The Methodology and Implementation of Unique Technology Focused Entrepreneurship/ Intrepreneurship Programs

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ABSTRACT

This paper describes a unique methodology for technical entrepreneurship education and it's application to real world situations. The methodology provides a general domain independent approach, which has evolved over a number of years, and been adopted in universities and technology start-ups. We believe that this approach can have additional domain specibic imact and one such case is presented herein.

Keywords: Technical Entrepreneurship, Innovation, Medical Devices, Education, Cross Diciplines.

1. INTRODUCTION

This methodology and courses were developed to demonstrate the concepts involved in the management and evolution of rapidly growing (or want to be rapidly growing) technology based endeavors. The genesis of these courses began a number of years ago; which to the author's knowledge, was the first such course offered in any engineering college, or certainly one of the first. Now, virtually every engineering school offers some form of an entrepreneurial course or courses. The methodology and courses, described herein, still remain unique in their approach and history of success. Since their inception, these courses have been taught yearly by the authors at four universities, at both the undergraduate and graduate level.

The development of these courses is based on the premises that:

1. Many of today's graduates of engineering and science programs are interested in starting their own companies. However, they usually have little or no business background. This lack of business preparation may be part of the reason for the very high failure rate of these start-ups.

2. Furthermore, scientists and engineers are increasingly being called upon to assume early management roles in entrepreneurial start-ups, and small to mid-sized companies. This is in addition to the normal management roles they assume in larger corporations.

Most engineering and science programs provide intense technical education with very little preparation for these management and entrepreneurship roles. Many individuals who have been in a position of promoting engineers have observed that this has usually resulted in losing a good engineer and gaining a poor manager; with the obvious cost implication for the ventures and opportunity limitations for the individuals.

This problem is compounded by the fact that technology management, and technology entrepreneurship/intrapreneurship are unique and not addressed by typical business management courses. This uniqueness has both advantages and disadvantages. The advantage is that not everyone can utilize technology to build businesses. Engineering and science academic programs and experience provide specific technical knowledge that enables these individuals to thoroughly understand the underlying technical issues, processes, and procedures. The disadvantage is the lack of basic knowledge in the non-technical areas of entrepreneurship; whether it is entrepreneurship in start-up businesses or intrepreneurship in larger technical companies.

Since many of the problems arising in technical businesses are unique, these courses address these unique areas as opposed to focusing on purely business topics. One goal for the courses is to demonstrate various situations (as seen through personal experiences) of *what not to do* in building technology endeavors. The intent being to reduce the cost of technology projects, increase productivity, optimize technology security and compliance, and increase the probability of success. This approach is based on the premise that making fewer mistakes will provide more staying power (through the more efficient use of cash) for start-ups, and higher profits for the technology endeavor; with a more satisfied and supportive customer base.

In addition to this approach being developed for the general engineering and scientific population, the approach has been used to specifically address the domain of highly regulated industries through the biomedical device industry[1]. From experience in this domain, it has been observed that universities have largely provided the science and engineering curricula and research that supports the technical capabilities and aspirations of delivering these innovations for broad clinical use. However, they have not adequatly considered the business regulatory and quality aspects, driven by the explosion of new or changing regulations, and their impact and application throughout all critical stages of the biomedical product development lifecycle and, holistically, throughout the technology biomedical business. This deficiency is due to the failure of consistently and reliably bridging the gap between what the engineer learns in school and what they must do on the job in a regulated industry, to effectively bring a product to market. This deficit is a global problem that seriously affects our ability to deliver critically needed biomedical solutions in a timely manner. Engineers must be equipped to navigate the increased complexity of this modern regulatory landscape, address the nuances of the biomedical industry, and lead the delivery and preservation of innovative technologies that can withstand intense regulatory scrutiny while satisfying the clinical needs and stakeholder expectations. The course developed to address this domain has used the structure of the domain independent general course, to be described. Specifically, the use of real life projects are as integral to this domain, as are other general considerations.

