



Medical Devices Investigation and development & Advanced Manufacturing Techniques

Boston Scientific Puerto Rico



Boston Scientific at Glance

Boston
Scientific

45,000 employees at
~147 sites including **15**
principal manufacturing
& distribution centers
worldwide.

8 Divisions

33 Million Patients
each year

Over **\$67.2+ million** contributions for medical
research, fellowships, educational and charitable
giving

EUROPE

Ireland:
Clonmel
Cork
Galway

Ontario,
Canada

Spencer, Indiana
Alpharetta,
Georgia
Minnesota:
Maple Grove
Arden Hills

Dorado,
Puerto
Rico

NORTH AMERICA

Costa Rica:
Coyol, Heredia
Cartago

LATAM

Belo
Horizonte
Brazil

Yokneam
Illit, Israel

Penang,
Malaysia

ASIA



Dorado Site Overview



~1,500 employees
24-7 Hour Schedule
93% Retention Rate

182k ft² Building
~68k ft² Clean Room



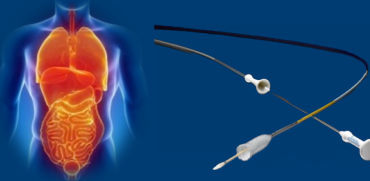
PR Best Employers



**DIVERSITY
EQUITY &
INCLUSION**

50% Female Directors
41% Female in SUP+ roles
8 Years W Certified

PI, ENDO & URO



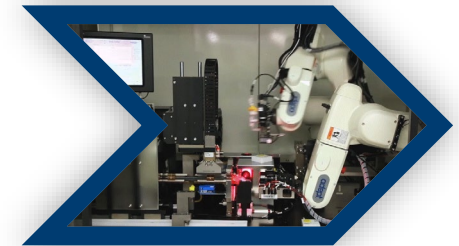
Cardiac Rhythm Management



Neuromodulation



Knowledge in Advanced Manufacturing



Partnership with Industry and Academia to strengthen capabilities and enable growth



DEPARTAMENTO DE DESARROLLO ECONOMICO Y COMERCIO
DDEC



Giving back to the Community

- Connecting with students to create an interest in Manufacturing & STEM Careers
- Development Programs
- Community Outreach
- Patient Connection



Introduction to Medical Devices

Alex Sepúlveda, R & D Fellow





The medical technology (**medtech**) industry encompasses a wide range of products, services, and technologies designed to improve healthcare delivery, diagnosis, treatment, and patient outcomes.

Medical Devices

Medical Robotics and Automation

Digital Health and Health Information Technology (HealthTech)

Wearable Health Technology

Healthcare IT Infrastructure and Services

Regulatory and Compliance Services

Is diverse and interdisciplinary, involving collaboration between healthcare professionals, engineers, scientists, regulatory experts, and business professionals to **develop, manufacture, and commercialize innovative medical technologies aimed at improving patient care and advancing healthcare delivery**



What is a Medical Device?

An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.

Medical devices are NOT Pharma products although they could contain pharmaceutical agents

Medical devices are NOT biological or biotech products although they could contain those agents

- Regulated by health authorities (Ex. FDA)
- Classified into different risk categories such as intended use, potential risks, and the invasiveness of the device



- Combination products



- In Vitro Diagnostics



- Radiation emitting products



- Durable medical equipment



- Life sustaining



- Mobile medical applications

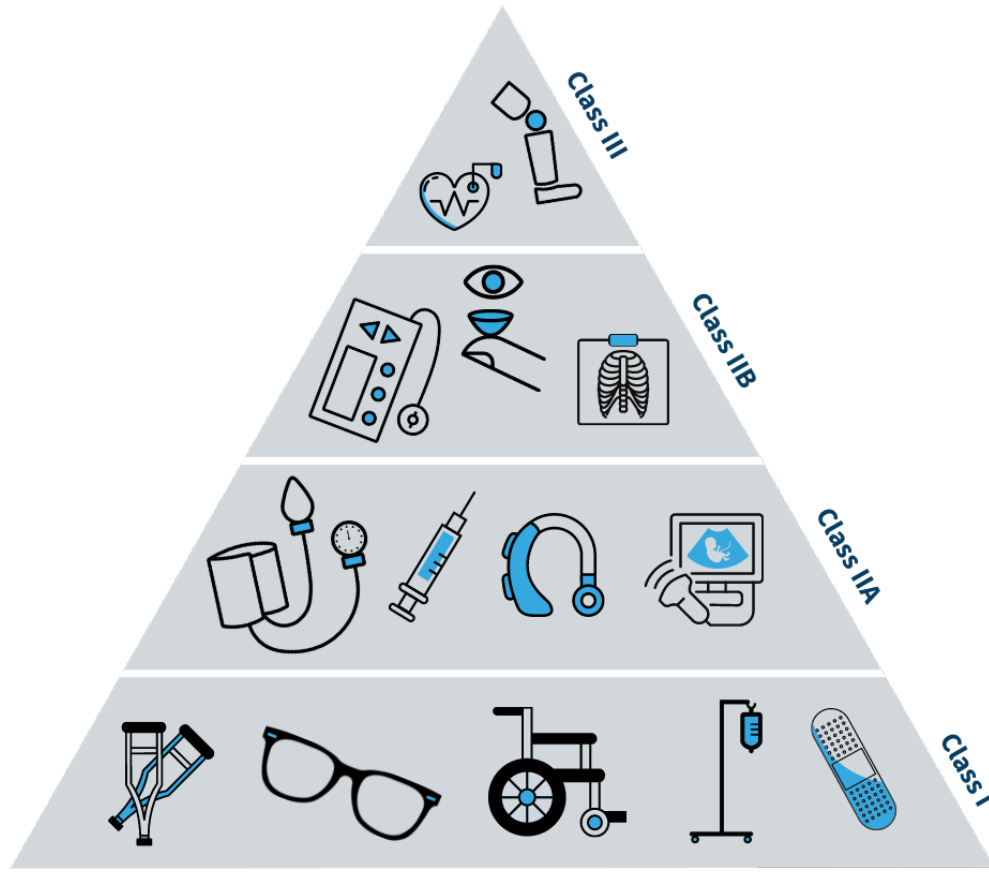


Complexity
Intended use
Regulatory classification



Medical Devices Class I-III

Medical devices



High risk

Low risk

FDA Approval
Required
Premarket approval
process

FDA Clearance
Required
Premarket
notification to FDA

No FDA
Approval
Needed
Must register and list
device



Manufacturing in Puerto Rico

OVER **60** YEARS

of experience in Pharma & Medical Device Industry

OVER **30** YEARS

of excellence in sterile manufacturing

CONTRIBUTES

30% of Puerto Rico's GDP

50% of manufacturing activity

30% of manufacturing jobs

Over **80,000** jobs

LOCAL EXCELLENCE

Over 30 medical device mfg sites including

15 of the top **20**

FDA class 3 device manufacturers. **5.5x** more industry experts medical devices and **8.6x** more pharma experts than national average



Largest reporter of pharmaceuticals in the United States.



