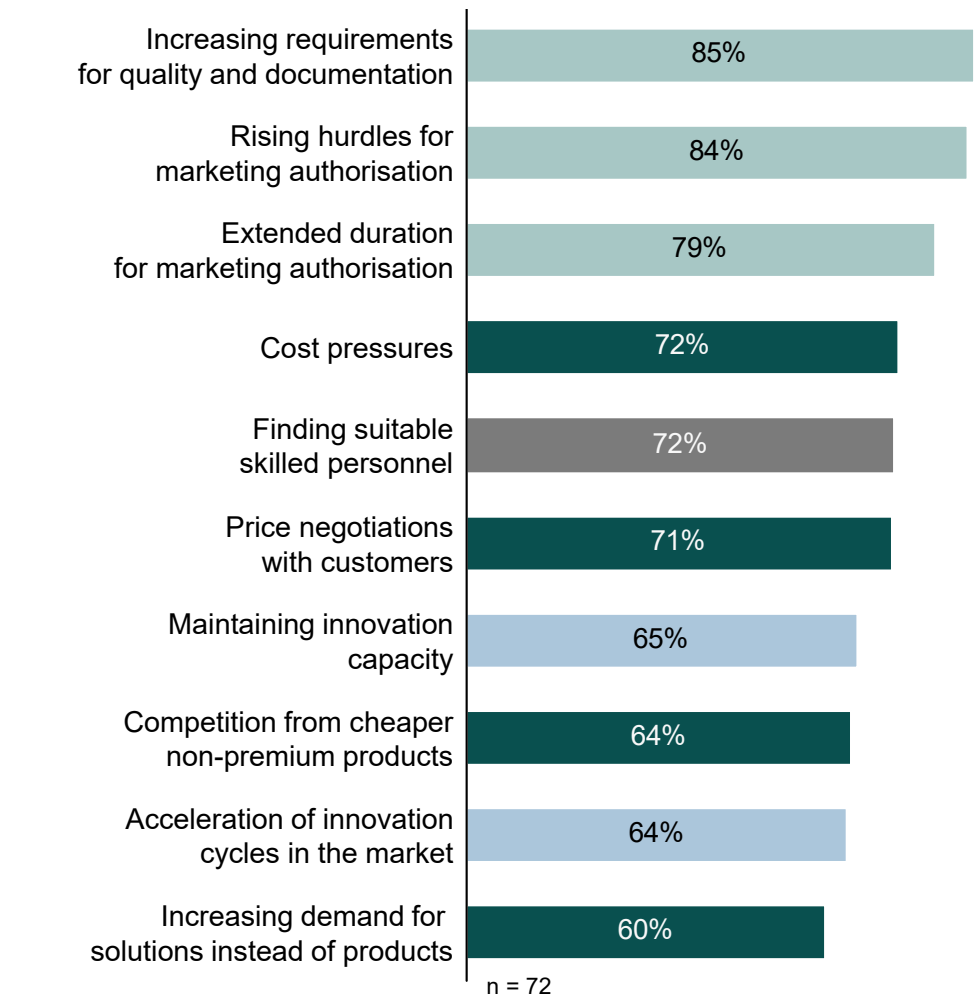
Key figures for Great Britain and Spain from Switzerland's perspective (in million CHF)



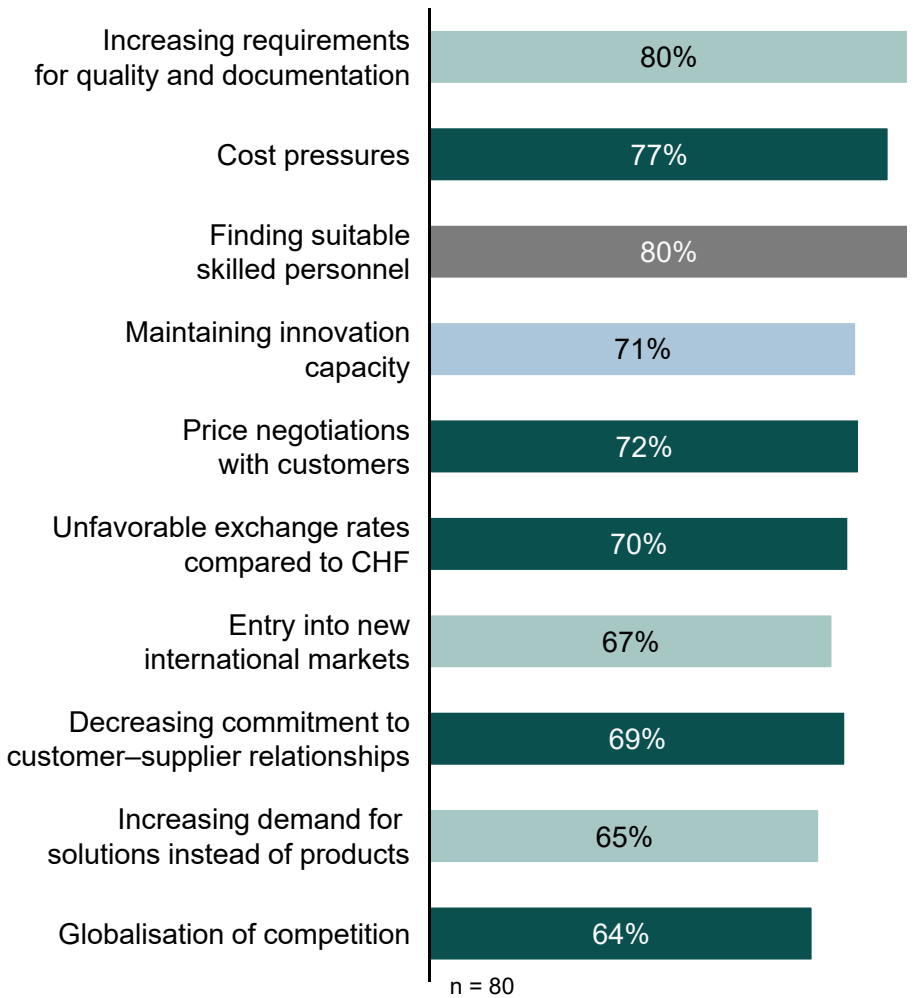
Note: Trade figures (exports & imports) reflect finished products only; trade/sales of semi-finished products are not included
Source: Swiss Federal Customs (FCA)