Again, a goal of these courses is to provide real life experience in an academic enviornment to the benefit of students, employers, and start-up ventures. In all ventures in the techno-business area it is usuallly the things you don't kow that will get you into trouble. That is why experience is so important.

1. BACKGROUND

You can find numerous attempts at defining entrepreneurship, but they usually end up describing characteristics of an entrepreneur, the value of entrepreneurship to the economy, creativity and innovation derived from entrepreneurship, etc. It seems that this animal---an entrepreneur---is hard to define. This difficulty is similar to attempting to define creativity, innovation, leadership, risk taking, dedication, etc., which are characteristics usually attributed to entrepreneurs. Since these courses are directed towards demonstrating the process of entrepreneurship, we will not try to develop a precise definition of the word entrepreneur. Instead, we actively get evolved with the process and, we dare say, that we will come to the conclusion that this animal has various sizes, colors, personalities and motivations, all of which can be called entrepreneurial. For those of you who must have a definition, we provide you with Mr. Webster's definition "one who organizes, manages, and assumes the risks of a business or enterprise".

It is somewhat easier to describe intrapreneurship because we describe it utilizing the nebulous definition of entrepreneurship. As described by Robert Hisrich in his book Entrepreneurship, Intrapreneurship, and Venture Capital, The foundation of Economic Renaissance, Lexington Books, 1986, where he states "The second mechanism---existing businesses---can also bridge the gap between science and the marketplace. These companies have the existing financial resources, business skills, and usually the marketing and distribution system to successfully commercialize a new invention. Yet, too frequently the bureaucratic structure, the emphasis on short term profits, and a highly structured organization inhibit creativity and new products being developed. Corporations recognizing these inhibiting factors and the need for creativity and inventions have attempted to establish an intrapreneurial spirit in their organization. What is this intrapreneurial spirit and intrapreneurship? It is entrepreneurship within an existing business structure." This definition also extends to government entities, as well as non-profit organizations and research labs. A root problem for academia and industry in attempting to address these issues, specifically in technical areas, is what these courses address.

We are also operating on the premise that trying to teach entrepreneurship/intrepreneurship in the typical business fashion has not been terribly successful. If it was, we would not have the large number of failures we see in start-up ventures and corporate innovation endeavors, specifically in the technology areas.

2. A UNIQUE FOCUS

A uniqueness of these courses is that they focus on students learning by being involved in hypothetical technical endeavors, making mistakes and learning from their mistakes and the mistakes made by their classmates, as well as learning, from domain experts, what to do in growing these ventures.

This approach is intended to address the things that comprise The Complete Entrepreneur as shown in figure 1.

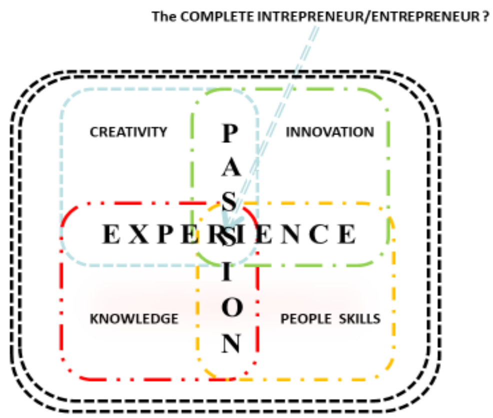

Figure 1

Most will agree that experience with passion is the ultimate way to learn to be successful, as noted by *Albert Einstein "The only source of knowledge is experience" and Abraham Lincoln "Your own resolution to succeed is more important than any other one thing."*

While experience may be a great teacher, real world experience (and failure) is usually very expensive, personally traumatic, and fraught with numerous other problems, including running out of money for start-ups and losing money for larger companies.

Hence, these courses attempt to provide some of the desired experience through realistic technical endeavors, built on hypothetical technical ventures, where students learn by being part of an entrepreneurial/intrapreneurial team, without the personal and financial risks incurred in real world technology ventures.