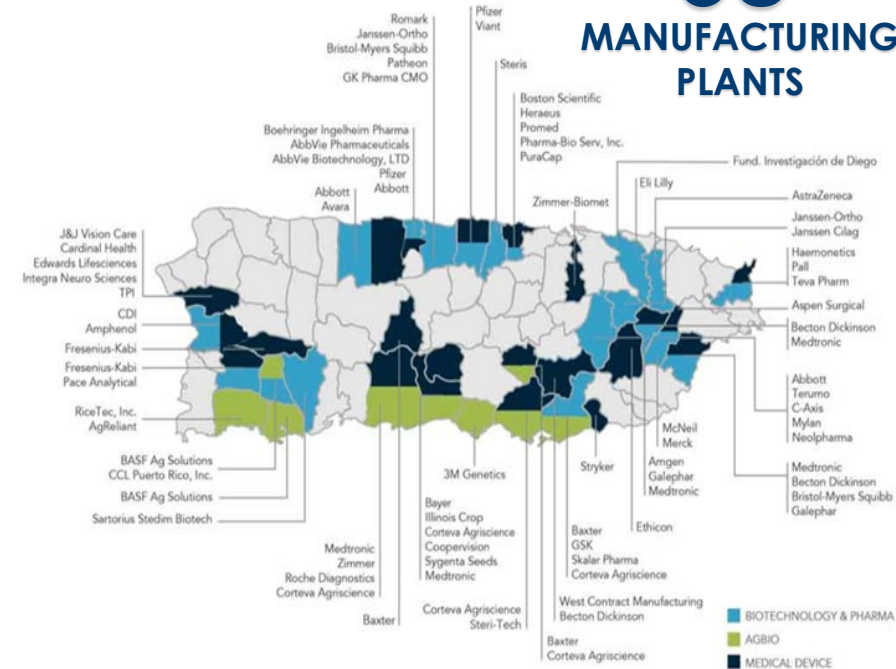
Highest concentration of Pharmaceutical Manufacturing and Medical Device experts in the U.S.



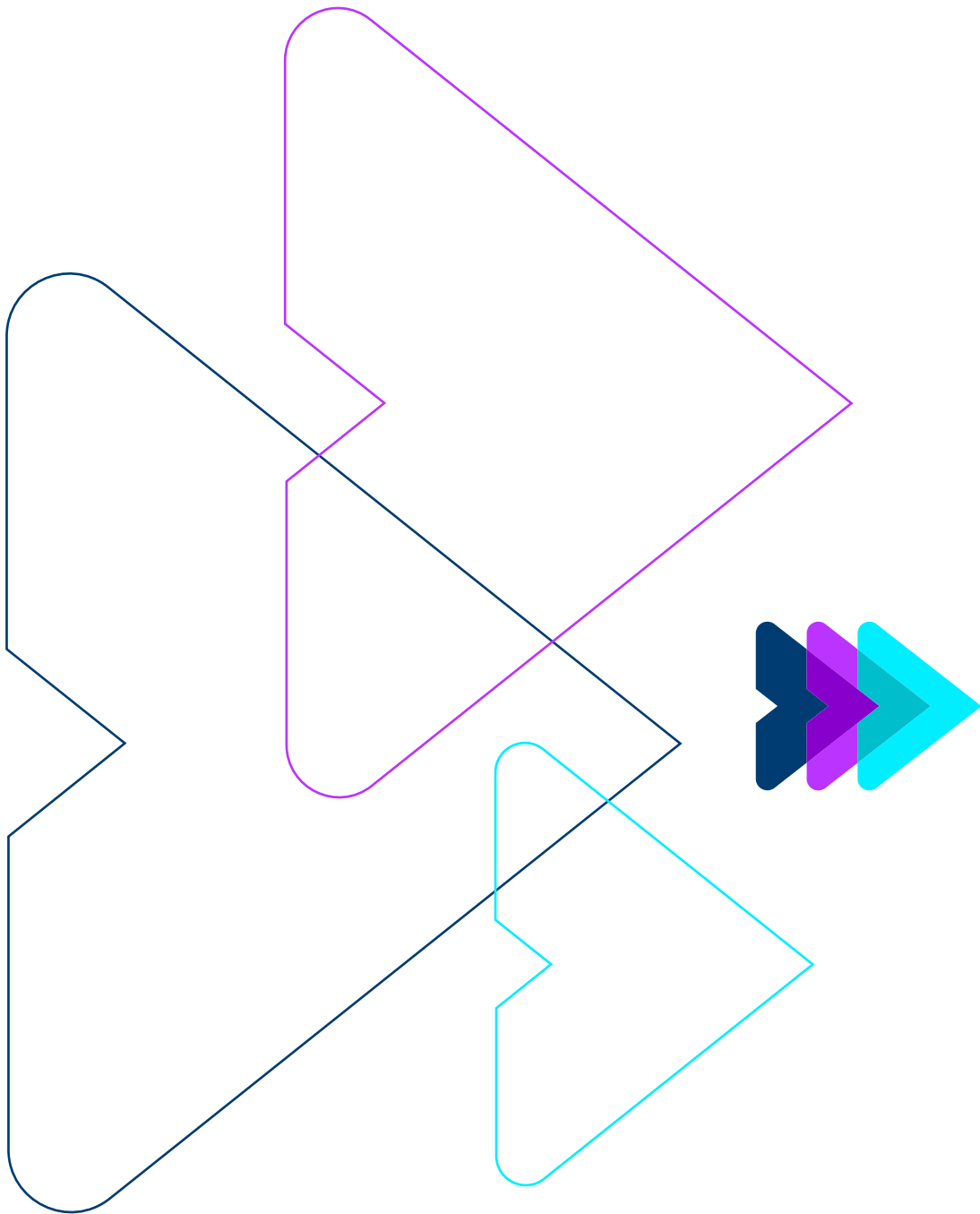
Highest proportion of STEM Degrees in the U.S.

