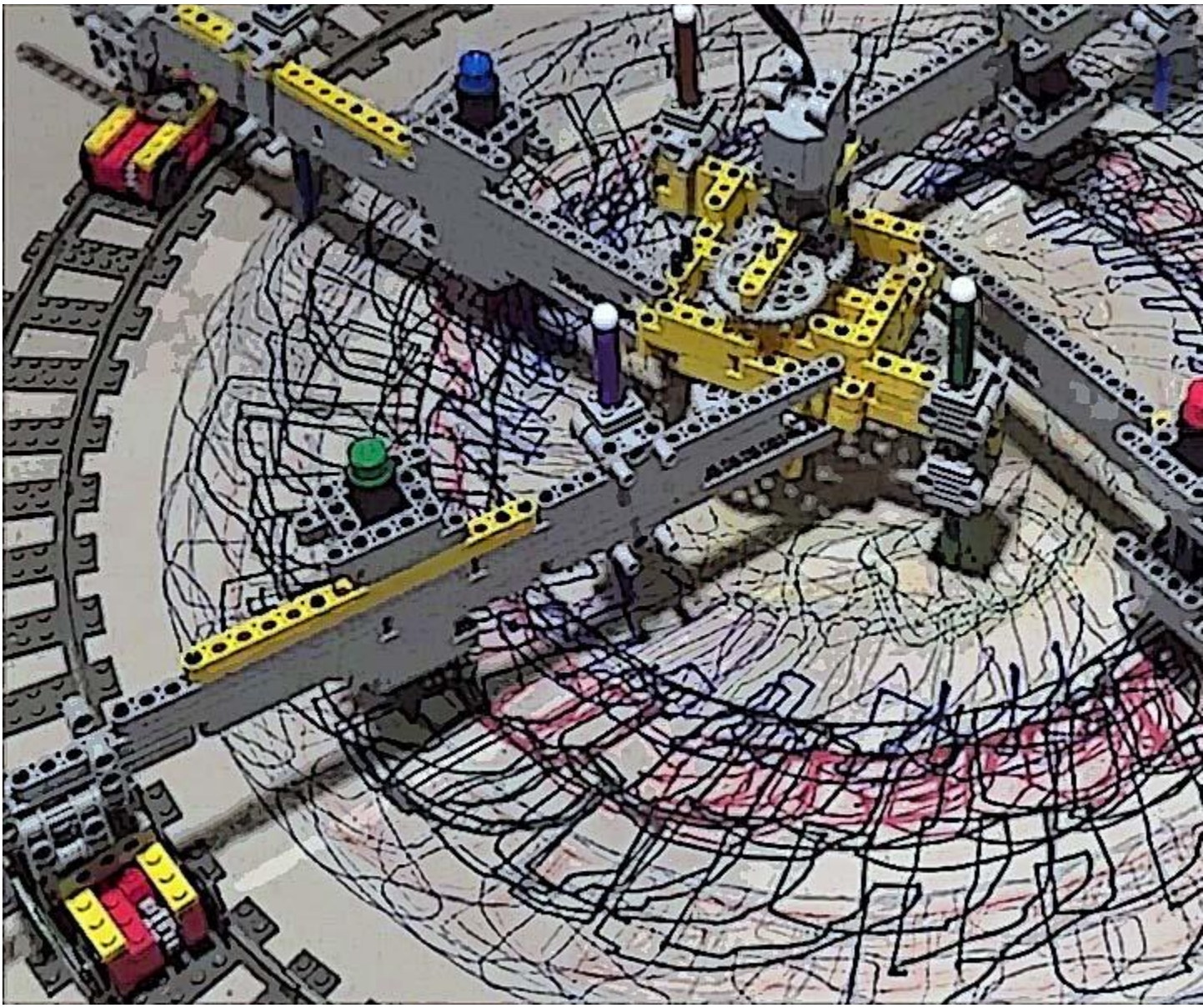


Expert Contributors

MEMS Commercialization Report Card – Part 5: Design For Manufacturing & Test Part 2

By Roger H. Grace & David Dipaola

Introduction

Episode 5 of the MEMS Industry Commercialization Report Card is a continuation of the materials presented in Episode 4[1]. In Episode 5, we will continue to address the topic of Design for Manufacturing and Test (DM&T) by reporting on the employment of these principles in several applications that have been shared by the respondents to the Report Card. We will take a look into the special requirements of DM&T from a medical device development perspective.