Top 10 challenges for manufacturers and suppliers

Top 10 challenges for manufacturers
(% of all responses)



Top 10 challenges for suppliers
(% of all responses)

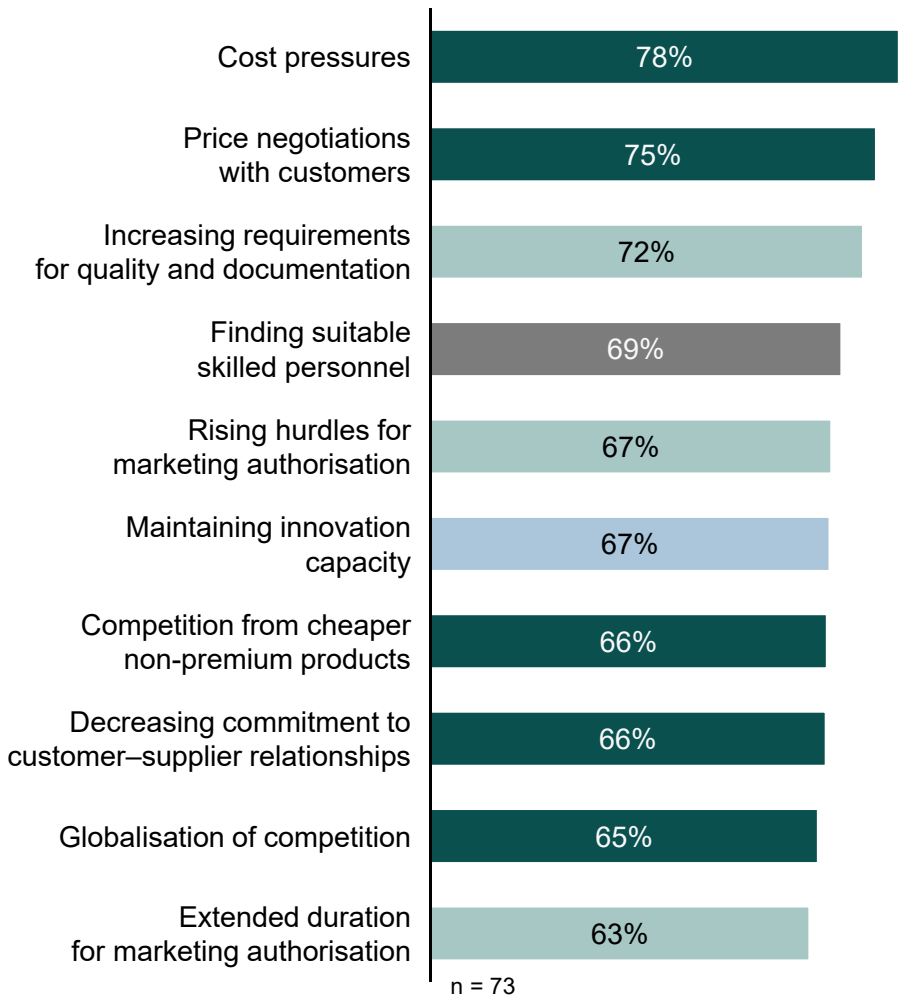


Market access | Market conditions & competition | Resources & know-how | Innovation

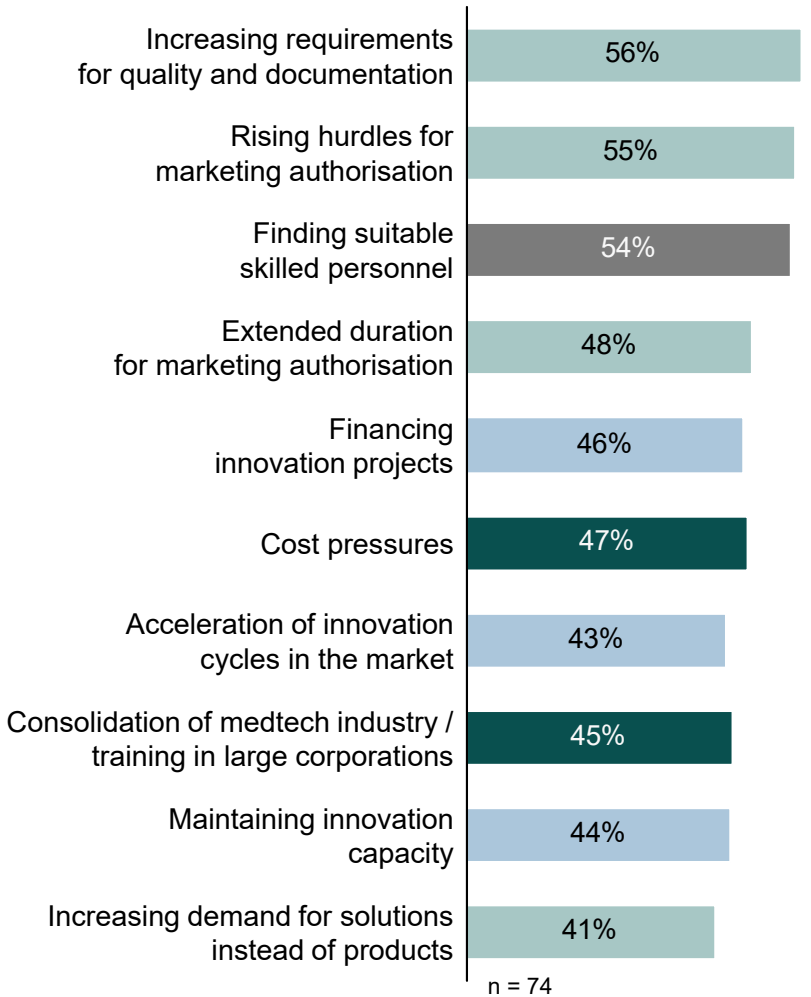
Source: SMTI survey results 2018

Top 10 challenges for trade & distribution and service providers

Top 10 challenges for trade & distribution
(% of all responses)



