




CASE STUDY: REVOLVER 2017

A SABRE SIGHT TOOLKIT

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BACKGROUND

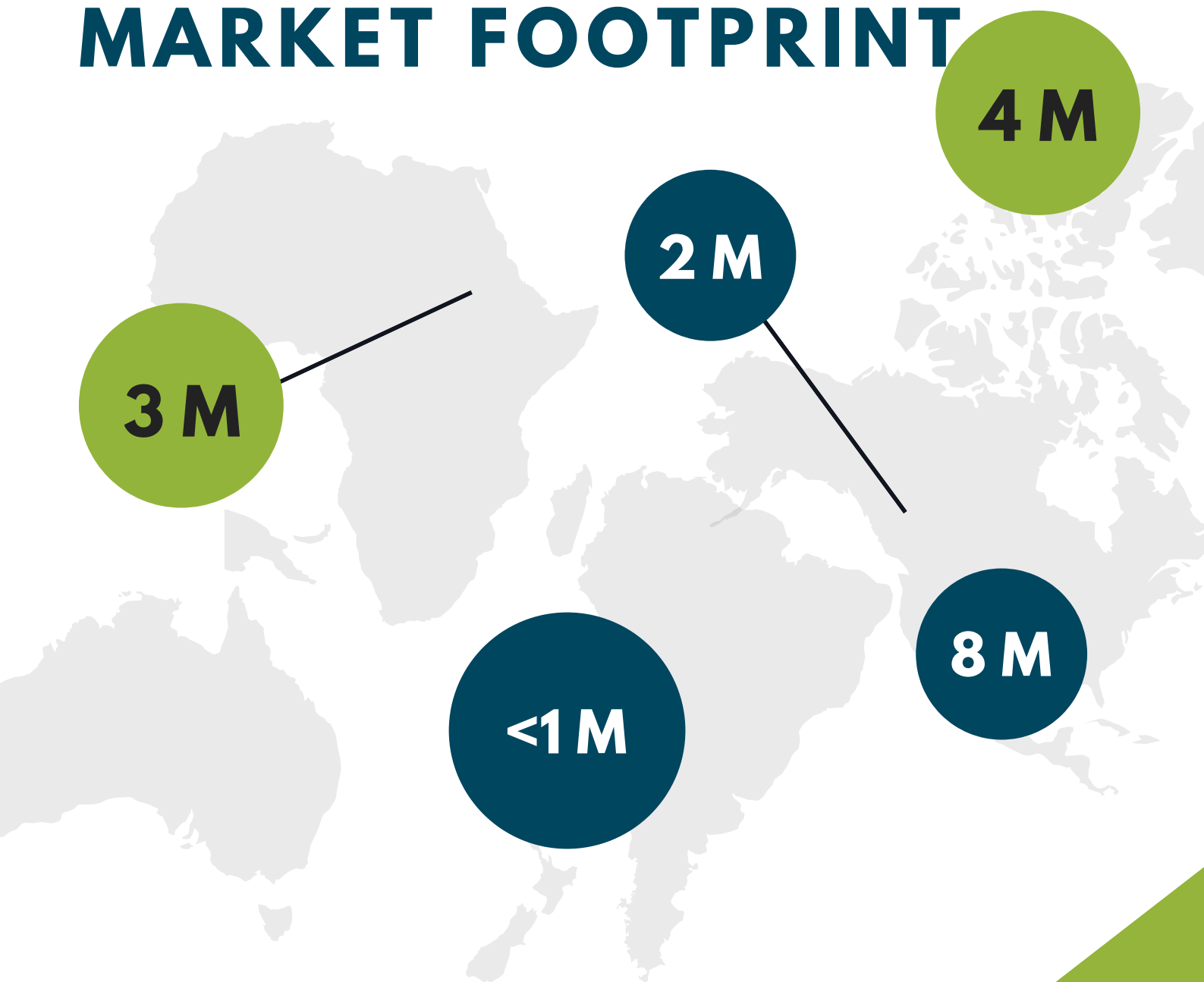
This case study has been developed by our consultants, from our SABRE Sight Design Thinking platform, as a template on the competencies of how the REVOLVER method has connected teams and developed specific process understanding to fully harmonize gaps within the product development cycle for diagnostic healthcare, stemming from initial conceptualization to market feasibility to consumer integration.

About Rubix LS:

Formed in 2016, Rubix LS is a full cycle ERO (engineering research organization) within the life-science sector, that fully develops product engineering technologies stemmed from translation of heavily intensive research and development, engineering feasibility, product development, market implementation and post-market analytics and resolution augmentation through federal regulatory agencies such as the FDA.

