https://www.nninc.com/life-sciences/

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When **07 Apr 2020**
7:00 PM - 8:30 PM

Location FREE ONLINE
WEBINAR

MEDICAL DEVICE OUTSOURCING

Harry Martins

A WORLD OF OPPORTUNITIES

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MEDICAL DEVICE OUTSOURCING

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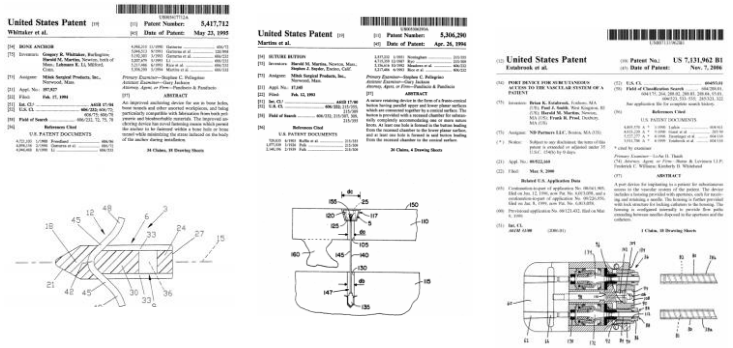
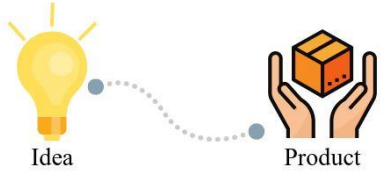
WHO AM I?

- Degreed engineer
  - BSME 1986 UMASS Amherst
  - MSME 1987 Stanford University
  - MSBioE 1991 University of Michigan
- Patent Holder
  - 28 Issued
  - 25 Pending
- Product Developer





Harry Martins | Senior Manager, New Product Development
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MEDICAL DEVICE OUTSOURCING

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WHO IS BRIDGEMEDICA?

- A contract medical device product design, development and manufacturing outsource partner
  - Our people bring you over 175 years experience in both medical device development and manufacturing
  - We excel at working on mechanical and electromechanical single-patient disposable products

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Concept Development

- Brainstorming
- Initial Concepts & Ranking
- Industrial Design
- Feasibility Studies
- Rapid Prototype Creation
- 3D Printing
- Material Selection

Product Development

- Project Management
- Design Inputs/Outputs – Product Specification
- Detailed Design
- Tolerance Analysis
- Process Development
- Risk Analysis - DFMEA & PFMEA
- Design for Mfg. and Assembly
- Packaging Design
- Design Verification/Validation
- Aging, Transit & Bio Testing
- Design Controls/DHF
- Regulatory Support
- Pilot/Clinical Builds

Commercial Launch

- Production Tooling Conceptualization
- Component Process Development & Optimization (DOE and Scientific Molding)
- Assembly Process Development & Optimization (DOE)
- Automated Processes and Equipment Development
- Component & Assembly Validation
- Packaging Validation
- Sterilization Selection & Validation
- Production Scaling
- Field Return Analysis
- Warehouse and Shipping Logistics

FDA / OUS Registration

- FDA Registered
- ISO 13485:2016 Registered
- Drug License
- FDA 510k Preparation & Submission
- Foreign Territory Registration Preparation & Submission
- Quality System setup and support

Address: 111 Forbes Boulevard, Suite 101, Mansfield, MA 02048

Disposable Product Examples

Key Contacts

- Harry Martins — Sr. Engineering Mgr., NPD — harry.martins@nninc.com
- Robert Pelletier — Dir. of Strategic Accounts — Robert.Pelletier@nninc.com

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WHO IS NN LIFE SCIENCES?

- Tight Tolerance Metals and Plastics Machining
- Plastic Injection Molding
- High Volume Automated Assembly
- Additive Manufacturing (3D Printing): Metals & Plastics
- Metal Stamping
- Vapor Polishing
- Laser Welding & Marking
- Custom Automation Equipment/Machine Design & Build
- Metal Instrument Development & Manufacturing
- Surgical Cases & Trays
- Sterile-barrier Packaging and Labeling

