ACCESS TO NOTIFIED BODIES RESEARCH AND MARKET ENGAGEMENT 2016

Completed on behalf of Scottish Enterprise

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EXECUTIVE SUMMARY

A notified body is an entity that has been accredited by a EU member state to assess whether a product to be placed on the market meets preordained European conformity standards. Notified bodies commonly undertake product certification (CE marking), factory production control certification (ISO standards) and determine product-type/class of medical devices and in vitro diagnostics on the basis of type testing.

The number of notified bodies across the globe has been reducing over the last decade and timelines for EU product introductions have been growing. The medical technology (medtech) sector in Scotland requires notified bodies to accredit their products before they can introduce them into EU markets.

Four of the five UK notified bodies and six Scottish companies (four SMEs and two large companies) were consulted in undertaking this work.

Notified Body Insights

Notified bodies face a number of challenges:

- The retention and recruitment of auditors
- Dealing with changes in membership within the EU
- Coping with the changes and complexity of EU directives
    - In 2013 the EU Commission introduced measures to ensure stricter enforcement of the regulations across Europe. This update has been prompted by industry events that provoked product recall, endangered patient safety and had highlighted that the directives were falling behind industrial development. New European Medical Device Directives have now been drafted, pending full approval in late 2016. It is expected that this will have a large impact on the industry and this is discussed in detail.

Notified bodies undertake the following activities:

- CE marking and ISO accreditation
- Scheduled company audits
- Unannounced company audits
- Dealing with alterations to products
- Monitoring and reporting faults with products

The stage at which these activities fit with medtech company product development has been mapped.

Scottish market access by notified bodies has been investigated and key findings were:

- Notified Bodies operate on an international basis and consider Scotland as part of this market
- The timeline for CE marking was typically taking six to twelve months from engagement with a notified body and that Scottish companies approaching notified bodies were not aware of this
- Half of the notified bodies were not taking on new clients

The barriers for setting up a notified body have been mapped out in detail.

Scottish Company Insights

Access to notified bodies highlighted the following:

- Companies tend to stay with a notified body once they have appointed one however, it took time to appoint a notified body and companies should appoint one earlier
- The key challenge in working with a notified body was the time it took to get a company's product CE marked
- Dealing with changing personnel was an issue due to auditor staff churn
- Costs were generally transparent
- Understanding device classification and regulatory requirements was seen as a challenge for companies

Demand Modelling

A demand model for the current Scottish medtech company base (134 companies) and the anticipated future need has been built.

Currently, 70 companies require the services of a notified body to get their product to market. Of those 77% had engaged a notified body.

The current and future demand for notified body services does not justify investing in a new notified body to serve Scotland.

Recommendations

The following areas are recommended for follow up:

- Consider auditor training to increase the number of auditors available
- Undertake more work to learn about the upcoming changes that the impact the new directives will have on the medtech industry
- Increase awareness of the medtech community regarding how notified bodies operate and how to engage with them
- Increase awareness of the medtech community regarding device classification and regulatory requirements

INTRODUCTION

The following document outlines a research project undertaken for Scottish Enterprise across the following areas:

- An understanding of requirements for notified bodies services, including an outline of services, the stage at which these are required and their fit in the product life cycle
- An understanding of the capacity issues and Scottish market access challenges around provision of services by notified bodies through primary research with five notified bodies
- An understanding of the challenges around access to notified bodies for Scottish companies through primary research with Scottish medtech companies
- Building a demand model for current, latent and future market need for notified bodies
- Recommended solutions to reduce hurdles and open access to notified bodies' services for Scottish Medtech companies

The research has been undertaken between July and October 2016 by Innova Partnerships working in partnership with Compliance Solutions. Both have strong knowledge of the local life sciences environment with the latter bringing experience and an insight of the market from a regulatory perspective.

The project sought to understand the challenges faced by Scottish companies around securing the services of notified bodies. This research sought to investigate claims from the market of insufficient supply and barriers to access for Scottish medtech companies seeking these services.

Primary research was undertaken with a range of Scottish medtech companies to understand issues in this area. We also undertook interviews with four of the five notified bodies currently operating in the UK to understand barriers to access for the services of notified bodies and the driving factors behind this.

The report also provides a demand model for the services of notified bodies in Scotland, incorporating both current and future demand. Beyond this, the research will offer potential solutions for the challenges faced by Scottish companies around securing the services of notified bodies.

BACKGROUND

The medical technology market is a key part of the overall life sciences market. Medical technology represents 45% of all life science companies and 35% of life science turnover in Scotland. The medical technology sector is highly regulated with companies operating in this sector having to comply with various regulations depending on, for example, their manufacturing capability and the claims they make about their products.

A notified body, in the European Union, is an entity that has been accredited by a member state to assess whether a product to be placed on the market meets preordained European conformity standards. Notified bodies commonly undertake product certification, factory production control certification and determine product-type/class of medical devices and in vitro diagnostics on the basis of type testing.

Within the European Union (EU), the medical technology market is estimated at roughly €100 billion. Based upon manufacturer prices, the European medical technology market is estimated to make up

31% of the world market. It is the second largest medical technology market after the US. Regulatory compliance and adherence to EU legislation, most notably device classification and subsequent CE marking, is an important step in the commercialisation of medical technologies. The letters "CE" are the abbreviation of French phrase "Conformité Européene" which means "European Conformity". Only notified bodies can issue CE marks.

Securing a CE mark is a requirement to market and sell medical technologies in the European Union and any other non-European economic area countries, including Iceland, Liechtenstein, Norway and Switzerland. This requirement applies to any company wishing to sell products within these territories and not just European companies and manufacturers. It is estimated that over 4,500 Medical devices received CE Marking in 2014. Around 500 of these were class 3 devices, the highest risk category[1].

Beyond Europe, the CE mark is recognised as a global standard. Many countries in the Middle East and Asia accept a CE mark or FDA (US Food and Drug Administration) approval (the US market regulatory equivalent) as part of their compliance process. Whilst this is not essential proof of a CE mark, it can be used to fast track approval in many non- EU countries. Agreements on mutual recognition of conformity assessment currently exist between the European Union and other countries such as USA, Japan, Canada, Australia, New Zealand and Israel.

Feedback from the medtech sector in Scotland has suggested that companies are struggling to access the services of notified bodies. Such a lack of access would present a strong barrier to growth given the importance of regulatory compliance to subsequent commercialisation. A capacity issue has also been reported at EU and UK level but it is thought to be pronounced in Scotland, given a lack of auditors and notified bodies based in the local market.

We anticipate further complexity may be added, given ambiguity around future UK domestic adherence to EU regulatory standards, due to Brexit. We will seek to address this during the first part of our research by understanding precedents set by non-EU member states, such as Switzerland. Regardless of UK membership status, the European market remains a key market for Scottish medtech and having access to this market is crucial.

ROLE OF NOTIFIED BODIES

Directives are the most binding form of EU law - as soon as they are passed they are legally binding throughout every member state. Whilst national governments do not take action to implement EU regulations, they must ensure that their national law does not contradict EU regulations or place additional requirements around these. There are currently three EU directives[2] which cover medical device and in vitro diagnostics and specify the requirements for each member state for market entry. The current revision of EU medical device directives has been ongoing for eight years and will be put into effect in 2017 - nine years after initial public consultation. This is thought to be a typical timeline for drafting, approval and execution of new directives.

[1] BSI, Notified Bodies Guide, 2016 http://www.bsigroup.com/meddev/LocalFiles/en-GB/Services/BSI-md-notifed-body-guide-brochure-UK-EN.pdf

[2] See Appendix 1 for how EU directives are written

Each European country has a national organisation known as a "competent authority" that is tasked with overseeing compliance with EU medical device directives in their respective markets[3].

Notified bodies provide services around regulatory and quality management for companies taking medical technologies and devices to market. These services include:

- Conducting conformity assessments to EU directives
- Auditing quality systems and reviewing technical documents supporting safety claims
- Undertaking technical assessment against EU directives

Further to these assessments and audits, notified bodies issue certification such as ISO compliance (for example, ISO13485) and CE marking for individual devices. This enables the company to sell their devices in the EU.

Notified bodies are commercial companies that act as contractors to competent authorities. They are not quasi non-governmental or public sector organisations and make decisions on their provision of services on commercial and economic basis. Notified bodies are expected to be impartial and independent.

Whilst notified bodies implement European directives at a national level, and are invited to feed in suggestions on how these are shaped at the beginning of the development process, they do not define the directives. Notified bodies are overseen and audited by their national competent authority. Notified bodies do not get involved in the manufacturing process, nor do they offer consultancy services.

The companies we have spoken to, and those we have previously worked with, have tended to use UK based notified bodies recommended by the MHRA (Medicines & Healthcare Products Regulatory Agency) or those recommended by the regulatory consultants or manufacturers they are working with. This leads to a high engagement rate of UK based and approved notified bodies by UK, and specifically, Scottish based medtech companies.

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Since the early 2000's, there has been a trend towards reducing the number of bodies through a process of rationalisation. The number of notified bodies has been reduced from over eighty to the sixty currently listed[4]. Speaking to representatives in notified bodies there was a shared belief that this would reduce further to the low fifties over the coming year. This was due to the fact that auditing of companies by competent authorities was ongoing across Europe and implementation of the new directives in early 2017 may impact profitability and push some of the existing operators out of the market.

