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Description	一般講演要旨

針無し注射のベンチャー・ビジネスの成功・失敗要因に関する研究

A Study on Causes of Success and Failure in
The Venture Business of Needle Free Syringes

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Keyword: Management of Technology, Business Model, Causes of Success and Failure

Abstract: This paper examines the causes of success and failure of development and innovation of the needle free injection system. Most needle-free injection systems have been developed by venture companies or new entrepreneur startups. Large major companies have ignored this new market.¹ The World Health Organization estimates that 12 billion hypodermic injections are given in healthcare settings around the world each year.² In the past many companies tried to develop needle free devices. Some of these new technologies offer vastly superior capabilities than existing technology, however acceptance of many of these new innovative and superior medical device products often encounter tremendous resistance and neglect by major market players in the marketplace.³ In the USA, only about 0.10% of firms ever achieve revenues of more than \$250 million in sales and only 0.036% become successful attaining over \$1 billion in sales⁴ Most of the new startups have failed in the past or stayed small.

Introduction

In this paper, we examine several needle free injection startup companies and analyze weaknesses and failures, reasons why they failed and how they could have succeeded.

1.A Study of Failures

Why Startups of needle free injection systems fail or stay small:

- 1) Market Challenges.
 - A) High cost; Most of needle free injection systems are very high cost and could not compete with the needle syringe. (10 US cents/pc for syringe vs. US\$1.00/pc for needle free). For manufacturing new products, it requires setting new facilities, factory space, new machineries and equipments with new raw materials.
 - B) High cost of marketing. Set up a new marketing team. New Customer acceptance. Initial products may not be user friendly. Therefore initial products need to be revised or modified until customers are satisfied, which will be very costly for the startups if they conduct such innovations without alliances.
 - B) High cost of R & D
- 2) Business Model Failure
 - A) Business relies on only one customer i. e. Bioject Inc. relied on big pharma to market their product. (ie. Ferring, Growth hormone, Zomacton)⁵. The Medical device company is vulnerable and relies on big pharma companies' fate, meaning if the drug is to be used for needle-free and that particular drug is not approved by the FDA then its contract is canceled.
 - B) No Targeted market (lack of focused marketing)
 - C) Poor Management Team / inexperienced, incompetent leader or founder. Such leaders have no vision and fail to create a powerful guiding coalition-partners. Kotter adds (1)allowing complacency, (2)underestimating the power of vision, (3) grossly under

communicating the vision. (4) permitting people or structures to block the new vision, (5) failing to Create short-term wins, (6) declaring a premature victory, and (8) neglecting to anchor changes in the corporate culture.⁷

- D) Running out of Cash: High cost of marketing and R & D / daily operations.
- E) Product Challenges/Poor Quality Problems/Dislike appearance-unattractive, “tool-like”

i. e. Antares Pharma Inc. marketed needle free syringe in Japan through JCR. The products were recalled because of ampule breakages.

- F) Competing against the existing major needle syringe companies, startups will not be able to compete against financially strong competitors. For example B. D., Terumo, Nipro etc.

We found that the major medical device and needle syringe manufacturers have generally overlooked needle-free drug delivery technology. They have their substantial business of needle syringe which are their core business. Takayama illustrates the importance of the mode of competition of a new product with existing products, regardless if the two are in the same market sector, has been amply illustrated so far. The practically deterministic situation may be summarized in a matrix shown in Table 1. An enterprise (major or otherwise) will make serious efforts in developing a new product that may compromise existing core products. In this case, leading companies with a wealth of experience and information associated with those core products are in a highly advantageous position, so that chances for inexperienced newcomers are scarce.⁶

Table 1

	Direct competition	Indirect competition
Majors	Win	Loss
Newcomers	Loss	Win

2. A Study of Successes

A) Why Startups of needle free injection systems succeed:

- 1) Vision / Design i. e. Apple has been successful marketing the iPhone because of its design. “The design of a great medical product often requires that focus be on safety. Design of a great consumer product requires a focus on aesthetics and loyalty—users have to love it. The medical experience and the consumer experience are generally seen to be very different from one another. A medical device is something to be tolerated while consumer is something to be enjoyed. Medical products generally look serious and functional and dull. Consumer products are designed to evoke a delightful feeling from users.”⁷ Successful engineers in startups think that now patients are the same as consumers. Patients do not have to be patient any longer. Successful startups treat patients like a king.
- 2) Accurate Budgeting
Estimate sales based on a business plan. Make a system to get a hold of conditions of manufacturing goods—contract medical device assembler.
- 3) Discipline: Do not hesitate to execute “What and When”. Successful companies understand excuting “What and When”, “How” will follow from collaboration, alliances, partners or lead uses.
- 4) Persistence

According to the Journal of Business Venturing,

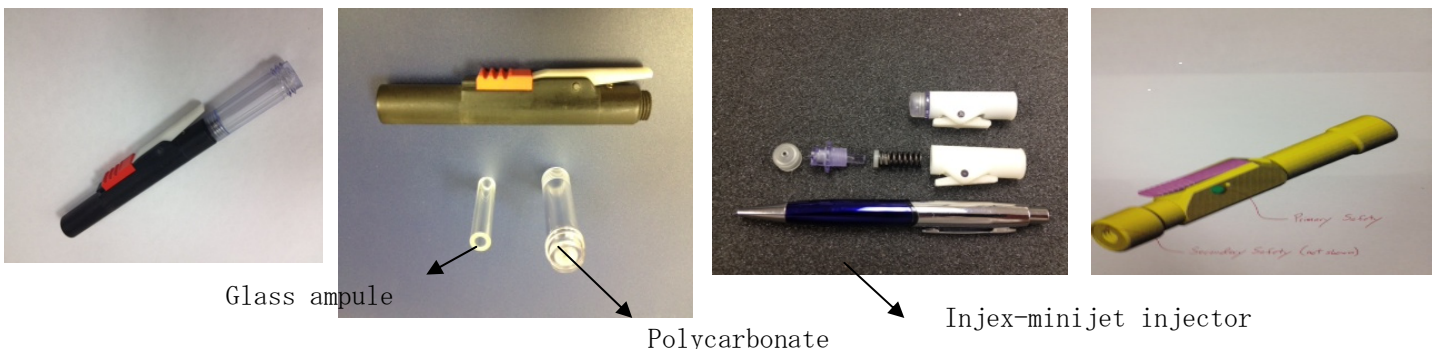
- 1) Potential entrepreneurs who offer internal and stable explanations for their