LIFE SCIENCES INDUSTRY IN PUERTO RICO

68 MANUFACTURING PLANTS



32 Medical Device Manufacturing sites

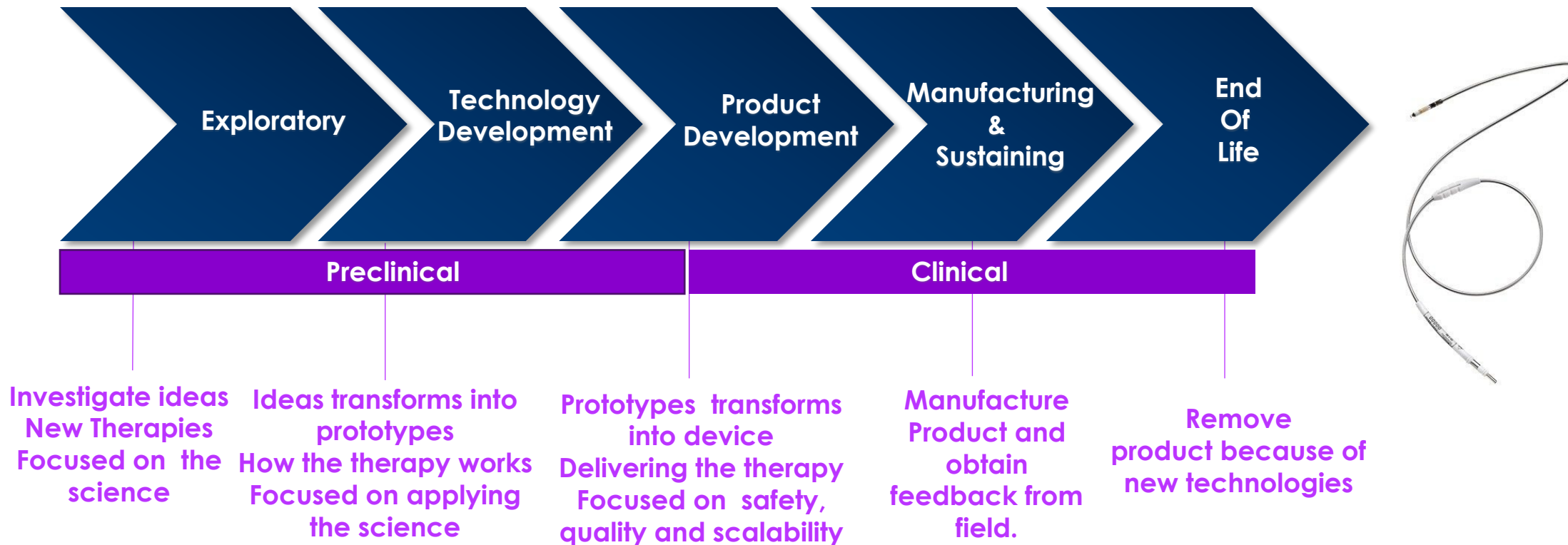


Product Life Cycle

Elliot Rodríguez, Process Development Director



How do we create a Product?





INGEVITY ImageReady™ MRI Pacing System

Active & Passive Fixation

- Wide placement option

Isodiametric Lead Body

- Designed for 6F Introducer
- Preferred for smaller venous anatomies

Irox coated Anode

- Improved electrical performance

Steroid eluting collar

- Reduced pacing threshold

Stylet Stop

- Improved handling and delivery

Flexible Neck

- Reduced trip pressure

High Impedance Coil

- Increased battery life

Improved Marking

BSC ImageReady™ Pacemaker

Single Chamber: VITALIO™ MRI
 Dual Chamber: FORMIO™ MRI
 Extended life: INGENIO™ MRI

7742 / 59c
 Boston Scientific
 71770



Technology Development

Requirements

- **MRI compatible**
- **Small diameter**
- 15 yr life
- Low energy consumption
- Reliability



Product Development

- **Coaxial vs Co-Radial**
- Electrode coatings
- Insulation layers
- **Joint designs**
- Steroid Drug



Manufacturing & Sustaining





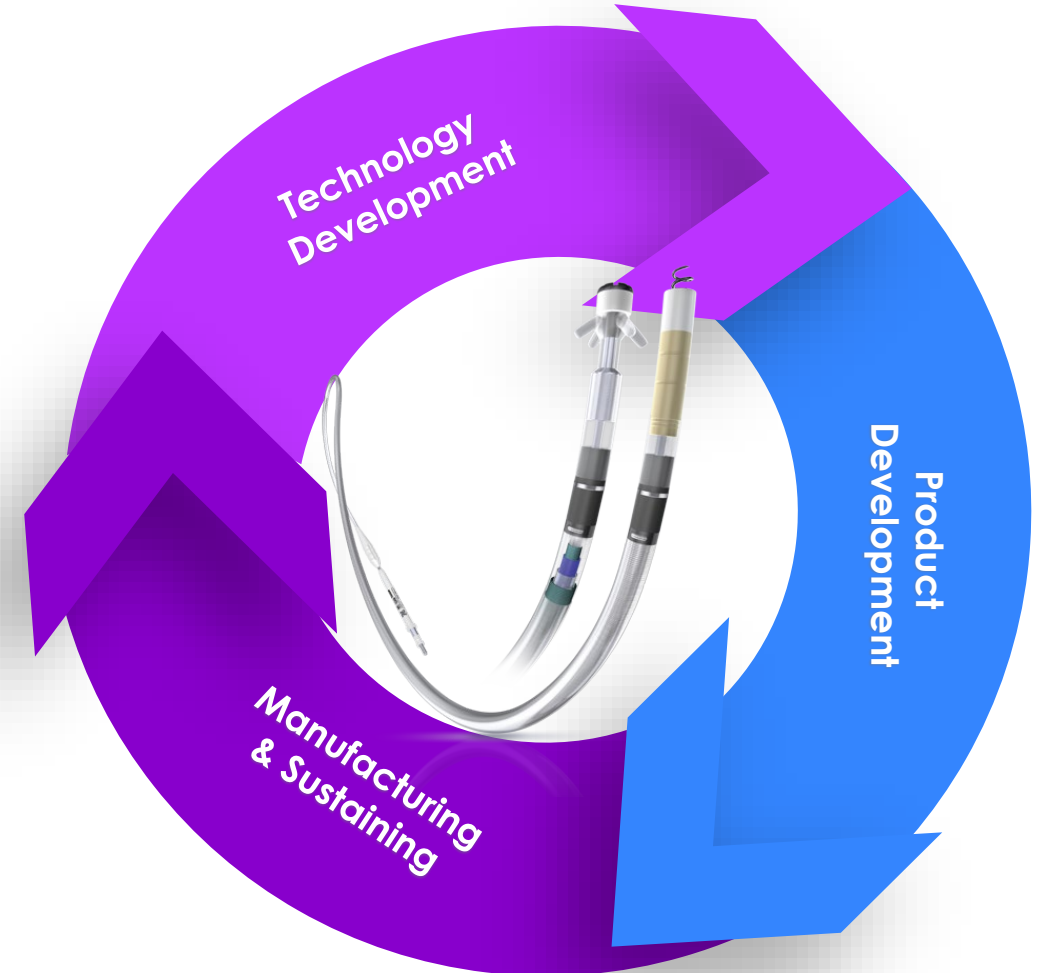
Physician-Inspired Design Enhancement

Manufacturing
&
Sustaining

BSC heard physicians' requests for more consistent turn count performance.

Physicians were involved in every step of the design process, including:

- ✓ Providing feedback on INGEVITY and determining the requirements for an enhanced design.
- ✓ Evaluating the performance of INGEVITY™+ throughout the iterative design process.
- ✓ Validating the final design.