For confidentiality, all client referenced information shall remain anonymous to protect the parties involved.

THE CLIENT'S PRODUCT MARKET FOOTPRINT



The client's profile of transactions spans the major continents in the field of general technological engineering in life-sciences, robotics & environmental sectors.

R.E.V.O.L.V.E.R & Business Process Optimization in Healthcare Product Development

A toolkit from the Rubix LS SABRE Sight solution based approach transforming how healthcare product research and development should be.

Overview

The need

Historically a contract manufacturing facility for manufacturing diagnostic care devices for their direct clientele in the United States. A Toronto based organization wanted to break into a secondary value stream of bringing to market a novel diagnostic renal care monitoring device. With no understanding of the regulatory challenges, product development challenges and internal collaboration they were looking to bring Rubix LS aboard to develop, from cradle to grave, the whole lifecycle of a healthcare device.

The solution

Rubix LS (formerly Rubix Strategies LLC) provided a toolkit developed through their SABRE Sight solution based approach otherwise known as REVOLVER. Elements of the toolkit abridges technical, business and performance dependencies and formulates it to a tailored market design project charter that becomes the roadmap to deployment success.

The benefit

Data and understanding has long remained a “tribal knowledge” center ideology. This tool becomes the pathway in disseminating information and methodologies that tools organizations to make informed and efficient decisions that will serve for the augmentation of product performance and business optimization.

A Toronto based contract manufacturing facility, processed assembly and subassembly units & technologies for diagnostic devices primarily in the healthcare biotechnology sector. Although they’ve had long standing operations and products within aerospace systems, robotics and consumer goods; they’ve been trying to overcome challenges within their manufacturing supply chain to be able to break into product development of innovative technologies to market to the end user: hospital administrations, surgeons and point of care facilities. Historically, they’ve had struggles on translating technological feasibility into the market due to large deficient gaps of a product deployment life-cycle; in-turn, our toolkit, REVOLVER, became the solution that helped transition the development to understand: market analytics of technologies, internal/external product development challenges, quality challenges, regulatory challenges and organizational support challenges.

The Challenge

The nature of the current contract manufacturing organization has relatively remained unchanged since the company inception. At the creation of the business, the core development was geared toward aerospace manifolds and turbine pieces. Through generational transitions, the company remained within the horizontal landscape of contract manufacturing but have explored and refitted the operation to encompass nuclear, technology via electronic PCB boards, and lastly medical diagnostic care assemblies. As the company shed its image from being a contract manufacturer of pure aerospace to transition into more of a technology development firm by way of medical devices, the inherent challenges presented itself in a compendium of forces: Business case, identified need, organization need, quality support, manufacturing support, regulatory support and many other minutiae that intersected with the overlying general elements.

“The whole supply chain didn’t start out in a disarray, it eventually descended into unyielding territory that we weren’t ready to be fully engaged in” says a Quality Manager. As many of the main clients they’ve been able to provide supporting operations for, have been in the diagnostic device space for point of care devices in a doctor’s office setting; The executive suite developed a business plan in which the company would seek to explore a new market opportunity for direct selling diagnostic care devices in the end stage renal disease care management arena. With an unpolished barometer about market space, the company chiefs commanded the rest of the operation to start product development of a novel device with no background and technical expertise in designing the operations to fit the strategy. After a numerous amount of sputtered starts, the company then seek to send out a request via a request for proposals on convening with a company with understanding how to deploy a product cycle to the market. After demonstrating subject matter expertise, Rubix LS (formerly Rubix Strategies LLC) was chosen to delve into the missteps that have been taken by the firm and the understanding of what product should actually be developed.



“The REVOLVER toolkit has really been a game changer for us. This toolkit has really transformed our operation on understanding the pitfalls of product development and how integrative the solution is for plugging right into the regulatory landscape.”