One of the objectives of these courses is met through the use of long-term, realistic, team oriented projects. Students are expected to learn by doing, through the use of extensive project interactions of their team and the other teams. The projects must be technically based, growth oriented business ventures.

3. PROJECTS

Hence, part of the requirements of these courses is an extensive semester project. Students must select a topic for an entrepreneurial (intrapreneurial) venture, form a management team, plan the venture, <u>and simulate the process lifecycle of up to five years of operations for the chosen venture.</u>

The projects can be hypothetical and <u>cannot</u> be anything that presently exists, but it should be technically feasible within five years and there should be a clear market demand and competitive advantage. *"If you don't have a competitive advantage, don't compete." Jack Welch.* The objective is to evolve a new venture, not to copy an existing venture. One goal of the course is to learn by actively participating in a venture, and learn from mistakes, as opposed to simply observing what someone else has done.

Each student is required to make an informal presentation describing a possible project. The ventures are then chosen by student vote, after the presentations.

Throughout the course, each team (venture) is provided with various realistic problems, drawn from actual experience in real ventures. The teams then have to develop acceptable responses to these problems, modify their plans and, possibly, redirect the venture. The reason for this approach is that we learn much from our mistakes; as noted by others including: *"I have not failed. I've just found 10,000 ways that won't work" Thomas Edison, and "Man learns some from success, but much from failure." Arabic proverb.*

This phase of the courses is time intensive and requires extensive group participation. The projects are intended to model an actual entrepreneurial (intrepreneurial) venture, where almost all are team efforts.

Student Requirements

The nature of these courses requires students to:

- work in teams,
- use interpersonal skills,
- demonstrate leadership,
- attend numerous meetings,
- perform extensive writing,
- develop long range strategic plans,
- develop short range operational plans,
- demonstrate creative problem solving in a technical business environment,
- study technical management and reward systems,
- develop, in a technical business environment, corporate structures for: finance, accounting, marketing, sales, operations, legal and insurance, ethics, capital formation, etc.
- study governmental regulations and requirements, and
- participate in numerous presentations.

Students are expected to participate in active learning, by doing, making mistakes and developing solutions, and observing mistakes and approaches taken by the other teams. *"Success is never final and failure never fatal. It's courage that counts." Unknown*

Project Schedule

A question that often arises is how students can participate in the five year growth process of their ventures, in a semester. The following schedule gives a week by week description of what has evolved over the years. This schedule has been modified to conform to an executive weekend format for some of the graduate students. Lectures are part of each class and will be specifically addressed below.

Weeks 1-2:

- Students propose products and/or services. Topics can be hypothetical and cannot be anything that presently exists. Each student presents a brief synopsis of their proposal. Ventures are chosen based on student votes, and teams are formed.
- Project teams consist of 3 to 6 students. (Each student must make, at least, three formal presentations).
  - Teams are made up of volunteers, after student presentations of possible ventures that are based on the selected products and/or services.
  - Each team is responsible for the following functions:
    - CEO and president,
    - legal & financial,
    - operations,
    - engineering & manufacturing,
    - marketing & sales.

  With team members assuming the roles of CEO or vice presents of these areas.
  - Each team has a board of directors and they are on the board of directors for one of the other ventures.

Weeks 2-4:

- Teams prepare strategic plans. *"Failing to plan is planning to fail." Chinese Proverb*
  - Various assumptions, such as: products, credentials, maturity of the venture, past history, affiliations, etc., are made at the initiation of the project. After the initial assumptions, everything must evolve from those assumptions with no further assumptions allowed.
  - Plans typically are 5-10 pages in length and should, at least, include:
    - executive summary,
    - statement of business,
    - goals and objectives,
    - legal structure (proposed),
    - products or services and status,
    - market analysis and plan,
    - competition and advantages,
    - management plan,
    - resources needed and use of funds,
    - risks,
    - key people,
    - financial projections,
    - the proposal,
    - etc.
- Teams present their plans to sources of capital investments (the other teams).
  - Examples of investment groups (which the other teams represent) are:
    - management,
    - industry,
    - venture capitalists (formal venture capital),
    - government,
    - banking,
    - public,
    - individuals or groups (informal venture capital),
    - family and friends (informal venture capital),
    - etc.
- Venture negotiations and commitments are established.