Top 10 challenges for service providers
(% of all responses)

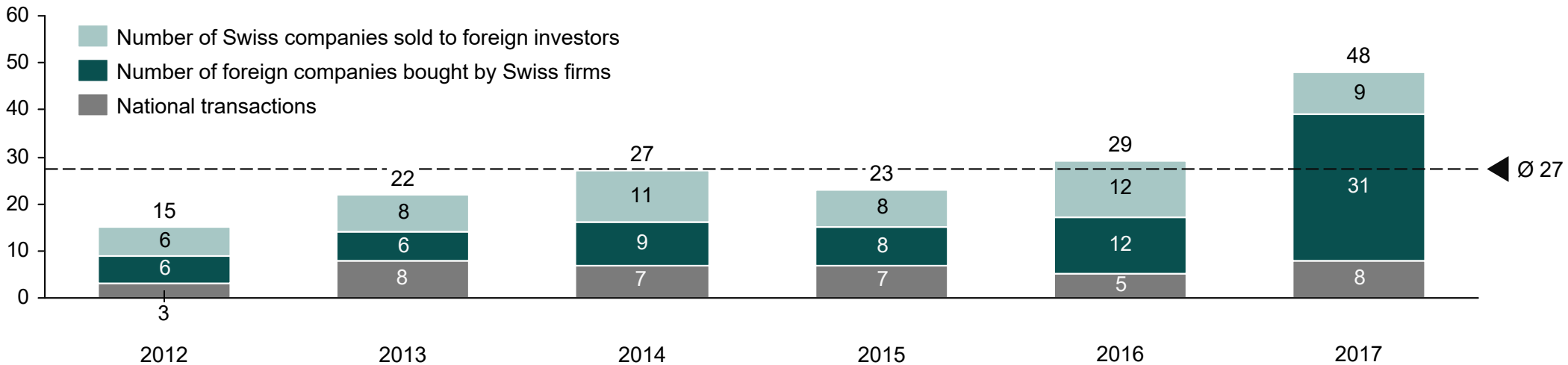


Market access | Marktet conditions & competition | Resources & know-how | Innovation

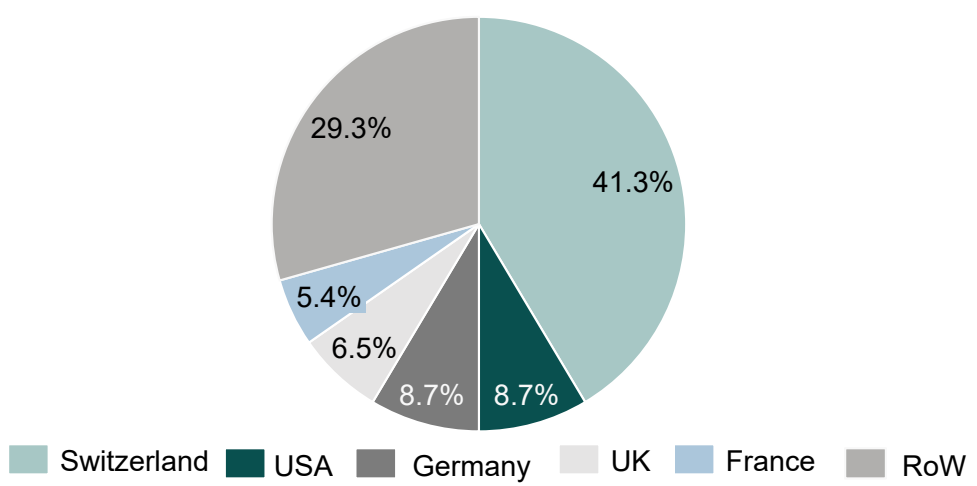
Source: SMTI survey results 2018

M&A ventures in the Swiss Medtech Industry and related fields

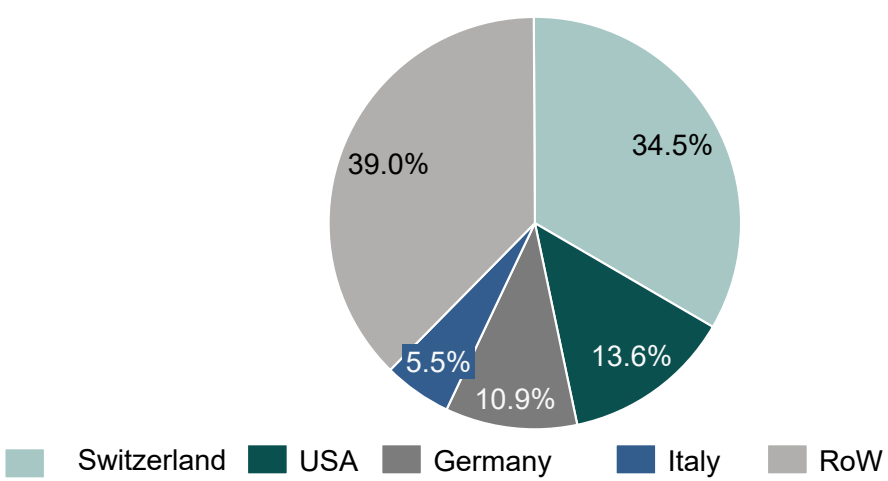
of deals involving Swiss medtech companies



