



COCOON

LIFE SCIENCE

Medtech's single partner delivering the most complete, comprehensive and highly regarded Packaging Design & Validation Service



Damien Rosney
BSc. MIEI
Director

- 30 yrs medical device design & development experience.
- Senior Leadership Roles in USCI Ireland as Head of R&D & R&D Manager with TE Medical.
- Leadership role in growing the largest medical device contract design house globally.
- Leading groups delivering Peripheral, Coronary, Structural Heart & Neuro Device & Packaging applications from Concept to Commercialisation.



John Muga
MSc. BSc. MIEI
Director

- ➔ 28 yrs medical device design & Operations Management experience.
- ➔ Mechanical Engineering Manager in Respiration & Senior Process Development Manager in TE Medical.
- ➔ Building & leading teams to deliver business strategies and developing core technologies.
- ➔ Covered all aspects of the product and process development building Roadmaps & Toolkits that others now follow.

Challenges in our work place



Device design challenges may consume your development team



Multiple Packaging Design & Validation Vendors resulting in lost time and budget pressure



Your organisation may not have Packaging Design & Validation expertise



Problems with bandwidth challenges may exist



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comprehensive and highly
regarded Packaging Design
& Validation Service

HOW WE HELP

SCOPING PROPOSAL



**Design
& Source
Components**



**Source
& Validate
Equipment**



**Manage
Project
End to End**



**Plan &
Complete
all Testing**



**Compile
Regulatory
Documents**

How it works



Provides Bespoke offerings

Documentation

- VOC
- User Needs
- Design Input Requirements
- DFMEA
- Master Validation Plan
- Raw Material Specs
- Incoming Inspection
- Manufacturing Procedures
- Component / Assy Dwgs
- Statistical Analysis
- Pallet Layout / Design

Design Elements

- Blister Tray Design
- Backer Card Design
- Hoop Design

Provides Bespoke offerings

- Hoop / Backer Card Combination
- Pouch (Tyvek / Foil)
- Header Bag
- Unit Carton
- Graphics
- IFU's
- Shipper Carton
- Labels
- Sterile Indicator
- Tamper Proof

Project Management

- Design Proposal
- Scope Change Management
- Design Change Management
- Project Plan
- Design Stage Gate Reviews
- Design History File
- Monthly Report

Provides Bespoke offerings

Project Management

- Project Scorecard
- Stakeholder Reviews
- Team Meetings

Regulatory

- Regulatory Submission Test Protocol
- Regulatory Submission Test Report
- Reg Submission Support
- Essential Requirements
- Risk Plan

Clinical

- User Needs Design Input
- Risk Management Input

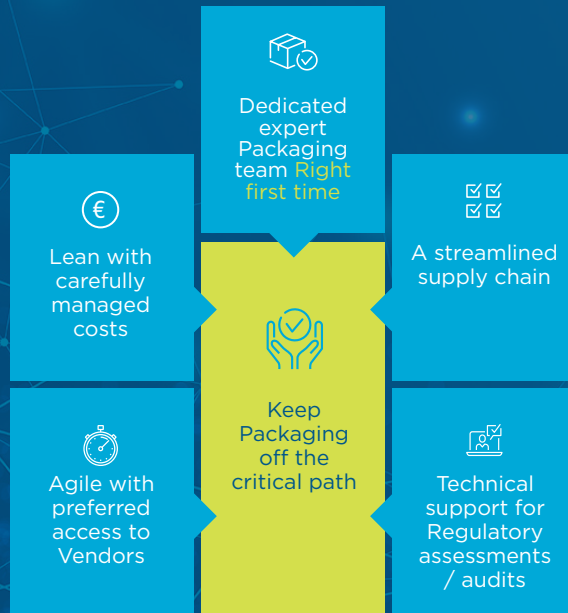
Provides Bespoke offerings

- Packaging DFMEA Input
- Design / Documentation Approval

Services

- Manage Environmental Conditioning
- Manage Aging
- Manage Transportation Testing
- Manage Logistics
- Complete Heat Sealer Validation
- Complete Vacuum Sealer Validation

Why Cocoon?



Thank you
we look
forward to
working
with you
soon.



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