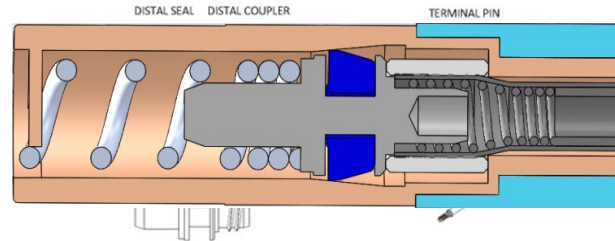
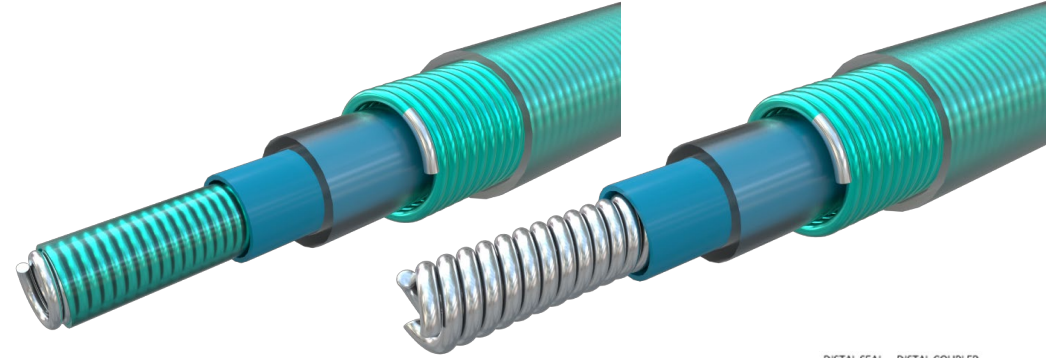
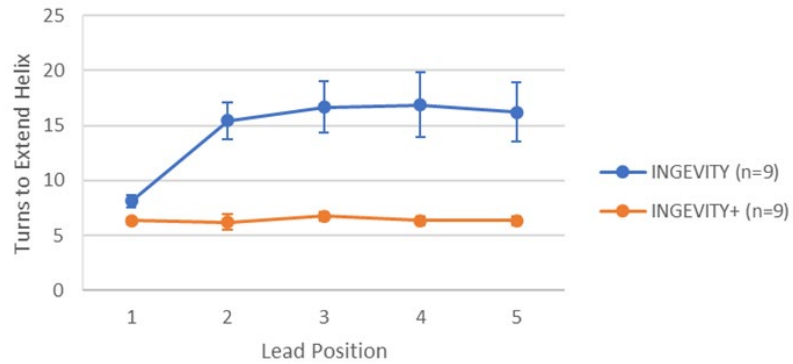




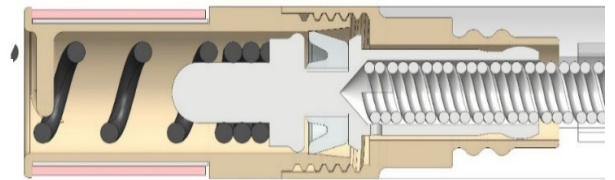
INGEVITY+ Technology & Process Development



Average Turns to Extend Helix in Right Atrium - Left Cephalic Vein Access in Swine Model



INGEVITY



INGEVITY™ PLUS

Feedback from Physicians:¹

Very smooth

Handled well

Normal

Excellent handling. Helix performed very well.

The extension/retraction mechanism is significantly better

Able to use less fluoro due to consistent turn count.

Helix extension was very smooth and predictable. Lead performed well

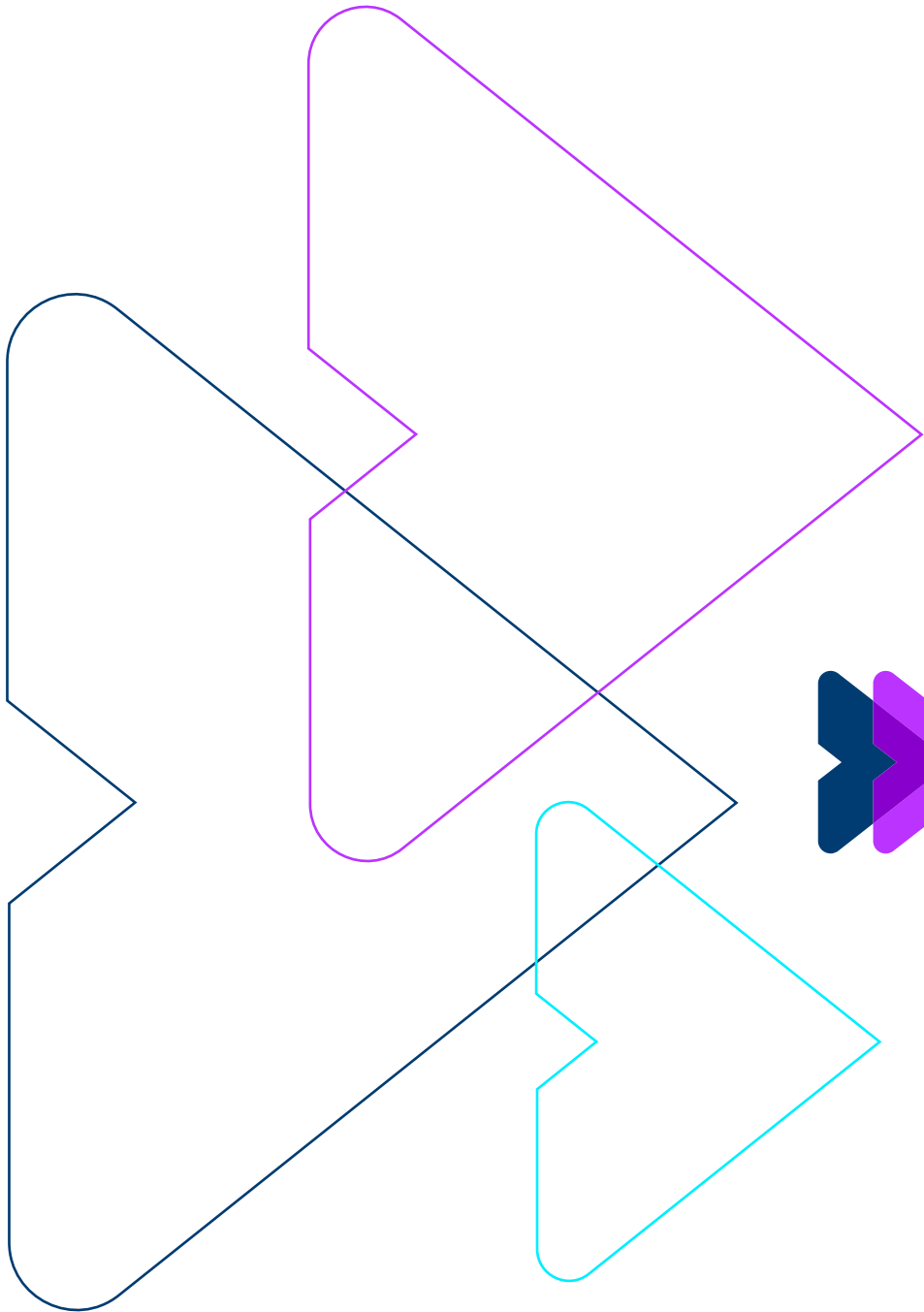
**Boston
Scientific**

Advancing science for life™

Manufacturing Technology and Enablers

Luis A. Torres Morales

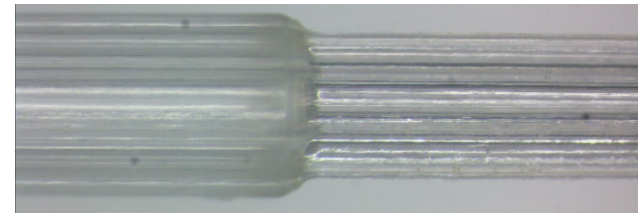
Engineering Associate Director





Manufacturing Technologies

Journey to Eliminate Shielding Gas



Boston
Scientific



Background:

Laser ablation process uses shielding gas.

Shielding gases have experienced worldwide shortage and an incremental price increase of 100% in the last 3 yrs.



Business impacts:

High business risk to continue depending on shielding gas supply and impact the worldwide medical devices supply



Proposal:

New technology and/or design change to eliminate the use of shielding gas.



