

White Paper Series – Part II:

BioCompat^{ic}®

A ROBUST USP CLASS VI SILICONE ALTERNATIVE

NEWLY RELEASED SECOND GENERATION

BioCompat^{ic} II

Softer Durometer Offers Optimal Glide and Increased Flexibility



EXTREME ENVIRONMENTS | COMPLEX REQUIREMENTS

CUSTOM INNOVATIONS
CONNECTOR + CABLE

EXECUTIVE SUMMARY

Combining decades of field-proven life science experience, LEMO and Northwire's collaborative white paper series highlights the professional expertise and continual innovation necessary to design and manufacture end-to-end (E2E) connector and cable assembly solutions that meet the rapidly evolving demands of the medical market. Fully integrated and proven in the most severe applications, these E2E custom systems and components are tailored to the specific requirements of each individual customer. In the manufacturing companies' constant pursuit of 100% reliability, extended life cycle, and safety in cables and connectors, LEMO and NWI are pleased to introduce *BioCompatic* and *BioCompatic II*, durable USP Class VI alternatives to silicone-jacketed cable. Ideal for use in medical applications and beyond, *BioCompatic* and *BioCompatic II* highlight R&D advancements and next-generation technology offered by LEMO and Northwire. As Northwire's second generation cost-effective USP Class VI silicone alternative, *BioCompatic II's* softer durometer was specifically engineered to provide a cable with optimal glide, increased flexibility, and robust resistance to chemicals, cuts, crush, and abrasion. Discover the competitive advantages of these silicone alternatives, the unique product enhancements of *BioCompatic* and *BioCompatic II*, and how to ensure your success with these cost-sensitive innovations.

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STEP INTO THE FUTURE WITH *BioCompatic*. AND *BioCompatic II*

As medical devices, industrial control systems, and critical communication tools grow more complex, electrical component manufacturers must respond with innovative solutions that utilize cutting-edge technology and the advantages of next-generation materials. In cooperation with The LEMO Group, Northwire has risen to this challenge by successfully designing and manufacturing an original alternative to silicone-jacketed cables and cable assemblies.

Silicone is a popular material for applications where reliable high performance is imperative. Commonly used in medical tools, hospital equipment, and surgical devices, silicone is flexible and smooth while still providing durability and thermal stability. When produced at medical-grade, these qualities allow the material to meet FDA, USP Class VI, and ISO 10993 biocompatibility requirements and stand up to the intense demands of medical environments, such as sterilization.

While medical-grade silicone is one of today's most prevalent solutions for these applications, using the polymer is not without downsides.

ADVANCED TECHNOLOGY SUPPLIES A SOLUTION TO SILICONE

Procuring sturdy, medical-grade silicone can be a long and costly process. As a thermoset material, silicone must go through a curing stage. This adds significant cost as the curing process necessitates additional equipment, curing catalysts, and a longer lead time to production. Leading OEM silicone brands range from 8 to 12 weeks lead time in the United States.

In addition to the lost time and added expense that comes with curing, silicone's durability does have limits. While material resists medical sterilization well in general, it is more vulnerable to cut, abrasion, and tear. The fast-paced environment of a hospital or clinic, with repetitive use, constant movement, and heavy rolling equipment, creates a harsh setting for cable systems that ultimately decreases the lifetime of the products.

Along with REACH and RoHS2 compliant products, Northwire has offered both silicone-jacketed and silicone-free products for years. While each has its merits in their respective applications, there is a need for a silicone alternative that retains the benefits of the material without the lengthy curing process and physical weaknesses. That market-gap is filled with Northwire's newest price-competitive innovation, *BioCompatic*.

A NEXT-GENERATION BIOCOMPATIBILITY SOLUTION

As Northwire's R&D engineers and Subject Matter Experts (SMEs) developed the project charter for the alternative to traditional silicone jacketing, the voice of the customer and the demands of the market shaped the solution. Biocompatibility and resilience were vital, but this new product had to be market-ready much faster than silicone – and at a lower cost.

***BioCompatic* achieves optimal biocompatibility under USP Class VI, ISO 10993-5, REACH, and RoHS2 by passing a battery of tests that include analysis of cytotoxicity, systemic toxicity, intracutaneous response, muscle implantation response, and beyond.**

Additionally, *BioCompatic* cable systems offer features such as:

- High flexibility and durability for a long lifetime
- Excellent endurance to sterilization
- Bisphenol, phthalate, and halogen free
- Resistance to chemicals, abrasion, crush, and cut
- Retractable options
- Wide range of durometer hardness
- Low co-efficient of friction – soft and smooth surfaces that do not bind or catch on itself or patients
- Custom printing that withstands autoclave and other sterilization procedures

With Northwire's rapid response capabilities and mindful design, *BioCompatic* saves customers time and money. No curing process is needed, shortening lead times and lowering expenses. Combined with the cable's robust resistance to environmental factors and sterilization, *BioCompatic* offers a quick, reliable, and cost-effective path to market.



