

WEST COAST DEVICE ALLIANCE CHARTER

MISSION AND VISION

The West Coast Device Alliance is an affiliation of independent but unified service providers to the life sciences and medical device industries. The WCDA will provide roadmaps to medical device, biopharma, and biotech manufacturers seeking the most efficient path through the outsourcing landscape. WCDA members will collaborate and share information for these purposes:

- 1. To achieve efficient and accurate quoting;
- 2. To provide a better understanding to our customers on boarding requirements and expectations;
- 3. To facilitate continuous improvement of processes.

OBJECTIVES

Optimal speed-to-market is achieved though effective collaboration with all WCDA Members involved. For every new project, WCDA will provide a customized 'Outsourcing Roadmap' as well as a detailed 'Readiness Checklist'. The Outsourcing Roadmap defines the role and responsibility of each Member company in a new project. The Readiness Checklist(s) supports the customer's pre-commercialization efforts and certifies that their project has met specific criteria to ensure a well-coordinated launch.

Through mutual sponsorship of cross-training between WCDA Member Companies, in customer readiness, expectation-setting, and expert preparation 'know-how' introductory information sharing, WCDA offers critical advantage-making services, saving our customers time and money. By choosing to work with the WCDA Member Companies, customers solidify their reputation with shareholders, and build credibility in the marketplace.





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KNOW YOUR PRODUCT REALIZATION LANDSCAPE

The WCDA provides end-to-end access to experts who have a combined 80-year history of collaborating in the fields of testing, packaging, and sterilization to determine optimal processes and materials unique to each project.



PACIFIC BIOLABS

WESTPAK

BLUE LINE

PACIFIC BIOLABS PBL

SteriTek 🚅

KNOW € EagleMedica **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.

PRODUCT LAUNCH

After validations are complete and product is delivered, Pacific Biolabs provides ongoing vigilance testing of raw materials and finished product. ensuring a successful launch.

PRODUCT DEVELOPMENT

Material composition of a device determines many future decisions including:

- Sterilization compatibility
- Package Material Compatibility
- Package Design
- Chemical Characterization/Biocompatibility



PACKAGING DESIGN

Pouch or tray? Off-the-shelf or custom? Should development be assigned to in-house staff or could outsourcing prove more efficient? No matter the situation, the WCDA has a solution.



BUILD TO STOCK

After completion of validations, the WCDA commences Build-to-stock efforts in order to exercise:

- > The proposed supply-chain
- > Receiving/inspection processes
- Prepare for sales in the field

PACKAGING VALIDATION

Complete packaging validation services are provided by WESTPAK, and include:

- Shelf Life & Distribution Testing
- Package Integrity Testing
- Material Analysis





STERILIZATION VALIDATION

The WCDA covers all of the most common Established Category A sterilization modalities:





Ethylene Oxide small batch:

BLUE LINE

VH2O2 & Gamma:



Testing Services: PACIFIC BIOLABS