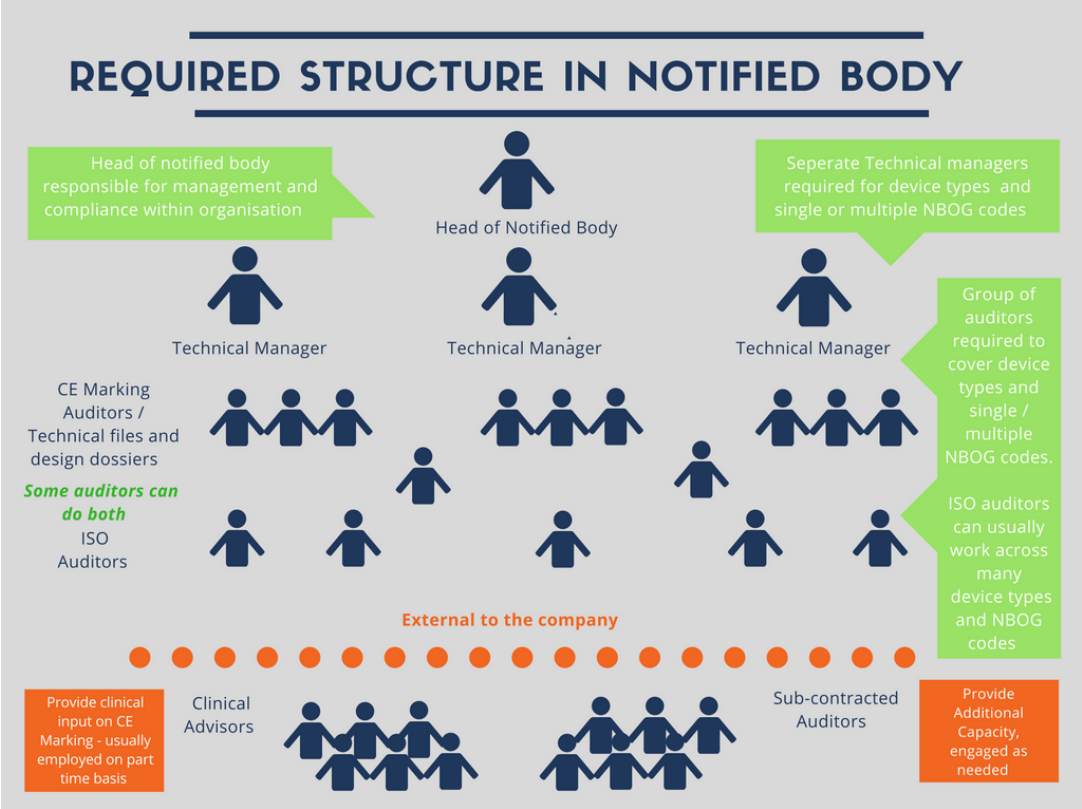
[3] In the UK this is the MHRA

[4] http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.pdf&refe_cd=93%2F42%2FEEC&requesttimeout=900

HOW NOTIFIED BODIES ARE STRUCTURED

All notified bodies require designation to work with product categories that are classified using Notified Bodies Operations Group (NBOG) codes[5]. To cover an NBOG code a notified body needs to evidence that it has a pool of auditors for each code (usually this will be a minimum of two or three) and evidence that the individual auditors have experience in working with products in their chosen product categories as well as the relevant training in auditing processes. Figure 1 shows the typical structure of a notified body. This shows a minimal structure; the headcount required would grow in proportion to the device types and NBOG codes covered by the notified body.

Figure 1. Required structure in a notified body



De-designation, in working with certain product types and codes, is an ongoing threat within a notified body organisation, as a result of auditors leaving and teams being depleted. De-designation is hard to deal with as it means losing or offloading customers in the specific product category; it also impacts upon the credibility and perceived reliability across the notified bodies' wider customer base. Many notified bodies are narrowing their fields of operation to increase their sustainability.

Prior to the early 2000's, skillsets required of auditors were more generalist, similar to the skillsets required for auditing ISO accreditation but regulatory changes have meant that auditors for CE marking require more specific skillsets to comply with NBOG codes; these requirements are becoming more specialised as new fields emerge. Notified bodies cited that they now employ a cast of hundreds to ensure that they have adequate coverage in the fields in which they operate and to sustain operations across the range of NBOG codes they work with.

Auditor Recruitment and Retention

[5] http://www.nbog.eu/resources/NBOG_BPG_2009_3.pdf

Challenges identified by notified bodies include attracting and retaining a pool of qualified auditors to service the breadth of device types and NBOG codes required. The more experienced individuals sought by notified bodies were less likely to be attracted to auditor roles due to the demanding schedules and extensive travel required in these positions.

A huge barrier to auditors moving between notified bodies, or coming in from industry, were non-compete clauses in their contracts which prohibited them from working with existing clients, competitors or existing employers in the industry. From discussions with notified bodies, it is generally believed that auditors from notified bodies who were rationalising services, tended to be retained in the company or absorbed into regulatory roles in private medtech companies.

The upcoming new directives (see below) have put pressure on notified bodies in terms of the increased volume of audits and, for unannounced audits, two auditors are now required where a single auditor was previously used. Recruitment and retention of auditors and clinical advisors in the industry is an ongoing challenge. Emphasis of recruitment is therefore focused on accessing people with distinct experience and skillsets, as opposed to recruitment with a geographical focus.

Servicing New Companies Offloaded by Other Notified Bodies

Notified bodies observed that the switch to another notified body by existing customers was minimal. Where this had occurred it was often on the basis of price or a negative experience (e.g. accreditation not secured). There was also a level of attrition in the customer base due to company failure, however this was not felt to be large given most companies were engaging notified bodies close to the point of market entry.

Most of the notified bodies we spoke to felt that the switch of suppliers within the industry was chiefly driven by other notified bodies offloading customers and deciding not to service certain NBOG codes and product types. Whilst this was often as a result of notified bodies ceasing to trade, or being de-designated in certain NBOG codes, it was most often due to companies exiting NBOG codes and product categories for commercial reasons.

New Directives/European Membership Status

Notified bodies had observed that the majority of their client companies have taken a “wait and see” attitude and many are struggling to keep up to date with current directives. Notified bodies felt that the regulatory environment was still in flux but would also continue to evolve beyond implementation of the latest set of directives. All notified bodies who were questioned agreed that scrutiny and pressure on notified bodies would be an ongoing trend. Two respondents said that this was a concern that has been raised by notified bodies and competent authorities across the EU for many years but that there did not seem to be a plan to address this at EU level.

WHAT NOTIFIED BODIES REVIEW AS PART OF THE PROCESS

CE marking requires a facility audit that typically looks at elements including manufacturing processes and systems, controls, material handling, compliance of microbiological and sterile systems. Medical technology companies are typically audited to ISO13485 standard[6], the harmonised European standard for medical device manufacturing published in 2006. Certification of this has a three year validity with an annual surveillance audit required as part of the process. Surveillance audits are periodic audits performed by auditors from the notified body to ensure that an organisation still meets BCM or ISO standard requirements.

CE marking is one of the main services offered by notified bodies. A CE mark ensures that a product meets the essential requirements of EU directives - a legal requirement for market entry. The three medical device directives are:

- Medical Devices Directive (MDD)
- Active Implantable Medical Devices Directive (AIMDD)
- In Vitro Diagnostics Directive (IVDD)

CE marking is currently applicable in all twenty eight member states of the EU plus Iceland, Liechtenstein, Norway, Switzerland and Turkey. It is anticipated that post Brexit, the UK will continue to adhere to CE marking.

Guidelines on device classification are published in Annex 6 of the current European Medical Device Directives (Directive 2007/47/EC). Where there is ambiguity around classification, which is often the case with new and emerging technologies, companies revert to their notified body for guidance on classification. See Appendix 2 for “Device Classifications” and Appendix 3 on “In Vitro Diagnostic Products”.

To attain CE mark certification, notified bodies assess the conformity of products and processes to the relevant directive for their class of device. This includes assessment of a quality management system. A quality management system (QMS) is a set of policies, processes and procedures required for planning and execution (production/development/service) in the core business area of an organisation.

Discussions with representatives of notified bodies revealed that many companies have previously set up and undertaken certification of their QMS to ISO standards using separate suppliers - this is increasingly being done through notified bodies as it is considered synergistic to do so, since audits for both can typically be done by the same auditor. This offers cost savings and convenience to companies. There is a wealth of companies in the market accredited to assess ISO standards across a range of industries, given that auditors require less specialised knowledge than is required for CE marking.

Notified bodies undertake both scheduled and unscheduled audits as part of the CE mark certification process. Design dossiers are required for class 3 products and technical files are required for all others. Whilst there is some overlap in the content of these, guidelines on what they include are stated in the

[6] http://www.iso.org/iso/catalogue_detail?csnumber=36786

directives. An overview of the requirements for each can be found in a guide, which is referenced below[7].

SCHEDULED AUDITS

These will be undertaken as part of the CE mark process and include an assessment of the quality management system (QMS) in place. They can be undertaken at any operational base or manufacturing site used by a company as well as any component suppliers - therefore adherence to regulatory standards across the supply chain can be critical for market entry. This is why many companies select a notified body based on prior relationships of their chosen manufacturing sub-contractor.

Where products have not undergone final manufacturing, notified bodies can actually award certification without seeing the final product - assessment can follow conformity assessment procedures, i.e. checking that manufacturing systems and processes are in place and required design dossiers and technical files are compliant to requirements. During audits companies are expected to have all supporting documents and files to hand that support their safety and performance claims.

UNANNOUNCED AUDITS

Under EU legislation notified bodies are required to undertake unannounced audits of manufacturers/ critical sub-contractors and component suppliers. These are additional to regular scheduled assessments and will be for a minimum of one day with two auditors on site. Companies are subject to unannounced audits once every three years with more frequent assessment for high risk devices or manufacturers with poor compliance records. They can also be undertaken where non-conformity to directives is suspected.

The focus areas for unannounced audits are manufacturing, testing and correlation of manufactured items to the supplied technical files and device specifications. Audits also focus on identification and traceability, reconciliation of materials and critical processes and further testing of devices that require design certification.

ALTERATIONS AND MONITORING AND REPORTING FAULTS

Manufacturers must inform notified bodies of any changes to products or manufacturing processes, e.g. new materials, designs or claims around product performance. Manufacturers must evidence that these changes do not have any negative impact and are still in conformance with the relevant medical device directive.

If the alteration is deemed to be significant, the notified body can request resubmission and recertification of the device. This decision lies with the notified body and in turn the competent authority who oversees them. In our primary research a Scottish medtech company had shared an example where their notified body had not deemed a change to their device significant enough to merit resubmission and assessment, however, when subsequently audited by their competent authority (MHRA) this was challenged and the notified body had to revert to the company and suggest reassessment. In this case the associated costs were picked up by the notified body that had overlooked this during their audit.

[7] http://www.tuv-sud.co.uk/uploads/images/1446043428118222590797/guidance-design-dossiers.pdf

Beyond market entry and securing CE marking, it is the responsibility of the manufacturer to report any faults or failures of the device directly to the competent authority (MHRA in the UK). Notified bodies will be informed as part of this process.

STAGE AT WHICH SERVICES ARE REQUIRED[8]/FIT IN PRODUCT LIFE CYCLE

There are three main stages when companies engage with notified bodies (Figure 2).

The first engagement is typically after requesting an initial quote for work to cover CE marking for the company's device. The second is during an in-house audit to secure CE marking and the final stage is during market entry of the company's product during post market surveillance.