Purchasing country 2010–2017



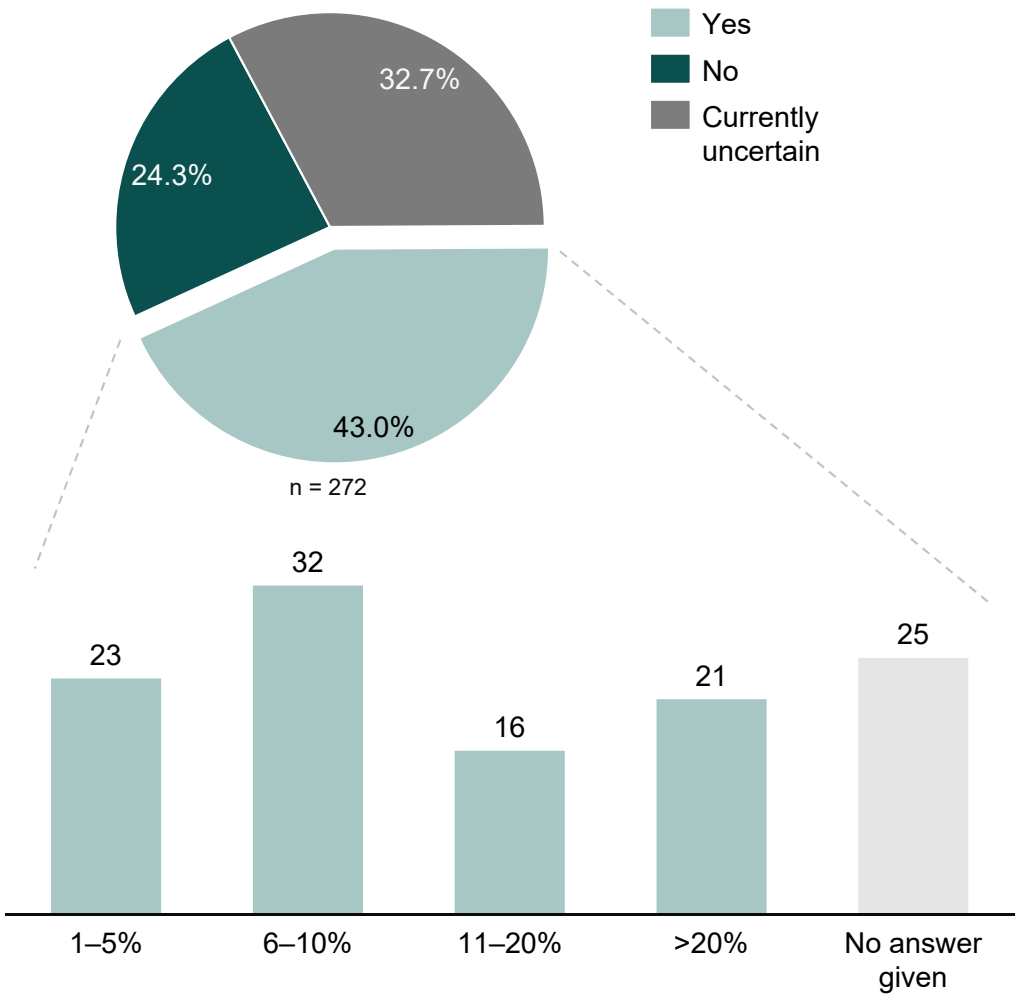
Target country 2010–2017



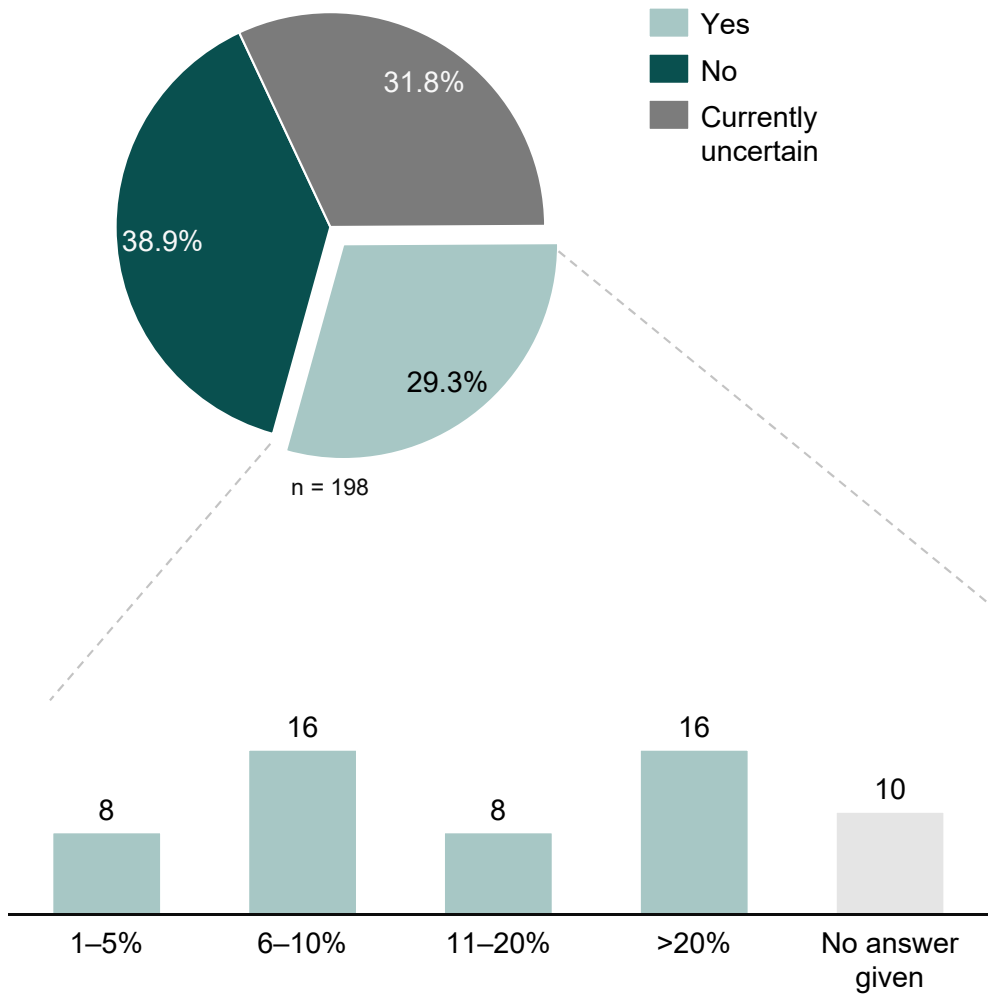
Note: M&A deals in "medical" segments
Source: Mergermarket 2018

