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# PURPOSE

This Business Market Assessment Tool provides guidance for the [Device Name(s)] designed by [Company name] to use as a guide for forecasting revenue and profitability taking into consideration regulatory requirements and changes in specific geographical markets. To estimate the regulatory and clinical costs, you will first need to complete the Regulatory Pathway Assessment Guide (RPA). It is a separate document that you can access from the leanRAQA website at [www.leanraqa.com](http://www.leanraqa.com).

The goal of this Business Market Assessment Tool is to help your company forecast revenue and costs by geographical location. This information can be used to assess feasibility of continuing to sell within a specific region, expand with new product lines and/or decide where to launch a new product, all based on geographical market revenue potential and regulatory requirements.

# MARKET OVERVIEW

The [Device Name] designed by [Company name] is [insert what it is used to treat…]. The estimated market size is […]. The unmet clinical need that [Device Name] solves is […].

The Market trends are […list market trends and how they impact sales of your product by geographical location].

The Clinical trends are [list clinical trends and how they impact sales of your product by geographical location].

For the U.S. market take into consideration reimbursement, GPO’s (group purchasing organizations) and IDN’s (integrated delivery networks). For the E.U. market take into consideration each countries buying cycle as well as the cost difference vs. the U.S. market. Make sure to list assumptions as to how you derived your numbers.

Use Table 1 if the goal is to forecast sales of existing products. Make sure to include what percentage you expect sales to increase or decrease in a specific region. Choose one currency (e.g. the euro or USD) for all calculations

## Table 1: [Insert Product Name] Sales

|  |  |
| --- | --- |
|  |  **[insert product name] Sales** |
| **Revenue**  | **Prior Year** | **Current Year (forecast)** | **Current Year +1 (forecast)** | **Current Year +2 (forecast)** | **Current Year +3 (forecast)** | **Current Year +4 (forecast** |
| **Europe** |   |   |   |   |   |   |
| **US** |   |   |   |   |   |   |
| **Other Geographies** |   |   |   |   |   |   |
| **Total Sales** |   |   |   |   |   |   |
|  |   |   |   |   |   |  |

Use Table 2 if you are launching a new device in a market that has data on device usage e.g. launching a new feeding tube in the EU. Include what percent you expect sales to increase or decrease in region. Choose one currency (e.g. the euro or USD) for all calculations.

## Table 2 [Insert New Product Name] Based on Annual Device Usage

|  |  |
| --- | --- |
|  | **New (insert new product name) Sales based on Annual Clinical Incidence** |
| **Market** | **Total Annual Incidence** | **% Device Usage** | **Total Potential Revenue** | **Year 1 (% estimated revenue)**  | **Year 2 (% Estimated Revenue)**  | **Year 3 (% Estimated Revenue)**  | **Year 4 (% Estimated Revenue)**  | **Year 5 (% Estimated Revenue)**  |
| **Europe** |   |   |   |   |   |   |   |   |
| **US** |   |   |   |   |   |   |   |   |
| **Other Geographies** |   |   |   |   |   |   |   |   |
| **Total Sales** |   |   |   |   |   |   |   |   |
|  |  |  |  |  |  |  |  |  |
| Assumptions |
| * List Assumptions here
 |

Use Table 3 if you are launching a novel technology that has no device competitor. In this instance you need to look at the annual clinical incidence of the disease by geography, clinical treatment methods and clinical practice to forecast how often your product will be used. Choose one currency (e.g. the euro or USD) for all calculations.

## Table 3 [Insert New Product Name] Based on Annual Clinical Incidence

|  |  |  |  |
| --- | --- | --- | --- |
|  | **New [insert new product name] Sales based on Annual Clinical Incidence** |   |   |
| **Market** | **Total Annual Incidence**  | **Clinical Practice Usage Estimate (define usage by day, week or month)** | **Total Estimated Market for Device (units)** | **ASP** | **Total Potential Revenue** | **Year 1 (% estimated revenue)**  | **Year 2 (% Estimated Revenue)**  | **Year 3 (% Estimated Revenue)**  | **Year 4 (% Estimated Revenue)**  | **Year 5 (% Estimated Revenue)**  |
| **Europe** |   |   |   |   |   |   |   |   |   |   |
| **US** |   |   |   |   |   |   |   |   |   |   |
| **Other Geographies** |   |   |   |   |   |   |   |   |   |   |
| **Total Sales** |   |   |   |   |   |   |   |   |   |   |
|  |  |  |  |  |  |  |  |  |  |  |
| Assumptions |
| * List Assumptions here
 |

# COST CONSIDERATIONS

The following section will outline the costs to take into consideration for [insert product name]. It is very important to include the regulatory costs to be compliant within a region, e.g. the U.S. requires compliance with the FDA, E.U. Medical Device Directive to Medical Device Regulation transition period. Make sure to incorporate all the information gathered from the leanRAQA Regulatory Pathway Assessment in terms of device classification, applicable testing, registrations, annual fees and on-going reoccurring costs including annual registrations & market surveillance. It also important to include other costs such as prototypes, clinical testing, clinical support, preparation and transfer to manufacturing (IQ, OQ, PQ) if design changes were required to become compliant to a new standard. Choose one currency (e.g. the euro or USD) for all calculations