Year one of the project begins and operational plans are generated. *"The secret of getting ahead is getting started." Agatha Christie*

Week 4:

- Problems for year one are provided, based on the strategic plans.

- Teams continue with year one growth and the development of operational plans.
  - All aspects of the ventures must be developed in detail and substantiated.
  - Provided problems must be "realistically" solved. This could necessitate major changes in direction, finances, etc.

Week 5:
- First year venture development.
- Preparation of report of problems solutions.
- Preparation of any special reports.
- Preparation of the first year's annual report, including detailed:
  - performance and plans,
  - projections,
  - financials (monthly), etc.

Week 6:
- Teams present year one reports to investors.
- Teams obtain approval of problem solutions, year one performance, and future plans.
- Year two problems are provided to the teams.
- Teams work on problems and year 2 development.

Weeks 7-8:
- Teams work on problems and year 2 development.
- Preparation of report on problems solutions.
- Preparation of any special reports.
- Preparation of second year's annual reports.

Week 9:
- Teams present year two reports to investors.
- Teams obtain approval of problem solutions, performance, and future plans.
- Year three problems are provided to the teams.
- Teams work on problems and year 3 development.

Week 10:
- Teams work on problems and year 3 development.
- Preparation of report on problems solutions.
- Preparation of any special reports.
- Preparation of third year's annual reports.

Week 11:
- Teams present year three reports to investors.
- Teams obtain approval of problem solutions, performance, and future plans.
- Year four problems are provided to the teams.
- Teams work on problems and year 4 development.

Weeks 12-13:
- Teams work on problems, year 4 development, and liquidation plans.
- Teams get board approval for liquidation plans.
- Teams prepare reports and prospectus.

Weeks 14-15:
- Teams make extended presentations of reports and liquidation proposals to investors.

5. THE MULTIPLICATIVE FACTOR

It is of utmost importance that adequate time is allocated after each student project presentation for dissuasion of the situations (problems) provided by the instructor and the proposed solutions. Remember, each group has a unique venture, hence, the situations and proposed solutions are unique to that project. Furthermore, each group acts as a board of directors for one of the other groups. Therefore, adequate discussion time and review provides all groups with the opportunity to see what the other groups have done. This results in a multiplicative factor of the unique real world situations and solution approaches to which the students are exposed.

4. LECTURES

In addition to the projects component of these courses, there is a lecture component which considers numerous business related topics in technology related ventures.

Lectures are used to:

1. Provide basic background material about the responsibilities, interactions and various roles involved in entrepreneurial ventures, related topics, and personal experiences, including:
   - entrepreneurship and intrapreneurship,
   - management, finance, marketing, sales, legal, operations, customers, engineering, manufacturing, and people,
   - planning, strategic and operational,
     - resource acquisition,
     - branding and image,
     - intellectual property,
     - financial planning and projections,
     - negotiations,
     - networking,
     - leadership, and ethics,
     - regulations and compliance, quality, etc.
2. Address specific discussion items which are relevant to the projects, in detail.
3. Address topics, situations, and solutions, that are specific to the projects, in detail.

In Today's techno-business world, teamwork is not optional, it is essential. This teamwork is necessary at all levels of the organization, not only at the product development level. Therefore, it is important that each component of the organization understand and appreciate the importance of all of the other components. Often, conflict exists between components of a techno-business because of erroneous perceptions about the roles and responsibilities of the various parts of the organization.

We look at these perceptions and some reality, for the following functions.