To briefly recap, the 2018 MEMS Industry Commercialization Report Card grade of B+ is one grade lower than that that of the A- grades that it has received in 2015, 2016 and 2017. Since the inception of the Report Card in 1998, grades for DM&T have risen from the C+ and B- levels prior to 2007 to B+/A- levels. The levels and constancy of these recent high grades supports the authors' opinions that MEMS commercialization, as especially DM&T, has reached a mature level in the technology life cycle (see figure 1).

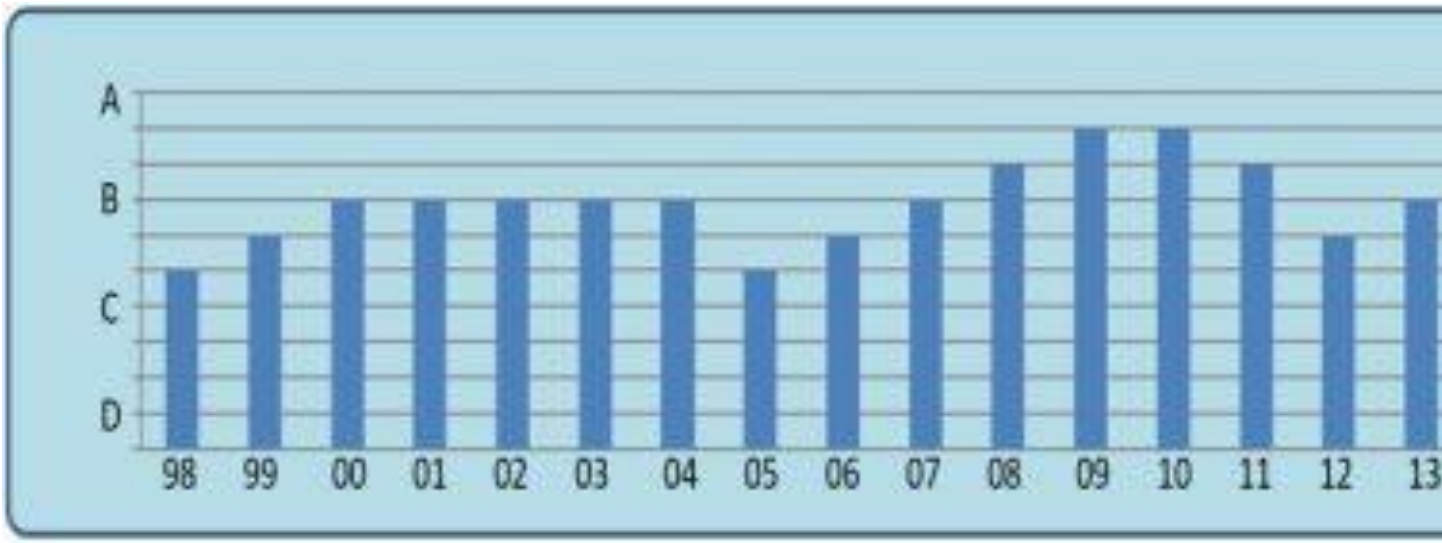


Fig. 1: The Report Card grade for DM&T dropped one grade to B+ in 2018. It had enjoyed A- grades from 2015-2017. DM&T's recent high grades are attributable to the level of maturity in the MEMS product life cycle. Copyright 2019: Roger Grace Associates

Case Studies

In the following paragraphs, we will continue to report on the results of the follow-up interviews to several of the respondents to the Report Card who were kind enough to share some of their experiences of DM&T for MEMS/sensors; the good, the bad, and the ugly.

Matt Apanius, Director of Smart Microsystems said, "We established the Smart Center to provide the MEMS and sensors industry with a resource to help accelerate the packaging and testing of our customers' MEMS/sensor-based products which they could not accomplish in-house from a lack of equipment and expertise perspective. A typical scenario was that companies come to us with a design that they have created and breadboarded with a lack of understanding how to make it in volume. Our job is to make it look pretty and get it to the point where it can be mass produced."

"We then can hand off our process design and expertise to the high-volume manufacturer thus facilitating the go to market timeline since this approach would eliminate the timely and costly reproduction of processes. We constantly found that when we receive an order to create a solution, the design does not take into effect the material qualities, compatibilities and limitations and printed circuit board layout principles that will allow for high-volume manufacturing. We have adopted a 'concurrent engineering' strategy by beginning with the end in mind. This strategy encourages the design engineer to consider the process and the process engineer to consider the design[2]."