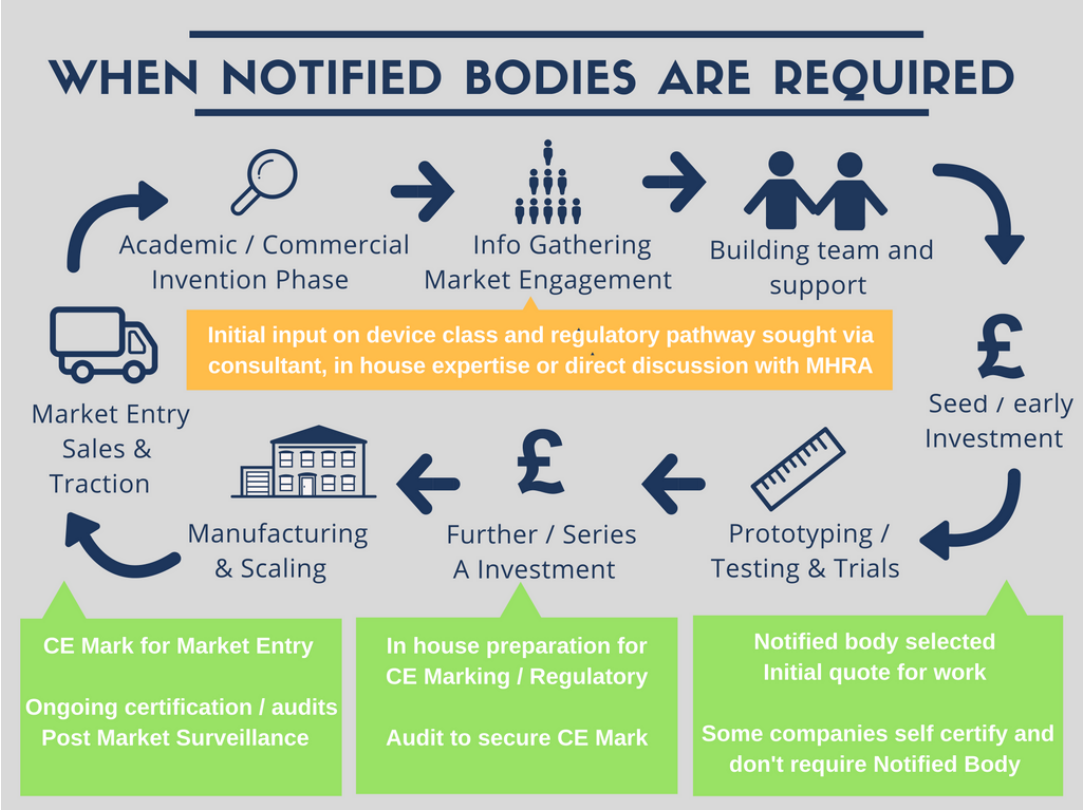


Figure 2. Schematic showing when companies engage with notified bodies.

Based on the product development process, as developed by Product Development Technology Inc.[9], Figure 3 shows when companies engage with notified bodies.

Initial engagement was found to happen prior to clinical development for simpler (class 1 and 2 devices) and prior to pre-clinical development for more involved (class 3) devices. The CE marking process was triggered once manufacturing development was nearing completion and processes for mass manufacturing were in place for the device. This was a precursor to market development activity and subsequent introduction of the product to the market.

[8] Data generated from consultation with Medtech companies operating in Scotland
[9] http://www.slideshare.net/bob12east/medical-device-development0327

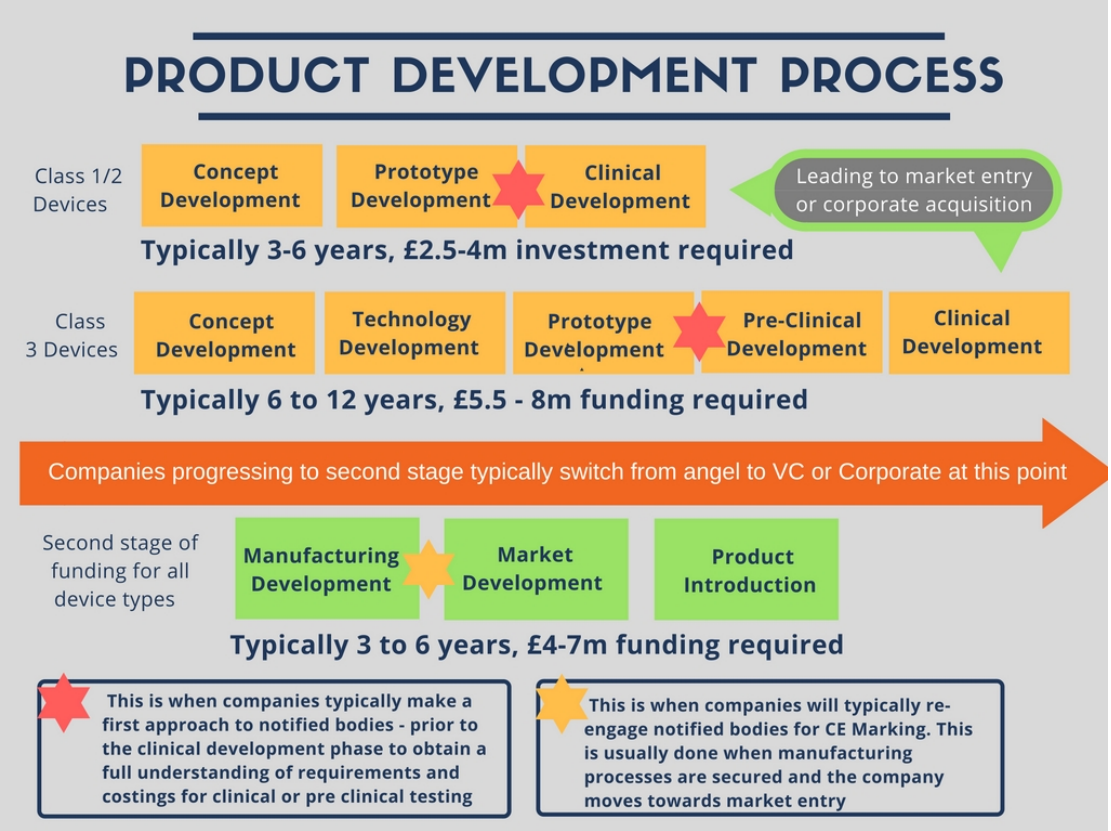


Figure 3. Schematic showing when, in the product development process, companies typically engage with notified bodies (as shown by red and yellow stars).

The majority of the startup companies spoken to during the course of the research used the external services of regulatory consultants to map their initial pathway. For more established companies who had scaled to reach thirty to fifty employees, the regulatory function was typically undertaken in-house with a full time employee or group of employees who managed the process.

A clear understanding of the regulatory pathway is required at a company's seed and initial investment stage. Typically, this is secured without the help of a notified body. However, early stage companies still engage notified bodies at this stage for an understanding of costs and requirements (i.e. which class of device they are and which directives they need to comply with) going forward with limited success as the main role of the notified body is in the conformity assessment of a device. Regulatory consultants can provide guidance regarding an estimation of costs and a view of device classification to help companies.

As companies move beyond initial prototyping, those companies who have not already approached a notified body will tend to engage their services at this stage. Companies will typically be doing work in-house to prepare for audit and prepare technical files or design dossiers as required. Companies will seek input from notified bodies on requirements and structures for compliance.

Companies should ideally approach notified bodies between eight and twelve months in advance to schedule audits for CE marking and certification of ISO standards. It can take six to eight months to schedule an audit date by a notified body. Furthermore, if amendments are required to secure

certification, this can mean a considerable delay to market entry. Hence an early engagement approach is advised.

THE CHALLENGES OF ACCESSING NOTIFIED BODIES

There are a number of challenges facing companies wanting to access notified bodies. Some of these include:

- The current pressure on the capacity of notified bodies in the UK and EU
- The decreasing number of notified bodies available
- The uncertainty around Brexit and whether notified bodies in the UK will be allowed to administer CE marking, or whether as a consequence, two different accreditation systems will be required
- The uncertainty over the new European medical device regulations which is now discussed in greater detail

NEW EUROPEAN MEDICAL DEVICE REGULATION (MDR) AND POTENTIAL IMPACT

In 2013 the EU Commission introduced measures to ensure stricter enforcement of the regulations across Europe. This update has been prompted by industry events that provoked product recall, endangered patient safety and had highlighted that the directives were falling behind industrial development. High profile events such as the PIP implant scandal[10] and recall of transvaginal mesh devices in 2011[11], albeit largely in the US, highlighted shortcomings of the current EU directives.

New European medical device directives have now been drafted, pending full approval in late 2016[12]. Until now there has been limited patient access to information regarding performance and safety of medical devices and tracking of devices to original manufacturers was limited. Some of the anticipated key reforms are highlighted in Figure 4.

Key Reforms Anticipated in New EU Directives

- A requirement for **clinical trial data** to be provided before a CE mark is granted for implantable and high- risk devices
- **Pre-market and post-market approval processes** for high risk, implantable devices
- **Data transparency** - including publication of clinical trial data and safety summaries
- **Defined content and structure for technical files** to support registration
- **Tightening of vigilance reporting timelines** from the current thirty days to fifteen days
- **A unique device identification (UDI) system**, possibly similar to the one used in the US
- **Establishment of Eudamed medical device database,** through which regulators, providers and the public can access technical data, clinical trial results and adverse event reports
- **Expanded "directions for use" content associated with products**
- **A possible ban on some restricted substances in the manufacture of products** and a requirement to track certain chemicals and restricted substances throughout the supply chain

[10] http://www.bbc.co.uk/news/health-16391522
[11] https://www.drugwatch.com/transvaginal-mesh/recall.php
[12] http://www.raps.org/Regulatory-Focus/News/2016/06/15/25142/EU-Council-and-Parliamentary-Committees-Sign-Off-on-New-Medical-Device-IVD-Regulations/

- **More power for notified bodies, including the establishment of "super notified bodies"** which will be responsible for high risk implantable devices
- Companies required to retain at least **one person responsible for regulatory compliance**

Figure 4. Key reforms anticipated in the new EU directives.

By mid 2015 the final text had been prepared, whilst notified bodies are preparing and training their staff around working with the new directives - medtech companies have been adopting a "wait and see" approach until the legislation is published. This holds true of the companies we spoke to during this project and other companies we are working with in the market. An Ernst and Young report on the topic[13] suggested that despite the implications for EU medtech being huge, the majority of companies were under prepared due to an uncertainty of what would be included in the final text and the implications for individual companies were not fully understood.

Notified bodies will not only be issuing new certificates and auditing against the new regulations, but also having to maintain existing certificates for existing CE marked products for a period of four years after the new directives are implemented.. This represents additional work to what is currently done and will require more auditor time. The addition of unscheduled audits will impact the requirements for auditors, with the requirement of two auditors for thisbeing of particular concern. This is an area we have further explored in our discussions with notified bodies.

Some of the key implications for companies include:

- More clinical evidence will be required for market entry or to keep existing products on the market
- Relabeling products will be required once new certification has been issued. This means that companies will not be able to sell products with existing labels once the directive has passed. It is anticipated that there will be a grace period to help transition but the length of this has not been published as part of the draft directives. Notified bodies are expecting a bottleneck in companies trying to get certificated once this timeframe is published.
- Unique Device Identification and associated relabeling is a paradigm shift and may lead to products being withdrawn from market due to the financial viability of doing this

The new regulations will have particularly strong impact in the field of IVD devices. The scope of IVD devices will be extended into some existing lifestyle tests and a new risk classification will mean that more existing devices will need to be certified by a notified body.