- Board of Directors, Board of Advisors, CEO and President, Officers,
- Middle Management,
- Engineering/Development/Manufacturing,
- Operations/Personnel,
- Marketing/Sales,
- Finance,
- Legal,
- Planning and Customers will be considered separately.

In actuality, responsibilities may be assigned to areas based on needs and staff expertise. However, it is of paramount importance that the various functions are considered and not overlooked. These lists of responsibilities are intended to be representative and not comprehensive. Each venture must attempt to generate comprehensive lists of responsibilities to best meet their objectives and these lists should be regularly reviewed for adequacy.

Also, each class includes a number of discussion topics related to the areas being addressed in the lecture.

An example of the lecture topics and discussion items is provided for the Engineering/Development/Manufacturing area.

The Engineering/Development/Manufacturing areas;

- Are responsible for the company's technical credibility and image,
- Must stay abreast of technical advances,
- Should provide consultation to other areas,
- Should maintain contacts with leading technical professionals,
- Are responsible for the technical plans,
- Must evaluate technical needs and resources,
- Must develop technical procedures, methodologies, and documentation,
- Must provide a synergistic technical environment,
- Must have an appreciation of the other areas,
- Must perform research,
- Are responsible for product development, product maintenance, and product updates,
- Must deliver to their plans,
- Must understand the corporate goals.

Some of the related discussion Topics for this area are:

- Development process – where it starts, where it ends,
- Productivity – its importance, monitoring, and establishment,
- Recruitment of technicians – what to look for,
- Customer Service – where it really begins,
- Documentation – preparing for the acquisition,
- Problem tracking & reporting – it's never too soon,
- OEM component selection,
- How do you handle sales – "make these changes & I'll sell your product",
- Personnel types to be aware of during employment,
- Security – ideas, people, products, customers,
- Idea management – what to do when you get one,
- Marketing/Sales – a view from the developers' perspective,
- Advisors – what to expect, how to use, when to use,
- Project management – an overview,
- The developer's relationship within the corporation,
- Delegation of technical ability and responsibility

Similar lists of topics and discussion items are covered for all of the topic areas specified above.

6. THE DOMAIN SPECIFIC APPROACH

The Specific Domain

The medical device industry is a highly diversified industry that produces a range of products using advanced technologies designed to diagnose and treat patients worldwide.

New healthcare needs, an aging population, and people living longer, drive a demand for innovative medical products. Regulations define how these products get into clinical use and the scope spans across a business and throughout the entire product lifecycle. Having an isolated, point-in-time knowledge of a specific regulation is not adequate.

In the past 20 years, the medical device industry has been profoundly impacted by significant technological advancements. These innovative technologies are outpacing the already dynamic regulations, laws, and regulatory guidance; breeding new or changing regulations, increasing the volume and complexity of global regulations and the number of regulatory bodies increasing their oversight of biomedical products.

Hence, the sophistication of today's technology, the advanced innovation of tomorrow, the expansion of global regulations, and changes to global regulatory requirements for biomedical products have dramatically altered the medical device regulatory landscape; creating profoundly new complexities affecting the innovation - to - commercialization pathways, process and timelines. This impacts efforts in research, as well as in academic and industry environments

The US FDA's Center for Devices and Radiological Health (CDRH), a government branch responsible for interpreting and enforcing regulations, indicates that 'barriers for moving a device out of the research lab into the clinic are navigating the FDA and lack of knowledge and experience with the regulatory process.' [2]

There has been an increasing number of regulatory education programs developed in response to the growing need by academic researchers, medical device and healthcare industries and regulators. These programs have been independently developed, housed in different departments or schools, and with curriculum content ranging anywhere from a general focus on a broad spectrum of regulated product, to a specific focus on one type of product technology.

