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Art and Science of Managing Paradox of Open Innovation

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Introduction (context, key players, scene)

In April 2021, Edward Robb, an entrepreneur, who has been running the family business for the past twenty years, looked back at the last decade's performance of their companies Applied Medical Coatings and Robb Surgical. Applied Medical Coatings was born as a spinoff company from Metal Cladding in 2003. However, Metal Cladding was established in 1943 by Edward Hupt Robb' great uncle of Edward Robb. In the last 75 years, Metal Cladding has been an industry leader in providing applied coating technologies that enhance products' performance while increasing market sustainability at the optimum cost. Metal Cladding has mainly provided products and services to United States Federal Agencies and Armed Service Branches for nearly six decades. In comparison, Applied Medical Coatings (AMC) was established to provide services to the medical industry. The core capability of AMC is that it has the potential to design and develop multiple coating solutions according to the needs of its customers. The company values and uses feedback from its two main stakeholders- corporations and healthcare surgeons- to develop, design, and refine the products. Using a multiple-step iterative process, the company collaborates with stakeholders on developing a range of products manufactured in the USA. However, deliver at the same or lower price developed outside the USA, where production costs are much lower. To achieve this goal, the company collaborates, putting its core knowledge at risk. Each time it collaborates with partners, the company faces the classical paradox of open innovation – how to protect its knowledge while benefiting from external knowledge. So far, it has managed to preserve its internal knowledge and capabilities while collaborating with external stakeholders. However, a new partner has brought colossal business but has asked for complete information about the product development process. It has demanded that it inspect each step in order to ensure that the products meet the criteria. Edward doesn't want to lose this big customer; however, he can't also take the risk of sharing the core knowledge.

Second, in 2013, another company, Rob surgical, was established as a spinoff company of applied medical coatings. This company works in collaboration with doctors and people who work at universities and has an idea about developing a new product. This company manufactures new medical devices and sells them directly in the market. This collaboration brings other communication challenges because doctors and engineers speak different languages. Besides this, the Covid-19 crisis has disrupted supply chain issues due to the lockdown and closing of elective hospital units. These challenges are critical and pose a risk to the sustainability of the companies; hence, Edward is thinking of approaching his father and engineering team, who has vast experience, and trying to find a way to address these issues to ensure the survival of his family business.

History and Evolution of the Family Business and Birth of Applied Medical Coatings

Applied Medical Coatings started as a spinoff from the parent company, Metal Cladding. Metal Cladding was a family-owned company established by Edward Hupt Robb almost eight decades ago in 1943. Initially, the company Metal Cladding worked for the automotive industry. It provided coating solutions to multiple U.S. government independent agencies such as NASA (National Aeronautics and Space Administration) and the department of defense. Over these 60 years, the parent company Metal Cladding has evolved and worked for different industries (see appendix 1 for details about the goal, achievements, and services). As a result of these diverse experiences of working with several industries, a new company was named applied medical coatings. The main goal of applied medical coatings is to better cater to the needs and demands of the ever-growing medical device industry. This goal is achieved by bringing the technology previously used for automotive and defense industries to medical devices.

The idea to target the medical device industry first came under discussion when founders were getting contacted by medical device original equipment manufacturers (OEMs[1]), one of them being the Conmed Corporation[2]. The founder of applied medical coatings recalled that Conmed contacted them because they had heard about the parent company's capacity to provide quality coating solutions for various applications, mainly in the automotive and military fields. In the early 2000s, Conmed was searching for a company that had the technology and the ability to increase the lubricity of their electrosurgical blades and other similar products in the line they were making. Applied medical coatings developed a silicon coating for Conmed products, which they still apply over the products.

Another reason to enter the medical industry was founders also noticed a business opportunity in the medical industry while noticing a decline in the profits in the automotive industry was shrinking due to globalization, as explained by one of the employees of the company as under:

> So, the reason for entering the medical industry is that there was ample business opportunity back then. It's not just automotive, back in the 2000s or 1990. This is an anecdote

1. The term "original equipment manufacturer" (OEM) is used differently. For example, historically this term referred to a business that supplied intermediary equipment to other companies. The term "OEM" is now a days used to refer a product that a business purchases with the intention of reusing it or incorporating it into a different product under the reseller's brand. When a company manufactures an end product using components from another manufacturer, it is sometimes referred to as an OEM.
   The original equipment manufacturer firm design, develop, or produces the parts components or subsystems that are utilized by other companies to create the finished product.
2. CONMED is a global medical technology company that specializes in the development and sale of surgical and patient monitoring products and services that allow our physician customers to deliver high quality care and as a result, enhanced clinical outcomes for their patients (Conmed corporation, 2022).