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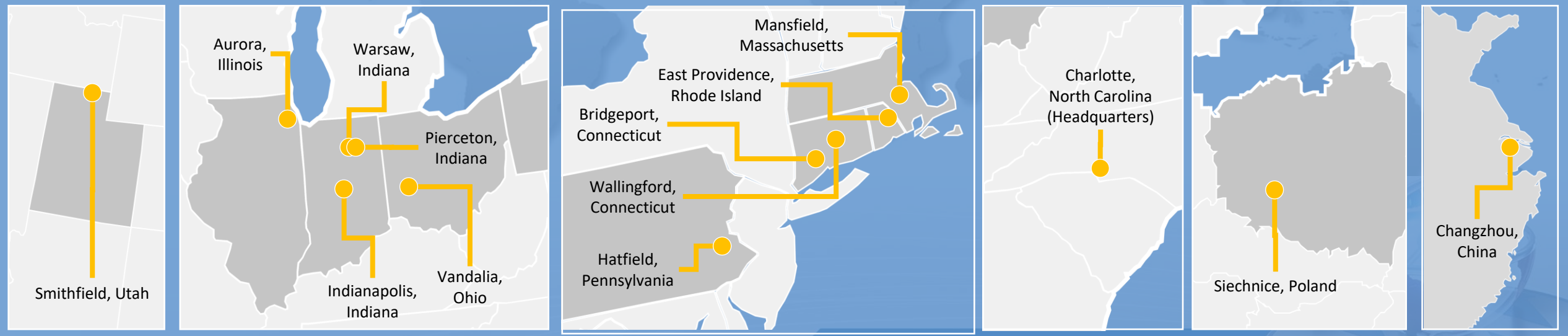
WHO IS NN LIFE SCIENCES?



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- WHY OUTSOURCE?
- CHALLENGES/RISKS
- FINDING A GOOD FIT
- OPTIMIZING YOUR WORKING RELATIONSHIP

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WHY OUTSOURCE?

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ACCELERATE TIME TO MARKET

- Immediate staff and facilities
- Eliminate cost and time for HR and hiring
- Work at a start-up pace
- Speeds return on investment

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WHY OUTSOURCE?

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ACCESS TO RESOURCES

- Provide specialized knowledge and expertise
- Complement your knowledge

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WHY OUTSOURCE?

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COORDINATION OF SERVICES

- Leverage pre-existing supply chain
- Control over processes

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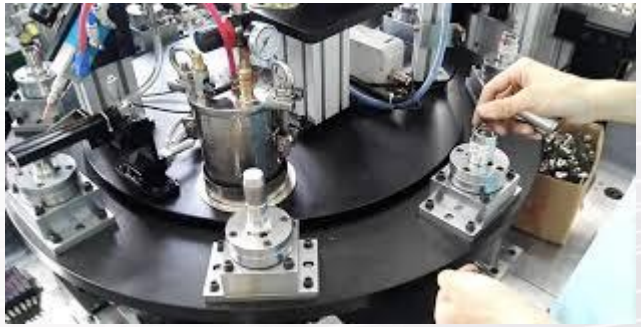

FLEXIBILITY OF PRODUCTION

- Batch-Basis
  - Small (DV&V, Clinical studies)
  - Medium (Scale-up & launch)
  - Intermittent Builds (Gain market penetration)
  - Large (Full market penetration, Automation)

WHY OUTSOURCE?

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SIMPLIFY EXIT

- No staff to compensate or eliminate
- No facility lease to absorb

CHALLENGES/RISKS

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MANAGING THE RELATIONSHIP

- Containing costs & ensuring deliverables
  - Means to deal with scope and schedule change
  - Means to track costs

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CHALLENGES/RISKS

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PROTECTING AND ENHANCING INTELLECTUAL PROPERTY

- Confidentiality and Non-disclosure agreements
- Ownership of patent rights

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CHALLENGES/RISKS

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QUALITY SYSTEM INTEGRATION

- Select an ISO 13485, FDA-registered partner
- Assess fit of your QSM with theirs
- Consider a Quality agreement

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FINDING A GOOD FIT

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FIT - MATCHING NEEDS WITH EXPERTISE

- Select a partner experienced with similar class/type of device
- Check culture match
- Visit the site!