In 2011, the FDA CDRH launched their Innovation Initiative to help decrease development costs and accelerate regulatory evaluation of innovative devices.[3] This initiative established a Medical Device Technology Forum (MD-TIP), bringing regulators, academic institutions and key opinion leaders together to discuss experiences and identify the academic needs of entrepreneurs, students, and faculty, to share information and to assess how to train and equip the next generation of biomedical innovators. They presented their inputs and discussed the need to develop educational programs specifically in device development and assessment, as well as to enhance academic knowledge and experience with regulatory process. [2]

There is an unmet need to educate engineers, researchers, and technical entrepreneurs on the practice of medical device regulation through the critical phases of the product lifecycle. Therefore, engineering, management and entrepreneurship academic programs must build the bridge to traverse the gap between what one learns in school and what they must do in the real world of the regulated industry to successfully bring a safe and effective product to market, in a timely and cost effective manner, and keep it there.

The Academic Process

Clinicians using medical devices in their daily work often identify unmet needs or areas for improvement and in many cases, creatively develop product concepts to address these unmet needs. While they are far and away the best resource to understand the clinical need, it is an interdisciplinary team, equipped with knowledge to navigate the regulatory commercialization pathways, that is necessary to formally develop the solution for commercial clinical use.

The focus of this course is intended to follow the structure of the general course, and is aimed at cross training, equipping, developing and preparing the next generation of engineers, entrepreneurs and innovators, with the necessary understanding to effectively address the increased complexity of the modern regulatory landscape.

The Domain Project

As the regulatory landscape has changed, so have the demands on engineers that practice in this environment. These professionals must develop, in addition to technical skills, the strategic, business and operational skills necessary to move the technology through the development phases, and beyond. This domain specific course follows the model used for the general entrepreneurship course, namely an integrated real world team project core component. This project core has introduced some nuances to address the specific domain. Namely:

- Students tackle real world clinical problems needing a biotechnology solution,
- Students use:
  - critical thinking,
  - information analysis, and
  - data interpretation to deliver a Global Regulatory Strategy that encompasses:
    - project management,
    - product concept development,
    - technology analysis,
    - market analysis,
    - business operations analysis, and
    - regulatory analysis, strategy and planning.
- The team project must demonstrate the rigor, structure, and essential skills and tools necessary for biomedical technology innovation and commercialization.
- This domain specific process introduces a combined engineering and entrepreneurship effort as it is influenced by the global regulations.

This course generally follows the weekly format specified above, and students are presented current, real world clinical problems, by physicians, for which there is no viable solution that addresses the unmet need. Students begin by forming a management teams and selecting which unfulfilled clinical need they will address. Then they research and engineer a concept for an innovative technology solution for the clinical problem, and develop a commercialization strategy and plan for bringing that solution to the global market; constrained or informed by variable regulatory pathways and restrictions. This phase is analogous to the project selection and strategic plan phases of the general course.

Students employ learned and practiced concepts that span several regulated aspects of a venture including: commercial strategy, execution, and sustainability of a regulated product, such as:

- the regulated product development process,
- the global regulated commercialization pathways,
- clinical and preclinical studies to ensure the safety and effectiveness of the technology for human use,
- regulatory submissions required for putting a device on the market,
- quality management systems that define business operations,
- the regulated business and industry controls and requirements, and
- other regulatory influencers that impact or limit a biomedical technology venture.

This is a domain specificity of the strategic plan items enumerated for the general course. Namely:

- throughout the semester, students are presented with variable real-world it-depends scenarios which they must evaluate and as a result, refine their product and strategy solutions,
- teams must defend their solutions to other teams throughout the semester, addressing any unjustifiable approaches,
- the course culminates with student presentations of their final scientific and legally justifiable approach for the commercial introduction of the biomedical technology.

This is the same uniqueness introduced above, in that the project, the provided scenarios, the team interactions, and the continual experience based input provided by the instructor and other domain experts, results in the students learning by doing. Hence, acquiring experience by being involved in real-world projects and observing the situations being addressed by the other teams.

Domain Lectures

The lecture component of this course addresses many of the topics enumerated previously and the following domain specific topics are added:

- regulations,
- clinical investigations,
- quality and operations,
- strategy,
- communications, and
- technical and interdisciplinary topics applicable to the various phases of the lifecycle.