> told by my boss, Fred Rob, the company's President. So, he told me that when one big automotive company started something called a global supplier portal. So basically, what it means is this big multinational auto company is not. I mean, they were our number one customer of the parents. Okay, we were doing a lot of automotive products. And when they started a global supplier portal, anybody could coat from any part of the world. So, let's say you would be coating a sheet metal job. And let's say sheet metal chart for you to manufacture. It's going to cost you $3 in the United States. Okay, for the same sheet metal chart, In India, it could cost just 180 Indian rupees, okay, or maybe 25 rupees Indian rupees, let's say. So, 25 rupees is less than 50 cents, do the shipping or add the shipping, and it's going to be like $1 or something. So, what happened was, because of globalization, the automotive market in the U.S. started to go down. If you see now, you don't have any manufacturers for the automotive, like you have the assembly guys. Big companies get the parts from China, India, Vietnam, Bangladesh, or Pakistan. Then they assemble it here, then sell it, right. It's not something they manufacture here in the USA; they do the assembling and other things here and then sell it. So basically, when the global market opened up, the market for automotive in the U.S. was shrinking. And med devices. Surprisingly, this is a fact. A medical device, they try to stay within the United States. They just tried to stay because of all the rules and regulations of the Food and Drug Administration (FDA). Even you can get the steel for the med devices from China or India, no matter what that says, the raw material, but post raw material, and everything is done in the United States.

As a result of this successful collaboration, they entered the medical device industry in the late 1990s. The product line started with a discussion with partners and then the research and development phase. After this, the company grew further and started catering to the broader needs of the original equipment manufacturer market.

The company started receiving offers from other companies in the original equipment manufacturing industry, for example, Medline[3] and Intuitive Surgical[4], and then started working with some sub-suppliers of these big companies. In the beginning, the company was approached by suppliers making components. For example, a supplier who was manufacturing the needle stamped the parts or molded the injection contacted for coating services, and then these suppliers would sell the finished product.

Over the years, medical professionals such as surgeons who run small clinics or work in the operation theatre started to approach for the modification in the devices they were using to improve the performance of existing apparatus or put forward a proposal to make a new apparatus. This

3. Medline is a healthcare company–a manufacturer, distributor and so much more, doing business in more than 125 countries and territories around the world (Medline Industries, LP, 2022).
4. Intuitive (Nasdaq: ISRG), headquartered in Sunnyvale, Calif., is a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery (Intuitive, 2022).

collaboration is crucial because these doctors bring the clinical experience of what they would prefer to see, want, or need, and AMC shares its engineering and technical knowledge.
As a result of these organization-level and individual-level collaborations, the company is continuously developing new products and has recently celebrated its 75th anniversary (figure 1 shows the historical timeline of the company and collaborating companies). Moreover, a decade ago, the founders established another company named Robb Surgical that takes care of manufacturing and launching these products in the market.

Figure 1. Historical timeline of the company and List of collaborators worked with Metal Cladding and applied medical coatings

Current Services of Applied Medical Coatings (AMC)

AMC is an ISO[5] 13485:2016[6] certified registered company. In addition to strict compliance with ISO medical standards, the company utilizes advanced tools and techniques such as PFMEA,

5. ISO stands for International Organization for Standardization, it is an independent, non-governmental international organization with a membership of 167 national standards bodies (ISO.org, 2022).
6. ISO 13485:2016 is for medical device's quality management systems and requirements for regulatory purposes. This specifies requirements for a quality management system given to an organization that demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements (ISO.org, 2022).

Value Stream Mapping, I.Q. OQ P.Q. Development and Anylogic Simulation for manufacturing capability. Besides maintaining the highest standards in manufacturing & quality systems, the company also provides extensive testing for product development and quality verification following medical standards of ASTM (American Society for Testing and Materials) as well as specific customer requirements. The company uses a wide range of application technologies to ensure high output and good product quality for small, customized orders and a vast number of orders that can go up to millions of components. The company's coating technology has multiple application methods: automated spray systems, robotics, ultrasonic, and dip (appliedmedicalcoatings.com, 2022). Moreover, a further breakdown of the services is elaborated in table 1.

Table 1. List of services provided by Applied Medical Coatings (source - AMC website)

Service	Description
Design and Engineering Assistance	We offer design and engineering assistance from the outset, using our extensive product development experience to deliver the highest-performing product possible to our customers.
Complete Component Sourcing	Our network of suppliers and manufacturers delivers unique insight into the cost-effective sourcing of components without sacrificing performance.
Contract Manufacturing	We not only design, engineer and source, but can manufacture your product too. We offer a variety of contract manufacturing solutions and options.
Assembly	We offer a full range of assembly operations that can vary based on your product.
Testing	AMC offers a wide range of testing specific to your device requirements.
Packaging and Labelling	Our packaging options can range from individually protected single components to high-volume packaging in specifically designed containers.

The company has received supplier excellence awards consecutively from its customers and also working towards FDA (Food and Drug Administration) certification.

Organizational Structure

Applied medical coatings is a family-owned company; twenty-seven people work in the company. The father and son govern the whole company. The company is divided into engineering and manufacturing departments, and the supply chain and marketing departments are merged. The President of the company is Mr. Fred Robb. He looks at the manufacturing department of the company. In other words, you can say supervise the manufacturing of all products. He holds daily meetings with shop flow technicians, and everyone in the manufacturing department or external people from other partner companies with engineering knowledge talk to him. His son, Edward Rob, is a general manager and responsible for the supply chain and marketing department. So, this department takes care of the raw materials, finished goods, shipping to the customer, and receiving goods from vendors.