## Table 4 Cost Considerations by Geographical Region

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Cost Considerations** | **Year 1** | **Year 2** | **Year 3** | **Year 4** | **Year 5** |
| **Cost/Unit by Location:** |  |  |  |  |   |
| EU |   |   |   |   |   |
| US |   |   |   |   |   |
| Other Geographies |   |   |   |   |   |
| ***One Time Costs***  |   |   |   |   |   |
| Marketing  |   |   |   |   |   |
| EU Regulatory cost (MDR compliance gap analysis, audits, testing such as biocompatibility testing, etc.) |   |   |   |   |   |
| US Regulatory cost |   |   |   |   |   |
| Other Geographies Regulatory cost |   |   |   |   |   |
| R&D |   |   |   |   |   |
| Other (prototoypes, IQ, OQ, PQ testing, etc.) |   |   |   |   |   |
| ***Recurring Costs*** |   |   |   |   |   |
| EU Regulatory cost (e.g. notified body fees, audits, etc.) |   |   |   |   |   |
| US Regulatory cost ( FDA registration, audits, etc.) |   |   |   |   |   |
| Other variable cost as % of revenue |   |   |   |   |   |
| **COGS per Unit** |   |   |   |   |   |
| EU |   |   |   |   |   |
| US |   |   |   |   |   |
| Other Markets as applicable |   |   |   |   |   |
|   |   |   |   |   |   |
| Other OPEX |   |   |   |   |   |
|  Commissions |   |   |   |   |   |
|  Maintenance |   |   |   |   |   |
|  Other |   |   |   |   |   |
| Total Other OPEX |  |  |  |  |  |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
| **Total Operating Costs** |  |  |  |  |  |
|  |  |  |  |  |  |
| **Assumptions** |
| * List Assumptions here
 |

# DECIDING WHICH GEOGRAPHICAL REGIONS TO MARKET & SELL

A basic high level Proforma is helpful to understand revenue, costs and margins in each geographic market segment. The information can be helpful in determining which markets to continue selling in or decide whether to launch in new locations. It will also give an idea of the profitability of markets where there are regulatory changes that require a significant investment to become compliant such as the MDD to MDR transition. Choose one currency (e.g. the euro or USD) for all calculations

## Table 5 Proforma [insert product name or company name]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Proforma | **Year 1** | **Year 2** | **Year 3** | **Year 4** | **Year 5** |
| **Revenue (use revenue from the Table that best fits your business model)** |  |  |   |   |   |
| EU Market |   |   |   |   |   |
| US Market |   |   |   |   |   |
| Other Markets |   |   |   |   |   |
| **Total Revenue** |  |  |  |  |  |
| *Revenue Growth* |  |  |  |  |  |
|   |   |   |   |   |   |
| **Cost of Goods Sold (use information from Cost Considerations)** |  |  |  |  |  |
| EU Market |   |   |   |   |   |
| US Market |   |   |   |   |   |
| Other Markets |   |   |   |   |   |
| **Total Cost of Goods Sold** |  |  |  |  |  |
|   |  |  |  |  |   |
| **Gross Profit** |  |  |  |  |  |
| EU Market |  |  |  |  |  |
| US Market |  |  |  |  |  |
| Other Markets |  |  |  |  |  |
| **Total Gross Profit** |  |  |  |  |  |
|   |  |  |  |  |  |
| *Gross Margin* |  |  |  |  |  |
| EU Market |  |  |  |  |  |
| US Market |  |  |  |  |  |
| Other Markets |  |  |  |  |  |
|   |  |  |  |  |   |
| **Expenses**  |   |   |   |   |   |
| List all expenses from Cost Considerations |   |   |   |   |   |
| EU Market |   |   |   |   |   |
| US Market |   |   |   |   |   |
| Other Markets |   |   |   |   |   |
| **Total Expenses** |  |  |  |  |  |
|  |  |  |  |  |  |
| *Expense to Revenue* |  |  |  |  |  |
| EU Market |  |  |  |  |  |
| US Market |  |  |  |  |  |
| Other Markets |   |   |   |   |   |
|   |  |  |  |  |   |
| **Net Income** |  |  |  |  |  |
| EU Market |  |  |  |  |  |
| US Market |  |  |  |  |  |
| Other Markets |  |  |  |  |  |
| **Total Net Income** |  |  |  |  |  |
|   |  |  |  |  |  |
| *Net Margin* |  |  |  |  |  |
| EU Market |  |  |  |  |  |
| US Market |  |  |  |  |  |
| Other Markets |  |  |  |  |  |
| **Total Net Margin** |  |  |  |  |  |
|   |  |  |  |  |   |
| **EBITDA** |  |  |  |  |  |
| EU Market |   |   |   |   |   |
| US Market |   |   |   |   |   |
| Other Markets |   |   |   |   |   |
| **Total EBITDA** |  |  |  |  |  |
|   |  |  |  |  |   |
| *EBITDA Margin* |  |  |  |  |  |
| EU Market |   |   |   |   |   |
| US Market |   |   |   |   |   |
| Other Markets |   |   |   |   |   |

# CONCLUSIONS

[Use this section to bring together the data from the Market Overview, Revenue Estimates, Cost Considerations and Proforma to create a marketing/sales strategy based on geographical location]

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