"Recently, we were awarded a contract that included a project with a wire bonding requirement. The customer did not take into effect the bonding strategy and its effect on the requirements of the plating of the printed circuit board. We had to solve this problem and make it compatible for high volume manufacturing. It is necessary to determine up front as to what the production quantities will be since it will affect our selection of the proper processes and tools to optimally achieve the price target. Our goal is to provide as much as possible identical tools and process that will be used in handoff to the full manufacturing and test production cycle. The determination of the NRE required by us to support the customer's needs is highly affected by the end game of required manufacturing quantities."

Lessons Learned

Know up-front the level of production that is required of the design. This helps optimize the processes and equipment to best successfully accomplish the job at the fastest time and with minimum human and financial capital.

David Harris, Director of North American Sales for Mega Fluid Systems states, "I believe that many engineers live in a vacuum. They create designs without a clue of how they will be manufactured. I suggest that they spend some time on the manufacturing and test floor to witness first-hand the production and testing process."

"MEMS companies need to include and align all elements of their design and manufacturing process including quality control and reliability functions in the creation of their products. Having spent a great deal of my career in the semiconductor industry, I believe that there is much to be learned from these organizations, especially in the DM&T area by the MEMS and sensor industry. A good story to describe a major failure to not embrace DM&T is when we were creating a MEMS actuator device to be able to test the magnetic qualities of materials. The design team did a great job in analyzing and designing the test device; however, they did not take into effect the requirement for the test actuator beam to have a process to release it from its surrounding structure."

"As a result, the solution was a failure. What was needed here was a much closer alignment of the design and process engineers to be able to achieve the end goal."

Lessons Learned

Have the design team spend time on the manufacturing and test floor becoming familiar with the processes and people who are responsible for the successful manufacture and test of the part.

Chip Spangler, President of Aspen Microsystems says, "In our role as a design organization that assists customers to create cost-effective, robust and high-volume compatible packaging solutions for MEMS, we recommend that our customers leverage their existing infrastructure when they are in the design for manufacturing and test planning phase in the product development process. We encourage them to use standard processes, materials and equipment thus minimizing overhead and reducing risk and time to market."

"This all needs to be done in the early R&D phase of the product design process. There needs to be a great deal of thought in the creation of the proper fixturing for manufacturing and test and it is important that the people within the organization responsible for these functions interact with the device designers early on. We devote a great deal of time analyzing the 'thermal hierarchy' of the proposed design to ensure that all bonding-and-solder attach processes are compatible with the previous and subsequent ones. Sometimes, this poses a big challenge."

"Our rule of thumb is that there must be less than a 40°C maximum difference between adjacent thermal-based process steps. This brings to mind a scenario where a customer's design used a wafer-level packaging approach and a low melting point solder to attach the lid of the package. The gold wedge ball bonding process used to attach the MEMS device to the package required 180°C, which was higher than the melting point of the solder, thus a disaster in the making. The only solution to overcome this problem was to use an aluminum wire bonding process which was much more expensive and increased the cost of the product since the WLP would have been much too costly to change."

Lessons Learned

1. **Consider the processes, materials and equipment to be optimum for the high-volume production in the early phases of the design process**
2. **Proper consideration must be taken to best understand the proper fixturing to hold the product in the manufacturing and testing processes to reduce time, cost and maximize throughput.**

DM&T for Medical Devices

It is often mistaken that the commercialization process prior to scaling is a design, a lab prototype, and experimental validation. Too often entrepreneurs and companies are ready to launch a medical product without a customer or an understanding of their needs or consideration for manufacturing, testing and quality (see figure 2).

Fig. 2: Typical design for manufacturing and test process for medical devices. Courtesy: DiPaola Consulting, LLC

Here we will challenge this thinking and present an alternative process that addresses the DM&T process to commercialize a medical sensor for scale, quality, performance and profit. It starts with an idea accompanied by the end customer's specifications, a thorough review of the method for manufacturing, definition of a quality plan, and an understanding of your validation requirements at the component and device levels.