Industry Description

Initially, the parent company worked for the automotive industry and defense industry. A brief description of these industries is given in appendix 2. However, currently working for the medical device industry, specifically original equipment manufacturers (OEMs).

Description of the Medical Coating Industry

The global medical coatings industry's market size was around $ 3.95 billion in 2021. The report of fortune business insights projected that the global medical coating industry is expected to grow from $4.27 billion in 2022 to $8.20 billion by 2029. Moreover, the market is mainly dominated by North American companies, and the major players are Hydromer[7], Harland[8] Medical Systems, and Surmodics[9]. The pattern of growth from 2017 to 2029 in the medical coating industry is shown in figure 2.

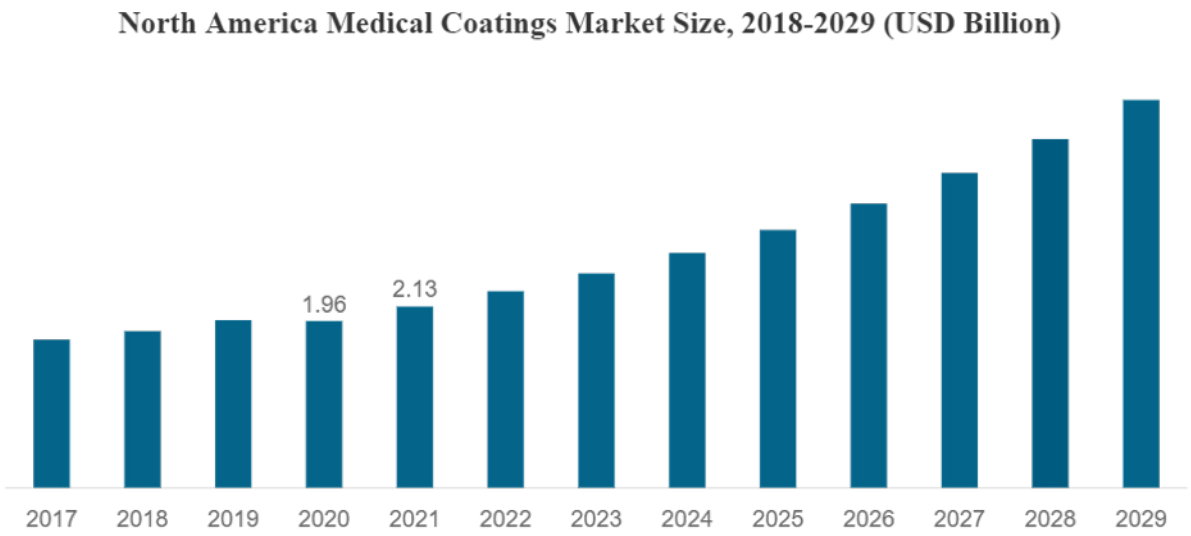


Figure 2. The North America medical coatings market size expected growth patterns from 2018 to 2020

7. Hydromer® is a leading global surface modification and coatings solutions provider (Hyrdomer.com, 2022).
8. Harland is a multinational coating company having presence in the USA and Europe (harlandmedical.com, 2022).
9. Surmodics is the global leader in surface modification technologies and produce differentiated medical devices (surmodics.com, 2022).

Description of the Global Medical Industry

The United States comprises over 40% of the global medical technology market; hence the country has the largest medical device industry. According to one report published in 2017, the U.S. exports more than imports and therefore receives a trade surplus of $1.1 (Advamed.org, 2022). In the industry, medical technology inventors are dedicated to giving healthcare professionals and doctor the tools and resources for patient diagnosis and treatment. Data shows that more than 6,500 medical technology businesses in the U.S. operate today, most of which are small and medium-sized businesses. All these companies need coating services. In an interview conducted by the authors of this study, the general manager of applied medical coatings said that around seven or eight companies specialized in coating services.

After the U.S., the European medical technology market is the second largest, worth around €115 billion as per projections for 2017 (MedTech Europe, 2019). The European medical technology market is predicted to account for 27% of the global market based on manufacturer prices (MedTech Europe, 2019). The medical technology industry spends a considerable number of resources on research and development, and firms' survival (at least profitability) depends on the constant flow of innovations. Another significant characteristic of the industry is that it works with the close cooperation of users. The product life cycle is estimated at 18-24 months before an improved product arrives in the market. Therefore, firms create an organizational culture that helps them to transform their capabilities. In other words, firms focus on dynamic capabilities (for details about organizational culture and dynamic capabilities, see Menghwar and Daood, 2018). In 2017, the European Medical Technology Industry reported that more than 13,000 patent applications were filled with the European Patent Office (EPO) in the field of medical technology, which is 7.9% of the total number of applications (MedTech Europe, 2019).

Challenges, problems, and positives of operating in the healthcare industry

The healthcare industry is thriving and will always be needed until humans exist on this planet. However, the Porter five forces model that shapes the industry determines the profitability of the industry, indicating that the health industry is highly competitive (Maresova and Kuca, 2014). Moreover, researchers have identified particular challenges for the firms operating in this industry.

