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<th>An exploratory framework for the successful commercialisation of combination products</th>
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<td>Cormican, Kathryn; Masterson, Fiona</td>
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SUCCESS ENABLERS FOR THE DEVELOPMENT AND COMMERCIALISATION OF COMBINATION PRODUCTS: AN EXPLORATORY STUDY

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ABSTRACT
Combination products are at the forefront of innovation in the biomedical technology sector. The successful commercialisation of these products, which combine two or more different single-entity products: a drug combined with a medical device, a drug combined with a biologic, or a medical device combined with both a drug and a biologic, has proven to be particularly challenging. However, little is known about the experiences of firms that are involved in this area. Combination product commercialisation has remained an underdeveloped area in the literature.

In this paper we report on the results of an exploratory study that investigated the experiences of key informants from the biomedical technology sector that are involved in the commercialisation of combination products. This research will inform managers, R&D personnel, scientists and engineers in biomedical technology development contemplating entering the area of combination products about the experiences of those who have successful navigated the commercialisation process. The results of this research identify key factors that were found to have helped successful firms in this area.

Results of the study indicate that there are a number of factors that influence the successful commercialisation of a combination product. These factors are: opportunity recognition, strategic regulatory management and product development management.

INTRODUCTION
The development and commercialisation of combination products is not an easy task, as is the case when commercialising any new innovative technology (Christensen, 1997; Moore, 1991; Slater & Mohr, 2006). Because of the complexity and the long times involved with bringing a novel biomedical product like a combination product from idea to market place, few companies enter the area with an understanding of the pre-clinical, clinical, manufacturing, commercial and regulatory issues, and expertise needed (Eselius, Nimmagadda, Kambil, Hisey, & Rhodes, 2008; Kramer, 2007; Mitri & Pittas, 2009; Muni, Gross, Boam, Wang, & Zuckerman, 2005; Shaffer, 2009; Wechsler, 2005). Combination products are defined by the Food and Drug Administration (FDA) as products that combines two or more different single-entity products such as a drug combined with a medical device, a drug combined with a biologic, or a medical device combined with both a drug and a biologic. These single-entity biomedical products that are combined to form a combination product are from industries that were long regarded as separate and distinct (Couto, Perez-Breva, Saraiva, & Cooney, 2011). These are the medical device, pharmaceutical, biotechnology and diagnostic industries. Examples of combination products include drug eluting stents, antibiotic bone cements, surgical meshes with antibiotic coatings and orthopaedic implants with genetically engineered human protein.

Despite the acknowledgement that developing and commercialising combination products is
a uniquely challenging process (Pietzsch & Paté-Cornell, 2008; Zenios, 2009) there is no study available that reports on the experiences of companies who have been successful in this arduous task. The study described in this paper aims to address this research gap. There are a number of texts published on the topic of Combination Products. They focus on such topics as safety evaluation (Gad & McCord, 2008; Lewis, 2010), a review of drug-device combinations (Lewis, 2010) and regulation of combination of products in the U.S (Siegel, 2008). None however discuss the experiences of companies that have successfully developed and commercialised combination products.

In this paper we attempt to address the identified research gap by investigating the experiences of companies that have successfully developed and commercialised combination products. This is done by 20 in-depth interviews with a diverse range of professionals involved in this process. In particular we focus on uncovering the factors that enabled the successful development and commercialisation of their products. Such research is warranted because combination product development and commercialisation is extremely complex (Foote, 2005; Kramer, 2007; Muni, et al., 2005; O'Grady & Bordon, 2003; Pietzsch & Paté-Cornell, 2008; Wechsler, 2005; Zenios, 2009). Reasons for the complexity of this process include the presence of multiple interested parties, the interface of several scientific disciplines (Waters, 2011), the need for coordination between technology and clinical use. Every stage in this process is subject to a different combination of these factors and to the pressures from different stakeholders.

The contributions of this research are twofold. First, this paper should improve the readers understanding of the challenge of developing and commercialising a combination product. Secondly, this paper highlights key factors that if taken into consideration when developing and commercialising a combination product might help improve chances of success.