Currently 80-90% of current IVD devices do not require the services of a notified body to get a CE mark. It is anticipated that under the new directives 80-90% of existing IVD devices will require a notified body. Many of these have previously been self-certificated and a rush of companies seeking new suppliers is expected. This will place considerable strain on a shrinking pool of suppliers. One Scottish IVD manufacturer we have spoken to has reported that the percentage of their products affected will increase from 5% to 95%.

[13] http://www.ey.com/Publication/vwLUAssets/ey-how-the-new-eu-medical-device-regulation-will-disrupt-and-transform-the-industry/$FILE/ey-how-the-new-eu-medical-device-regulation-will-disrupt-and-transform-the-industry.pdf

The new directives will include a programme of unannounced audits of notified bodies themselves. This has led to a number of notified bodies withdrawing from the medical device market and to others having the scope of their activities restricted, e.g. to low risk products.

Among the representatives from notified bodies we spoke to, it is perceived that time to market will increase and increased costs and complexity of entry into EU markets may lead to companies looking away from Europe as first port of entry. CE marking and compliance to EU directives had traditionally been considered as easier and cheaper than FDA approval in the US as a means of market entry and was therefore chosen as a first point of entry by global medical device companies ahead of the US market.

A full outline of the final reforms anticipated in the legislation is outlined in the table below. This will not be confirmed until final publication of the directives in late 2016.

Whatever the final text, it is widely agreed that these changes will be transformational in the industry and represent a huge cost and higher barriers to market entry than presented by the current directives. The aforementioned Ernst and Young paper stresses that these changes have to be implemented during "business as usual" - this is likened to changing the tyres on a moving car. It is suggested that the key things companies can do to prepare for the new directives are:

- Invest in qualified persons to take the role of the person responsible for regulatory compliance
- Plan and budget for anticipated changes
- Identify what additional data will be required to achieve compliance or market entry

An industry survey by Eucomed estimated that costs to the industry globally over a five year period include £7.5bn for full compliance to the Unique Device Identification system and £17.5bn for centralised pre-market authorisation[14]. A BSI whitepaper[15] on the implications for the market of the proposed changes, suggests that there may be a shift to a slower pharma-like model of approval as emphasis shifts to pre-market evaluation and more clinical data is required. It reflects that other regulatory organisations, such as the FDA and EMA (European Medicines Agency) have recognised this as a limitation of their own regulatory models and are trying to shift emphasis to post-market surveillance to enable increased market entry.

The Ernst and Young paper suggests that some of the most pronounced impacts on industry will include:

- Increased time and cost to get new products to market
- Increased failure of market entry due to higher barriers to entry
- Many products to be withdrawn as relabeling or revisiting clinical data not financially viable
- Smaller companies disadvantaged in terms of funding to market entry may lead to increased mergers and acquisition activity in the market
- Larger companies may seek to build portfolios, taking advantage of the above

[14] http://archive.eucomed.org/newsroom/115/187/17-5-billion-for-unnecessary-measures-will-be-a-blow-to-medical-device-innovation-in-Europe?cntnt01template=detail-pr

[15] http://www.bsigroup.com/localfiles/en-gb/medical-devices/whitepapers/wp_eu-regulations.pdf

Research published by ABHI (Association of British Healthcare industries) in early 2016 revealed that 52% of the UK companies questioned believed that the actions of a notified body had compromised their ability to place products on the EU market and 64% of those questioned revealed that notified bodies had missed or postponed a scheduled audit or product assessment. This typically led to an additional two to four months of waiting to rearrange the original audit. Half of the companies questioned have had a certificate renewal delayed by a notified body such that it impacted negatively their business. This research was based on a pool of forty eight respondents working with forty nine notified bodies.

Key issues identified by the ABHI research are outlined below:

Selection and retention

- New companies looking for certification are being quoted a timeline of up to six months before they can have an initial audit
- Some notified bodies are not taking on any new companies
- Other notified bodies are offloading existing customers in non-focus areas

Operational/Service Delivery

- Interpretation of the current standards or guidelines changing in relation to more testing and pre-market approval. Many companies were being asked to provide additional data which was not required during original certification of their product
- Time to plan changes to products/QMS now taking two to three months longer and lead time for audit is anything between four to six months - companies can't make changes to products as quickly as previously
- Lack of co-operation when issues arise, fear of the notified body falling foul of MHRA or EU commission, e.g. where notified bodies were previously happy to make a call on device classes and regulatory requirements they are now more likely to revert to the competent authority or EU for clarification
- Poor communication - poor indications of timescales etc.

Expertise/Personnel

- Lack of availability of auditors
- Lacking in product technical knowledge in some areas (animal origin, genetic testing, software)

Costs

- Rising costs of both ISO 13485 audits and technical file audits
- Travel charges are increasing as one day is charged for travel time and this can be up to £2,000
- Number of audit days for both ISO 13485 audits and technical file audits increasing, leading to increased costs

Despite recurrent issues around timelines and delivery, 80% of companies questioned in the ABHI research had received no communications from notified bodies detailing capacity issues and only 9% (four of forty five) of respondents have had an enquiry rejected by a notified body due to lack of capacity. The rate of switching or transferring to a new notified body was low and only 2% of respondents (one company) had switched to a new notified body for a specific product line or device class.

Industry feedback suggests that some Scottish companies are considering ceasing to market some of their products due to the upcoming changes in the new regulations. Furthermore, the changes could

lead to a slower “pharma-like” model of device approval. Together these could have a potential economic impact.

BSI published a review of the likely consequences of these changes in October 2015 and feels that these directives present a particular challenge to notified bodies and will fundamentally change the scope and volume of work they do. Notified bodies will be required to employ more expertise and bring roles that had previously been sub-contracted in-house. They will also play more of an enforcement role than previously required, as the new directives will increase the required number of unscheduled audits. It is also thought that some current notified bodies, who do not have the required people and resources to attain super notified body status, may need to offload customers and, in more extreme cases, cease to trade. One of the suppliers we spoke to during the course of our research felt that this was likely to be the case with their company, given that they had be de-designated in some of their core areas of operation. They had also started to reject new clients and offloaded existing clients in other areas of operation as they felt they would not have adequate coverage to meet the demand of the new directives.

SCOTTISH COMPANIES’ EXPERIENCE OF WORKING WITH NOTIFIED BODIES

As part of this project we undertook interviews with six Scottish medtech companies. This research was undertaken to investigate prior feedback from the market via ABHI and the Scottish Life Sciences Association around problems with access to notified bodies.

SELECTION AND RETENTION

Of the six companies spoken to, five were engaged with UK based notified bodies and one was still in the process of seeking a notified body. A range of reasons were cited for selection and retention of the notified body they worked with. These were:

- Ability to deliver ISO13485 alongside CE marking
- Formal tendering selection
- Reputation of the notified body
- Proposed delivery time
- Existing relationships
- Recommendation from regulatory consultants

A key finding was that there can be a disjoint between the understanding of the CE marking process between operational staff and board members, which presented a challenge. Having board members with current experience of securing regulatory certification in industry tended to resolve this issue.

None of the companies spoken to had switched notified bodies despite some challenging relationships being cited. There was an understanding among all respondents that many of the issues around timelines and auditor availability exist at an industry level; multiple respondents cited that starting again with a new provider would require a lot of time and effort to share existing learnings which could prove costly. There was also a sense that joining a new notified body may put them to the bottom of the list in terms of scheduling and some cited that they had heard a number of notified bodies were not accepting new customers so a move could be considered an unnecessary risk for any business in this area.

OPERATIONAL/SERVICE DELIVERY

Four of the six companies we spoke to had some difficult experiences in working with notified bodies. Of the five who were currently engaged with notified bodies, timelines for delivery and scheduling audits were felt to be particularly problematic. The majority of respondents understood that this was endemic in the industry and not a problem specific to their notified body.

Some common issues cited in discussion included:

- Long timelines for scheduling audits
- Certificates and formal reporting taking three to six months to deliver
- Ambiguity/uncertainty on how to classify and assess certain device types
- Ambiguity/uncertainty on impact of new directives – this was felt to be evident within notified bodies
- Early stage companies were unsure if they needed a notified body and if so, what for? They are reliant upon consultants
- Unsure when to engage (e.g. for quotes and scheduling future work) as roadmap unclear

Companies felt that the lack of clarity around timelines and scheduling was the biggest problem for them and led to unnecessary downtime and delays. Some suggested solutions to this included forced response times or better management of expectations on timescales from notified bodies.

The larger companies spoken with had dedicated regulatory teams who were proactive in managing their relationships and engagement with notified bodies and had open dialogues around their product development pipelines and anticipated needs. Their teams were very engaged with changes in the industry and were undertaking planning exercises to mitigate risk to the company and impact of the pending directives. These companies also had a tendency to book in audits well in advance and rearrange as necessary. Where internal timelines led to a delay, the financial penalties of doing so (paying for a two day audit) were considered negligible and could often be recouped as part of a rescheduled audit.

For the smaller (predominantly one device) companies this was not the case and they felt uncertain of when they should engage and inform notified bodies of their requirements and felt ill equipped to do so.

More information and consultation on what is required, prior to product submission, was felt to be something that would be helpful to small companies. Two respondents cited a similar system being introduced by the FDA in the US market as a potential means of achieving this. Details on how this pre submission process works **can be found in FDA documentation[16].**

EXPERTISE/PERSONNEL

At the point of recruitment it was felt that the five notified bodies operating in the UK had a good spread of expertise in their team, when viewed on paper, and it was rare to rule out a notified body on the basis of a lack of expertise in a specific domain. However, once appointed, companies felt it was difficult to secure the required individuals for audits in the timelines desired and this was often a barrier to efficient service delivery.

[16] http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf

Some common issues cited in discussion included:

- Different auditors were being used at each point of engagement (audits/reviews)
- Lack of consistency in areas of focus by auditors - each had their own areas they fixated on
- Securing an auditor with experience relevant to the product was often difficult and impacted upon timelines
- Notified bodies felt to be playing catch up in the area of expertise for emerging technology fields

However, this was not the case of the larger companies who cited a reasonably consistent level of contact with their notified bodies and specific auditors. Despite this, there was a tacit understanding that the relationship is at arms length and notified bodies and their individual auditors should be contacted sparingly outwith audits and product submissions.

Multiple respondents cited high staff turnover in the industry as a particular challenge and some mentioned that attempts had previously been made by their current notified bodies to recruit and retain auditors in the local market but these had been relatively short lived and did not have much impact on their businesses.