plans for getting into business (e.g., “I have always wanted to own my own business”) should be more likely to persist in actions that lead to successfully starting a business.

- 2) Potential entrepreneurs with high personal efficacy scores should be more likely to persist in actions that lead to successfully starting a business.⁸
- 5) Ability to Adapt to Change like a chameleon. ; Medical devices need to be innovated through “Patient Experience Design” - “Drug or molecular-driven design perspective→A system or service design perspective. Adapting to unforeseen circumstances requires the ability to act decisively, to be both open-minded and confident, and to have a talent for reading messy or hidden data.⁹
- 6) Good alliances for worldwide-Longer-term alliances and collaborations. Injex has been successful in collaboration with universities and research organizations in Germany, Singapore, Japan and USA for many years by not focusing on the deal itself but with value-creating relationship. Intel’ s success was the company managed relationships with complementors according to M. Cusumano.¹⁰ Injex uses direct sales through INJEX’ s exclusive distributor worldwide as well as beauty clinics and anti-aging clinics. Direct sales to market via own distribution and clinics make it competitive and self reliant, which allows Injex to create strong customer relationships. Injex has successfully entered into niche markets with huge profits such as the beauty market where regulatory and restriction is milder than in the medical field. These fields are neglected by the major needle syringe companies such as Becton Dickinson.
- 7) Creating to new niche marketing - INJEX created the “Shireen” brand for the niche beauty market. www.beauty.injex.com Lead users or early adapters of a product or process may become general in the marketplace in five to 10 years. New niche market has been created in collaboration with INJEX and beauty practitioners since they are familiar with conditions which lie in the future for most others, they can serve as a need for casting team for INJEX marketing research.
- 8) Defined goal; “Systems behavior is particularly sensitive to the goal of feedback loops. If the goal-the indicators of satisfaction of the rules-are defined inaccurately, the system may obediently work to produce a result that is not really intended or wanted.” Need to set goals that reflect the real welfare of the patient. The profit or success will follow.
- 9) Execution: Challenge it continuously with corporation’ s activity with IT tools.

B) Incremental Innovation by INJEX

- 1) Glass Ampules into COP Ampules - Glass was too costly and difficult to manufacture. COP is an inert plastic ideal for this use. FDA does not approve glass ampules because of the reason that it could be dangerous and harmful if glass particles get into the human body in case of breakage, etc. The best of breed theory is applied here. Innovation

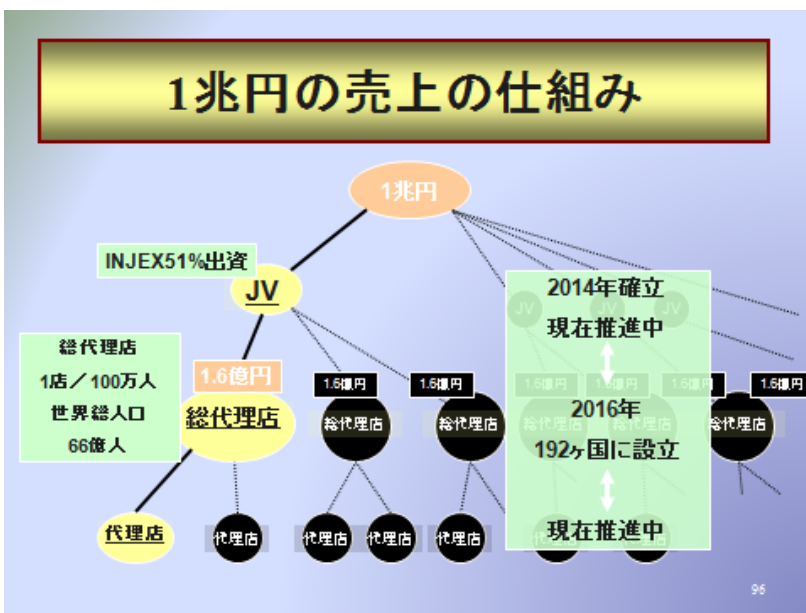


3. Strategic marketing

Successful needle free startups start with niche market, i.e. very wealthy class at high profited price as painless, easy to use, convenient, accurate, compact, friendly, and not tool like, setting many joint ventures and distributors worldwide. Each distributor gets a good compensation and exclusive sales in certain regulated communities. Its strategy is marketing new products without any salesperson's salaries, any advertisement, no office or warehouse expenses which makes new products competitive. The key milestone for the success of venture firms is well-known as Darwinian sea at the start of the marketing. To show the KFS in the marketing, such a success case as INJEX is investigated. As shown in the figure 2.

Figure 2

Marketing Strategy for achieving \$1 billion in sales is started from small and niche market, not in the major countries-KFS for venture marketing.



4. Conclusion

Startups cannot afford expenditure similar to large companies. This paper showed how small companies can conduct new business successfully and can join the 0.036% of successful corporate community. In order to be successful, new medical products must be helping patients better. Customer is King. The next picture illustrates success of any products or services. Is our product a king?



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