When a product is first being conceptualized in modeling, these prior topics need to be at the forefront of the designer's mind. Once this is complete, an iterative design is developed with a constant reassessment of performance, manufacturing, quality and validation. Figure 3 shows

an alternative proven approach that has been used for many years commercializing products in both automotive and medical devices.

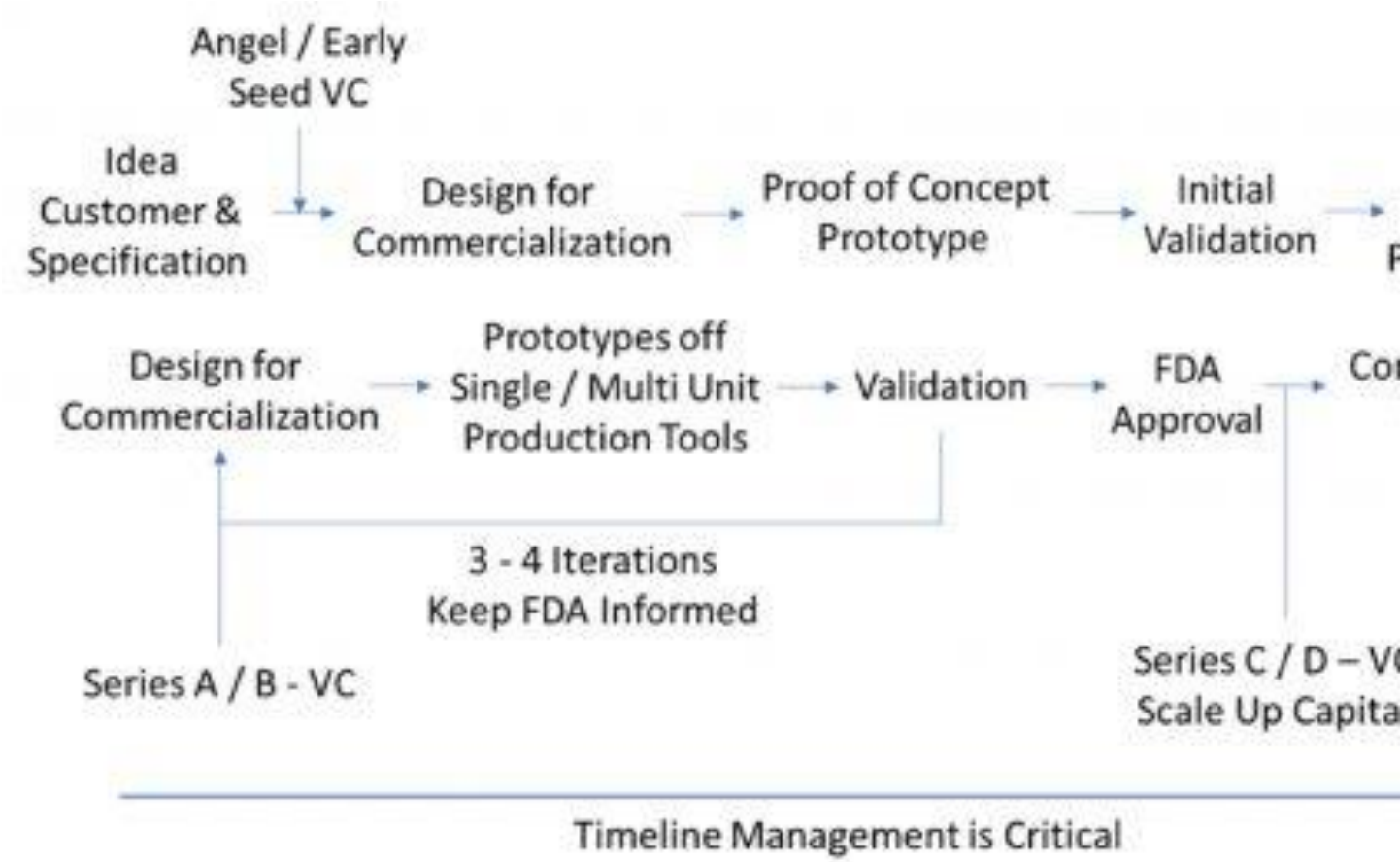


Fig. 3: An alternative and improved process design for medical device commercialization adopts early DM&T principles in a complex multi-iterative fashion that requires constant reassessment of performance, manufacturing issues, quality and validation. Courtesy: DiPaola Consulting, LLC