The remainder of this paper is organised as follows: first, an overview of the existing literature on combination products. Second, we present our research methodology. Third, we present our results. Fourth, we discuss our results. Fifth, we conclude and discuss some managerial implications of the findings, important limitations of our study and some suggestions for further research.

BACKGROUND
Combination products are already well established in the areas of drug delivery technologies and cardiovascular care. The most famous combination product is the Drug Eluting Stent (DES). The DES is a combination of a drug and a medical device. The metal stent (the medical device) is coated with a drug. It is used in the treatment of coronary disease. It successfully delivers drugs directly to targeted areas instead of having the patient ingest higher quantities orally (Maluenda, Lemesle, & Waksman, 2009). The DES has a market range of US$ 5.5 billion globally. The DES has demonstrated that combination products could improve patient care and be profitable for companies that manufacturer them. It is anticipated that the number of such products will grow significantly in the coming years. Table 1 lists a number of combination products that are currently on the market in Europe and the US.
<table>
<thead>
<tr>
<th>Combination Product</th>
<th>Type of Combination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antimicrobial catheters</td>
<td>Device/Biologic</td>
</tr>
<tr>
<td>Surgical Kit with Drug</td>
<td>Device/Biologic</td>
</tr>
<tr>
<td>Dental device with fluoride</td>
<td>Device/Medicinal Product</td>
</tr>
<tr>
<td>Pacemaker leads tipped with steroids</td>
<td>Device/Biologic</td>
</tr>
<tr>
<td>Heparin coated catheter</td>
<td>Device/Biologic</td>
</tr>
<tr>
<td>Drug-eluting stents</td>
<td>Device/Medicinal Product</td>
</tr>
<tr>
<td>Nebuliser</td>
<td>Device/drug</td>
</tr>
<tr>
<td>Prefilled syringes</td>
<td>Device/drug or biologic</td>
</tr>
<tr>
<td>Pen Injector with drug or biologic</td>
<td>Device/drug or biologic</td>
</tr>
<tr>
<td>Transdermal patch (e.g. Nicotine patch)</td>
<td>Device/Drug</td>
</tr>
<tr>
<td>Antibiotic Bone Cement</td>
<td>Device/biologic</td>
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</table>

Table 1; Examples of Combination products

Despite the growing number of combination products being developed, the literature on their development in the drug, biotechnology, diagnostics and the medical device industries has not intersected. There is a abundance of literature on the development process in each individual industry; drug (Dimasi, Feldman, Seckler, & Wilson, 2010; Kaitin, 2010), biotechnology (Korwek, 2007), diagnostic (Phillips, Van Bebber, & Issa, 2006) and the medical device industry (Hodgins, 2004; Shah, Robinson, & Alshawi, 2009). Perusing these does not unearth any major focus on combination products.

Studies done on the product development process of combination products are sparse in the literature. Pietzsch & Paté-Cornell. (2008) noted that there are challenges associated with the successful development combination products due to the significant differences between medical device and drug discovery and development (Pietzsch & Paté-Cornell, 2008). Their study results suggested that regulatory requirements play a substantive role in shaping activities and decisions in the development process. Furthermore (Zenios, et al., 2009), acknowledged that there is limited guidance available at present to help navigate the combination product landscape.