Long duration of product manufacturing and launching. One of the main challenges is that drug production and launching in the market takes a lot of time. As explained by the general manager of the applied medical coatings:

> "My journey has been a good learning process, but some of it has been painful, a lot of it takes a lot of time because it's just, you know, you have to get through regulatory things

> when you launch a new medical device. So, it can take six months, that's a great thing, or it can take two years. It's not quite like pharmaceuticals, though; it'll take 3-5-7 years to market".

This was evident in the Covid-19 case, for example only in the case of Covid-19, "there are 734 drugs and vaccines in development (544 drugs and 190 vaccines). Among these vaccines, 152 are preclinical; only eight are in Phase III" (Ey.com/lifesciences, 2020). Moreover, according to analyses spanning all therapeutic areas, developing a new drug takes more than 12 years and frequently considerably longer, from target identification to marketing approval (Mohs and Greig, 2017).

High cost for research and development. The second related challenge is the cost, research and development require heavy investment, and then patent filings are successful for the companies that big companies own. For example, "Verily Life Sciences have dominated most of the sectors in patent filings. This can be attributed to the fact that it is a subsidiary of Alphabet Inc, owner of Google" (Singh et al., 2012, p. 209). Verily Life Science's association with google helps the company to get much more capital for research and development expenses. Although it was founded in the year 2015, the however company has raced far ahead in competition with its peers (Singh et al., 2012).

Patent rights – a barrier to innovation and welfare. Patents are given to an organization by a state for disclosing an invention. Thus, the state gives a legal monopoly for that particular invention in the market. Scholars and policymakers have believed for a long time that patent encourages innovation. However, researchers have recently found that patents and patent disputes in some industries (for example, chemical and pharmaceutical) are high; hence they are major barriers to innovation (Bessen and Meurer, 2013; Akcigit et al., 2021). Some argue that intellectual property rights are an incentive for innovation. Still, this approach neglects critical features of technological innovation and ignores the significance of non-market institutions in the innovation process (Dosi et al., 2006). In sum, scholars believe that patents create a barrier to innovation, reduce competition, and put a barrier to the entry of firms into the new market. This problem is prevalent in the pharmaceutical industry.

Promote manufacturing inside the USA and discourage imported medical equipment's from underdeveloped countries. During the interviews with an engineer working at applied medical coatings, we found that pharmaceutical manufacturing companies prefer that their suppliers produce products inside the USA. As elaborated:

> So, for some reason, medical device customers, I would say they, don't prefer Chinese products or Indian products or any products out of the United States. And the reason I tell them

> I mean I quoted when I was giving interviews for the other companies, like moving from my old company to the new company, I was giving interviews for many big companies for different roles. And one of those roles I interviewed for was an industrial engineering manager. And then, the position was to evaluate all the customers from big countries. So, BRIC nations are present in Russia, India, and China. So, the evaluation is different. Based on the FDA guidelines, you need to evaluate everything, and at least it would take six to eight months for you to go through the validation and evaluation. So maybe, that's why they don't prefer something out of the United States that med devices try to stay inside the United States. I'm not speaking about the general medical products, like a bed or a pillow, or something like a pump or something like the things that touched the patient's body; basically, they just tried to stay here" (Chemical Engineer, Applied Medical Coatings).

Increasing collaboration among competitors. Those mentioned above are some of the classical challenges in the pharmaceutical industry. However, after Covid-19, we have witnessed more partnerships; a recent report has highlighted this "The crisis appears to have fostered an attitude of collaboration and cooperation within the MedTech sector and between the industry and its stakeholders" (Ey.com/life sciences, 2020 p. 29). Moreover, the report has highlighted the positive attitude of the FDA towards collaboration as stated, "The receptive attitude of the FDA and other regulatory bodies offers great scope for the industry to shape the dialogue about how it is regulated in future" (Ey.com/life sciences, 2020, p. 23).

Hence, it is expected that medical technology will go under transformation into the current digital period, more driven by the data collected through smart devices, and this data can be collected from all over the world; hence these tools can potentially transform the industry. These across-the-globe collaborations would negatively impact the profitability of local manufacturing organizations in developed countries, or they will find new ways to make profits by transforming their business model or entering into new the business as founders of applied medical coatings did in the past. This shows that hrough collaboration organization can create shared value (making profits while solving soclietal probems)— for details see (Menghwar and Daood , 2021; Menghwar and Freeman, 2023).

Inside Applied Medical Coatings, The Critical Process of Manufacturing a Product

The company-applied medical coating is part of the process industry, which usually coats the manufactured products. The process industry is totally different from the product industry. A company in the process industry primarily doesn't manufacture the products, but they do the process on the products. For example, company X working in the product industry can manufacture sheet metal for the card. But, applied medical coatings, part of the process industry, will paint the card that another company manufactures. The step-by-step illustration of the design process is elaborated in table 2.

Table 2. The design process at the applied medical coatings

Step-1	Any "New Process Line" will undergo set of processes before being established.
Step-2	New process line will be designed based on analytical approach involving the following tools • PFMEA • VSM • AnyLogic Process Simulation • Testing Procedure These four processes are useful in achieving the required level of consistency
Step-3	Unique selling point of AMC's process line is Ultimate Capability in Manufacturing Quality

This coating process is simple; however, the engineer needs to repeat it million times, and it is important to ensure the same consistency. To achieve that, a new process goes through the following stage reviews.