The following are the questions that need to be answered specific to assessing the applicability of adopting DM&T principals for medical devices that require FDA approval for commercialization. Prior to the design of the medical device, one must address the following questions:

- **How will it be manufactured and what tools and processes will be used?**
- **How will it be tested?**
- **How will dimensional analysis be completed?**
- **What controls are needed to ensure quality?**
- **Who will be the suppliers of the components and what are their capabilities?**
- **What is your path for FDA approval?**
- **What are the customer's specifications and how will they be validated?**
- **What are potential failure modes and how can they be mitigated?**

- **How can this core technology be used as a building block for derivative products once in production?**

Case Study: Medical Devices

The Podimetrics Remote Temperature Monitoring (RTM) System is a scale-like device that monitors temperature differences between multiple locations on the same foot and between feet to detect a future diabetic foot ulcer before it occurs. Diabetics are at risk of developing neuropathy, presenting as numbness in the extremities, that results in uneven foot pressure distribution and foot ulcers. Actionable information is then provided via a smart device, like Podimetrics SmartMat[3], to patients and doctors to prevent a foot ulcer from occurring.

Now, we will consider some of the areas that could've been improved upon and thus expedite time to market. DM&T involves consideration of manufacturing and quality in addition to testing and measurement of the device and subcomponents at the forefront.

Podimetrics brought their manufacturing partner into the game very late, eight years after startup. In an optimum design for commercialization, one would have selected the manufacturing partner early in the process, after initial concept validation, and involved their feedback into the design of the device to make it easier to manufacture and lower cost. One would also use the same manufacturing processes as the preferred partner to understand how production variation effects device performance beyond acceptable limits. This would prevent an expensive design change or yield loss when scaling the product. Many startups are resourced challenged and cannot afford production equipment in the early stages.

This is where commercialization centers come into play. The Smart Center, previously addressed, provides packaging and testing capabilities to overcome this limitation. Also, wire-bonding company Hesse Mechatronics is creating centers of excellence for wire bonding development and low volume runs. This is an excellent way to get access to extensive wire bonding expertise and test how production variation affects the performance of your product.

Summary

The 2018 grade for DM&T was B+, one grade lower than the A- grades of 2015, 16 and 2017. We attribute these favorable grades to the fact that MEMS are becoming a mature technology and, as such, practitioners have significantly built up their knowledge base in DM&T, especially in the current high-volume markets driven by the recent explosion of MEMS role in mobile phones.

In this and in the previous episode of the 2018 MEMS Industry Commercialization Report Card, we addressed what we consider to be the many benefits of the adoption of the principles of the design for manufacturing and test. Insufficient and/or late adoption of DM&T principles in the product design process places products in the precarious position of assuming higher cost, longer time to market and lack of reliability and robustness. Several case studies have been presented to clearly demonstrate that if a product is to be successful, it must have considerable DM&T considerations addressed in the product development process and, most importantly, the sooner in the process the better.

It is important to note that the necessity to adopt DM&T principles is amplified when it comes to the design and development of medical devices, especially when they must be FDA approved. DM&T details specific to medical devices as well as a case study need to be provided.

The authors trust that these two episodes have informed, enlightened, and amused the readership with valuable content and that the lessons learned offered by the case studies from these experienced practitioners in MEMS and sensors will be of value and judiciously emulated by all who wish to adopt the principles of DM&T. To quote the famous philosopher George Santayana, "Those who cannot remember the past are condemned to repeat it[4]."

Learn More

Design for Manufacturing and Test will be one of the many tracks scheduled for the upcoming MANCEF Commercialization of Emerging Technologies Conference (COMS) to be held from October 19-22, 2020 in Rockville, MD. For more information, visit MANCEF 2020.