These topics affect all aspects of technology development and commercialization to variable extents, nothing of which is black and white. Every scenario can be different depending on:

- the technology itself,
- the complexity of the technology,
- the intended use of the technology,
- the current regulatory environment surrounding all aspects of the technology,
- the legal type and scope of the business (e.g. will it be a specification developer, a manufacturer, a contract manufacturer, a distributor, an importer, etc.),
- what a company wants to claim about the technology,
- where they expect to have the product used (hospital, home, outside, etc.),
- how the technology will be made,
- the expected life of the product, and
- the risk of the product to potentially cause harm to the patient, the physician, the healthcare worker, or others.

Therefore course content has been developed to reflect current, real-world topics applicable to various phases of the lifecycle, in addition to many of the business topics addressed in the general course.

The knowledge of key, influential, interdisciplinary information across a product lifecycle is critical to the success of a biotechnology venture. For example, understanding how the design and technology decisions at one stage can critically affect the business activities in a seemingly unrelated stage, and being able to navigate through this fluctuating global regulated minefield of "it depends" pathways is a critical competency. This can dramatically influence the efficient translation and effective commercialization of research and innovation in a timely fashion. This is a unique problem combining the need for practical expertise in engineering, science, regulation and business.

Just as the specified areas of the general course had to perform as an integrated team to achieve success, so must the domain specific course; simulating real world industry situations as a vehicle for acquiring experiential knowledge

Domain Goal

The goal of the domain specific course and project, which coinsides with the general course goal, is a multifaceted and regulatory-centric approach intended to address an unmet need; giving students the ability to define, demonstrate, and strategically integrate the application of regulation to innovation, engineering research, technical product development, and biomedical entrepreneurship.

Domain experiential learning is realized through close collaborations and project based opportunities with clinicians, medical device companies, regulatory agencies, and service organizations who support the program with current experience, state of the art software tools, case studies, guest lectures, and hands-on assignments which reflect current, real world deliverables in the medical device industry.

The knowledge and experience gained from this program provides immediate relevance and impact to engineers, researchers, medical device innovators, entrepreneurs and individuals who are currently employed in, or wish to enter the medical device industry; ensuring a tangible return on investment.

7. RESULTS AND CONCLUSION

The methodologies and courses described in this paper have been applied successfully in the areas of technology entrepreneurship/intrepreneurship, innovation, and creativity, in industry and academia. This approach is unique, in the integration of real world expertise into the learning domain of universities, to simulate the working environment where most of this knowledge is acquired in today's world. There is the obvious advantage to students seeking employment being better prepared to enter the work force and being more valuable to an industry, which would have to teach them or expect them to learn from their own experience. Hence, being of direct economic value to the industry. Also, this approach prepares employees to more quickly and effectively assume management roles; with advantages for both the employees and the industry. Finally, we must remember that a central focus of this methodology is to better prepare individuals to navigate the numerous complexities of the technology entrepreneurship area. This is all based on the basic premise that making fewer mistakes, because of a lack knowledge of process and procedures, preserves capital and provides more resources to pursue success. The ultimate goal being a higher success rate for technology entrepreneurship/intrepreneurship ventures.

5. REFERENCES

1Easton, Diana and Szygenda, Stephen, Facilitating Innovation through Regulatory Engineering Education: An Academic Program Overview, Proceedings of the 2017 ASEE Gulf-Southwest Section Annual Conference, 2017

2Kalush, Francis, National Medical Device Curriculum, Office of Center Director, Center for Devices and Radiological Health, Food and Drug Administration, Biomedical Engineering Innovation, Design and Entrepreneurship Alliance, Sep 25, 2013, accessed March 2, 2015

3Food and Drug Administration, Training and Continuing Education, *About the Curriculum*, http://www.fda.gov/Training/CourseMaterialsforEducators/NationalMedicalDeviceCurriculum/ucm404244.htm