FINDING A GOOD FIT

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FIT – GEOGRAPHY

- Driving distance
  - Allows easy access to facilities for participation in meetings, assembly and testing
  - Allows face-to-face issue resolution

FINDING A GOOD FIT

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FIT – VERSATILITY

- Breadth of experience
- Quality system complementation
- Relationships with other services

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OPTIMIZING YOUR WORKING RELATIONSHIP

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CLARITY OF OBJECTIVE

- Clearly defined scope
- Clearly defined responsibilities
- Clearly defined user requirements

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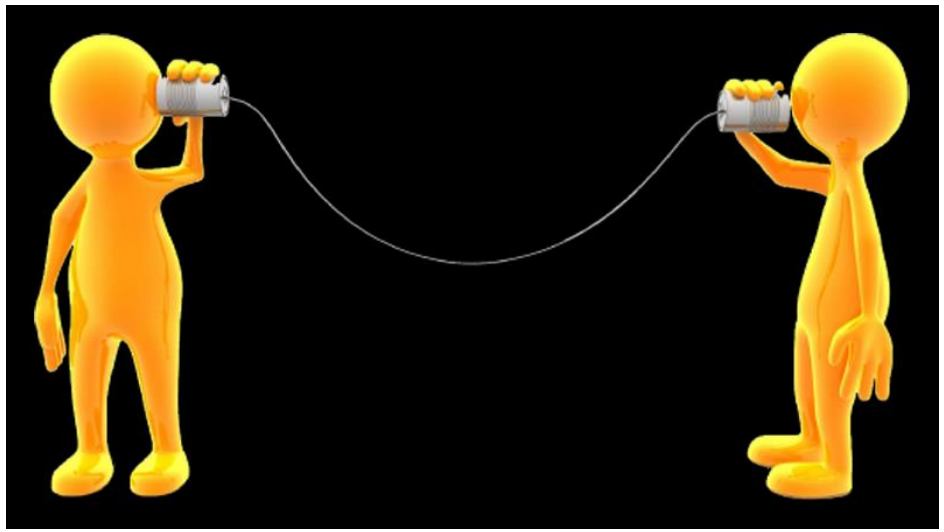

OPEN LINES OF COMMUNICATION

- Define a focused client contact
- Establish and maintain a good relationship with the project lead
- Speak up if you have issues
- Collaborate!

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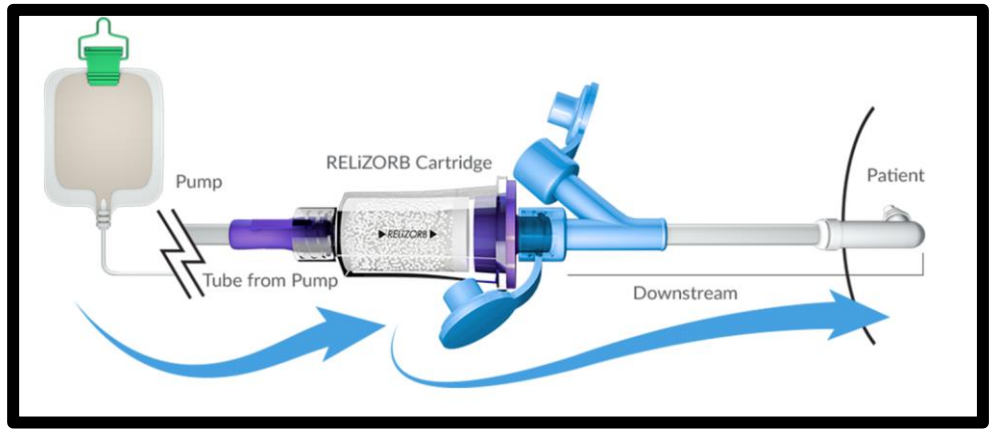
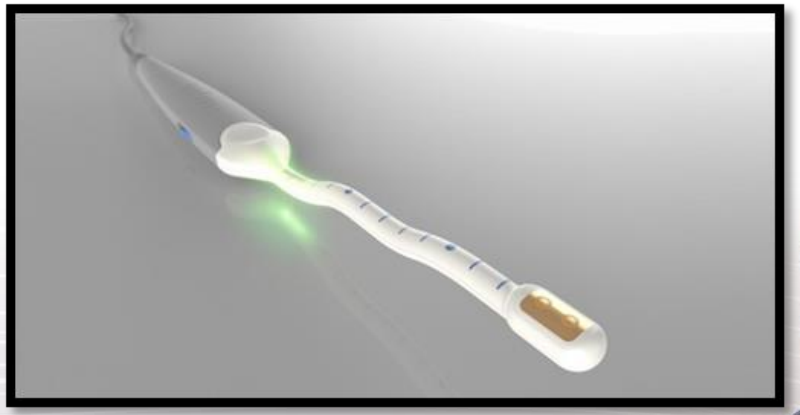
BRIDGEMEDICA PRODUCT EXAMPLES





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End-to-End Design, Development and Manufacturing Solutions

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