Case Study Description: Device Development Plan for an Insulin Infusion Pump to meet EU and US Regulatory Requirements

Making it the right way

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# Introduction : developing an Insulin Infusion Pump that meets EU and US regulatory requirements

**Introduction**

This Case Study deals with Continuous Subcutaneous Insulin Infusion Pumps, hereafter simply referred to as Insulin Infusion Pumps.

Insulin Infusion Pumps are medical devices that are in widespread use for the treatment of diabetes for the accurate delivery of a pharmaceutical substance (*i.e.* insulin) to a diabetic patient.

They are small, electromechanical, battery powered, and software driven devices that are carried continuously by the patient, *e.g.*, on a belt or in an other suitable way. For each patient, the pump is set-up (is programmed) to meet the specific therapeutic needs of that patient.

The insulin comes in a cartridge that fits in the Pump. A catheter connects the pump outlet (or cartridge outlet) on one end to a cannula that is inserted into the patient’s subcutaneous tissue on the other end. This establishes the fluid pathway from the insulin reservoir (cartridge) to the patient’s subcutaneous tissue.

Patients themselves interact with the Pump to adjust any programmed parameters to meet their insulin needs or to handle any alarm conditions. Patients are supervised by healthcare professionals to help ensure the safe and effective use of their pumps and the management of their insulin therapy.

Well known manufacturers of such Insulin Infusion Pumps are, *e.g.*, Medtronic, Roche, and Tandem. Other manufacturers, *e.g.*, Insulet and Valeritas, propose Insulin Infusion Pumps with different designs and uses; however, they are out of the scope of the present Case Study.

**Case Study**

You have carefully studied and reverse engineered one of the commercially available Insulin Infusion Pumps. Based thereupon, you have identified the business opportunity to bring a similar Insulin Infusion Pump to market, however at much lower manufacturing cost and with a much more user-friendly user interface. You have created a small start-up company with some core staff. You also have ensured the financial resources necessary to undertake the design and development effort for your Insulin Infusion Pump and for obtaining market authorization in the EU and the US.

As per this Case Study, you are now going to identify how to meet EU and US regulatory requirements for bringing your Insulin Infusion Pump to these two major markets and how to plan for fulfilling these requirements as part of your design and development effort.

This Case Study is composed of four Case Study Exercises (A - D) as per the following paragraphs of this Case Study Description.

# Identifying EU Regulatory Requirements for Your Insulin Infusion Pump.

Among the goals in the Design and Development Plan for your Insulin Infusion Pump is to meet all applicable EU Regulatory Requirements as per the new European Medical Devices Regulation (EU) 2017/745.

For the purposes of this Case Study, we will limit ourselves to demonstrating compliance with the applicable “General Safety and Performance Requirements”, abbreviated as GSPRs. These Requirements are defined in the MDR’s Annex I : General Safety and Performance Requirements. They are split into three Chapters as follows :

|  |  |  |
| --- | --- | --- |
| **Chapter** | **Title** | **Requirement nos** |
|  |  |  |
| I | General Requirements | 1 - 9 |
| II | Requirements regarding Design and Manufacture | 10 - 2 |
| III | Requirements regarding the Information Supplied With The Device | 23 |

**Case Study - Exercise A : Planning for Compliance with EU MDR – Annex I : GSPRs**

|  |  |
| --- | --- |
| **Step** | **Task** |
|  |  |
| A1 | Create a table (in Word or Excel) with the 23 GSPRs.  Make sure you can expand the table to include the results of the other Steps of this Exercise. |
| A2 | For each of the 23 GSPRs, evaluate whether it applies to your Insulin Infusion Pump or not.  If you believe a GSPR does not apply to your Insulin Infusion Pump, then provide a brief justification thereof.  Add a column to the table that you created in A1 that states whether a GSPR applies or not (yes/no). |
| A3 | For each GSPR that applies to your Insulin Infusion Pump provide a high level description on how you plan to fulfil it. Add a column to the table to document this high level description.  In practice, there may be different ways to fulfil a GSPR.  Inherently safe design is one option (and usually the best).  To provide evidence your Insulin Pump fulfils a particular GSPR, you may need to perform testing, often following an International Standard issued by IEC or ISO. In this case, state which International Standard you would use and whether you would perform the testing in-house (in your own laboratory) or in a renowned outside test laboratory.  If you are not sufficiently expert in how to fulfil a particular GSPR, you could decide to work with an outside Expert/Consultant. After all, most companies have their core expertise in house, but you cannot be an expert in everything. For those GSPRs for which you do not have the required expertise in house, you might state that you will work with a to-be-identified external Expert/Consultant to find a suitable route to fulfil those GSPRs. |
| A4 | Now that you have a plan to fulfil each of the GSPRs that apply to your Insulin Infusion Pump, briefly comment on the following issues :   * Which GSPRs do you find most difficult to fulfil and why? * Which GSPR do you think will be most time consuming to fulfil and why? * Which GSPR do you think will be most costly to fulfil and why? |

# Identifying US Regulatory Requirements for Your Insulin Infusion Pump

Among the goals in your Design and Development Plan for your Insulin Infusion Pump is to submit a 510(k) application to the FDA to get clearance to market the pumps in the USA.