MDR/IVDR: Details regarding increases in human resources and reduction of product portfolios

Increases in human resources
(# of responses in %; all categories)



Reduction of product portfolios
(# of responses in %; manufacturers, suppliers, trade & distribution)

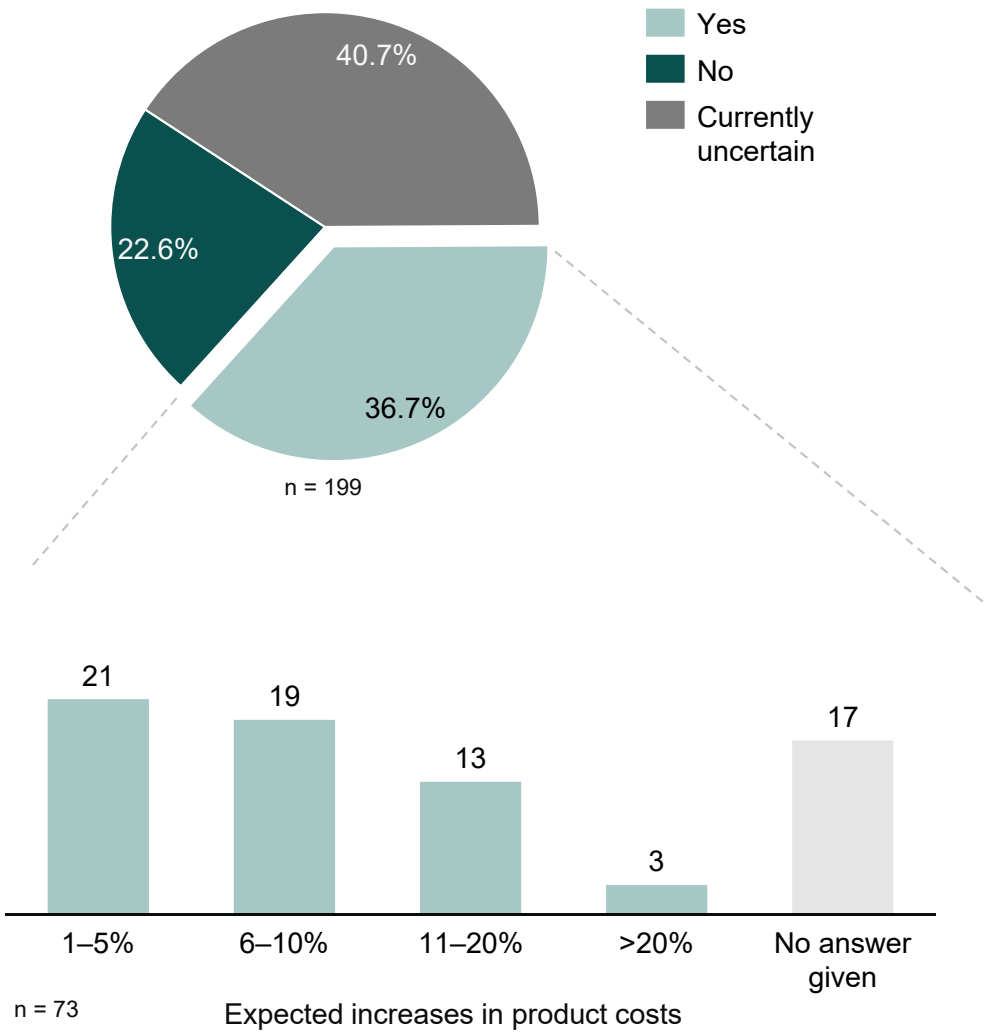


Source: SMTI survey results 2018