DR0- Concept Stage or Review Stage-1. This is a designed review zero. The first step is when the company gets an email from the customer asking if they can coat a particular product. The email will also have the statement of requirements (SoR[10]), and they can send a piece of the product they want to get coated. Another main component of this stage is DVP requirements, which is a designed verification plan in which the company will test if the coating/design can sustain under prescribed conditions. Once the design is made per the statement of requirements, it will be sent back to the customer, who can place the order in return.
Then the discussion with the customer will start, who can place a large order. In this case, the company gets involved in negotiation as explained below:

10. SoR will contain all the information for example type of (Teflon coating etc), the job is going to be made up of stainless-steel material, size of the job for example two millimetres in diameter and 15 millimetres in length, drawing for the same job. Moreover, it will also contain expected number of pieces for example 15,000 to 20,000 parts per month and required number of parts needed for the validations.

For example, the company can ask that they need 15 to 20,000 parts per month, and then we will be like, no, it is not humanly possible because there is a supply chain delay. Now, these delays should be accounted for. We need a lead time of three weeks or four weeks or something like that. Can you do that? So those are the kinds of negotiations that will happen in the first phase, and we will declare the project quote, including the engineering cost. If satisfied, the customer will negotiate and ask for a prototype. In this case, we will design a manual prototype and send it to customers (Engineer, applied medical coatings)

Table 3. The new product development stage reviews

NPD stage reviews	
DR0- Concept Stage	Check the SOR Creation of 3D models and 2D drawings Working on the DVP and requirements Review with the customer
DR1 – Costing and feasibility	Review the suppliers Review with the manufacturing team Work out the cost based on the process and intricacies involved in each and every step
DR2 – Manufacturing feasibility	Design of the entire process
DR3 – Tooling drawings	Authorize the tooling level drawings to the suppliers and final drawing to the customers Ready for the SOP date
DR4 – ECN/ECR	If there are any engineering level changes this step is required
DR5 – VAVE	Yearly once the product will be reviewed for cost reduction proposals

DR1-Concept Stage. This step involves costing and feasibility. Before providing the estimated budget to the customer, the company will review the cost with its suppliers, as explained by one of the managers as under:

If the customer is satisfied and willing to place an order, we will contact our suppliers and ask what the raw material cost is. And what's the logistics cost involved? After coming to

> the manufacturing team? Okay, what is the process cost involved? And what are the utility costs involved? How many people are going to look at this process? Let's say I have two laborers dedicated to this process. That's two laborers' times, like nearly 10 hours a day working wages plus their expenses, so their benefits will also be covered in the cost. We ensure our workers' safety and ensure that expenses of the insurance and health benefits and everything are covered in the estimated cost. This cost would be labeled under the overhead cost.

At this stage, three-level costs will be calculated, for example, the company to suppliers and the company with the customer who placed the order. Usually, the company doesn't reveal the details of the suppliers. However, some customers are so insistent that they prefer to get the details. This is where collaboration with the customer enters into the difficult phase, as described by the engineer below:

> "In some projects, we don't reveal our suppliers. However, in some projects, out of compulsion, I would say we will be forced to reveal our suppliers because some customers are really pushy. They will be like yeah, okay, who are you working with? Okay, where are they located? Are they inside the U.S. or outside the U.S.? Okay, so if your suppliers are outside the U.S. in Europe, India, or China, how do you validate them? So those are all the challenging questions that come up during the design review one" (Chemical Engineer, applied medical coatings).

The level of complexity in dealing with customers depends on the nature of the customer or the level of the customer. These discussions are very complicated because the company needs to protect its core capabilities while closing working with the customers.

Levels of Collaborative Innovation[11] or Open Innovation Process for Developing a New Product

Two levels of collaboration- There are two main ways of working in partnership: firm-level collaboration, in which AMC works with big companies like Medline, Conmed, and several others (A list of companies worked in collaboration is attached in appendix -3). Besides this, the second way is individual-level collaboration, which is to work directly with doctors (such as physicians and surgeons). The company adopts a different process in both of these partnerships and encounters different challenges.

11. Open innovation is defined as "a distributed innovation process based on purposively managed knowledge flows across organizational boundaries, using pecuniary and non-pecuniary mechanisms in line with the organization's business model" (Chesbrough and Bogers, 2014, p. 17)

Challenges in firm-level collaboration for new product development. The collaboration for developing a new product starts when an outsider company approaches to applied medical coatings for a developing a product or apply coatings using the technology they have on the product developed by them. In this case, the final product would not have the name of the applied medical coatings on it but of the company that brought the product, as highlighted by one of the engineers in the interview:

> Big companies approach us for particular services. In this case, our company's name won't be on it. It would say Medline-electrocautery blade, Conmed – electrocautery blade. It won't have anything related to applied medical coatings, they own the design, but they do not own the manufacturing process. We will have rights and ownership of the manufacturing process. And they own the product and product design. So that's how it works (Chemical Engineer, applied medical coatings).