COSTS

The majority of the medtech companies we consulted felt that the costs of accessing notified bodies and using their services were relatively open and transparent. Notified bodies were happy to share pricing lists and day rates were widely available.

There has been incremental price rises over the years but respondents felt that these were proportionate and adequately explained. Many of the notified bodies scaled pricing by number of employees in the client company, which worked well with smaller companies and those who outsourced manufacturing.

In two examples, where mistakes had been made by notified bodies that had impacted company timelines to market, the notified bodies had covered the costs of the further work required to make up for the delay. This was common practice where mistakes had been made in the industry and companies who had experienced this expressed a stronger and more loyal relationship with their notified body as a result.

Three of the six companies cited that due to their location it was necessary to pay for an extra day to cover travel costs of auditors. There was a general perception that they were being penalised for their location in Scotland and other UK based companies were not subject to these elevated charges. Notified bodies often tried to offset this by scheduling audits and visits when they were in Scotland for other company audits and meetings.

While some of the earlier stage companies were happy to work on this premise, the more established companies felt that the saving was negligible given the impact on market entry and subsequent revenue from sales. The companies at a later stage of engagement felt that the costs were not a big consideration, especially when compared to costs associated with US market entry and FDA approval.

Typically, larger companies expressed a desire to cover all associated travel and accommodation costs separately with a view to securing the earliest possible appointment with auditors to the notified bodies they worked with. However, it was felt that the planning and scheduling decision often fell to the auditors

themselves and there was a preference to cluster visits to locations such as Scotland where multi-day trips are required for management of their own travel, rather than for cost savings.

A main issue around costs was getting an understanding of device classification and regulatory requirements prior to submission. This would inform wider development costs, e.g. the need for a clinical trial. Some companies struggled to get accurate foresight of these which subsequently led to funding gaps and, in some cases, abandonment of specific products.

GENERAL OBSERVATIONS

A key observation was that some of the highlighted issues suggest that some companies do not understand the market in which they are operating. This lack of understanding and clarity of their responsibilities leads to a difficulty in navigating their regulatory pathway.

Of the companies we spoke to, some respondents stated that they felt there was a lot of ambiguity and grey areas in the current medical devices regulatory space. Auditors and notified bodies were often unable to provide clear directions and guidelines and commonly reverted back to the MHRA for clarification, which could impact severely on delivery times for audits and certification. One individual, with experience of working in medicines, stated that MHRA guidelines on medicine were much clearer and easier to work with.

NOTIFIED BODIES' EXPERIENCE OF WORKING WITH SCOTTISH COMPANIES

The second part of the research focused on understanding market challenges from a notified bodies' perspective. In this phase we spoke to a range of notified bodies working in the UK market.

SCOTTISH MARKET ENGAGEMENT AND IMPORTANCE

The notified bodies we spoke to all served a variety of clients in Scotland. However, although Scotland was an important market in the context of the wider UK landscape, it was not seen as a standalone opportunity or a key focus market by the notified bodies.

Customers from Scotland were commonly acquired through word of mouth, introduction by key regulatory consultants and direct approaches. Most companies invited multiple notified bodies to respond to a tender process and it was felt that work was won on the basis of both price and experience. Once engaged, notified bodies kept track of, and informed companies, of upcoming requirements, in terms of future audits and requirements to maintain certification.

Perception of the market was that it was rich in small companies and startups but that the companies scaling globally in different market segments were few. Two individual respondents shared the opinion that there were probably "a handful" of truly global companies emerging from the market. The notified bodies we spoke to commonly had multinational and large clients across a range of geographies which shapes their perspective of the scale of opportunity offered by the Scottish market.

Of the four notified bodies we spoke to, all considered their market opportunity to be global and they serviced a range of clients from the North American, Asian, Middle Eastern and other key markets. When queried about additional expenses of travel faced by Scottish companies, this was felt to be negligible given that their international customers were also charged for travel time and costs.

The perception from companies that their location was thought to impact timelines for audits was not felt to be reflective of practice. One of the major companies said that given that auditors commonly travelled globally and were predominantly UK based, the Scottish market was not perceived to be remote. Two notified bodies acknowledged that individual auditors had control over their diaries and scheduling that allowed them to cluster audits in specific geographies. This was done to minimise travel for auditors as opposed to driving cost savings for the companies that they were auditing.

TIMELINES

For low risk devices the whole process of CE marking should take three months end to end (based on industry expectation), but most devices were more complex and needed anywhere between six and twelve months, with nine months being quoted as an average timeline for end to end work on CE marking. The larger notified bodies typically gave a three month lead-time to the first audit in this process.

Two of the five notified bodies recognised that response times across the industry were under strain and getting longer. This pressure has increased as some of the smaller companies have offloaded clients. This has created a rush in market to service companies that already have CE marking or are well advanced in the process of securing CE marking. The two notified bodies we spoke to acknowledged that these clients would often take priority over new market entrants, as the

repercussions for these companies were greater for these clients as a lack of recertification could lead to withdrawal of their products from market.

Whilst this trend has been present in the market since early 2014 it has been particularly pronounced in the first two quarters of 2016 with a bottleneck of clients switching and requiring auditing services.

Two of the notified bodies said that the ideal time for companies to approach them was when they were ready for CE marking and had documentation prepared. All acknowledged that customers would need to factor extra timing into this as it often took three or more months to get initial audits scheduled. The other two we spoke to said that "the earlier companies approach them the better". Whilst they could not formally engage with, or provide consultancy to companies who approached them at an early stage, they could often provide whitepapers and templates to help them prepare compliant documentation and have an initial discussion setting expectations around timelines.

For new and less experienced companies, some notified bodies offered some basic support services such as a QMS and regulatory strategy review and a clinical trial review where applicable. It was also common for these notified bodies to do workshops for interested companies. These were typically delivered at their headquarters or key cities. Two of the notified bodies had both previously run workshops of this type in Scotland. Notified bodies said that at such workshops they could offer general guidance on the CE marking process but regulations dictated that they were unable to offer specific guidelines to individual companies in such a setting.

CURRENT CAPACITY AND CHALLENGES

Areas of Operation

Two of the notified bodies we interviewed were currently closed to new clients - the other two queried were open to new clients. One mentioned they were currently undertaking an internal review of key focus areas and geographic markets which may lead to them ceasing to work with some geographic markets and product types.

Three notified bodies we spoke to were confident that post-Brexit would see the UK continuing to use the CE mark domestically as well as for EU market entry. The one area of concern for these organisations was the perceived attractiveness of UK companies to global companies entering the European market. As a non-member state it was felt that the services of a UK notified body may be less attractive and may hold less credibility than they currently do.

COMMON MISTAKES FROM COMPANIES ENGAGING WITH NOTIFIED BODIES

Three notified bodies said they commonly found companies were viewing CE marking and regulatory as the final step in the process and were engaging notified bodies too late in the process. One cited the problem of companies actually approaching them too early when they had not yet prepared their QMS/ files for evaluation.

The repercussions of this were long lead times to initial audit and often companies had prepared documentation or put QMS systems in place that were inadequate and needed revision. Whilst they cannot offer consultancy, the majority of notified bodies welcomed early engagement and suggested that companies should engage a year in advance of when the first audit would be required.

Notified bodies felt that companies often did not recognise that the timelines they are given are due to the fact that notified bodies need to use specific auditors for their products and often have a small pool of auditors suitable to work with individual companies and devices. The availability and scheduling of these individuals is the single most important issue impacting timelines.

Two of the notified bodies we spoke to also felt that there was an issue in the varying standards of regulatory advisors and consultants in the market. Given this role does not have an official accreditation linked to it, they were commonly seeing consultants who were offering erroneous advice or "one size fits all" solutions to companies that would not help them attain European conformity.

APPETITE FOR INCREASED PRESENCE IN SCOTTISH MARKET

All of the notifed bodies we spoke to are actively recruiting auditors or clinical specialists in the medical device part of their business. This was seen as an ongoing struggle - recruitment was often location agnostic with emphasis being placed on getting a specific level of experience.

Notified bodies who were queried felt that the experience and suitability of their auditors was more important than their location. Of the three notified bodies who provided an answer to this question, they all had auditors based in Scotland. Building dedicated teams for specific geographies was not commonplace and the emphasis was placed on building teams with the depth and breadth to service a range of product types and NBOG codes across a range of global markets.

Notified bodies had many roles that were based at their head office or linked to national offices, however, remote working was common. Bricks and mortar was not felt to be an important part of their strategy and a base in Scotland was not felt to be important. Of the four notified bodies we spoke to, three felt that the Scottish market did not present an adequately large opportunity for a dedicated presence or team in the region. One individual queried felt they were unable to comment on the scale of opportunity in the region.

POTENTIAL SOLUTIONS TO ISSUES FACED BY NOTIFIED BODIES

Of the notified bodies queried all recognised that there were severe capacity issues across notified bodies. However, all recognised that this was not a specific problem to the UK market and it existed at an EU level. These were felt to be due to the rationalisation of notified bodies and increased regulatory pressures on them driven by the new directives being implemented. There was a shared feeling of frustration that a more systemic fix would be required to address issues around capacity and timelines and no solutions were forthcoming to address this at an EU level.

Some of the individuals we spoke to were conscious that there had been previous discussions around setting up a notified body to serve Scotland and felt that this was not a highly likely or feasible solution. The low feasibility was predicated on the perceived volume of demand and size of customer base in Scotland, coupled with the difficulty of new notified bodies entering the UK and wider EU Market.

The notified bodies we spoke to did not feel that it was feasible or likely that they would build a dedicated presence in the Scottish market - again this was due to the perceived level of demand and importance of the market from a global perspective. Many cited that they were actively recruiting auditors but the emphasis was on finding people with the skillsets to meet existing market demand rather than finding auditors in specific geographies. The dominant trend in notified bodies was to rationalise the product areas (NBOG codes) and geographic markets they served. This was being done

to ensure sustainability of notified bodies and to increase their ability to meet the scrutiny and compliance demanded of them.

Some notified bodies suggested that more company training and support on when and how to engage notified bodies would be helpful from their perspective. It was recognised, however, that this would have limited impact on timelines and the cost of services, which are the main concerns of the notified bodies interviewed.

Two of the five suggested that having a "go to" person in the region (within economic development agency support) or some sort of accreditation/recommended supplier system for regulatory consultants would be beneficial for early stage companies to navigate the environment.

Whilst notified bodies are able to deliver training and whitepapers as a way of helping companies understand and work through this process, they are unable to provide detailed guidance and responses to individual companies that would inform their regulatory approach at the outset of the process.