IDEAL FOR A DIVERSE RANGE OF USE

Due to its ability to meet stringent biocompatibility requirements while retaining strength and flexibility, *BioCompatic* is well suited to a wide variety of life science and medical cable assembly applications, including:

- Patient monitoring cables
- Endoscopic reusable/sterilized assemblies
- Imaging cables
- Diagnostic tools
- Catheter applications
- Dental cables
- Surgical cables – power & signal
- Single-use cables
- Drug delivery systems
- Defibrillation systems
- Therapeutic cables

NAVIGATE THE COMPLEXITIES OF COMPLIANCE

To offer customers the best in safe, dependable medical cables, *BioCompatic* meets some of the strictest standards of biocompatibility and hazardous materials. Rely on LEMO and Northwire to navigate these complex compliance requirements and gain assurance that your medical devices, surgical equipment, and other critical tools adhere to all needed criteria set by international and regulatory agencies.

Trust Northwire to direct you through highly technical, critically important standards:

USP Class VI

Developed by the U.S. Pharmacopeia Convention (USP) in 1965, USP Class VI Testing falls into a set of standards broadly recognized and respected across the globe. In addition to regulating pharmaceuticals, supplements, health technologies, and more, the USP provides a strict set of biocompatibility protocols that apply to plastics and polymers integrated into medical devices. USP Class VI is the most rigorous in its category, and requires a series of in vivo biological reactivity tests. The plastic or polymer must demonstrate extremely low toxicity and irritation when in contact with live tissue through systemic toxicity, intracutaneous, and implantation testing.

ISO-10993

Generally considered even more stringent than USP Class VI Testing, ISO-10993 analyzes the same tests as the USP biocompatibility standard while including additional testing for cytotoxicity, genotoxicity, chronic toxicity, and hemocompatibility. Extensive and intense, ISO-10993 testing is typically reserved for permanently or semi-permanently implanted components such as medical tubing.

REACH and RoHS2

Both REACH and RoHS, directives set by the European Union, deal with the restriction and evaluation of chemicals in certain products or equipment. These regulations seek to prevent and monitor the use of potentially dangerous substances while increasing industry responsibility and consumer safety. Learn more about NWI's XRF Material Analyzer test services now.

Offering Hundreds of Engineering and Test Services

In addition to common certifications of biocompatibility and chemical safety, other standards may apply to your product. To identify which standards your products are required to meet and which would be beneficial to meet, along with assistance for the design, testing, prototyping, and documentation necessary to gain these certifications, connect with a representative at Northwire today. The manufacturer's SMEs are highly equipped to guide and support you from the initial concept of a product through its introduction to market.

Toll Free: 800.468.1516 | [cableinfo@northwire.com](mailto: cableinfo@northwire.com) | Chat Live at Northwire.com

STRATEGIZE, CENTRALIZE, SYNCHRONIZE WITH LEMO

“LEMO’s and Northwire’s innovative solution offerings allow our customers to resolve their toughest interconnectivity challenges.” – Fabian Weber, VP of Innovation and Business Development

In 2014, Northwire solidified its partnership with LEMO, an international leader and the originator of Push-Pull connectors. With nearly 70 years of engineering expertise, the connector manufacturer boasts local experts in 80 countries who have achieved over 100,000 custom solutions.

The LEMO Group’s subsidiaries include Northwire as well as REDEL, a precision manufacturer of advanced medical connectors. REDEL’s series of self-locking, plastic circular connectors deliver extensive autoclave capabilities, a highly secure Push-Pull latching system, and a diverse array of contact configurations. Available in single-use and reusable designs, the connectors are lightweight and resilient. REDEL’s medical connectors include the REDEL® 1P series, SP02 connectors, ECG wire connectors, IP68 connectors, and the company’s newest offering, the REDEL SP connector.

The partnership between LEMO, REDEL, and NWI gives customers a decisive E2E advantage. Fully integrated and streamlined, the proven connectors manufactured by LEMO and REDEL work seamlessly with Northwire’s BioCompatic cables. A winning combination and your one-stop shop for custom medical cables, connectors, and cable assemblies, the partnership between these field-proven manufacturers allows customers to centralize and rationalize their supply base with one strategic solutions provider.

When you partner with LEMO and Northwire, you access a globe-spanning wealth of resources for the rapid design, integration, and deployment of your high tech silicone cable solution.