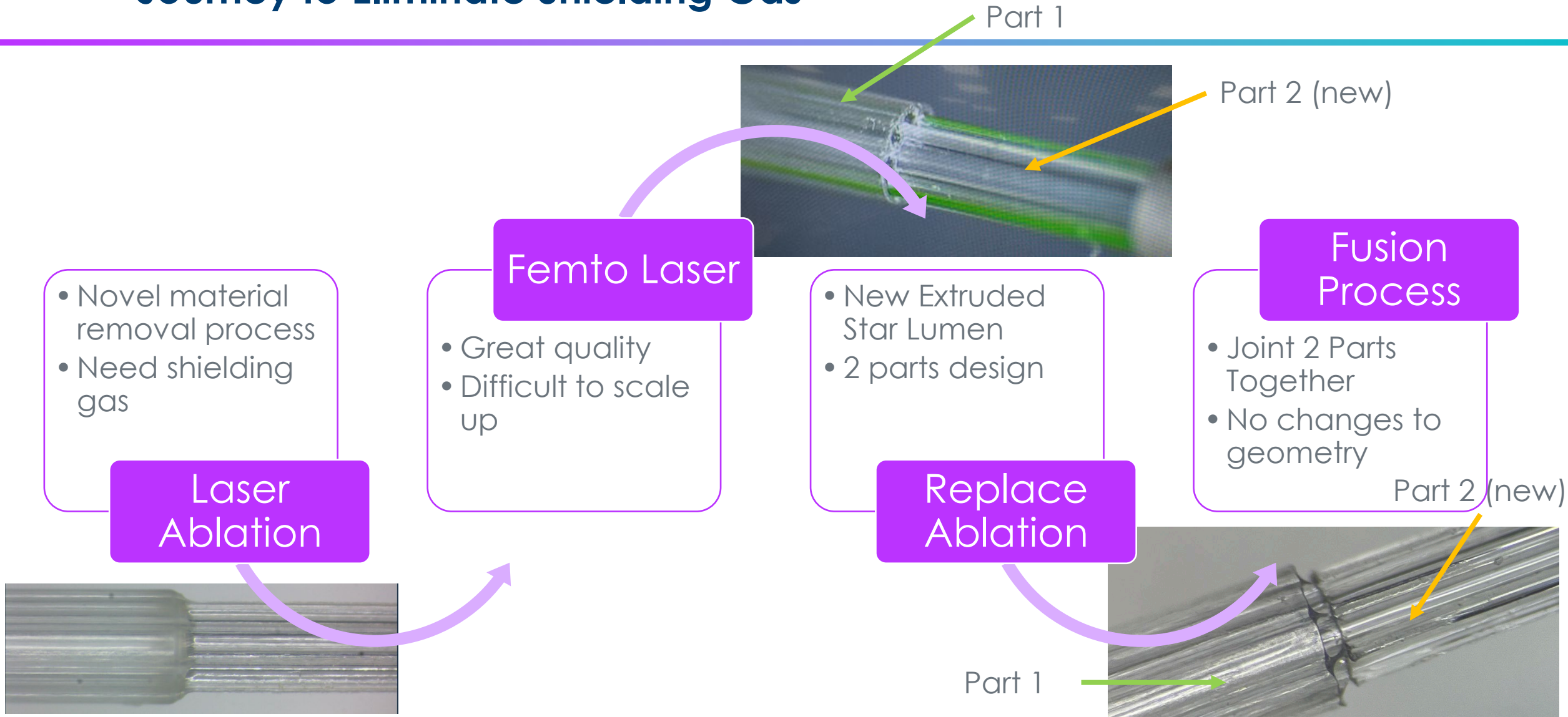
Solution:

Develop Fusion Process to joint body tubing and extruded tubing



Manufacturing Technologies

Journey to Eliminate Shielding Gas





Manufacturing Technologies

Technology Development Enablers

Technology
Concept &
Development

Technology
Concept &
Enablers

Timeline

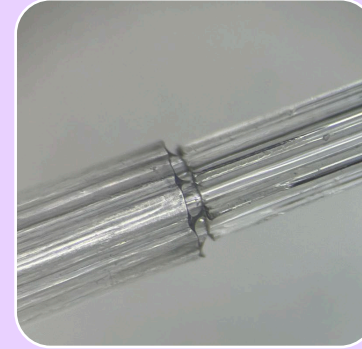
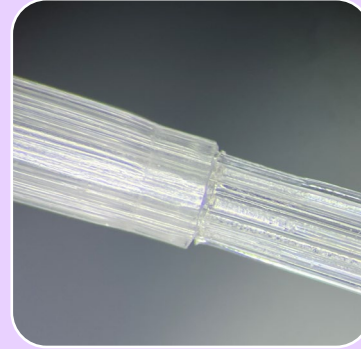
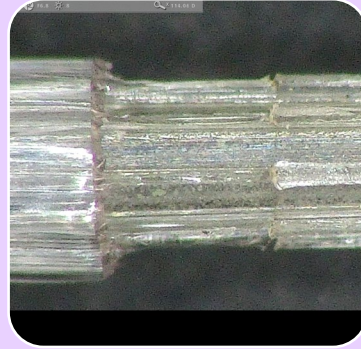
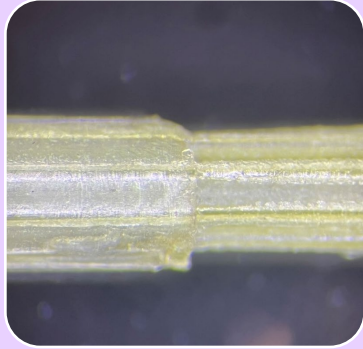
1st Trial