MHRA REQUIREMENTS FOR SETTING UP A NOTIFIED BODY

Some of the individuals we spoke to also felt that services (and even the number of notified bodies) in the UK could be subject to further rationalisation. The competent authority is currently assessing all notified bodies providing CE marking. Two out of five are known to have been fully assessed and one is ongoing. Two notified bodies still have to undergo this process and it is believed that this may result in de-designation for existing notified bodies to service specific market areas and NBOG codes. At worst this could lead to some of the smaller operators choosing to exit the market completely.

In order to set up a notified body there are some key requirements. These are listed in Appendix 4.

KEY BARRIERS TO SETTING UP A NOTIFIED BODY

Compliance Solutions principle Edwin Lindsay, who is involved in the delivery team for this research, had worked with Kalitest, a Turkish notified body in 2008, to assess the opportunity and market pull for setting up operations in the UK with specific emphasis on the Scottish market.

This provided insights into the market demand for inbound providers and challenges around serving the UK/Scottish regions. During this process a range of issues were encountered around setting up a new notified body in the UK. A proposal for this was submitted to the MHRA but was ultimately unsuccessful due to the requirements needed to set up in the UK as a notified body.

Key barriers to setting up new notified bodies in the UK were as follows:

- Competencies had to be built within the organisation and key staff to be directly employed by the notified body. Staff could not be hired on an ad-hoc basis or on a part time/zero hours contract.
- The notified body was also required to have staff retained in the UK - these cannot be subcontracted or virtual roles
- Upfront investment was required for team training and retention as the employees had to be in place to undergo auditing and regulatory approval of the notified body. The process from initial set up to approval was estimated to take between two and three years
- During this period the organisation could not undertake consultancy work as this would compromise its eligibility to provide notified bodies services once approved

After a period of consultation and submitting a proposal to the MHRA, Kalitest decided not to proceed with the setup of a notified body in the UK. The team felt that the time commitment until revenue was too much of a burden for their parent company to bear and that it was difficult to truly understand the volume of demand in the Scottish market. At the time it was felt that the compliance requirements for notified bodies themselves were becoming increasingly onerous and that there was no real incentive to set up a new notified body in the UK.

It should be noted that this venture took place prior to current amendments to the directives. In our discussions with notified bodies there was a sense that the competent authorities had increased scrutiny on existing notified bodies. As a result the barriers to entry in this area had increased despite a rising demand for notified bodies services. Of the representatives we spoke to they felt that the only feasible market entrants to the UK would be established regulatory companies operating as notified bodies in other geographies who had the financial means and existing base of expertise to underpin market entry.

Also of note are the requirements for setting up a notified body (see Appendix 4). Given the demands required here these also form a natural barrier for companies wishing to set up as a notified body.

APPETITE TO INCREASE NUMBER OF AUDITORS IN SCOTLAND OR ATTRACTING A NOTIFIED BODY TO SET UP IN SCOTLAND

From our conversations with Scottish medtech companies there was a strong demand to increase the number of auditors based in Scotland or attract a new or existing notified body to set up in Scotland. Four of six companies queried felt that having auditors closer and in market would shorten timelines to accessing the services of notified bodies and would potentially represent a cost saving in terms of travel for auditors and accelerated time to market.

From the notified bodies' perspective this appetite to have increased presence in the Scottish market was not present. Respondents from notified bodies recognised that the Scottish market was an important part of the UK market but did not present enough demand for dedicated resource in the region.

DISINCENTIVES TO USING NON-UK NOTIFIED BODIES

The companies we spoke to were questioned about their propensity to use an overseas notified body as opposed to a UK based one, if this would positively impact on the timelines for delivery. Whilst there was no objection to doing so, in principle this was not common practice.

Two medtech company respondents were under the belief that the notified bodies recommended by the MHRA were the only options available to UK small to medium enterprises (SME's).

Those questioned felt that the likelihood of using an overseas notified body was unlikely at the initial engagement stage unless there was a reason to do so, e.g. their manufacturer recommended the notified body. Overseas notified bodies were thought to have limited visibility to UK companies. Other issues, such as language barriers, were mentioned as a disincentive. It was also felt that using notified bodies from other countries could also impact timelines adversely. Where the services of notified bodies in some countries, such as Germany, were perceived to be of high quality, those in other countries, e.g. Hungary/Turkey were perceived to be of lower quality and subject to more scrutiny.

The main disincentive in working with overseas notified bodies was the cost. The issue of paying excess for travel and scheduling of auditors from UK notified bodies would not be addressed by doing so and taking this approach would increase costs.

DEMAND MODELLING

Working with a Scottish Enterprise database of all active medtech companies in Scotland, we found 134 companies were currently active and thought to be involved in the manufacturing of medtech products. This represented 26% of the 508 life science companies in the data provided.

Using Companies House records, all companies were qualified as still being operational in financial year 2015/2016. Further research was undertaken on device class, products in market and certification secured through company websites and other online information. Inputs were also sought from Compliance Solutions who had advised or worked directly with many of the companies listed.

From the data our analysis found that the companies were split, as shown in Figure 6, in terms of requirements for notified bodies.

Status	No. of Companies	Percentage of Manufacturing Companies	Percent of Scottish Life Science Companies
Required services of notified body to get product to market	70	52%	13%
Do not require notified body (self certification possible)	18	14%	3%
Do not require notified body as products not medical devices or company not directly selling them	42	31%	8%
Unknown (Incomplete data or info available on company)	4	3%	0.7%

Figure 6. Breakdown of Scottish medtech companies requiring notified body services.

Analysis of the database showed that of the manufacturing companies over half required the services of notified bodies. From the data we could find on the companies who required CE marking over 60% had secured this and are actively selling products in market. 18 companies were able to self-certificate and did not require the services of a notified body. This represented 14% of the medtech companies manufacturing in market.

42 companies did not require the services of a notified body for a variety of reasons. Although these companies are classified as medtech companies actively manufacturing in market, many of the offerings were focused on research and lab equipment which did not qualify as a medical device and some were software products (e.g. patient/workflow management) which did not qualify as medical devices either).

Some of the 42 companies identified were also supply chain providers and manufacturing instrumentation and consumables for medical device use. Others were still in the early stage proof of concept phase for development of eventual medical devices and diagnostics. These technologies were not yet market ready or were being developed for channel partners/distributors who would oversee the final part of commercialisation. Given that these companies were not selling the products directly to market it has been assumed that the responsibility for regulatory compliance will lie with their customers.

For four companies we had incomplete data and were unable to determine whether these companies were active in market (although all were still registered as operating in the UK) and we were unable to determine whether these companies would require the service of notified bodies. Of the seventy companies found to require the services of notified bodies the stage of engagement is shown in Figure 7.

Status	No. of Companies	Percentage of Companies who Require NB services	Percentage of Manufacturing Companies
Actively engaged with NB – CE mark secured or pending	54	77%	41%
Early stage – seeking NB, pre NB stage	10	14%	7%
Not engaged with NB	6	9%	4%

Figure 7. Status of medtech companies requiring the services of a notified body in Scotland.

The majority of companies listed seemed to be actively engaged with notified bodies and had CE marks secured or pending whilst only 14% of companies were still at the stage of selecting or understanding how and if they require the services of a notified body. Six companies were not thought to be engaged with a notified body - this may be due to the fact that these companies are not currently active or at an early stage and unsure of their needs.

Using a SE new start up database it is estimated that twelve new medtech companies enter the sector each year. Assuming the following:

- that each company has only one device that may need a CE mark
- that 50% of new start medtech companies fail before they CE mark a product
- it takes two years from start up to engaging with a notified body,

the number of new customers for a notified body (including the ones not currently engaged [6] and those already at pre notified body stage [10] from Figure 7) would tend to six per year. The total new customers over the initial five year period would be thirty four. Assuming a typical CE marking sale of £20k for a notified body this gives a total revenue over the five year period of £680k from CE marking services with a sales run rate of £120k per year from the Scottish market alone (assuming no conversion of customers away from the current notified bodies). This should be compared against the costs for setting up a Scottish notified body which have been estimated at between £150,000 and £500,000 (see page 29).

Our research suggests that a majority of companies are engaged or sequestered with a notified body, which leaves a small addressable market to completely new companies entering the market. However, as other notified bodies offload existing clients or cease to offer services in specific device types, a proportion of those already engaged with a notified body may re-enter the market. Where notified bodies continue to provide services to existing clients a low level of switch to other notified bodies suggests that medtech companies will remain with their existing provider.

POTENTIAL SOLUTIONS

Using the feedback from our primary research and demand modeling, the final section of this report will look at a variety of options for augmenting access to notified bodies in the Scottish market. We have looked at a range of options and highlighted the strengths and weaknesses of each.

NO INTERVENTION – MAINTAINING THE STATUS QUO

Strengths	Weaknesses
• Market forces dominant, companies and notified bodies will focus on commercially viable and profitable sectors • Changes in regulatory ongoing – market flux unlikely • This is true both at EU level and for international market standards	• Timelines remain unchanged • Impact on market entry times longer for companies • The capacity problem is at EU level – systemic fix required for fuller impact • Companies may fail to survive (run out of funding) • New company entrants at disadvantage – NB's focused on serving existing clients – many have closed doors to new customers • Number of NB's in UK may decrease further • Could be harder to fix later on for the sector and SE • Potential loss of revenue for companies • Risk to jobs
Of the medtech companies we spoke to, there was a desire for changes to the current situation in order to help them access the market. The companies we spoke to recognised that the issues around capacity and timelines required a more systemic fix and were not specific to individual notified bodies or UK based notified bodies. Of the notified bodies we spoke to, there was a desire to move beyond the status quo, however immediate focus for notified bodies was on servicing existing markets and clients and meeting increased regulatory demands linked to the new directives. For this group maintaining a status quo in terms of levels of service delivered was felt to be the most realistic option to address the needs of Scottish, and other, client companies in light of their current capacity and recruitment issues.	
Investment Required	
No investment would be required to maintain the status quo for current access to notified bodies for medtech companies in Scotland	

SETUP OF NEW NOTIFIED BODY IN SCOTLAND

Strengths	Weaknesses
• Strong and growing medtech market • Proximity to companies may increase likelihood of engagement • Reduced travel costs? This is not a certainty and will be dependent on location of staff with required skillsets • Opportunity to build inbound business (gateway to EU) • Costs will increase > MADSAP single audit programme	• Relocation of staff • Limited auditor pool available to existing notified bodies may hamper set up of new NB • Depth and breadth of staff needed – combination of CE/ISO experience across NBOG codes may mean large number of auditors • Time to revenue for a new notified body (est. at 2-3years) • Justifying demand to support the work

	• Retained staff expensive, MHRA not open to using zero hours contracts • Uncertainty of Brexit implications diminishes global opportunity • Existing Scottish experts or auditors may not be able to work with existing companies in market – most have non compete clauses in existing contracts of up to 3 years • Reputation important – need a known team/ figureheads in market

Medtech companies who were queried felt that having auditors in Scotland would potentially reduce the current timelines and costs of working with notified bodies. None of the companies queried specifically mentioned the setup of a new notified body but all agreed on a need for increased access and resource in market.