Both companies sign formal agreements to protect and safeguard their rights and knowledge. These agreements are called design transfer agreements. After the signing of the formal agreements, the manufacturing process starts, which involves the following stages:

Stage -1. The design review stage is usually the first stage of developing a new process. That's when a firm creates a concept. This starts with a series of meetings, roughly 25-30 meetings during the development stage. In these meetings, customers will share their demands, and we will review our capabilities to understand if we can develop a product that the customer wants.
Stage -2. The second stage would be the prototype stage, where you release the prototype. At this early stage, the prototype of the coating will be tested by the customer. The customer would say that's good, or it could ask for changes in the product. More importantly, customers can ask for information on how the prototype was developed, which material was used, at what temperature, and other critical information.
At this point, the company needs to be very careful because sharing all the information about the business model[12] or core capabilities would lead to leakage of its core capabilities. If it fails to satisfy customers, it could lose business. This situation is elaborated by an engineer who worked with customers and asked for the information. Below is the discussion between the author of this study and the engineers; when inquired about the particular example. The engineer explains that the nature of the challenge depends on the customer, some customers are easy to handle, but some customers are demanding.

12. Daood, A., Calluso, C., & Giustiniano, L. (2020). Unveiling the dark side of business models: A novel framework for managerial cognition and decision-making. In Business models and cognition (Vol. 4, pp. 39-56). Emerald Publishing Limited.

EXAMPLE-1.

Author – So, once you give the prototype to customers, what questions can a customer ask, and how do you make sure that crucial information is not shared?

Engineer – Even during the developmental phase of a product, our customers like to know every piece of information we won't be giving them because there will be some proprietary information about the process. Assume that we are quoting silicone for a customer. Okay, that's just an example. Now customer will be asked to me, Okay, what creative silicone coating? We will say that we are coding a medical-grade silicone. And then the second question would be, okay, can you tell me the code number, product number, and catalog number of the silicone? And then what basically happens is we would qualify that as the metal claddings are applied medical coatings, silicone, and then give them our internal number, we will not share the actual product number. So that's the main challenge because the product number gives you the whole process. If you can Google what silicone you're using, it will tell that the first challenge. And if they are insistent about who's the supplier from where you are getting and everything, okay, fine, we are getting from x supplier, this is what we are getting. And then what happens is for the silicone to, for you to coat the silicone, you can do it in like more than two types of processes, you can dip it, or you can spray it. Okay, for dipping, the temperature is different for spraying, the temperature is different. Next, they will ask the following question: Can you tell the temperature? Because if we can tell the temperature, they could be a corporation like that they can set up this own line in their medical device itself, inside their facility, they can have a small room, and they can do these things, right? So we won't reveal it. If they're so insistent, what we will do is the silicone temperature can be between 500F to 700F. We will give the range, not the specific temperature. Those are all the main challenges. But there are some cases I don't like to reveal the customer's name, but there are some cases where this specific customer was so insistent, but the business was huge. The business was huge. He was insistent that we should share all the processed data, and then they were auditing. Like, like, it was like a crazy audit. It ran for days together with each and every parameter. But the thing is, we got the business, which is good. But the bad part about that is they also know the details now there is an agreement like you shouldn't leak the details and everything. But after the agreement expires, that's where the whole thing comes, which will not happen in the near future. You know, but that's where the difficulty is.

EXAMPLE-2.

Author – Is this the prescribed way to deal with all the customers, or do you deal with each customer differently?

Engineer – There is no single way because it depends on the situation and challenges a customer poses. For instance, some customers who are insistent on such types of things, even I would say some departments, okay, because when you work with a big company, you work with different engineering teams for different products. One of the teams was insistent on all the details, like, who is your supplier? And then, where is this supplier from? Are you auditing them? Or are you going there and auditing them? Okay, you're getting the products from country X. How do you know he's a good supplier? Do you have a CPCP critical analysis, like this level of detail, but on the other end of the spectrum, same company, I'm saying, but different department? They were like, hey, please, make me this product. Okay, here's your product. Okay, you're doing good. I will audit you to show me your documents. We are fine. No need for secondary suppliers' details. No need for any data to give them, just like Are you doing fine? Can we audit your facility? That's it. I mean, which is general, you can audit anyone's facility.
I don't think it is even dependent on the industry or department. Maybe it depends on the product and the person handling it. If they are an engineer keen on knowing all the details about the products, they will come right at you because I remember working with the same company for two different products. And for one product, they were insistent on revealing everything. But different from the other product. They were like, hey, make me this component. Okay, fine. We are making you this component. Is it ready to manufacture? Okay, give us like three or four months to validate it, then we can manufacture boom, three or four months. Hey, we are ready to manufacture. When can you do the scaling process? How does it work? How can you scale it from 10,000 quantities to 100,000? Those were the types of conversation and not the technical details. You know? So basically, it depends on the product. And it depends on the people who handled it. Those are people-centric things, and I would say that they product-centric. If some engineers are like I need this, then we will have a difficult conversation. Now this one is complete concerning all the companies.