REDEL SP Connector

Experience the benefits of the REDEL SP connector, a revolutionary, patented latching system ideally suited for use in medical environments. With a world-renowned self-latching system, REDEL’s user-friendly system affords absolute security and efficiency with a single motion. Equipped with enhanced ergonomics and extended sterilization resistance, the REDEL SP connector is optimized for medical applications.

The innovative medical connector possesses a number of features that make it well-suited to this high-demand environment:

- High number of mating cycles for guaranteed extensive product life
- Better performance in smaller spaces (high density contacts)
- Available with up to 22 contacts
- Ergonomic shell with a sculpted thumb grip location
- Operating temperature from -50°C to 170°C
- High electrical insulation and mechanical resistance
- Excellent endurance under sterilization
- Low contact resistance for high signal integrity

As medical devices become smaller and more complex, REDEL's SP connector offers exceptional performance and data integrity in small spaces and when subjected to repetitive handling and wear. Heavy-duty materials give the connector remarkable durability, and purposeful design makes it supportive of medical staff and patients through ergonomic advantages.



REDEL SP's ergonomic design

These circular plastic connectors are especially adapted for applications such as medical electronics, catheters, test and measurement equipment, and beyond.



REDEL P (left) and REDEL SP in white and grey

The SP series also offers a patented latch sleeve recessed into the connector body to ensure greater resistance to shock and repeat sterilization. Connect with LEMO or Northwire to explore your options for the REDEL SP connector and secure your tailored product.

INCREASE YOUR SPEED TO MARKET

One of the primary reasons for designing an effective silicone alternative is the drawn-out time to market presently necessitated by traditional silicone production processes. Typical lead times from silicone OEMs run between eight and twelve weeks. Additionally, cable manufacturers utilizing silicone in jacking often apply “parlylene coating” in a time consuming curing catalyst process that may necessitate reoccurring recoating.

To overcome long lead times and traditional curing practices, *BioCompatic* is designed for rapid deployment. No curing or coating is necessary, and with Northwire Express Design-to-Ship in 5 Days or Fewer program, customers can receive a rugged silicone alternative in record time. Standard lead times of 5, 10, and 15 days, along with NWI's rapid deployment technology, gives medical device manufacturers an advantage over competitors waiting on silicone.

MAKE IT TO MARKET FASTER THAN EVER

“At Northwire, our customers deserve the best. Not only is it paramount to have the fastest lead times with the highest quality, our team collaborates with you to customize flexible inventory management programs designed to meet your exact needs.” – Kevin Rector, Technical Sales Manager

NWI EXPRESS

5 Days Design to Deliver

www.northwire.com/products/nwi-express

Utilize *BioCompatic* in conjunction with Northwire's rapid development and deployment services to be the first to market. Discover the benefits of:

- **Custom contract manufacturing**
- **Time-sensitive product launch support**
- **Free sample cable and wire**
- **Full research and development capabilities**
- **Rapid prototyping and 3D printing**
- **Advanced testing and trial support**
- **No minimums on order volume**
- **Quotes in 24 hours or less**
- **Personalized service excellence**

TORQUE-FREE RETRACTABILITY

Intense and demanding, medical procedures require tools that are not only biocompatible, but also ergonomically congruent with the health professionals utilizing them. When a doctor applies constant motion or rotation to medical devices during a procedure, the cable powering or controlling that instrument is stressed. The repetitive torquing and precession leads to tangled, twisted cable that has the potential to interfere with the operator.

To solve this problem and support the end-user – and ultimately the patient – *BioCompatic's* design allows for torque-free features. The retractable cable is engineered to optimize rotational motion, decrease resistance to repetitive flex, and maintain its original shape when not in use.

By eliminating key concerns with torque and retractability, medical professionals utilizing devices built with *BioCompatic* gain support and focus for crucial procedures.

MEETING A HIGHER (FLEX) STANDARD

Flexibility and retractability are key features of many Northwire products. To optimize these features, the cable manufacturer performs ongoing, on-site testing for cable flex life. This rigorous procedure, known as the Northwire Standardized Flex Test Protocol (NSFTP), verifies new product designs, improves on existing products, and assists in new material evaluation.

The NSFTP judges six primary types of flex:



Continuous and repetitive motion, like that exhibited in hospital or medical environments, greatly decreases the performance and lifetime of cable assemblies. Extend the life of critical tools and systems while increasing reliability by using a cable specifically designed for constant flexing – *BioCompatic*.

BEYOND THE SURGICAL TABLE

While *BioCompatic* retains the advantages of traditional silicone jacketing such as biocompatibility and sterilization resistance, it is not limited to medical usage. The material's robust strength, broad resilience, thermal stability, and ability to meet strict quality and safety standards lends it to a diverse range of extreme engineering applications in industrial, energy, aerospace and defense industries.