From speaking with notified bodies, the idea of a new notified body in the UK, or specifically in Scotland, was felt not to be feasible. Many cited the dominant trend at EU level to decrease the number of notified bodies across European markets and it was felt that the MHRA were putting increased scrutiny on existing notified bodies and approval for new market entries would be highly unlikely. Long timelines to revenue (two to three years) would also decrease the likelihood of a "new" notified body entering the market.

Two areas that may be barriers to the setup of a new notified body are the level of demand for this and the low likelihood of companies engaged with existing notified bodies to switch suppliers.

Our demand modeling exercise suggests that a small number of companies (14%) will be in the pre-engagement phase at any given time. Whilst this does not represent a huge volume opportunity there is room for a new operator in the market to pick up new clientele.

Investment Required

For a completely new notified body to set up in market the cost is estimated to be relatively high. As well as legal and regulatory set up costs for their own auditing and compliance process by the competent authority (estimated at £40-50k), a new company would have to retain highly skilled staff over the two to three year set-up period. We have modeled that a minimum of six staff would be required at an average salary of £50k per annum over a three year period, this would represent a £900k investment over a three year period.

From an economic development perspective, support may be required to help with the set up of the company through products like regional selective assistance or where possible support for training and capacity development to cultivate a skilled auditor base and help individuals transition from industry into notified bodies. A 30% contribution to overall costs would represent £285k contribution.

This is not a commercially viable option as judged by the demand modelling.

ATTRACT EXISTING NB TO SET UP IN SCOTLAND

Strengths	Weaknesses
• Strong and growing medtech market • Demand from existing companies • Existing resource and expertise to draw from	• Likelihood of switch limited • Companies rationalising services and geographic coverage (playing to strengths) • High risk as market limited in terms of volume

	• Base is nominal – increasingly global and virtual • Increased risk with independent Scotland operation

As stated above, medtech companies queried felt that having increased access to auditors in Scotland would potentially reduce the current timelines and costs of working with notified bodies.

Of the notified bodies queried, the idea of setting up a dedicated Scotland base or team to service the market was not felt to be feasible or strategically important to them.

This was due to perceived level of demand from the Scottish market and also a dominant trend to rationalise markets and products served for increased sustainability of notified bodies. Furthermore, notified bodies are closing down due to lack of sustainability.

Investment Required

The cost for an existing notified body to set up in Scotland would be considerably less than the estimated £950k for a completely new notified body.

Existing auditors could be relocated from other markets or recruited to a new Scottish branch of the organisation and would be able to generate revenue through working in other markets whilst a customer base is built in Scotland. If the notified body already has a UK base there would be no need to go through the approval process with the competent authority and the company would engage with Scottish medtech companies immediately. If the company is coming from an international market it would need to go through the two to three year's approval process with the MHRA - existing knowledge and systems from the parent company may help accelerate this process. Costs for these options are estimated to range from £100k to £500k.

From economic development perspective, support may be offered to attract an existing UK operator or an overseas operator in the market, or where possible, support for training and capacity development to cultivate a skilled auditor base and help individuals transition from industry into notified bodies. A 30% contribution to this would represent between £30k and £150k.

MORE AUDITORS FOR EXISTING NB'S IN SCOTLAND

Strengths	Weaknesses
• Less cost for companies around travel • Hopefully will reduce timelines • Companies likely to stick with existing suppliers - cost of switch is too high (perceived risk and cash)	• Recruitment of auditor difficult • Retention of auditors difficult • Skillsets, not geographies important for NB's as they are recruiting • They have fixed costs in HQ and other UK bases already • Are already open to recruiting in Scotland with limited success • Not all companies will be served by Scottish auditor base – will depend on their focus and experience. Full coverage unlikely.

The idea of notified bodies recruiting more Scottish based auditors was felt by companies to be a potential fix that would enhance access and decrease price of these services in the Scottish market.

Notified bodies that were actively recruiting for new auditors had no issues with recruitment of more auditors based in Scotland but this was not felt to be of strategic importance to them. Recruitment was heavily focused on finding people with specific skillsets who could service their existing client base and ensure they had adequate coverage across areas of strategic importance.

There is an issue that current consultants could not join a notified body and work with any companies with whom they have had contact in the last three years. The new auditors would also require six months' training with the specific notified body. Together this would limit rapid movement of resource. Furthermore, as notified bodies need auditors to be in house more so than as consultants, and companies also require consultants, both the companies and notified bodies would be competing for the same pool of expertise.

One issue to be considered is that this assumes all of the countries are manufacturing in the UK. For companies who manufacture elsewhere issues around travel costs would still be a big consideration

Investment Required

There are no strong financial requirements for companies to recruit more auditors in the Scottish market. Many companies are proactively recruiting across UK and Europe seeking specific auditor skillsets and this is ongoing. Whilst building a dedicated Scotland team would require investment from notified bodies our research revealed that this was not a strong commercial proposition for existing notified bodies and that there was limited desire to do this.

From an economic development perspective support could be offered to train and develop an auditor base in market to work with existing notified bodies. Recruitment support could also be offered using platforms such as Talent Scotland to attract and build an auditor base in the Scottish market.

TRAINING MORE AUDITORS

Strengths	Weaknesses
• Will enhance talent pool for NBs • Could reduce audit scheduling times for medtech companies • Potential to create a world class center for auditor training	• Not a system fix • Cannot guarantee that the trained talent will stay in Scotland

This could benefit from apprenticeship schemes and align with University courses.

Investment Required

From economic development perspective this would require relatively low investment in terms of time and personnel to organise a training program. Partnerships could be developed with existing teaching/learning initiatives or hubs to minimise costs. However, it should be noted that while this exercise would help notified bodies in accessing talent it would not immediately impact the timelines expressed by medtech companies.

AWARENESS RAISING AND TRAINING FOR SME'S

Strengths	Weaknesses
• Will enhance medtech company understanding of how to engage NB's • Will enhance medtech company's expectations around required timelines for NB services • Opportunity to signpost existing training • Opportunity to signpost or develop specific funding for regulatory	• Not a system fix • Will not impact timelines for service delivery and may lead to wastage (booking early and cancellation) • Not just an issue for startups and SME's – larger companies subject to timeline and cost issues too

• Opportunity to educate investors and board members on regulatory process too	• NB's need to be impartial – can't consult so workshops or training will offer generic guidance • May be perceived as a sales exercise with NB's pitching for business
Of the medtech companies we spoke to, understanding of how and when to engage notified bodies was mixed. Some companies had experienced teams who were au fait with the process and had a proactive approach in engaging notified bodies whilst others found this a challenging area to navigate The notified bodies themselves felt that any educational efforts to help SME's understand this area and how to best engage with them would be beneficial. However, it was recognised that this would not impact timelines or travel costs.	
Investment Required	
From economic development perspective this would require relatively low investment in terms of time and personnel to organise an event or event series. Partnerships could be developed with existing medtech initiatives or hubs to minimise costs. However, it should be noted that while this exercise would help notified bodies in their engagement with companies it would not address the main issues of cost and timelines expressed by medtech companies. During the course of our research notified bodies have shown a willingness to help build understanding of how companies can better engage with them through provision of workshops and sharing of whitepapers in market. The notified body assumes the costs of this as part of an inbound marketing strategy and market engagement exercise.	

REGULATORY SUPPORT SUPPLIERS - ACCREDITATION AND RECOMMENDATIONS

Strengths	Weaknesses
• NB's say they see huge variation in quality, this can impact timelines • Ensure accurate preparation • No one size fits all - no one expert works for all	• No go to person at SE • Understanding of cost/funding • Investment community
As above some of the companies we spoke to felt that the regulatory environment and when and how to access notified bodies was a difficult area to understand. Notified bodies commented that they often see medtech companies approach them at the wrong time and inadequately prepared. One area of concern for notified bodies was the varying quality in regulatory consultancy and support that companies new to the process were receiving. Two of the notified bodies questioned suggested that some sort of rating or accreditation of regulatory suppliers by economic development agencies or provision of help in this discipline in-house might help companies improve readiness. It was felt that this could accelerate time to CE certification from a readiness perspective but would have no impact on the capacity issues or auditor availability that currently impacted service provision timelines.	
Investment Required	
This would require a low level of investment in terms of time and resource to implement if done solely in the local market. Any larger initiative would be likely to require the co-operation of a range of industry bodies, elongating the process and raising the amount of support required. However, in all cases this should consider any SE reputational risk in supporting such an endeavor.	

Again, whilst this initiative may help notified bodies and companies in their preparedness for certification, it does not necessarily address the key issues of travel costs and timelines shared by Scottish medtech companies.

One other area that was suggested during discussion was the potential of a dedicated competent authority for Scotland. This was investigated and it was found that this would only be relevant in the case of Scotland becoming an independent country. Such a move would require buy in at both government and EU level. Whilst this solution could help with clarity and definition of EU standards for Scottish companies at a competent authority level it would not address any of the capacity issues companies are experiencing around access to notified bodies.

CONCLUSIONS

CE marking is important for EU market entry and a globally recognised standard. Directives for this are set at EU level and managed by competent authorities in EU member states. Notified bodies are independent companies who are accredited to audit and assess adherence to CE marking for individual medical technology products. There are five appointed notified bodies in the UK.

Recent and forthcoming changes to the directives around CE marking have led to a rationalisation of notified bodies across Europe with many refining the services they offer and offloading clients accordingly. Increased pressure and requirements placed on their auditor base has led to a bottleneck in demand and elongated timelines to secure the services of a notified body.

Our research has investigated the claim that Scottish companies are experiencing issues around access to notified bodies and timelines for delivery of their services. There is a perception that location in Scotland impacts both of these issues and having more auditors and notified bodies in market would help reduce costs and timelines to access.

From a notified bodies perspective they all recognised that the current timelines for delivery of services were not meeting the needs and expectations of their client base - this was true of clients globally and throughout the UK. They acknowledged that companies not located close to their auditors were often subject to additional travel costs but this was not felt to be pronounced in the Scottish market as they served a global client base that was subject to much greater charges for travel.

Timelines for audits were a problem in servicing their entire client base. This was due to increased requirements of auditors to service their existing client base, difficulties around recruiting and retaining auditors and scheduling for auditors with specific skillsets and designations to work with relevant companies. Flux in the industry has also led to existing notified bodies taking on new clients that have been offloaded by notified bodies exiting areas of operation or ceasing to operate as a notified body ahead of new directives being implemented in early 2017.

