

# KNOW YOUR PRODUCT REALIZATION LANDSCAPE



## KNOW WHERE TO START!

Complete the Readiness Checklist supplied by the WCDA. This document helps the WCDA members understand where you are in the product development cycle and will inform timeline estimates

## PACKAGING DESIGN

# 1

Medical device packaging design is dependent on many variables and should be carefully considered. Pouch or tray? Off-the-shelf or custom? What sterilization modality is selected and are the packaging materials suitable? Do you have package engineers on staff or are you outsourcing those efforts? No matter the scenario, the WCDA Alliance Partners have a solution.



**WESTPAK**  
TESTING. OWNERSHIP. INTEGRITY.

# 2

## PACKAGING VALIDATION

Most packaging validation services are provided by WCDA partner Westpak, and completed successfully before moving on. To potentially go faster, packaging validation can run concurrently with sterilization validation. Although fast, this strategy is risky and not highly recommended



**BLUE LINE**  
EO STERILIZATION SERVICES

## 3 STERILIZATION VALIDATION

Your sterilization validation partner depends on the modality you choose. Eagle has Alliance partners that cover all established sterilization modalities:

VH2O2: Eagle Medical

Ethylene Oxide small batch: Blue Line Sterilization

Irradiation (E-Beam & X-Ray): SteriTek

Testing services provided by: Pacific Biolabs



# 4

## BUILD TO STOCK

Upon news of successful validation completion your Build-to-Stock effort must take place to exercise:

1. Your supply-chain
2. Receiving/inspection Processes
3. Prepare for sales in the field

EMPS and the WCDA are ready to deliver end-to-end support for these efforts.

# 5

## PRODUCT LAUNCH

Validations are complete, work instructions and drawings are approved and released, DHR and BOM's are finalized, and protocol reports have been submitted to the FDA...it's time for your sales force to go to work!