MDR/IVDR: Details regarding increases in product and development costs

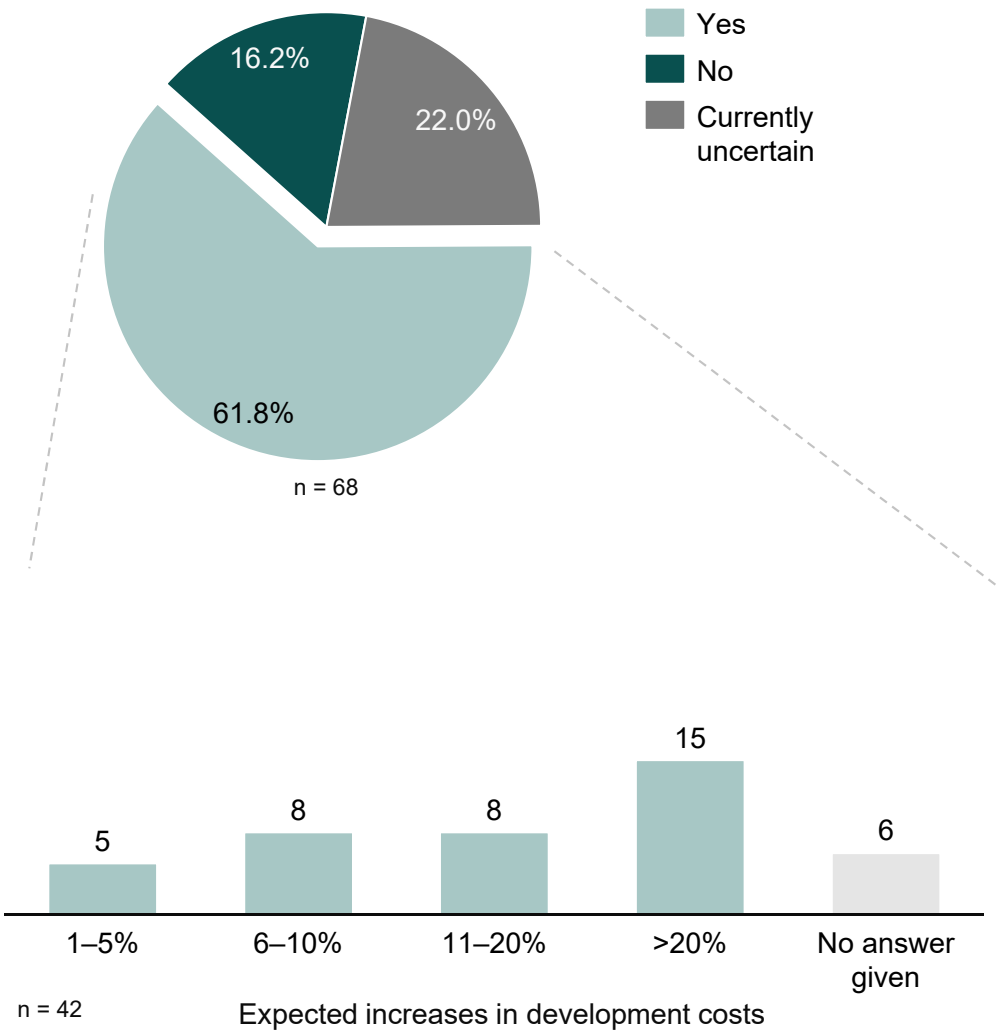
Increases of product costs

(# of responses in %; manufacturers, suppliers, trade & distribution)



Increases in development costs

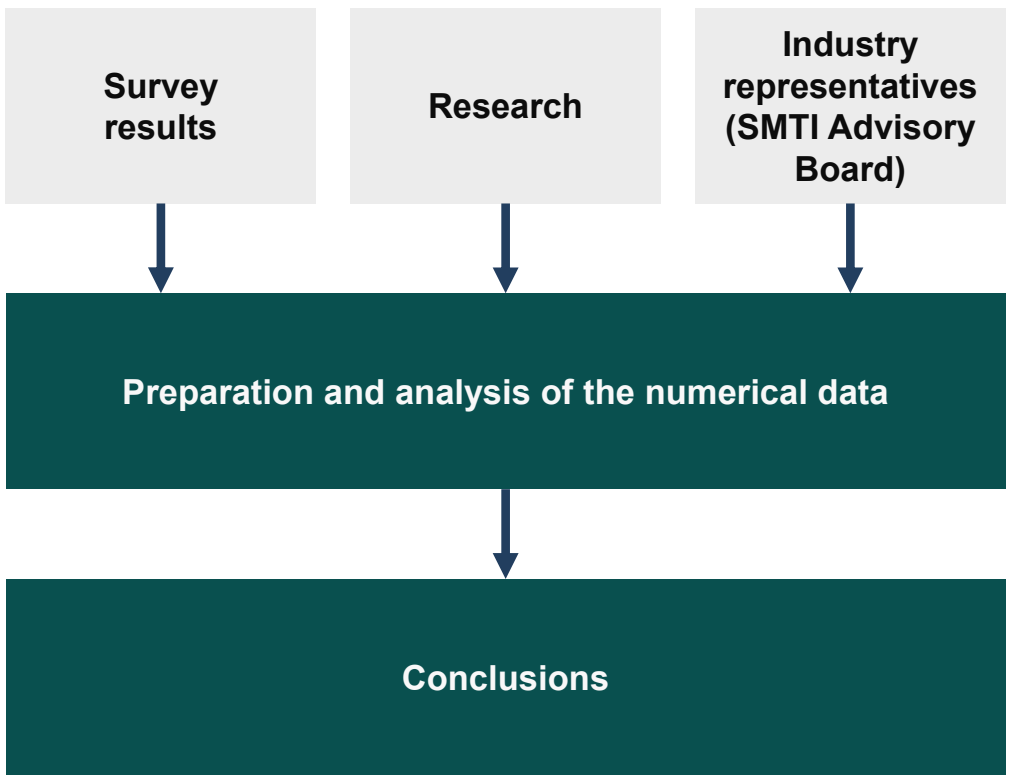
(# of responses in %; manufacturers)