FEATURES: Signal, control, instrumentation, and power



BENEFITS:

- Compliant to USP, ISO, RoHS2 and REACH Standards
- FDA and Food Grade material
- Superior flex – retractable, torsional, rolling, variable, bend and continuous
- Gurney wheel crush resistance to 186,100 cycles
- Long life expectancy
- Resistant to steam autoclave sterilization to 500+ cycles
- Resistant to gamma and ETO sterilization
- Custom colors, legends, and private labels
- Conductor count of 2 or more with AWG range 36 - 2 (.0127-33.6 mm2)
- Temperature range of -80°C to 105°C
- Options for wide range of stranding and outer diameters
- Cost competitive filler, shielding, armoring, wraps, and strength member options
- Anti-counterfeiting technology options from overt to covert
- 100% lot traceability anywhere in the world

DYNAMIC RANGE OF USE:

Industrial Instrumentation & Automation	Aerospace & Defense	Information & Networking Systems
Electronics & Machinery	Test & Measurement	Marine & Underwater Use
Medical Engineering & Life Sciences	Communications & Audiovisual	Alternative & Nuclear Energy
Public Sector & Automotive	Decorative & Architectural Lighting	And much more...

EXTREME TESTS REPLICATE EXTREME ENVIRONMENTS

Excel in harsh conditions and under challenging requirements with products that are tested to exceed real world applications. In order to ensure reliable high performance and provide customers with cost savings and added value, LEMO and Northwire subject cables and connector to extreme testing for success in extreme environments.

Northwire's SMEs and R&D engineers tested *BioCompatic* cables to an intense protocol of tests. A key metric was the silicone alternative's chemical resistance to the most common hospital disinfectants and concentrates. Typically, medical cable and devices are not exposed to these substances for more than 10 minutes. Instead of only testing to realistic conditions, however, NWI's engineers immersed *BioCompatic* in these chemicals for a full 24 hours.



Rugged, robust, and highly effective, the silicone cable alternative performed excellently in this difficult evaluation. BioCompatic demonstrated resistance to harsh agents including:

- **Betadine**
- **Cidex OPA**
- **Virex II 256**
- **Clorox Healthcare Bleach**
- **Isopropyl Alcohol, IPA**
- **Hydrochloric Acid, HCl**

RUGGED CABLE THAT LASTS

In addition to chemical resistance, *BioCompatic* was tested to withstand other factors common within hospital and industrial environments. Traditional silicone cable does not only face biocompatibility requirements; day-to-day use also takes its toll on the cable.

A key example is gurney rollover. When a 200 pound hospital gurney rolls over a silicone cable assembly, tests show that the cable fails in fewer than 9,300 cycles. In the same tests, *BioCompatic* sustained rollover from the gurney in over 186,100 cycles.



Beyond physical resistance to the abrasion and constant crush from a gurney or similar piece of hospital equipment, Northwire's custom silicone alternative works in a broad scope of temperatures. With a brittle point of -80°C and a high-temperature rating of 105°C , *BioCompatic* can be tailored to fit most needs.

Conquering electrical, environmental, and ergonomic extremes, *BioCompatic* is a long-lasting, ruggedized solution to both complex and commonplace challenges.



PATHOGEN PROOF UNDER INTENSE STERILIZATION

Another example of typical usage comes with sterilization. For many applications, medical grade cable must undergo rigorous sterilization to avoid contamination by bacteria, viruses, and other pathogens.

A common way to sterilize a medical device or piece of equipment is to use a steam autoclave. The high pressure, high temperature steam effectively sanitizes hospital supplies, but can negatively affect a tool's appearance and performance over its "cycle life."

COMPETITIVE ADVANTAGE

In tests compared to competitors, *BioCompatic* retained full tensile strength and elongation after enduring over 500 steam autoclave cycles. Additionally, when compared to the leading brand of silicone cable alternatives, Northwire's solution demonstrated 50% longer color clarity.



BioCompatic also exhibited excellent resilience under Gamma and Ethylene Oxide (ETO) sterilization and hydrogen peroxide sterilization. Further, the cable actively works to prevent contamination through fungal resistance.

BioCompatic II

SECOND GENERATION USP CLASS VI SILICONE ALTERNATIVE



NOW AVAILABLE

For extreme engineering and cable assembly applications ranging from health care to industrial, Northwire's second generation cost-effective USP Class VI silicone alternative, BioCompatic II, was engineered by Northwire with a softer durometer to specifically provide increased flexibility, maximum glide, and robust resistance to chemicals, cuts, crush, and abrasion.

VELVET LIKE CABLE FEATURES SOFTER DUROMETER

This velvet-like cable meets customer requests for a softer silicone alternative cable solution.

BioCompatic II optimizes end-user experience by reducing cable tackiness and ensuring the smoothest device for patient and practitioner interaction.