While our research has shown that there is a desire from medtech companies for notified bodies to have an increased presence in the Scottish market, this is not a view shared by the notified bodies themselves. Whilst important, the market is felt not to have adequate demand to merit a dedicated team. A claim reinforced by our demand modeling which suggests that at any given time only around 14% of the market is not sequestered with a notified body. While this, combined with market flux, may create an opportunity for a new market entrant, there are considerable barriers to setting up a new

entity and it is only felt to be feasible for those already registered as a notified body in another territory or elsewhere in the UK.

From the UK companies we spoke to, current emphasis is on sustaining their auditor base and ensuring they can meet current client demands as the new directives are implemented in 2017. There was no appetite to set up a dedicated Scottish office or team and focus was on building a globally distributed workforce to service global client bases across a range of device types and NBOG codes. While recruitment of auditors was an ongoing challenge there was not necessarily a geographic focus for this.

Should an overseas notified body seek to enter the market this would entail a two to three year accreditation process with MHRA - the UK competent authority and the company would need to employ a team on territory during this period. Whilst economic development support may be feasible through products such as RSA this would require strong commitment and investment by the parent company.

Post-Brexit, the prospect of doing this may prove les attractive to notified bodies. There is a confidence in the market that adherence to CE marking and associated directives will continue and this will be of continued importance to UK companies. However as a non-member state, the attractiveness of the UK market as an entry point to Europe may be diminished and opportunities reduced to attract a global client base reduced as a result.

Should an international notified body be interested in UK set up this merits further discussion around how adequate demand will be and opportunities to build a global customer base. The capability to do this will largely depend on the existing product types they have expertise in and the focus and scale of the team to be built in Scotland.

Other suggested solutions, such as training provision for companies, expertise or funding for regulatory within economic support services or accreditation of regulatory consultants in market. The notified bodies mainly suggested these, as they could prove useful in setting expectations and growing preparedness of companies engaging and using notified bodies. However, it should be noted that these would have limited or no impact on timelines and cost of engagement, two of the main concerns expressed by medtech companies.

The main option favored by notified bodies was a status quo – as the new directives come into place focus was on sustainability of these organisations and meeting the demand of their existing and emerging customer base. Many were undertaking their own process to rationalise product codes and geographies they serviced globally to ensure sustainability of their company and services and adequate provision of auditors for UK and strategically important geographies such as the US and Middle East.

All parties we spoke to understood that the issues around timelines and securing auditors were in part due to the demands on notified bodies and part of a larger regulatory flux in the market and not solely related to location in Scotland. This was perceived to be a longstanding issue that will be further exacerbated as the new directives are implemented. There was desire across the board for a more systemic fix and commitment to ensuring an adequate supply of notified bodies at UK and EU level. All parties we spoke to were keen that this was an area that trade organisations and economic development services were raising with appropriate bodies and the desire for better access to notified bodies in Scotland was effectively communicated and addressed at a UK and EU level.

Appendix 1 – How EU Directives are Written

Figure 8 shows the process of how EU directives are written and implemented across member states.

Figure 8 provides a brief overview of how EU directives are written for Medical Devices. The first phase of this is a two stage consultative process with member states and parliamentary representatives which may also include input from citizens. Industry enterprises are then consulted on the needs around new directives. Here notified bodies are consulted alongside trade associations, patient groups and clinical societies. The EU commission uses these inputs to draft directives that are put forward to the EU Parliament for consideration.

Beyond this a three party negotiation follows; this will include representation from member states (typically MEP's) representation from industry (notified bodies are usually represented by NANDO, the European Association of Notified Bodies) and representation by employees of the EU commission.

Once both European Parliament and Council have approved the final text of a legislative proposal, it is jointly signed by the Presidents and Secretaries General of both institutions. After signature, the texts are published in the Official Journal and become official. Regulations are directly binding throughout the EU as of the date set down in the Official Journal.

Competent authorities then translate EU directives into the law of the country in which they operate. Competent authorities also specify and oversee notified bodies that can act as independent assessors of compliance with these directives. In the UK the competent authority is the MHRA, the Medicines and Healthcare Products Regulatory Agency. There are five notified bodies with designation to undertake

work under the Medical Devices Directive 93/42/EEC. These include Amtac Certification Services Ltd (Part of the Intertek Group), BSI Healthcare (BSI) Lloyd's Register Quality Assurance Ltd (LRQA), SGS United Kingdom Ltd (SGS) and UL International (UK) Ltd

Appendix 2 – Device Classification

Notified Body Requirements by Device Class (for MDD and AIMDD)		
		Example Products
Class 1 *Low risk*	**No notified body required *** Self certification by manufacturer **If device is sterile or a measuring device a notified body will be required only for measuring function or factors around sterility. For non-measuring / sterile devices no notified body is needed.*	Bandages, Wheelchairs, Glasses, Walking Frames
Class 2a *Low to Medium Risk*	**Notified body required** Audits QMS – manufacturer requires favorable audit to proceed to CE Mark	Disposable contact lenses, sutures, dental fillings
Class 2b *Medium to High Risk*	**Notified body required** Audits QMS – manufacturer requires favorable audit to proceed to CE Mark	Wound dressings, baby incubators dialysis equipment
Class 3 *High Risk*	**Notified body required** Audits QMS – manufacturer requires favorable audit to proceed to CE Mark NB evaluates design dossier submitted by manufacturer and awards certificate of conformity if satisfied with device safety and performance data	Hip Replacements, Drug eluting stents, implanted cardiac pacemakers

Table (above) showing class into which devices fall and some examples of product types.

The classification will be undertaken and approved at competent authority and EU level and is largely based on predicates in market and the other factors listed below:

- How long the device is intended to be in continuous use
- Whether or not the device is invasive or surgically invasive
- Whether the device is implantable or active
- Whether or not the device contains a substance, which in its own right is considered to be a medicinal substance and has action ancillary to that of the device

Where a company has erroneously classified a device this will be pointed out by the notified body or competent authority and they will be asked to resubmit any submissions for approval.

For non-sterile or measuring class 1 devices, generally companies do not need a notified body for audit of the manufacturing process or audit of the company to ISO 13485, unless they have requested it themselves. Self-certifying companies can use the CE mark on their products but are open to challenge on this. For class 1 devices with a measuring function or sterile device, companies require a notified body approval only for the measuring function or the factors around sterility.

Class 2 and 3 devices require the services of a notified body for CE mark approval.

AIMDD (Active Implantable Medical Device Directive) devices are considered high risk by their nature and as such must undergo full quality assurance including design of the product and post market surveillance. These are considered a class 3 device but subject to additional compliance requirements as set out in EC Directive 90/385/EEC.

Appendix 3 – In Vitro Diagnostic Products

In Vitro diagnostic products are medical devices and accessories used to perform tests on samples such as blood, urine or tissue. This applies to any sample that can be taken from the human body to detect infection or presence of a disease or condition, prevent or monitor these or monitor efficacy of drugs and therapeutics. For regulatory purposes IVD's are grouped into 4 categories according to perceived risk/benefit of the IVD failing to perform.

Notified Body Requirements by Device Class (for IVD Medical Devices)		
		Example Products
General	**No notified body required,** Manufacturer self declares	Tests for hormones, cardiac markers, haeomaotology and clinical chemistry kits
Self Test	**Notified body required** Review design/ labels for user suitability	Pregnancy, fertility and cholesterol home tests
Annex II, List B	**Notified body Required** Audit of technical documentation and quality management systems	Rubella, PSA (prostate cancer screening) Self test for blood glucose
Annex II, List A	**Notified body Required** Design dossier review including compliance to the CTS, Audit of quality management system. Batches to be approved and released by notified body	HIV, Hepatitis, ABO Blood grouping test

Table (above) showing class into which In Vitro Medical Devices fall and some examples of product types.

Appendix 4 – Key requirements (and barriers) for setting up a notified body

General
- Resources/services provided in competent, transparent, neutral, independent manner - NB is a legally defined entity and this is documented (legal status, accounts, organisational structure & responsibilities) - Membership of group or larger entity is openly declared
Independence
- No involvement or links with manufacturers - No consultancy services offered, clear separation if part of larger group offering consultancy - Documented processes and resolution for conflicts of interest
Impartiality
- Pay/remuneration not dependent on number of inspections or outcome of inspections - Personnel free from pressure/inducements (especially financially) influencing judgements - Shared procedures on above understood throughout organisation
Technical Competence
- Staff knowledge on training on medical applications, technology and performance of devices being audited. This extends to clinical methodology, technology and performance of devices being assessed under the IVDD - Records of experience and training - For assessment under annex 2/5 of AIMDD, 1,4 and 5 of MDD and 4, 7 of IVDD assessors need experience and knowledge of the technology they are assessing - Sufficient scientific knowledge and expertise within the organisation
Guidance
Management in notified bodies are tasked with ensuring that the personnel used to deliver services are adequately trained and competent in required skills and one member of any audit team hold required qualifications for assessment, these include: - Experience of production methods, testing and verification procedures applicable to type of medical device - Experience of assessing design documents where relevant - Experience of sterile medical devices, microbiological compliance, environmental control and sterilisation process assessment - Experience of biocompatibility assessment - Assessment and evaluation of quality management systems - Application of statistical controls to device verification - Understanding of clinical pathology and conditions/diseases states being assessed by product Assessors must also have personal experience in assessment and management of QMS. A record should be held (and openly available under the QMS) for each assessor detailing their name, areas of competence, education and professional qualifications, relevant work experience and details of further training on assessment approaches, directives, EU guidance and documents.
Facilities
Facilities to carry out assessments, including access to and full control of manufacturing systems being assessed.

Confidentiality
Documented non-disclosure arrangements and processes to ensure client confidentiality. Some exceptions where other notified bodies request access to certification information or information on issue, refusal or suspension of certification. This also has to be shared with the competent authority and designating authorities upon request. Notified bodies are also allowed to share information on devices that are found to risk patient safety with relevant authorities and third parties.
Liability Insurance
Notified bodies are required to have liability insurance valid in the territories in which they operate, This is to protect from misadventure. The notified body itself decides the level of cover. Manufacturers and importers remain responsible for product liability.
Subcontractors
All subcontractors used must conform to the same requirements outlined for notified bodies and the onus is on the notified body to ensure that this is the case and required documentation is in place. Notified bodies cannot subcontract overall responsibility for assessments and audits. Competent authorities must be informed if subcontractors are being used - a register of these must be provided detailing company status, precise duties and roles and individuals providing the service.
Quality Management Systems
Notified bodies need to have an up to date QMS – detailing legal status of entity, responsibilities and reporting structure and the rationale for their scope of responsibility. Documentation needs to include details on assessment personnel (both internal and subcontractors) details on the application process and also on the application review procedure as well as time limits completion and evaluation of verification services and the rationale for these. QMS documents should also detail control and implementation measures to ensure consistent and ongoing management of quality.