3 Weeks Later

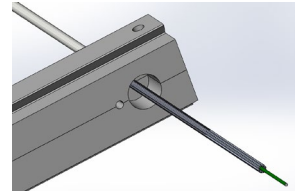
2 Weeks Later

After 2 Months

Development
Maturity

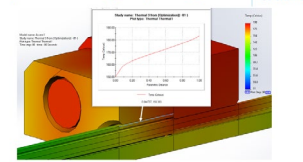


1st Prototype

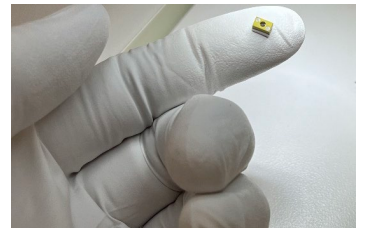


FEA Optimization

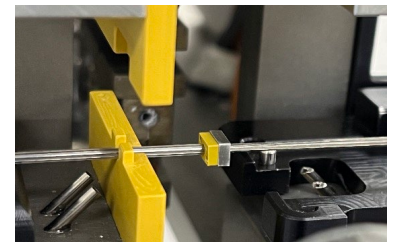
Temp. Gradient Along Body Tubing OD



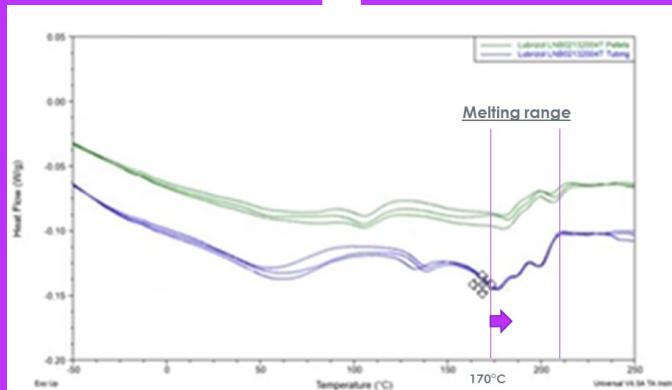
1st Production Mold



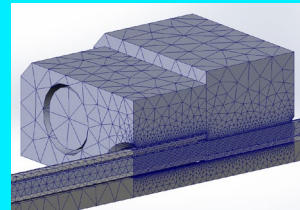
Process Characterization



DST Data – Leverage from Other Divisions



Finite Element
Analysis



Rapid
Prototyping



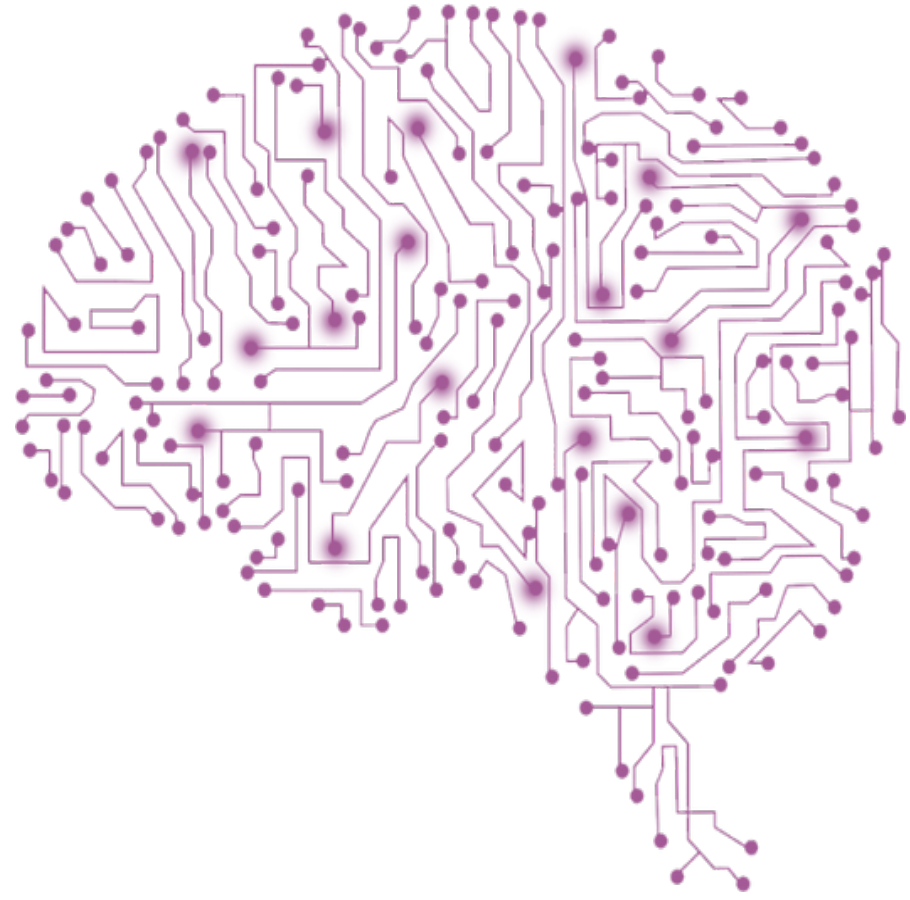
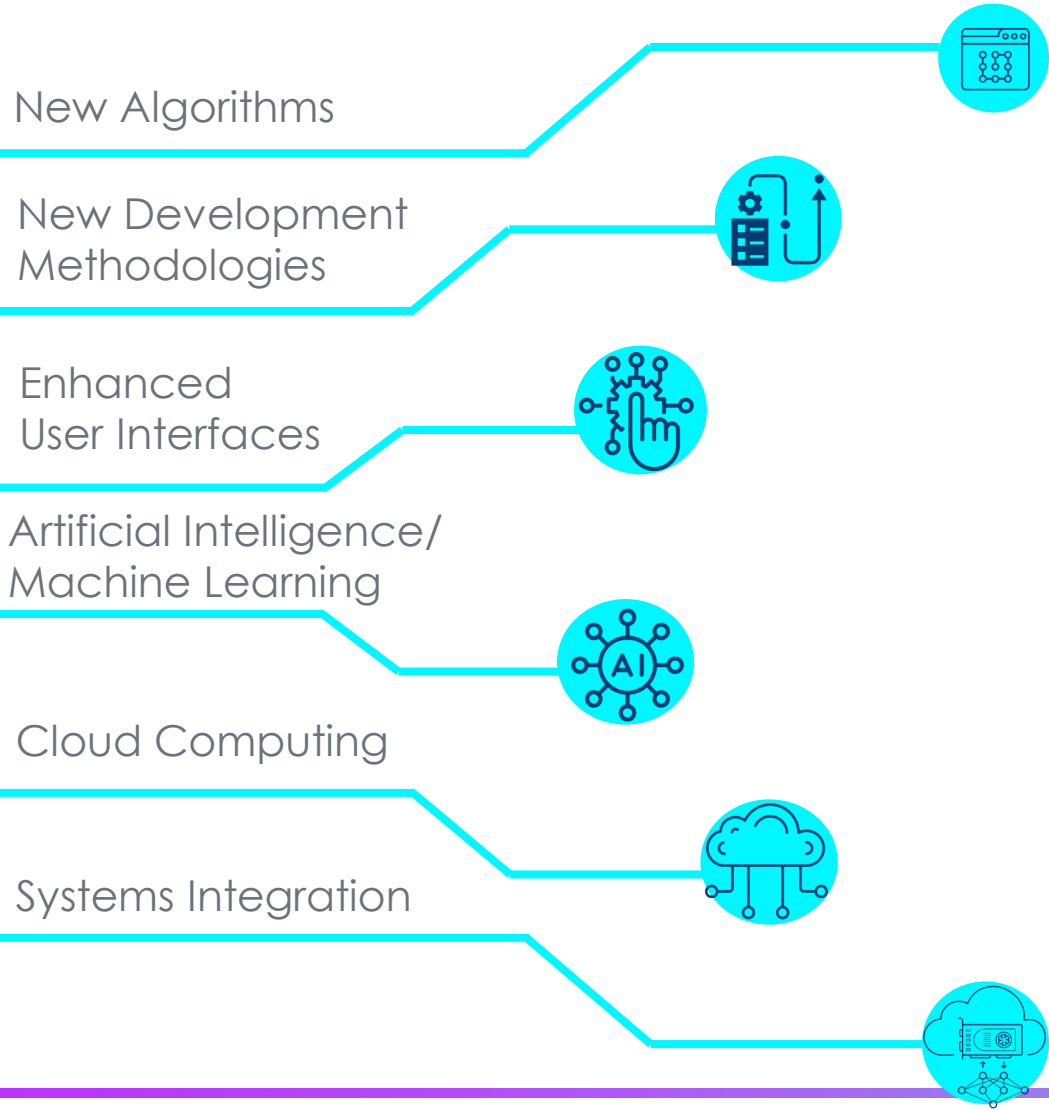