Combining biomedical products from industries that were long regarded as separate and distinct creates challenges. The medical device, pharmaceutical and biotechnology industries each have their own distinct characteristics. The medical device industry is characterised by rapid technological change, short product life cycles, constant iterative improvements or changes. Device ideas are typically originated by individual clinicians or academics (Vecht, et al., 2010). It can take from 2 to 5 years to develop a medical device. The pharmaceutical industry is significantly different to the medical device industry. It is characterised by a highly risky and length development timeframe. It takes 10-20 years to develop a drug, and most drugs fail to get to market (Dimasi, et al., 2010; Paul, et al., 2010). New pharmaceutical drugs are discovered rather than invented. The biotechnology industry also has a number of unique characteristics (Friedman, 2004, 2008; Hine & Kapeleris, 2006). The development of new biotechnology products is based in university laboratories, research institutes, and dedicated biotechnology firms (DBFs) (Powell, Koput, & Smith-Doerr, 1996). Long product-development cycles make biotechnology a capital-intensive business.
A recent study investigated the development of drug-device combination products (Couto, et al., 2011). This study examined the development of two combination products; drug-eluting stents and transdermal patches which combine a medical device and a drug. The authors analysed all the drug-eluting stents and controlled drug delivery system currently approved by the FDA and that required New Drug Application submission. Their investigation found that that the largest barrier to introduce a new kind of combination products is the determination of the regulatory centre that is to oversee its approval.

RESEARCH METHOD AND ANALYSIS
As there have been no systematic studies that have investigated the successful combination products our research is exploratory (Babbie, 2007). Exploratory research is conducted to develop initial insights and to provide direction for any further research needed. Although the number of combination products being manufactured is increasing, there is little empirical evidence to help companies thinking of entering this area fully understand what factors lead to the successful commercialisation of combination products. Therefore, the imperative of an exploratory study is to gain much-needed background information about the process.

This research study targeted firms selling combination products into the European Union (E.U.) and United States (U.S.) markets as they are the largest markets. The U.S. medical technology market is the largest in the world with an estimated market volume of 8.5 billion dollars in 2011 while Europe is the next largest.

The research follows the grounded theory methodology (Strauss & Corbin, 1998). In this method, each research participant is interviewed and the interviews are analyzed using a constant comparative method of analysis, allowing the researchers to develop categories, properties, hypotheses, and theory from the data. Research participants were selected to clarify or confirm emerging themes, and research is discontinued at a point of saturation, when disparate themes no longer emerge. Because the development and commercialisation of combination products is not well understood, we have chosen to use a theory-building approach grounded in the context of rich data. This draws on established procedures for generating theory from qualitative data.

Participants
Participants were selected by a process of theoretical sampling. In this process, participants are selected according to evolving research needs to examine variation in themes or categories. Among the interviewees were senior professionals within medical device manufacturing companies, pharmaceutical manufacturers, contract research organisations and regulators (Table 2). The companies ranged in size from start-ups to early stage to major biomedical technology manufacturers. The companies vary widely in size with a range of approximately $1 million to $8 billion in sales revenue. The combination products studied ranged from drug eluting stents, transdermal patches, drug eluting beads, nebulisers to prefilled syringes. The selection criteria for the interviewees were:

1. The informant must have experience of the development or commercialisation of the combination product
2. The person must be working in the area for at least 2 years.
3. The company must be selling product into the E.U. or U.S. market
<table>
<thead>
<tr>
<th>Interviewee</th>
<th>Position</th>
<th>Business Type</th>
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<tbody>
<tr>
<td>01</td>
<td>Head of Business Development</td>
<td>Device/Drug Manufacturer</td>
</tr>
<tr>
<td>02</td>
<td>Vice President of Product Development</td>
<td>Device/Biologic Manufacturer</td>
</tr>
<tr>
<td>03</td>
<td>Chief Executive Officer</td>
<td>Device/Drug Manufacturer</td>
</tr>
<tr>
<td>04</td>
<td>Head of Business Development</td>
<td>Device/Drug Manufacturer</td>
</tr>
<tr>
<td>05</td>
<td>Head of Business Development</td>
<td>Device/Drug Manufacturer</td>
</tr>
<tr>
<td>06</td>
<td>Director of Regulatory</td>
<td>US Regulator</td>
</tr>
<tr>
<td>07</td>
<td>Head of Clinical Research</td>
<td>Contract Research Organisation</td>
</tr>
<tr>
<td>08</td>
<td>Director of Clinical Research</td>
<td>Contract Research Organisation</td>
</tr>
<tr>
<td>09</td>
<td>Head of Regulatory Affairs</td>
<td>Device/Drug Manufacturer</td>
</tr>
<tr>
<td>10</td>
<td>Regulatory Affairs Specialist</td>
<td>Device/Drug Manufacturer</td>
</tr>
<tr>
<td>11</td>
<td>Chief Executive Officer</td>
<td>Device/Drug Manufacturer</td>
</tr>
<tr>
<td>12</td>
<td>Clinical Assessment Manager</td>
<td>European Regulator</td>
</tr>
<tr>
<td>13</td>
<td>Certification Officer</td>
<td>European Regulator</td>
</tr>
<tr>
<td>14</td>
<td>Quality and Regulatory Director</td>
<td>Device/Biologic Manufacturer</td>
</tr>
<tr>
<td>15</td>
<td>Regulatory Affairs Specialist</td>
<td>Device/Drug Manufacturer</td>
</tr>
<tr>
<td>16</td>
<td>Vice President of Quality Systems</td>
<td>Device/Drug Manufacturer</td>
</tr>
<tr>
<td>17</td>
<td>Quality and Regulatory Director</td>
<td>Device/Drug Manufacturer</td>
</tr>
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<td>18</td>
<td>Project Manager</td>
<td>Device/Drug Manufacturer</td>
</tr>
<tr>
<td>19</td>
<td>Chief Executive Officer</td>
<td>Device/Biologic Manufacturer</td>
</tr>
<tr>
<td>20</td>
<td>Chief Executive Officer</td>
<td>Device/Biologic Manufacturer</td>
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</table>

Table 2; Details about Interviewees

The Interviews
20 semi-structured interviews were conducted between February to September 2011 until theoretical saturation was reached. Interviews lasted between 60 and 90 minutes. The participants were interviewed using an open and then semi structured format based on a common protocol, with audiotape recording of the interview. In accordance with the principles of grounded theory, the topics explored in successive interviews developed according to ongoing analysis of the previous interviews (Strauss & Corbin, 1998). The interviews were fully transcribed.

Data Analysis and Coding Technique

The method of (Corbin & Strauss, 2008), was used for the analysis of the data gathered throughout the interviews. After transcription, the textual dataset was initially reviewed to determine the principal themes that could be found within the interview transcripts at a high-level. The transcripts related with each informant were loaded into Nvivo software to aid analysis. Codes were derived directly from each transcript and appeared as “free nodes” and were then sorted into “tree nodes” once patterns began to emerge. Next the data was analysed by open coding. As described by Strauss and Corbin (1998) the data was broken down into discrete incidents, ideas, events and acts. The data was subsequently broken into discrete parts and reassembled by axial coding. In the final analysis phase the categories were integrated and refined into a larger theoretical scheme by selective coding. The main themes are those drawn from multiple contributions and that represent issues that are clearly central to the participants themselves.
RESULTS
As shown in table 3 ten factors within three themes were identified that enabled the successful development and commercialisation of the companies. The three themes were opportunity recognition, regulatory strategy and product development management.

<table>
<thead>
<tr>
<th>Success Enabler Themes</th>
<th>Sub Success Enabler Themes</th>
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<tr>
<td>Theme 1; Opportunity Recognition</td>
<td>Problem Identification</td>
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<td></td>
<td>Strategic Alliances</td>
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<td></td>
<td>Leveraging Technology</td>
</tr>
<tr>
<td>Theme 2; Strategic Regulatory Management</td>
<td>Knowledge of Regulations</td>
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<td></td>
<td>Classification of Product</td>
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<td></td>
<td>Relationships with Regulatory Authorities</td>
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<td>Experience of EU and U.S. Regulatory Frameworks</td>
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<tr>
<td>Theme 3; Product Development Management</td>
<td>Managing a Complex Process</td>
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<td></td>
<td>Combination Product Skills</td>
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<td></td>
<td>Management of Collaborators</td>
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Table 3: Enablers for the Successful Commercialisation of Combination Products.