REFERENCES

[1] R. Grace, D. DiPaola; MEMS Commercialization Report Card – Part 4: Design For Manufacturing & Test; Sensors Daily, February 12, 2020

[2] M. Apanius, Engineering that Begins with the End in Mind, MEPTEC Report, Spring 2016

[3] "Podimetrics SmartMat." *Podimetrics*, Jan 2020, podimetrics.com/index.html

[4] G. Santayana, The Life of Reason, 1905-1906

Also See

1. **Grace: Call For Abstracts & Presentations: Printed, Flexible, Flexible & Fabric Sensors; Sensors Daily, February 21, 2020**
2. **Grace; Barriers to the Successful Commercialization of MEMS Devices, Part 1, Introduction; Sensors Daily, December 3, 2019**
3. **Grace; Barriers to the Successful Commercialization of MEMS Devices, Part 2, Technology Clusters; Sensors Daily, January 8, 2020**
4. **Grace; MEMS Commercialization Report Card – Part 3: Infrastructure; Sensors Daily, February 5, 2020**

About the Authors & Their Companies

 ***David DiPaola***

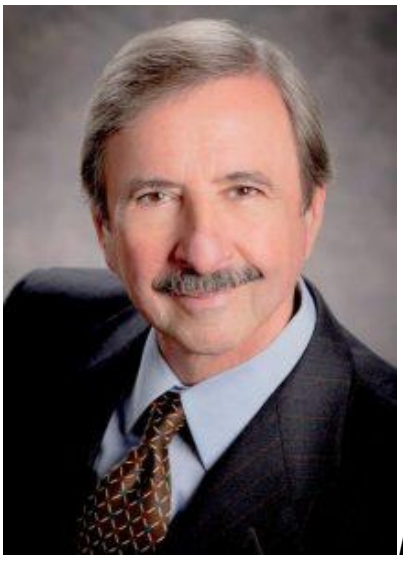
David DiPaola is Managing Director of DiPaola Consulting. As an engineer and entrepreneur, David specializes in providing inspiration, design and commercialization for his customers. Through inspiration he provides leadership and business consulting to startups and existing corporations. David also provides design and commercialization services helping customers bring their electromechanical products and sensors from concept to high volume production and all the steps in between.

David is also Chairman of the Operations Board at MANCEF specializing in Emerging technology commercialization and is Chairman of the COMS2020 conference in Washington D.C. Capital Region being held Oct 19-22, 2020. Previously, David held technical staff and leadership positions at Texas Instruments and Sensata Technologies and was VP of Global R&D for TT Electronics, PLC. He holds 6 patents and has 3 pending.

About DiPaola Consulting

DiPaola Consulting is located in Rockville, Maryland and provides leadership, business, design and commercialization consulting services for global customers from entrepreneurs and startups to multibillion-dollar corporations. The company's niche is electromechanical products, sensors, micro / nano, wireless, data analysis and software. It also provides complete system design and commercialization of converging technologies. This includes supplier and process development, FDA certification guidance and failure analysis from validations and field returns.

In leadership and business development, DiPaola Consulting helps companies drive new growth and improved margins by building new and derivative products that leverage their core expertise and technologies. This includes developing a company's vision and product roadmaps, intellectual property creation, clean room management, competitive analysis and technical due diligence of mergers and acquisitions. In 2020, the company celebrates nine years of service. For more information, visit www.dceams.com.

 ***Roger H. Grace***

Roger H. Grace is president of Roger Grace Associates, a Naples Florida based strategic marketing consulting firm specializing in high technology. His educational background includes a BSEE and MSEE (as a Raytheon Company fellow) from Northeastern University, and the MBA program at Haas Graduate School of Business at U.C. Berkeley. He has specialized in sensors and ICs for over 35 years with a focus on micro electromechanical systems (MEMS). He has authored over 75 technical papers and articles, organized, chaired, and spoken at over 50 international technical conferences.

Roger is frequently quoted as an industry expert in major international technical and business publications on the topic of technology commercialization. He was the co-founder, past president, and currently is the Vice President of the Americas of the Micro, Nano and Emerging Technologies Commercialization Education Foundation (MANCEF), and has served on the Board of Directors of the Florida Manufacturing Extension Partnership from 2008 to 2014. For more details, contact Roger via email at rgrace@rgrace.com.

Roger Grace Associates Company Profile

Roger Grace Associates; founded in 1982 and headquartered in Naples, Florida; is a technology marketing consultancy specializing in sensors and microelectromechanical systems (MEMS). Its founder, Roger H. Grace held positions in design engineering, project management, manufacturing engineering, applications engineering and sales and marketing for major electronics manufacturers. Roger Grace Associates' clients include the international "who's who" in the electronics, sensors and MEMS industry from startups to Fortune 50 organizations, regional and national governments and agencies. Roger Grace Associates provides custom market research, strategic marketing communications, M&A due diligence, business development and strategy consulting to domestic and international clients. Learn more, visit Roger Grace Associates.