The FDA has issued a comprehensive guidance document entitled “Infusion Pumps Total Product Life Cycle”, issued on December 2, 2014. The document specifies which information is recommended to be provided to the FDA as part of your 510(k) submission. The information FDA recommends to be included in your 510(k) submission is further described in Sections 4 and 5 of the guidance document as per the below summary table.

|  |  |  |  |
| --- | --- | --- | --- |
| **Section** | **Subsection** | **Title** | **Comment** |
|  |  |  |  |
| 4 |  | Device Description |  |
| 5 |  | Safety Assurance Case |  |
|  | A | General Considerations for Safety Case Development |  |
|  | B | Hazard Analysis |  |
|  | C | Performance Testing | In particular, this section deals with :   * Operational Safety * Environmental Safety * Electrical Equipment Safety * Hardware Safety * Software Safety * Mechanical Safety * Biological Safety * Use Safety   Each of these issues is further detailed in the guidance document. |
|  | D | Labeling |  |
|  | E | Alarms |  |
|  | F | Safety Control Mechanisms |  |

**Case Study - Exercise B : Planning for Compiling the 510(k) dossier.**

|  |  |
| --- | --- |
| **Step** | **Task** |
|  |  |
| B1 | Create a table (in Word or Excel) with the elements of Sections 4 and 5 of the cited FDA guidance document. Use a sufficient level of detail (but not too detailed) for a meaningful evaluation of each element. Make sure you can expand the table to include the results of the other Steps of this Exercise. |
| B2 | For each of the elements of Sections 4 and 5 of the cited FDA guidance document, evaluate whether it applies to your Insulin Infusion Pump or not.  If you believe an element does not apply to your Insulin Infusion Pump, then provide a brief justification thereof.  Add a column to the table that you created in B1 that states whether an element applies or not (yes/no). |
| B3 | For each element of Sections 4 and 5 that applies to your Insulin Infusion Pump provide a high level description on how you plan to fulfil it. Add a column to the table to document this high level description.  In practice, there may be different ways to fulfil such element.  Inherently safe design is one option (and usually the best).  To provide evidence your Insulin Infusion Pump fulfils a particular requirement, you may need to perform testing, often following an International Standard issued by IEC or ISO. In this case, state which International Standard you would use and whether you would perform the testing in-house (in your own laboratory) or in a renowned outside test laboratory.  If you are not sufficiently expert in how to fulfil a particular requirement, you could decide to work with an outside Expert/Consultant. After all, most companies have their core expertise in house, but you cannot be an expert in everything. For those elements for which you do not have the required expertise in house, you might state that you will work with a to-be-identified external Expert/Consultant to find a suitable route to fulfil those GSPRs. |
| B4 | Now that you have a plan to fulfil each of the elements that apply to your Insulin Infusion Pump, briefly comment on the following issues :   * Which element do you find most difficult to fulfil and why? * Which element do you think will be most time consuming to fulfil and why? * Which element do you think will be most costly to fulfil and why? |

# Comparing EU and US Regulatory Requirements for Your Insulin Infusion Pump

Based on the work done in Exercises A and B, you will now have a high level understanding of the most important regulatory requirements for your Insulin Infusion Pump and you will have a high level plan on how to fulfil those requirements as part of your design and development effort.

Many EU and US requirements are fundamentally very similar, as are the ways of fulfilling them. To a large extent this helps to avoid duplication of design and development efforts, if you want to bring your Insulin Infusion Pump to both markets.

Some requirements are specific to either the EU or the US and you will have to provide the specific efforts to fulfil them.

**Case Study - Exercise C : Comparing EU and US Regulatory Requirements**

|  |  |
| --- | --- |
| C1 | Give two examples of very similar EU and US regulatory requirements for your Insulin Infusion Pump and hence similar ways of fulfilling them. |
| C2 | Identify one requirement for a 510(k) submission for your Insulin Infusion Pump that is very specific to this submission (and that those not really have a comparable GSPR). |
| C3 | Identify one GSPR for your Insulin Infusion Pump that is very specific EU requirement (and that does not really have a comparable element in the FDA Infusion Pump guidance). |
| C4 | If you would only have the resources to bring your Insulin Infusion Pump to either the EU market or the US market (but not to both of them), which market would you go to? Briefly explain why. |

# Writing the Case Study Report

**Case Study – Exercise D : Write the Case Study Report using the Case Study Report Template.**