Building upon the strengths of the original, *BioCompatic II* maintains:

- Optimal biocompatibility within a USP Class VI, ISO 10993-5, REACH and RoHS2 compliant custom cable silicone alternative
- Compatibility with LEMO's REDEL Series Connectors
- Custom design-to-ship in 5 days or fewer services ensure rapid technological development compared to lead times from silicone OEMs which are typically 8 to 12 weeks
- Cost savings as *BioCompatic* eliminates an extra stage of production and associated equipment and curing catalysts associated with silicone
- Design and engineering to optimize torque-ability and retractable cable capabilities
- Extreme engineering capabilities for applications in life sciences, industrial, energy, aerospace and defense featuring signal, control, power, and instrumentation, *BioCompatic* is also ideally suited for hybrid fiber optic applications
- Tear strength and resistance to chemicals, cut and abrasion, boasting a brittle point of -80°C and a high-temperature rating of 105°C

BioCompatic - USP Class VI Silicone Alternative from Northwire and LEMO

Compatible with REDEL Series and features optimal cut, crush and chemical resistance and softer durometer options that offer maximum flexibility and are cost-effective

Robust materials are ideally-suited for health care that translate effectively to achieve high-flex life performance in industrial environments as well. Unlike traditional silicone with long lead times, Northwire's *innovative solutions* are available with the industry's fastest lead times of 5, 10, and 15 days.

BENEFITS:

Single-use and reusable medical-grade cable for applications requiring multiple sterilization cycles - GAMMA, ETO and AUTOCLAVE. Overmold compatible and free of Halogens, phthalates, toxins, and irritants and compliant to REACH, RoHS2, ISO 10993-5, and USP VI. Custom color options available, including exact matches to Pantone or RAL numbers.

DYNAMIC RANGE OF USE:	MATERIAL OPTIONS			
Diagnostics, patient monitoring, surgical devices, life support and therapeutic applications				
Systems for drug delivery and defibrillation				

Custom cables, retractiles, and assemblies designed for maximum continuous variable, torsional, rolling and bend flexibility	Silicone	Medical-Grade Santoprene™	BioCompatic	BioCompatic II
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FEATURES				
Signal	✓	✓	✓	✓
Control	✓	✓	✓	✓
Power	✓	✓	✓	✓
Instrumentation	✓	✓	✓	✓

ATTRIBUTES				
Halogen Free	-	✓	✓	✓
Specific Gravity	-	0.96	0.93	0.92
Shore Hardness "A" (+/-3)	60	65	69	55
Brittle Point	-	-60°C	-80°C	-80°C
Continuous Use Temperature	~180°C	105°C	105°C	105°C
Gurney Wheel Crush Resistance	9,260 cycles	94,800 cycles	186,100 cycles	90,400 cycles
Chemical Resistant	Excellent	Excellent	Excellent	Excellent
Cut Resistant	50 lbs.	75 lbs.	125 lbs.	100 lbs.
Abrasion Resistant	6,200 cycles	11,500 cycles	14,400 cycles	11,500 cycles
Fungal Resistant	*	*	*	*
Anti-Rodent Additive	*	*	*	*
Retractile Applications	Fair	Fair	Excellent	Excellent

STERILIZATION				
Steam Autoclave	500+ cycles	500+ cycles	500+ cycles	500+ cycles
(Discoloration observed)	100 cycles	150 cycles	150 cycles	150 cycles
Gamma	✓	✓	✓	✓
ETO	✓	✓	✓	✓
STERRAD	✓	✓	✓	✓

CHEMICAL RESISTANCE				
Betadine (100%)	✓	✓	✓	✓
Cidex OPA (100%)	✓	✓	✓	✓
Virex II 256 (100%)	✓	✓	✓	✓
Clorox Healthcare Bleach (100%)	✓	✓	✓	✓
Isopropyl Alcohol, IPA (99%)	✓	✓	✓	✓
Hydrochloric Acid, HCL (36%)	✓	✓	✓	✓

FLEXIBILITY				
Torsional Flex	*	*	*	*
Rolling Flex	*	*	*	*
Variable Flex	*	*	*	*
Bend Flex	*	*	*	*
Continuous Flex	*	*	*	*

STANDARDS, AGENCY AND ENVIRONMENTAL COMPLIANCE				
ROHS2	✓	✓	✓	✓
REACH	✓	✓	✓	✓
USP VI	✓	✓	✓	✓
ISO 10993-5	-	-	✓	✓
FDA	-	✓	-	-
FOOD GRADE	-	-	-	-