Software as an Innovation Enabler

José Rivera, Software Manager



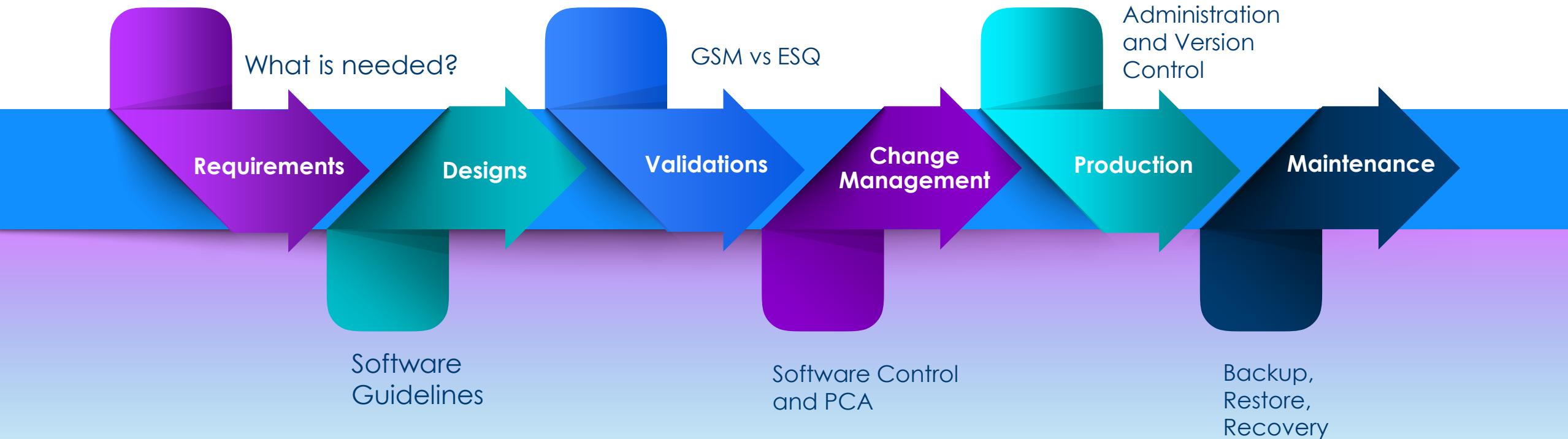
Innovation in the Software Landscape





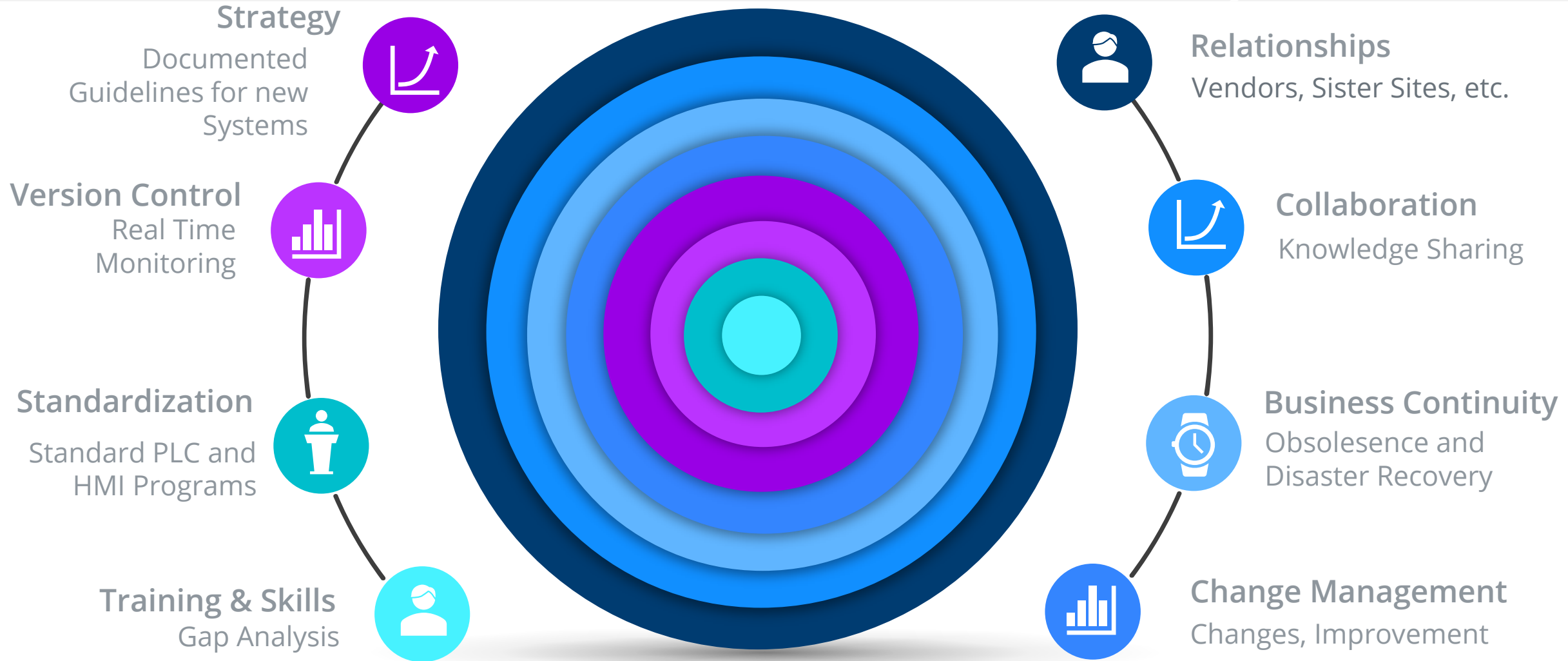
Benefits & Life Cycle of Software Engineering

- Customization and Adaptability
- Real-time Data Analysis
- Interconnected Systems
- Facilitates Smart Manufacturing:
- Enables Scalability





Best Practices in Software





Automation Engineer

Programmable Controllers
Human Machine Interfaces
Vision Inspection Systems
Motion Control
Machines Safety
Sensors and Actuators
Communication Networks
Databases
Read/Interpret Diagrams
Computers

Software Engineer

Development Methodologies
High Level Languages
Object Oriented Programming
Databases
Data sources
GUI Design
Integration

Data Scientist

Data Analysis Models
Data sources
Data Structures
Databases
Data Transformation
Data Extraction
Data Loading
Data Reporting



Collaboration in Software Engineering

Cross-Functional Teams

Engineering, Quality, R&D, IT, etc.

01

Community of Practices

AI, Analytics, OT, SQ

02

Centers of Excellence

Robotics and Vision Systems

03

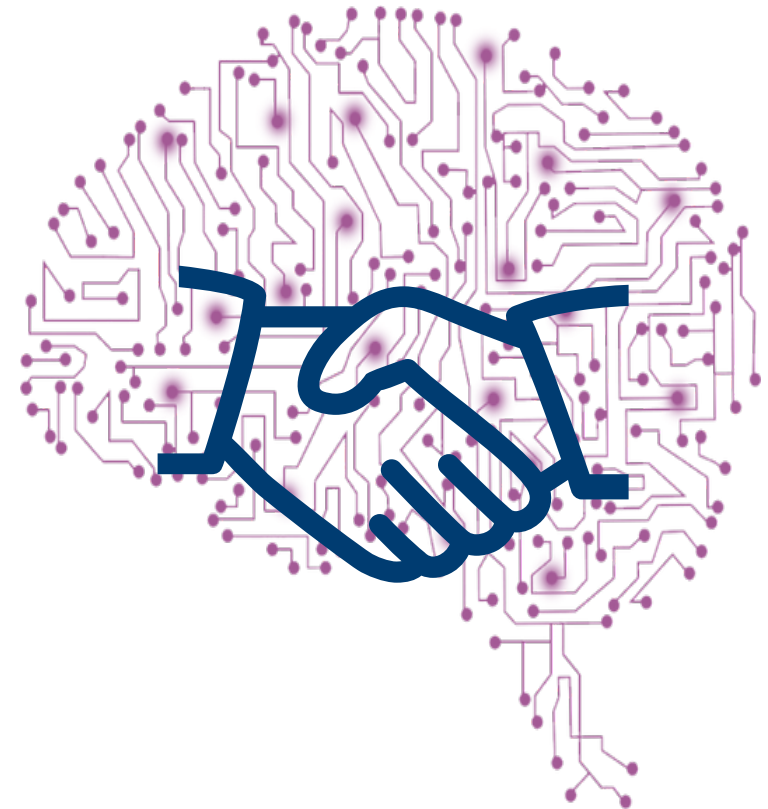


Collaboration
and Knowledge
Sharing

Vendors

POCs, Feasibility, etc.