**Theme 1: Opportunity Recognition**

*Problem Identification*
All informants highlighted that one should not go down the route of developing a combination product unless there was a clear need for the product. The increased complexity of developing a combination product introduces additional risk which must be offset by a clearly defined market. When a manufacturer of a drug eluting bead was asked how they came up with the product concept he said they developed their product because they could formalise an ad-hoc procedure performed in a hospital: “nobody likes a home brew in science and medicine, so we said that we could standardise that, we could take it through an appropriate regulatory process and therefore that is why we felt that we had established the right kind of entrance strategy [03].” Another informant had identified a clear market for their product, a prefilled syringe: “there are a lot of medical errors when time is of [the] essence. That is where our pre-filled syringes are positioned [04].” All of the companies that had successful commercialised their combination products where very clear about what the market was for their product and what the problem was that their combination product was trying to solve.
Strategic Alliances
The companies that had successfully commercialised combination products acknowledged that because of the complex nature of the product it was unlikely that they had all of the required skills “in-house” to bring their product to market. Clinical trials were highlighted as an area where strategic partnerships were important. Clinical trials for combination products are inherently more costly and complicated than those required for individual drugs, devices or biologics. Strategic alliances are commonly seen between the owners of different components that come together to form the combination product; rather than doing it all themselves, smaller companies licence out their technology to partners that is then incorporated in a combination product. This approach was a common practice that was found during this research. One informant noted that they licensed their technology stating “I think that is another thing that companies with combination products may need to do [03].”

Leveraging Technology
Leveraging an existing technology that has already achieved regulatory approval successfully and been commercialized is seen as a smart strategy when entering the combination product area. If components are already on the market and were a “proven technology”, when they were combined together this would facilitate quicker approval of this product. A nebuliser manufacturer noted “pumps are quite well understood entity with the FDA…they are a proven technology [11].”

Theme 2: Strategic Regulatory Management
Knowing the pathway for gaining regulatory approval for your combination product is seen as critically important by all informants. A number of areas that were cited by the informants are highlighted below.

Knowledge of the Regulations
The chief executive officer (CEO) of a start up company that is developing a new transdermal patch, but who has 18 years experience in the Medical Device industry, said that his strategy in choosing the product to develop was because there were published guidance documents available about this type of combination product and therefore this made him feel more comfortable about entering this field. He eloquently put it as follows “I prefer having tough rules and knowing what they are rather than having undocumented rules and wondering if you are meeting them [11].”

Classification of Product
A number of informants noted that the classification of the combination product is an important strategic decision. If possible, when developing a biologic-drug/device combination try and get your product classified as having its primary mode of action as mechanical and the medicinal action as secondary. As the medical device regulatory pathway is easier both in Europe and the US than the medicinal route. The CEO of a Drug Eluting Beads company said their strategy was to have the drug loaded onto the bead in the hospital, instead of selling it preloaded. This allowed for the product to be classified as a Medical Device in the EU and as a combination product in the US, but with its primary mode of action mechanical. “It was very important that we knew that we would get a 510k and having a device that was loaded by the hospital was crucial to be honest we have not made much progress with the preloaded device from a regulatory point of view, ...... at the outset could have done that we didn’t want to do, the regulators told us what they wanted but a PMA ....it was too expensive for the rate of return and I think that was the right decision, but I think some companies .... given what the product might be might be may not have the freedom to
be able to have a product that loads in the hospital [03].”

Relationships with Regulatory Authorities
One key informant (a Vice President of a medical device company) has been involved with the commercialisation of one of the most famous and established combination product, a Drug Eluting Stent (DES). He was asked what advice he would give to a new start up company who wants to start manufacturing combination products. He referred to the critical importance of the role of the Notified body in the process in Europe, when the medical device is the principal component of the product “The first bit of advice for a start up company is to choose the right Notified Body. I think that partnership is crucial. They will have to certify it, through them you will be reaching out to the drug authority [16]”.