Source: SMTI survey results 2018

Three main sources were used for this study

Basic methodology of the SMTI 2018 Sector Study

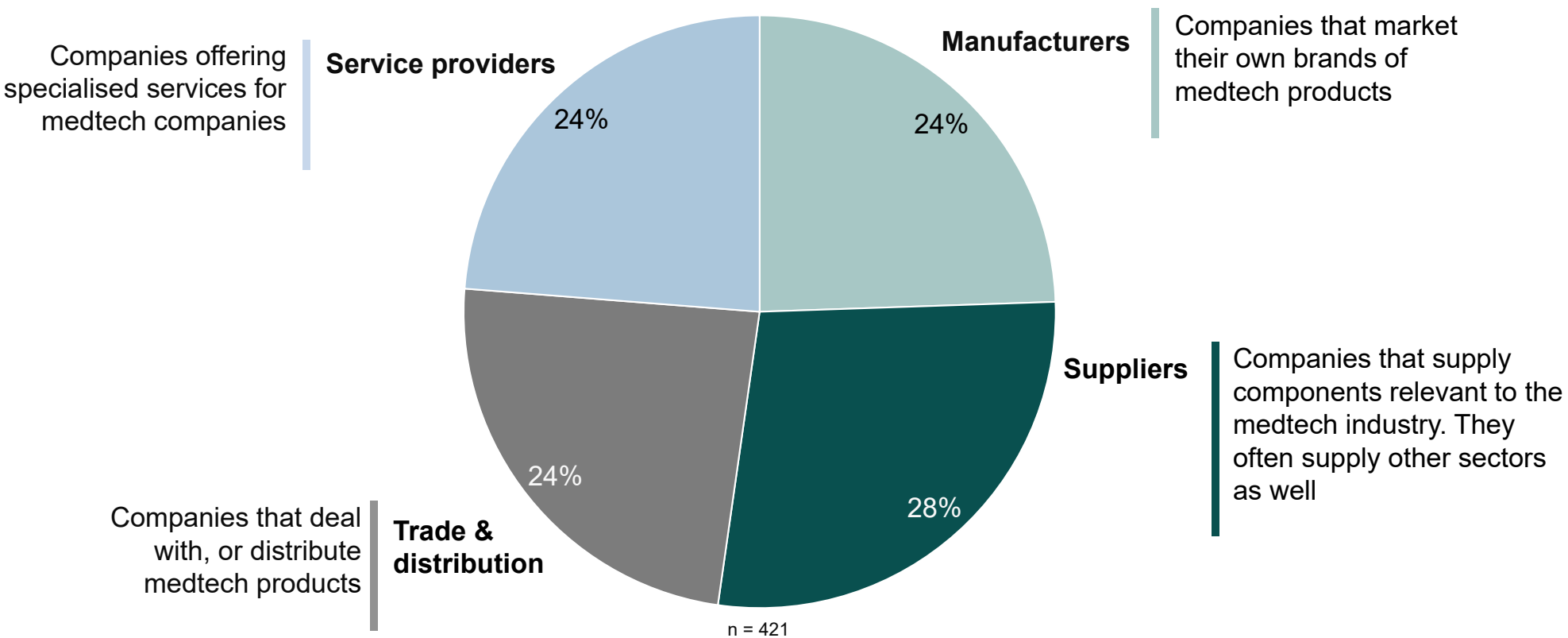


Methods

- The survey was conducted in the spring of 2018
- The SMTI study is based on three main sources:
  - Evaluation of an electronic survey, which was fully or partially completed by 421 medtech companies operating in Switzerland.
  - Research based on information from the Swiss Medtech database, earlier SMTI studies, public databases, and other sources
  - Information and opinions from industry representatives
- The information from the three sources was combined, compared, discussed, analyzed, and commented. The key figures were extrapolated for the SMTI
- The resulting conclusions were discussed and validated, together with the advisory board and other external experts

421 Medtech companies took part in the SMTI 2018 survey

Participating companies according to category (in %)



Source: SMTI survey results 2018

Explanation of medtech segments (I/IV)

Hospital equipment and consumables

- This area covers investment goods which are used in hospitals, practices and assisted living facilities or, under medical supervision, for private home use
- Also included in this area are single-use consumables

Rehabilitation, prothetics, orthetics and daily living aids

- Products used in rehabilitation help people who are impaired in their movement, and greatly facilitate the work of caregivers
- Robotic and sensor-based devices are used to re-learn functions in functional movement therapy
- Prosthetic products are not implanted but replace lost parts of the body externally
- Orthotics correct, support or relieve body parts with stabilising orthoses

In vitro diagnostics and laboratory equipment

- Products for in-vitro diagnostics are used to examine samples derived from the human body. They provide information on physiological and pathological conditions, congenital anomalies, for the review of tolerability and monitoring of therapies

Explanation of medtech segments (II/IV)

Orthopaedics

- Products used in orthopaedics support the treatment of malformations, diseases, wear and tear, or fractures/ ruptures of the musculoskeletal system
- Other products are designed to aid reconstruction. Osteosynthesis products, on the other hand, are used to treat bone fractures, caused in most cases through accidental damage to the musculoskeletal system

Dental care

- These products support the prevention, detection and treatment (including surgery) of diseases as well as the misalignment of teeth, the mouth or jaw region

Imaging techniques and radiotherapy

- Imaging technique equipment includes various apparatus examination devices that supply 2D, 3D or 4D image data of patients' organs and structures, and are primarily used for the diagnosis and treatment of disease-related changes. They also provide a visual presentation of a medical finding
- Radiation therapy products generate ionizing radiation; mainly to cure or delay tumor-related diseases. The ionizing radiation comes from radiation-generating devices or from radioactive preparations. The main types of ionizing radiation used are X-rays, electron beams, gamma rays, protons, heavy ions or neutrons

Explanation of medtech segments (III/IV)

Cardiology

- Cardiology products support the diagnosis and treatment of the heart and the whole bloodstream, including any surgical treatment

Ophthalmology

- Products and instruments in ophthalmology are used for the diagnosis and treatment (including operations) of diseases and dysfunctions of the visual organ, its appendages and sight

Drug delivery systems and diabetes treatment

- This area includes products used for the administration of medicine and the monitoring and treatment of chronic diseases such as diabetes

Explanation of medtech segments (IV/IV)

Wound treatment

- Wound treatment products are used to assess, cleanse and care for wounds, and promote the healing process

Ears/nose/throat

- Products in this category are used for the diagnosis and treatment of diseases, injuries, malformations and dysfunctions of the hearing, the nose and mouth, the throat, the larynx and the esophagus

e/m-health and software

- e-health includes ICT-based applications such as e-health, telemedicine, in which information is electronically processed, exchanged and used to support patient care and care processes
- Mobile (m) health applications provide e-health solutions on mobile devices. They support the diagnosis, prevention and treatment as well as the monitoring of diseases through smartphones, tablets and health applications (including software)

This is the 6th report on the Swiss medtech industry

	2008	2010	2012	2014	2016	2018
Title	The Swiss Medical Technology Industry 2008	The Swiss Medical Technology Industry 2010 Survey "Medtech at the Crossroads"	The Swiss Medical Technology Industry 2012 "In The Wake Of The Storm"	The Swiss Medical Technology Industry 2014 "The Dawn of a New Era"	The Swiss Medical Technology Industry 2016 – Sector Study	The Swiss Medical Technology Industry 2018 – Sector Study
Authors	▪ Dr. Patrick Dümmler ▪ Beatus Hofrichter ▪ René Willhalm ▪ Peter Biedermann	▪ Dr. Patrick Dümmler ▪ Beatus Hofrichter	▪ Dr. Patrick Dümmler ▪ Beatus Hofrichter	▪ Dr. Patrick Dümmler ▪ Beatus Hofrichter	▪ Laura Murer Mecattaf ▪ Jonas Frey ▪ Annebelle Smolders ▪ Peter Biedermann	▪ Laura Murer Mecattaf ▪ Jonas Frey ▪ Tobias Pieper ▪ Peter Biedermann
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Partner Profiles I/II

Swiss Medtech

The Swiss Medtech association represents and promotes the interests of the approximately 1,400 companies in the medical technology sector in Switzerland. The activities are divided into four strategic business areas: legal & regulatory, education, innovation, communication & representation.