— Client Executive, CFO

For the months of June 2016 through January 2017, Rubix convened with many of the stakeholders that ranged from sales, customer service, engineering (including R&D), manufacturing, to quality & shipping on the following:

- Initial conceptualization of need of business unit developing novel device
- Operation benchmarking
- Total Healthcare landscape market analysis
- Organization Inter-dependency development
- Regulatory Department formulation and governance
- Internal mechanisms to develop for industry and regulatory compliance

The Approach

From the initial kickoff meeting, our consultants and data scientists worked alongside the client’s team to develop the market research data and pathway report that would calibrate the executive team to plan and coalesce:

- A better understanding of the key market gates and touch points of supply chain management
- Patient engagement & data intelligence aggregation of market capture, qualitative population feedback & measurements, subject matter influence feedback (nuclear endocrinologists, nephrologists and other)
- Key Healthcare business drivers; Market liabilities, CMS rulings, Reimbursement, HIPAA & other security measures
- Comparable device investigations and predicate device inclusions
- Governing regulatory roadmap on:
 - Overall product approvals
 - Device technical approval & guidance
 - Internal best practices from current good manufacturing practice understanding (cGMP)
 - Quality mechanisms of measuring viability and continuing validation
 - Post Market surveillance and cost of maintenance
 - Software/Hardware product development & engineering guidance (Phase I – Phase IV)
- Engineering best practices and cost burden mitigation
- Aggregate predictive healthcare events to perform continuous product enhancements based on device security and performance data/reports.

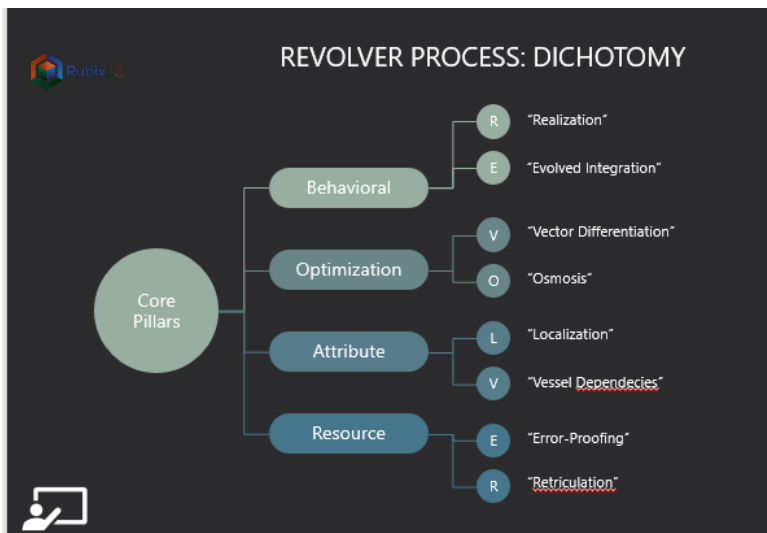
As the main market was to target Veteran Hospitals in the United States, since the manufacturing operation provided full level assemblies of their client to the same hospitals. The target approach was to take a thermostat of the current deficiencies oh comparable devices.

The platform builds on features within the Rubix LS consultant competencies products to help improve data aggregation and other operational processes.

The Solution Implemented

Aligning REVOLVER and the end need of client was to utilize a process method approach; the strategic roadmap developed by Rubix for the firm the cascading implementation was to arm the client with more data sets for an intelligent market analysis of product need. In August 2016, Rubix LS collaborated with the Veteran Affairs Medical Center in Buffalo, NY within the Nephrology ward, to perform a benchmark study consisting of:

- End user adoption quotient (a formulaic deployment tool; from 1-4; developed by Rubix on the likelihood of new product adoption)
- Population user preferences



Utilizing data sets of 184 devices used in the Nephrology ward, the consultants of Rubix LS developed stratification of performance data within each device to formulate a gap analysis between all the devices. A gap analysis consisted of input from device performance to interoperability within hospital system.

Translating the deficiencies identified from the gap analysis, armed the client organization with a blueprint of necessary action items (curated by the consultants of Rubix LS) to validate mechanistic and software programmatic designs that would specifically meet the details and needs identified by the ultimate end user and patient population. This in turn, developed a roadmap in which details the crucial steps of product development for viability of product realization that meets the user defined criteria and the touch points of how the operability of the device interacts within the landscape of CMS (Central Medicaid Services) and compliant with 21 CFR 11 & HL7 (software development security) standards.

The Future

As technological advancements from competitors, market adoption scarcity, and the nature of the regulatory landscape changes the configuration of how diagnostic device care is managed; the patient integrative feature is becoming one of the more vital points of consideration as technologies are being geared toward precision targeting and precision monitoring. Propelling organizations is a principal factor that Rubix considers as a success competency. See how the REVOLVER toolkit can augment your business.

For more information

To learn more about how Rubix LS can help you improve your project capabilities, please contact the team at info@rubixls.com, or visit our website: www.rubixls.com.





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