Theme 3: Product Development Management
Managing a Complex Process
The complex nature of the development of a combination product requires tight project management of the development process. One informant, a project manager involved in developing and commercialising a new Drug Eluting Stent in Europe and gaining approval in the U.S. identified the need for experienced people to be in the product development team: “they would have to be very experienced people...each person was chosen by previous experience...we knew each person had to be senior. These were not just people who were starting off; they were all A players [18]”. Combination products frequently are developed by the collaboration of two companies. This causes problems in the development process: “this is one of the inherent problems...more than one company involved...this integration between the two companies is one of the biggest challenges [09]”.

Appropriate Skills
Informants who have worked for companies that have successfully commercialised combination products were asked about why they felt they had been successful. Having the right resources working on the development of a combination product was deemed critical, specifically people who have firsthand experience of working with combination products. Forming partnerships with organisations that possess these skills is often necessary. The integration of the drug, biologic and device requires the merging of the engineering, chemical and biological fields. A Vice President of a DES manufacturer stated “you need people on both sides who aren’t stuck in their own preconceptions [16]”.

Management of Collaborators
Combination products are often produced collaboratively by two or more companies. This can lead to problems such as the ones highlighted by the head of Product Development in a medical device company that produced an insulin pen with a pharmaceutical company. The problem of a medical device company (insulin pen) working a partnership with a Pharmaceutical company was identified by the Head of Product Development mangers in the medical device company “the Pharma people tend to be very neurotic, because they work in Pharma, they almost do not know quite where or how to start when it comes to mechanical things, in principal you would expect it for Pharmaceutical people to understand medical devices as it is less complex [02]”.
DISCUSSION

This research provides some insight into the experiences of companies developing and commercialising combination products. It also provides insights into the views of regulators who are regulating this process. It suggests that there are a number of success enablers that should be focused on by a manufacturer if they wish to commercialise combination products. This discussion will focus on the three themes of success enablers that emerged from the interviews.

The first theme to emerge was Opportunity Recognition. There needs to be a real problem that the combination product is addressing. There is no reason to try and develop a combination product if there is only a small market for this product. Stoddard and Danielsen (Stoddard & Danielsen, 2008) in their discussion on what makes a biomedical technology idea marketable concur with this finding. The comments made by the companies that have brought successful combination products to market support this view.

Strategic alliances are another important success enabler that emerged in this research. This finding concurs with the views in the business and management literature that high technology firms extensively use strategic alliances to gain access to knowledge, resources and capabilities (Bengtsson & Kock, 2000; Haeussler, Patzelt, & Zahra, 2010; Rothaermel & Deeds, 2006; Van de Vrande, Vanhaverbeke, & Duysters, 2011; Zhang, Baden-Fuller, & Mangematin, 2007).

Smart leveraging of existing technology is also an important enabling success factor. The Pharmaceutical industry has been criticised for not putting enough effort into developing new drugs rather than utilising their existing drug portfolios in different ways (Cuatrecasas, 2006; Martinez, Goldstein, Rubenstein, & Winslow, 2007). This research observed Big Pharma partnering with medical device companies to use a drug that was already approved but combining it with a device to develop a new product. The main purpose for doing this is to facilitate better drug delivery. When medical device companies leverage their existing technology with a new component this opens up a whole new market for their product.

Strategic regulatory management is seen as critical when developing an innovative biomedical technology (Abraham & Davis, 2007; Davis, 2008). Researchers have acknowledged that having knowledge on how to determine the appropriate combination product path for regulation would be advantageous to organisations (Gibbs, 2006; Wechsler, 2005). The informants in this study highlighted a number of key areas that should be considered when a company is developing their regulatory management strategy for their combination product. Understanding the regulatory process for combination products will facilitate swift approval by the relevant regulatory authority. Regulatory requirements substantively impact the manner in which new biomedical technologies are developed and bought to market and, by impacting the time for product approval, largely determine when the product can be used on a patient. Pietzsch, Schluzas et al (Pietzsch & Paté-Cornell, 2008) suggested that regulatory requirements play a substantive role in shaping activities and decisions in the process. This was the view also held by the informants in this study.