04





Achievements

T REX SOFTWARE

Design and development were fully executed in Dorado.

Involves the creation of a customizable integration tool designed to streamline parallel transaction management and simplify operational sign-ups.

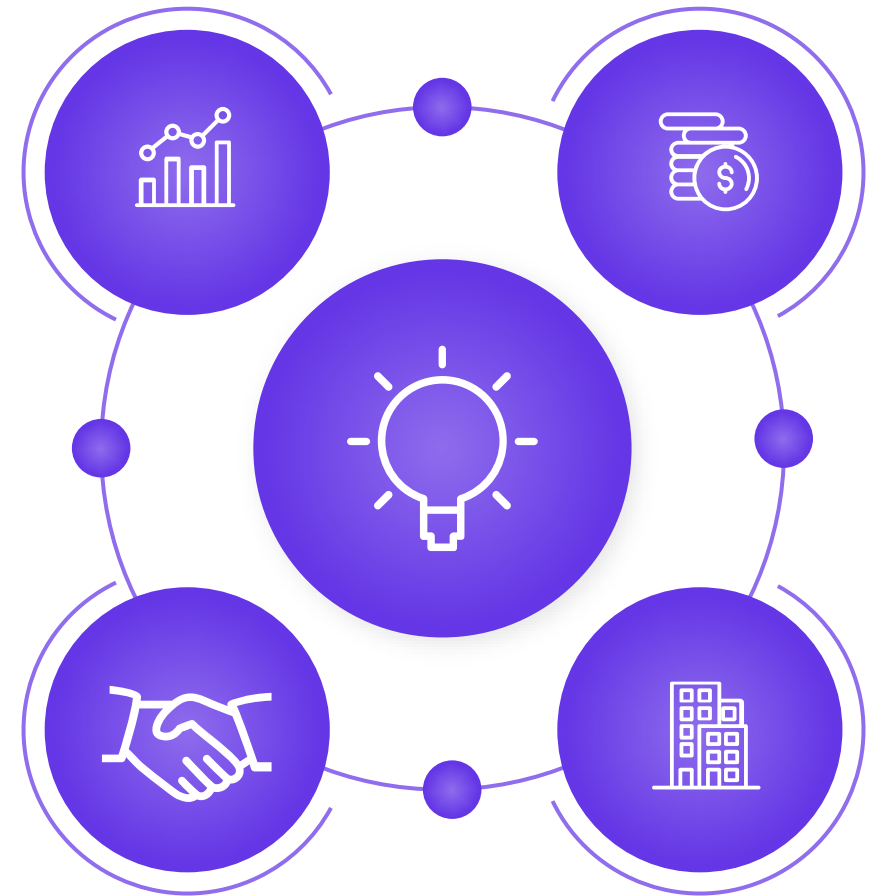
Reduction in machine transaction times. Optimizing operational efficiency, eliminating the need for additional equipment purchases.

The software is undergoing adoption across additional Boston Scientific sites in Costa Rica and has garnered significant attention and interest from the global community within Boston Scientific.



Lessons Learned

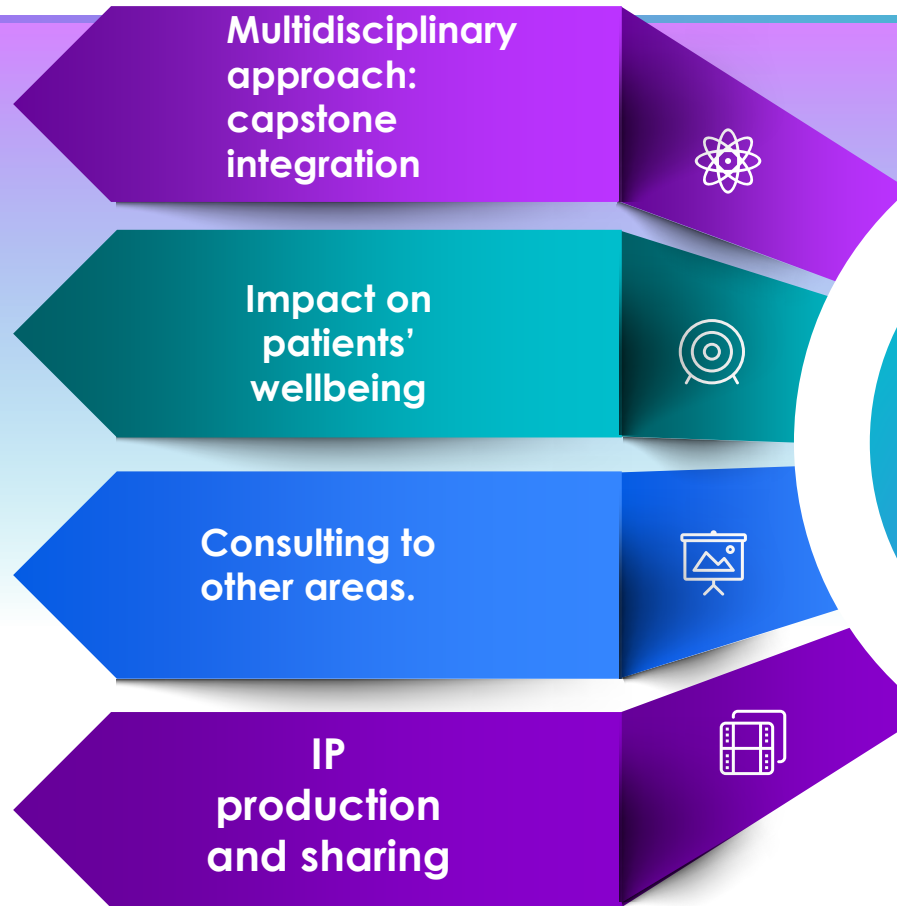
- ✓ Use context matters
- ✓ Hardware specifications are relevant
- ✓ Clear and concise documentation helps vendors and suppliers meet requirements and expectations
- ✓ Incorporate quality, maintenance and intended use into design.
- ✓ Make it flexible and scalable to adapt to business needs.
- ✓ Test it as much as necessary and more
- ✓ Obsolescence never stops.





Key Take Aways

**Fuels
Business
Growth**





Thank You For Your Time!

BSC Dorado Operations

Stay Connected with Us:



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@BSCDorado