PRODUCT SPECIFICATIONS

Key: - Not Applicable
 ✓ Featured
 * Cost Competitive Options Available



Cable Construction: BioCompatic	
INSULATED CONDUCTORS	
Conductor Count	2 or more
AWG (mm ²)	36-2 AWG (.0127-33.6)
Stranding - Minimum and Maximum Diameter of individual wires AWG in inches (mm)	*
Insulation Materials	ETFE, ECTFE, FEP, XLPE, PP, PE
OVERALL CABLING	
Fillers	*
Shielding	*
Armoring	*
Wraps	*
Strength Members	*
OUTER JACKET	
Material	TPR
Mutual Capacitance pF/ft (pF/m)	-
Inductance (μH/Ft)	-

KEY:

- Not Applicable
- ✓ Featured
- * Cost Competitive Options Available



TRUST A UNIVERSAL LANGUAGE OF QUALITY

When communicating critical-to-quality requirements, gain the support that comes from decades of expertise by relying on Northwire's recognized SMEs. A strong command of Quality Management Systems allows NWI's professionals to speak the universal languages of Project Management, Lean, Six Sigma, ISO, and ASQ.

This foundation means Northwire is communicating clearly on complex projects, leveraging international resources and processes, and translating your exact product specifications into an optimized, customized product.

Due to its Comprehensive Quality Management System, Northwire is:

- ISO 13485:2003 Certified
- SAE AS9100:2009 Certified
- ISO 9001:2008 Certified
- ISO 17025:2005 CSA Qualified Testing Facility

Additionally, the cable supplier's strong quality management and service excellence translate into a comprehensive suite of contract engineering services that give valued customers and strategic partners a clear advantage from Concept to Completion:

- Research and new product development
- Prototyping, pilots, and clinical trials
- Low volume through high volume production
- Logistics and life cycle management
- Fast delivery and quotes in 24 hours or less
- Same day custom cable products
- No minimums on volume or length
- Personalized service excellence
- And more

Benefit from Northwire's quality proficiencies, standardized protocols, and unique innovations. Contact a Northwire representative today to learn more about NWI's quality management offerings and contract manufacturing services.

Toll Free: 800.468.1516 | CableInfo_Northwire@lemo.com | [Chat Live at Northwire.com](#)

RAPID DEPLOYMENT OF R&D PROJECTS

Written by Kevin DePratter, PMP®, Director of R&D at Northwire

“Without order nothing can exist – without chaos nothing can evolve.” – Vadim Kotelnikov

All projects begin with an idea, a concept, or a problem that needs to be solved. It is usually random thoughts in the initiator’s mind or jotted down on a bar napkin. It is our job to capture these ideas in an organized way and take it to completion quickly. R&D is fun! It starts out being “organized chaos” and concludes with a successful product or process launch.

There are many ways and processes to tackle a project:

- Plan, Do, Check, Act (PDCA)
- Stage Gate®
- Project Management (initiate, plan, execute, monitor and control, and close)

We will use the project management process because it is simple to use along with being disciplined and methodical in its approach. When you follow these five steps, you can take any idea from Concept to Completion quickly without worry of forgetting an important element or step.

Most project leads and teams spend 80% of their time in executing and testing and 20% in initiating and planning. Successful teams and project leads spend about 80% of their time in initiating and planning and 20% on all other activities while accomplishing their goal quicker. You are probably thinking planning and organizing the project takes valuable time away from the important tasks of the project; in fact, it will save time overall. Let’s get started in the process.

INITIATING

Initiating the project is the beginning of the process. The project manager (or lead) meets with the owner of the concept or idea to design a project charter. Elements of the project charter include, but are not limited to:

- Identify key stakeholders and their influence, expectations, and impact on the project
- List high level project requirements, assumptions, constraints and risks
- Understand the business case and analysis for the project
- Define the project scope (be specific as possible)
- Ensure the project supports the company’s strategic objectives
- Define measurable project/product deliverables (this takes collaboration with the project initiator and/or customer) and key milestones
- Have project charter approved so you can begin working on the project and move on to the next phase



During the initiating process, gather as much information regarding the concept or idea as you can. Any source of information that will lead to higher performance (for the product, process, or team) and improved project time is considered fair game.

PLANNING

The planning process is considered by most successful project managers, leads, and teams to be the most important element of the five-step process. Proper planning ensures an efficient and smooth-running project. The planning process defines the elements that will be followed in the subsequent steps of the project. Spend the majority of your time in the planning step. Typically, the team should spend 65-70% of their project time immersed in this process.

One of the first steps in the planning process is to ensure that you have Subject Matter Experts (SMEs) on your cross-functional team. Successful project teams are not intimidated by having these experts (in procurement, finance, sales, manufacturing, engineering, IT, scheduling, quality, and/or human resources) on the team. These functional departments are brought into the specific parts of the process where they have the greatest impact and contribution; otherwise, this step in the process can get very costly.