Reasons for the collaboration despite the risk of knowledge leakage. The fundamental reason for collaboration is that company gets the new ideas, and we get the new designs. But the unfortunate thing about these collaborations is that since we don't own the design and if the partner company knows the entire procedure and secret recipe, they have influence/advantage over us in this case. Another reason for working with these companies is that they are well-known companies. Hence, they could sell the product developed in collaboration with us. It's as if you could create one of the most popular goods on the market. However, if you lack a marketing department to promote that, it won't work. As explained by one of the engineers of applied medical coatings:

> For example, I have the best electrocautery blade compared to these big corporations. But guess what? I don't have sales representatives visiting hospitals to communicate the use of medical coatings developed by our company. Besides this, we don't have credibility. It is a bitter fact that hospitals won't have any faith in us because we lack the credibility that large corporations have in the eyes of customers, who are the product's end users. That's why we manufacture it for large companies whose products are familiar. For instance, if you enter a hospital randomly, most of the equipment would be of one well-known company with almost 200,000 products in its catalog. Hence, competing with these companies doesn't make sense; therefore, we prefer to collaborate. The problem is that we always have a disadvantage when disclosing the entire method, which is why we try to be careful. However, occasionally we have been stretched to a limit. They would use the excuse that they need all the information because the food and drug administration (FDA) has asked for it. Indeed, FDA doesn't ask for minor details, but these are the common difficulties we face while working with larger clients.

Challenges and bright side of working with individual level collaborations for the new product development. The second mode of collaboration is with individuals, for example, doctors and surgeons working in hospitals. When the author inquired about the challenges and problems faced by the applied medical coating teams in dealing with these doctors, the answer was as under.

EXAMPLE-3.

Author – You mentioned individual-level collaborations. What challenges do you face, and how do you overcome them?

Engineer – The second way I was telling, right, we also work with people like us, individual designers and doctors. Those guys will be amiable. I have had an opportunity to work with Dr. Antonio, and I also had a chance to work with Dr. Edoardo[13]. Now, these doctors' approach is different. What they would do is, hey, I need something in my field that should be doing this job. I need a catheter that can help me remove the abscess. I have the design in my mind. Can you design and manufacture that? Okay, go ahead.
Dr. Edoardo said, "Hey, I need to design a device that removes the polyps and cysts from the uterus. Can we do that? So that's like a personal level collaboration. Now, what happens is we develop everything based on doctors' suggestions. It is more than the medical devices, we work directly with doctors, and doctors give you a lot of knowledge in the field. It's not the same as happened in the case of the medical devices company, who would say, hey, make me this product. But this company won't tell you where they are using it and under what conditions this product would be used. But doctors would share almost all the information, like, this device will be used against the skin, the skin temperature will be this one. And then, the rod will generate this amount of temperature. I would be dipping it in these solutions. So, ensure that the coating doesn't bear if you're doing all these things. Now, this level of detail is beneficial. And then doctors, we have regular meetings, weekly meetings. And the thing with the doctors is you don't worry about what process you use. Okay, they don't worry about the manufacturing thing. Because we will take care of the FDA, we will take care of the manufacturing and everything. We will manufacture and register the device for the FDA. And then things would be entirely on our plate, which is good. We will be in the driver's seat. And Dr. Will is like. I need this under my name. And how can we do that? That's it.

Once the company has managed to overcome the paradox of open innovation and the customer has placed the order, the stages DR-2 to DR-5 (as shown in table 3) are considered within the range of the engineering department of the company, hence, not discussed in the details because this teaching case is designed for management students and technical terms/engineering processes are outside the scope of management discipline. The company usually reviews the cost of the process and tries to find ways that can be useful to do the same process at a lower cost. This new reduced cost will be communicated to the customer to strengthen the collaboration further and get more orders. Based on this, it can be assumed that the company makes efforts to satisfy its em-

13. The names of the doctors are replaced with pseudo names in order to preserve the privacy, however, these are real life examples.

ployees (by giving insurance and health benefits) who are internal customers and external customers, this striving to achieve win-win situations, in other words creating shared value for employees and the company itself (Porter and Kramer, 2011: Menghwar and Daood, 2021).