Product Development Management is a complex process for combination products; the mixing of different technologies and people leads to its own set of unique challenges. Developing a biomedical product is a complex process but added different technologies together with people with different skill sets adds to the complexity (Rochford & Rudelius, 1997). Issues have occurred because of poor regulatory knowledge in the product
development process (Pangarkar, Pharoah, Nigam, Hutmacher, & Champ, 2010). Larger companies with more resources have advantages. For companies without the well-staffed infrastructure to marshal their product through the regulatory labyrinth, this can prove challenging. The results in this study show that successful manufacturers tend to use individuals experienced in combination product development.

Collaboration is at the heart of developing a combination product. This is the case with the majority of novel biomedical technologies. This can also be said for novel radical innovations (Tidd, 1995). Often the ideas for a new biomedical technology might come from a surgeon in the hospital who identified how a procedure could be improved. He/she will not have the resources to develop and commercialise this product so they have to collaborate with a company to translate this business idea into an actual finished product. Gingles and Knechtle, (2008), discuss how surgeons mostly work with collaborators when they want to commercialise a product concept. Others have highlighted the importance of collaboration in bringing a new biomedical technology to market (Riskin, Longaker, Gertner, & Krummel, 2006). The initial findings of this research support these views. Tight project management is required to manage the development process of a combination product. When one or more collaborators are involved, each with different backgrounds, expertise, and expectations problems can occur. Careful thought must be put into deciding who the collaborators will be.

CONCLUSION AND IMPLICATIONS
Developing combination products rapidly and moving them into the marketplace efficiently is important for long term corporate success. The ability to reduce time to market is key to innovation success and profitability (Griffin, 1993). In the competitive biomedical technology sector products must be developed and successfully launched in ever shorter time frames. This is not an easy task. A biomedical product that consists of the combination of products from different industries has its own particular challenges. In spite of the increasing growth in the number of combination products on the market there is lack of understanding about how these products can be commercialised successfully. The analysis of the interviews shows that there are certain factors that influence the likelihood of success when developing and commercialising a combination product.

These factors are:
- Opportunity Recognition
- Strategic Regulatory Management
- Product Development Management

The common theme that emerged from all of the informants is that the development and commercialisation of a combination product is extremely complicated and fraught with challenges. This research paper will hopefully provide knowledge that will help companies navigate through these choppy waters. This paper has contributed to our understanding of the product development process used by companies commercialising combination products in the European and US markets. It has also contributed to our understanding of what the regulatory strategy of such companies and their experience of the current regulatory regimes. As a contribution to knowledge, this paper has drawn together the factors that will impact a biomedical technology company that decides to develop a combination product. The research provides greater insight into the first-hand experience of key informants involved in commercialising combination products.
Managerial and Policy Implications
This paper offers several implications for managerial practice. First of all, the study confirms that the process of developing and commercialising a combination product is not an easy task. Managers contemplating entering this market need to think carefully before deciding on going down this route. Managers are advised to examine if their company is capable of doing it by themselves or should they form partnerships with other companies. Secondly, the results of the study provide valuable information for new product development managers contemplating developing and commercialising combination products. Thirdly, for organisations who already in the process of developing and commercialising combination products, the result of this exploratory study provides them with information on the factors that they should focus on when they are in this process.

This paper also contains suggestions for policy makers. Small medium size enterprises small biomedical companies need to be aware of how they can form partnerships with larger companies to produce combination products. State agencies should have a role in fostering and supporting these partnerships.

Future Research and Limitation:
Findings from this exploration provide the crucial starting point for subsequent investigation into the development and commercialisation of combination products. A quantitative study on a larger sample of companies would help to further support to confirm the findings in the paper. Future research could aim to provide more insights about the importance of each of the success factors. It could also try to determine the relative importance of each factor. This study is not without its limitations. As a result of our research approach, several limitations can be noted, which provide opportunities for further research. Given the small sample size, it is recognised that the results of this study should be considered as provisional. However, given the limited existing research in this area, the findings provide an important point of reference for further work.

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