Key elements of the planning process involve:

- **Determine detailed project/product requirements**
- **Create the scope statement**
- **Gather procurement documents**
- **Assemble work breakdown structure and dictionary**
- **Create activity lists**
- **Create network diagram**
- **List resource requirements (manpower, equipment, and systems)**
- **Estimate time and costs**
- **Perform critical path determination (what activity/task is going to take the longest time to complete)**
- **Develop project schedule and budget**
- **Develop quality standards, processes, and metrics (measures of success)**
- **Create process/product improvement plans**
- **Determine roles and responsibilities**
- **Develop communications plan**
- **Perform risk identification and analysis along with a risk response plan (this includes risks that can have a positive or negative influence on the project or product)**
- **Create a plan on how to handle project/product changes**
- **Finalize the plan (how to execute and control the plans that are in place)**
- **Develop performance level baseline for project/product**
- **Have plan approved by initiator and key stakeholders**
- **Decide the best time to kick off the execution phase of project**

You notice that risk identification and analysis is emphasized. Many teams and project managers minimize this step in the planning process. Failing to identify and plan for all types of risk (any item that can positively or negatively impact a project) can and usually will cause delay. By identifying and planning for risks, there are no surprises.

Another item that is commonly forgotten or underestimated is the time needed to gain external or agency approvals (such as USP Class VI, UL/CSA, FDA, ISO, etc.). If these activities are captured during the planning process, you may find out that you do not have to wait until the product is entirely finished prior to submitting it to those external agencies. This can gain valuable days or weeks. See how you are saving time already?

Most traditional engineers and specialists think sequentially. Project management teaches you how to re-orient your thought process. When you visually capture the process (for instance a work break down structure and activity list) it becomes apparent that work can be performed in parallel to other activities. This is the largest area where time can be saved.

Bringing in the best possible SMEs at the right time during the process enables a better understanding of how all this information is integrated into each of the processes of the project. One or two people can't do the planning stage justice.

“TEAM: Together Everyone Achieves More”

emphasizes Katina Kravik, CEO of Northwire Inc. This is why it is important to bring in specialized resources at the appropriate time during the planning process and the subsequent processes (executing, monitor and control, and closing).

EXECUTING

Many refer to the executing portion of the process as “Where the Rubber Meets the Road.”

During this part of the project, you see all of your plans and work packages being executed in the proper sequence at the correct time. The project manager/leader keeps everyone focused on completing their portion of the project charter and project plan on time with the desired results. With proper planning and risk assessments, the team can focus on preventing problems rather than only dealing with them when they come up.

The project lead can utilize his or her technical knowledge and that of the team's SMEs to manage the key stakeholders' expectations, increase project support, and manage the risks and problems as they arise. The team's goal is to solve problems when they come up (by planning properly, the team has time for this). When issues do arise, the team records the issues and details about their resolution, including who is responsible for resolving each issue and the impact on the timeline (if any).

Executing can be summed up by stating, “Say what you are going to do, and do what you say!”

MONITOR AND CONTROL

Monitoring and control can be stated simply as Quality Assurance. Activities in this stage include:

- **Perform all required inspections**
- **Work measurement data as outlined in performance plan**
- **Analyze and evaluate the work performance data**
- **Determine allowable variances from inspection data**
- **Recommend changes as warranted by measurement data**
- **Control scope, cost, and schedules according to the established plan**
- **Recommend changes based on data gathering**
- **Perform activities to improve quality:**
 - **Additional inspections**
 - **Pareto charts**
 - **Cause and effect diagrams**
 - **Flowcharts**
 - **Control charts**
- **Evaluate initiator or customer satisfaction**

CLOSING

Now is the time to validate and verify that all the project objectives and requirements have been achieved. Most project leads stop the process here once they believe the objectives are met, but there is still work to be completed.

You want to celebrate your success. This doesn't have to be anything elaborate, but every individual needs to be recognized for his or her contribution. In addition to celebrating the team's success, you should:

- **Obtain formal sign-off from the initiator that project objectives have been achieved**
- **Gather lessons learned to be used in future projects**
- **Ensure all project records are complete and updated**
- **Index and archive all project related records**
- **Create and issue a final report detailing the project/product performance**
- **Hand off the completed project deliverables to the appropriate functions**

CONCLUSION

By following these five simple processes (initiate, plan, execute, monitor and control, and closing) you can rapidly deploy almost any R&D Project. By following the specific methodologies within each process, it has been our experience you can improve the R&D process time by at least 30% to as much as 60%.

To achieve this increase in productivity, you must spend the majority of your time gathering important Critical-to-Quality Characteristics from key stakeholders and spending sufficient time planning the project. Planning each step of the process is just as important as the manufacturing or execution step(s).

During project closing, don't forget to celebrate the TEAM: "Together Everyone Achieves More".