Swiss Medtech advocates for the following objectives:

- Preservation and promotion of Switzerland as a workplace including attractive conditions, strong research institutions, continuing education programmes, symposia, export promotion services, and supportive measures for entrepreneurship;
- Preservation and strengthening of the domestic market through quality-oriented health care with fair reimbursement rates and progressive financing for innovation

Swiss Medtech advises and supports its approximately 560 members in legal, regulatory and tariff matters. The Swiss Implementation Task Force MDR/IVDR provides companies with competent assistance for the introduction of new EU regulations. At the same time, the association represents the industry on a political level within Switzerland as well as with European legislative processes.

SWISS MEDTECH

Helbling Group

Founded in 1963, the internationally active Helbling Group is owned by 32 partners and employs over 540 professionals in four divisions at sites in Switzerland, Germany, the USA, and China.

We distinguish ourselves in the market through our unique interdisciplinary range of skills in engineering and business consulting. We offer expert services in innovation, technology & product development strategy, restructuring and mergers & acquisitions, IT, real estate, as well as energy and infrastructure.

The unique combination of expertise in technological innovation and business consulting makes us as one of the few service providers able to deal with tasks from a subject-specific and project-oriented approach, as well as from an overall corporate perspective – both for strategic as well as operational projects.

Regardless of the specific tasks our customers entrust us to do, we always have one main objective in sight: to strengthen their capacity for innovation and their competitive advantage.

Our specialists consider their work complete when their client has achieved the goals of our guiding principle: “Valuable through Innovation”.

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Partner Profiles II/II

Bern Economic Development Agency

The medical technology sector in the Canton of Bern owes its success to the long tradition of precision engineering here. Today, the Canton is home to some 280 medical technology companies – manufacturers, suppliers and service providers – all of which contribute to a thriving innovation ecosystem.

The Canton's innovation promotion services boost the competitiveness of Bernese businesses. The Bern Economic Development Agency helps finance innovative, export-oriented projects, new products, and investment plans with macroeconomic significance.

The cantonal innovation promotion agency be-advanced AG acts as a central point of contact for businesses and puts them in touch with the right partners. It focuses on coaching tailored to the recipient's needs, with the emphasis on strategy, financing, organization and cooperation.

The service and research centers co-financed by the Canton of Bern – Switzerland Innovation Park Biel/Bienne, sitem-insel and EMPA Thun – enable businesses to carry out industry-related research and development. And finally, there is a range of scientific and technical infrastructure available for use by businesses in the Canton, including laboratories, clean rooms, workshops, and conference rooms, as well as demonstration centers such as the Swiss Smart Factory at SIP Biel/Bienne.

www.berninvest.be.ch

Bern Economic Development Agency

The SMTI Advisory Board provided valuable information and assessments for the SMTI Sector Study

SMTI 2018 Sector Study Advisory Board

Dr. Daniel Bühler

Managing Director

BIOTRONIK excellence for life

Dr. Gery Colombo

CEO Hocoma

Hocoma

Simon Michel

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- Dr. Christian Péclat, CEO, Helbling Group
- Peter Studer, Head Regulatory Affairs, Swiss Medtech
- Beat Lechmann, Director R&D Innovation, DePuy Synthes

Authors of the SMTI 2018 Sector Study

Laura Murer Mecattaf, lic. oec. HSG

Helbling Business Advisors AG
Hohlstrasse 614
CH-8048 Zurich

Tel.: +41 44 743 84 44
Email: info-hba@helbling.ch

- Laura Murer Mecattaf works as a senior manager in the area of strategy and organisation at Helbling Business Advisors
- She has over 10 years experience advising industrial, service, commercial, and public sectors
- Her specialty areas are strategy, organisation, performance management, marketing and sales, as well as market and industry studies
- Over the course of her consulting career she has conducted a wide range of projects and market studies for Swiss medtech companies
- She is Co-author of the SMTI Sector Study since 2016
- Laura Murer Mecattaf holds a degree from the University of St. Gallen

Jonas Frey, MSc ETH

Swiss Medtech
Schwarztorstrasse 31
CH-3007 Bern

Tel.: +41 31 330 97 71
Email: jonas.frey@swiss-medtech.ch

- Jonas Frey has been a Project Manager at Swiss Medtech since the association's founding in 2017
- He has over 8 years experience working with medtech organisations
- His specialty areas are industry reports, industry research, organising international trade fairs and seminars
- He is part of the Swiss Implementation Taskforce organisational team for MDR/IVDR and is the contact point for expert inquiries
- Jonas Frey has belonged to the core team of SMTI Sector Study since 2014
- Jonas Frey studied Human Movement Sciences at ETH Zurich with specialisation in biomechanics

Publisher of the Swiss Medtech Industry Sector Report 2018 is the industry association Swiss Medtech
Contact person: Jonas Frey; email: Jonas.frey@swiss-medtech.ch; Tel.: +41 31 330 97 71

Abbreviations

BCHF	Billion Swiss francs
ca.	circa
CH	Switzerland
CHF	Swiss francs
EPF	École Polytechnique Fédérale
e/m-health	electronic and mobile health
etc.	et cetera
ENT	Ears, nose & throat
ETH	Federal Technical University of Zurich
EU	European Union
EUR	Euro
ex.	for example
FCA	Federal Customs Administration
FSO	Federal Statistical Office
GDP	Gross Domestic Product
GER	Germany
IRL	Ireland
IVDR	Regulation on in vitro diagnostic medical devices
LATAM	Latin America
MCHF	Million Swiss francs
MDR	Regulation on medical devices
MEM	Mechanical and Electrical Engineering Industry
n	Sample size
n.a.	not available
No.	Number
Prof.	Professor
R&D	Research & Development
RoW	Rest of World
S-GE	Switzerland Global Enterprise
SECO	State Secretariat for Economic Affairs
SME	Small and medium-sized enterprises
SMTI	Swiss Medtech Industry
UDI	Unique Device Identification
UK	United Kingdom
USA	United States of America

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- This report was created in the summer of 2018 based on a survey of 421 medtech companies in Switzerland. The Swiss Medtech database, contributions from the Advisory Board and original research was also used. The statistical data represent the opinions of the participating companies at the time of the survey (March to May 2018) and may not necessarily indicate the current market situation at a later point in time.
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