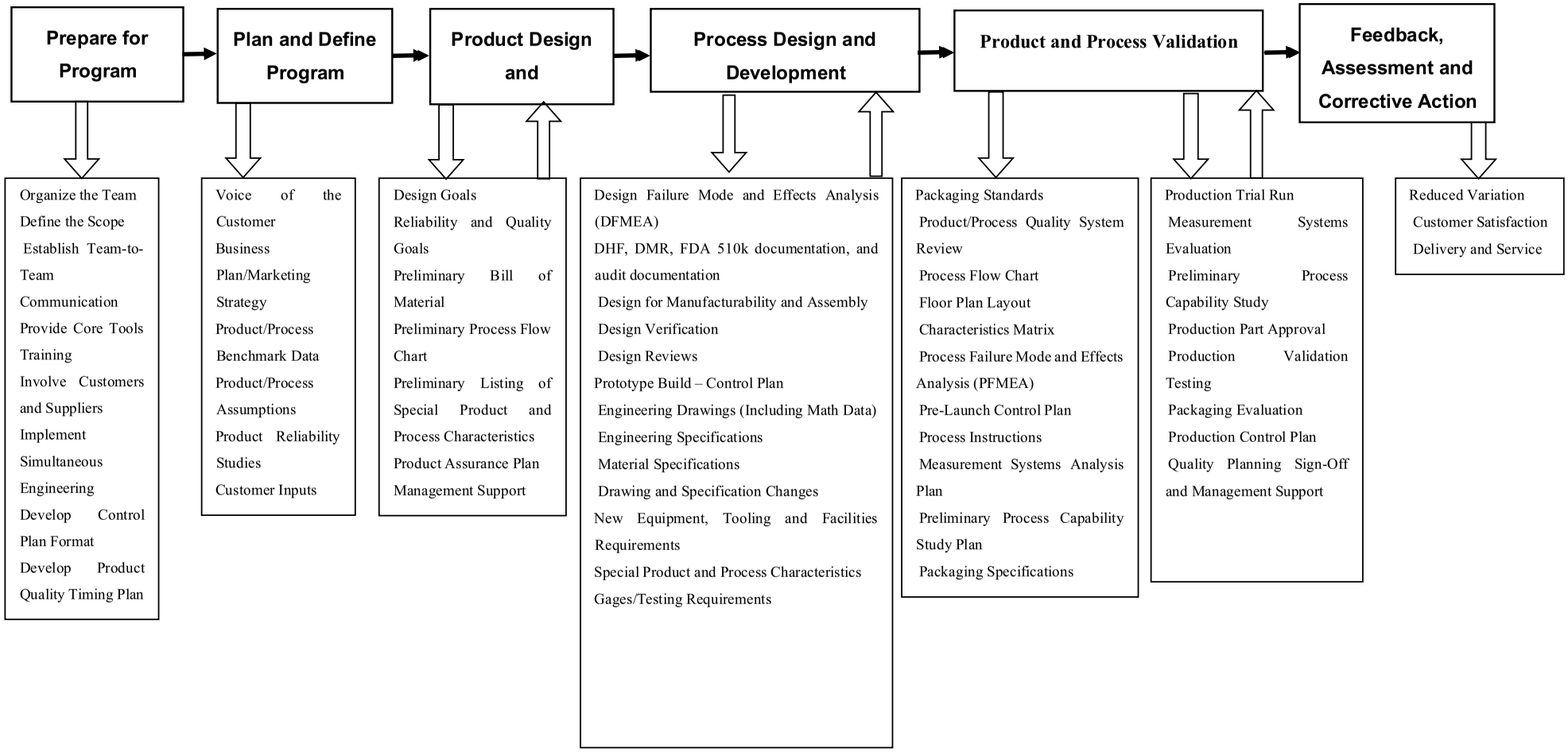
Robb Surgical

Robb Surgical provides complementary and novel surgical devices for the global marketplace. These products are established in relationships with device designers worldwide. While applied medical coatings does coatings of the already manufactured products, Robb surgical manufactures products. The company was born as a spin of applied medical coatings when people contacted Robb to manufacture the products. He describes this as under:

> Rob surgical is a spinoff company of applied medical coatings. People asked us to look at manufacturing their medical devices but then sell them directly to the market. So actually, we are manufacturing and then directly selling to hospitals or distribution companies. And that's not exactly something that applied medical coding does.

Typically, there are doctors or people in universities that have come up with their medical device idea but can't manufacture them. They contact this company because the big companies don't get involved unless the business is $100 million or more. They typically don't want to bring your device into the market until they see huge revenue. So, Robb Surgical takes the product to an early stage and tries to build them up in the marketplaces. Table 4 shows the process flow of Robb surgical.

Table 4. The process flow at Robb Surgical



Challenges in Supply Chain Management due to the Covid-19 crisis:

The supply chains have been disturbed since COVID-19. There are two main reasons for this disturbance:

Shortage of raw materials. Due to covid 19 crisis, companies have stopped producing, and consumption has been reduced. The raw materials to make plastics or to make rubber are in shortage. Now, demand has turned back, but the raw materials are unavailable. So, there is a tremendous increase in the lead time to build up these raw materials. Hence, lead time has gone up from 30 weeks to 40 weeks, around six to eight weeks before the Covid-19 crisis.
Decrease in revenue. This crisis has drastically affected things not just from a delay in supply of products standpoint but from a revenue point of view as explained by the supply chain head:

> So, I can't make something, I can't ship it, and I can't invoice it, which means revenues also take a hit because of the unavailability of raw materials to make the product.

So, post-COVID-19 world, the lack of availability has created big trouble for all stakeholders in the industry because it has delayed surgeries in the hospitals despite the lower load of Covid-19 patients. So, elective surgeries are started by hospitals that were paused during Covid-19 (Menghwar, 2021). Still, due to the unavailability of medical devices, hospitals don't get the necessary products to sterilize the equipment used in surgeries. Hence, hospitals can't do much work. However, people and the government are not paying much attention to this problem. Hence, it could take up to a year to resolve these supply chain issues in the manufacturing industry.

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