GROW YOUR BOTTOM LINE

Increase your system reliability, user safety, and company bottom line with Northwire's *BioCompatic* silicone cable alternative and REDEL connectors. Unlike the manufacturing process behind traditional silicone cable jacketing, which involves curing and coating in addition to normal production, *BioCompatic* offers simple, customized production and substantially shorter lead times. Once in use, *BioCompatic* lasts longer against sterilization and environmental factors – meaning fewer replacements and repairs are needed.

Realize cost avoidance and added profits as Northwire:

- *Eliminates extra production stages*
- *Rapidly deploys cable systems*
- *Frees inventory and cash flow*
- *Lengthens the useful life of your cable*
- *Offers a leaner supply chain*
- *Facilitates on-time delivery*
- *Increases productivity*
- *Provides value-added services*

How You Save	Traditional Silicone Cable	<i>BioCompatic</i> and <i>BioCompatic II</i>
Lead Time	8-12 weeks	5, 10, or 15 days
Stages of Production	1. Initial production 2. Curing 3. Coating (potentially multiple coats needed)	1. Production (no curing, no coating)
Minimum Order Quantity	Up to 50,000 feet	None
Additional Expenses	Curing catalysts and associated equipment	None
Environment Resistance (Chemical, Cut, Crush, Abrasion, Sterilization, Fungal, Rodent, Retractable)	Moderate	Excellent compared to traditional silicone cable and comparative silicone alternatives
Cable Lifetime	Moderate, depending on use	Durable and optimized for long lifetime.
Assembly Compatibility	Compatibility depends on researching and testing with an appropriate connector manufacturer	E2E Solution – Fully integrated with proven LEMO and REDEL connectors – work with one central supplier.

E2E: PARTNER WITH LEMO+NWI FOR END-TO-END SOLUTIONS

Be one of the first to benefit from an E2E, highly effective, cost saving alternative to traditional silicone cable. Durable, reliable, and customizable, LEMO and NWI's innovative *BioCompatic* cable and REDEL connectors is an exceptional solution to long lead times and other challenges associated with silicone.



To gain the full advantages of NWI's *BioCompatic* silicone alternative, connect with a representative today. Northwire offers comprehensive support from Concept to Completion by analyzing your application requirements, helping you navigate complex compliance standards, and optimizing your production process. When you speak with Northwire, you will be directed to an experienced SME in your field to discuss your unique requirements and vision. Beyond supporting an ideal design for your *BioCompatic* cable, the Northwire SME will help you select the appropriate connector from LEMO and REDEL, assisting with any customization or certification required as well.

Start on your rapid path to market and realize cost savings as soon as possible. To review your project with Northwire, call toll-free at 800.468.1516, email a team member at CableInfo_Northwire@lemo.com, or connect via live chat at www.northwire.com.

ABOUT US

LEMO is the acknowledged leader in the design and manufacture of precision custom connection and cable solutions. LEMO's high quality Push-Pull connectors are found in a variety of challenging application environments including medical, industrial control, test and measurement, audio-video, and telecommunications.

LEMO has been designing custom connectors for over six decades. Offering more than 75,000 combinations of products that continue to grow through tailored, specific designs, LEMO and its affiliated sister companies REDEL, NORTHWIRE, and COELVER currently serve more than 100,000 customers in over 80 countries around the world.

In the summer of 2014, LEMO Group acquired Northwire, Inc. with the goal of providing a seamless experience with expanded capabilities to both companies' valued customers by offering a comprehensive suite of custom connector, cable and assembly offerings for a diverse range of extreme applications. This means comprehensive product offerings, a wider range of resources, and rapid responses to your project needs.

Northwire, celebrating over 43 years of innovation, has corporate headquarters and manufacturing in Osceola, Wisconsin and engineering and manufacturing in Santa Teresa, New Mexico. The cable supplier is the premier partner for the design, manufacture and contract services of custom technical products including wire and cable, retractable cable, cable assemblies, connectors, harnesses, injection molding, over-molding and contract engineering and OEM (Original Equipment Manufacturer) for diverse applications in life sciences, energy, MIL-Spec, industrial, machine vision, architectural lighting, underwater, and more.

The custom wire and cable, retractable cables, and cable assemblies from Northwire work seamlessly with the diverse selection of wire connectors produced by LEMO.



LEMO

Ch. Des Champs-Courbes 28
P.O. Box 194
1024 Ecublens - Switzerland

Phone: 41 21 695 16 00
Fax: 41 21 695 16 01

www.lemo.com

NORTHWIRE

110 Prospect Way
Osceola, Wisconsin 54020
United States

Phone: 1 715 294 2121
Fax: 1 715 294 3727

Click for Live Chat
www.northwire.com

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