



Key Considerations When Choosing a Manufacturing Partner for Your Pulse Oximeter Device

The right manufacturing and design partner has a lasting effect on quality, scalability and regulatory readiness

Introduction

This paper provides guidance to manufacturers of pulse oximeter devices as they review options for a material design and manufacturing partner.

It briefly explains the design and manufacturing partner's role in the device development process. It then explores some of the most important factors to consider when choosing a design and manufacturing partner. They include:

- Alignment of operational and production practices with medical industry requirements.
- Ability to reliably produce delicate device components at scale.

- Experience and expertise in medical devices.

Such key considerations help ensure the manufacturer's pulse oximeter device is optimized for the segment and regulatory landscape, and positions the manufacturer for profitable growth.

Finally, the paper introduces Boyd. It outlines the company's pulse oximeter converting capabilities and explains why these capabilities provide an advantage to manufacturers as they design, launch, and iterate.

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The Pulse Oximeter Opportunity

According to MarketsandMarkets, the global pulse oximeter segment was valued at \$3.92 billion in 2025. It is forecast to grow at an 8.7% CAGR through 2032. This growth is being driven by a rising incidence of respiratory conditions, such as COPD, asthma and pneumonia and by an increase in hospital procedures requiring continuous patient monitoring. Another factor is the increasing availability of high-quality medical care in previously underserved areas of the world. North America, however, continues to account for the largest share of global sales.¹

This high growth forecast translates to a tremendous opportunity for device manufacturers. Successfully launching a pulse oximeter device in this complex, competitive, and regulated landscape is the result of a variety of factors: Design for caregiver ease of use, wear-time performance, sensor reliability, patient comfort; strong corporate strategy to navigate regulatory requirements; and the ability to scale mass production needs while delivering medical industry quality requirements.

Few pulse oximeter device manufacturers possess the in-house combination of expertise and resources needed to smoothly navigate all of these factors. That's why choosing a design and manufacturing partner is one of the most crucial decisions made during the device development process.

The Role of the Design and Manufacturing Partner

A design and manufacturing partner is a third-party that offers expertise in materials and capabilities for processes such as fabricating, stamping, printing, device assembly, and packaging. They work with global brands in a wide range of industries to help bring product designs to life and get them to market faster. However, not all manufacturing partners are equal in what they offer. Some provide layers of value-added support that go well beyond these core capabilities.

Leading manufacturing partners position themselves as true partners to global brands. They specialize in special industries, applications, and materials where they

develop deep expertise. Then they build a solid track record of success on behalf of their global brand clients. This expertise and experience translates to significant value for the global brands.

Global Brand Client and Customer Benefits

When working with a client, a manufacturing partner engages in the product design process early. Global brand clients benefit from the design and manufacturing partner's insight and guidance throughout the development process.

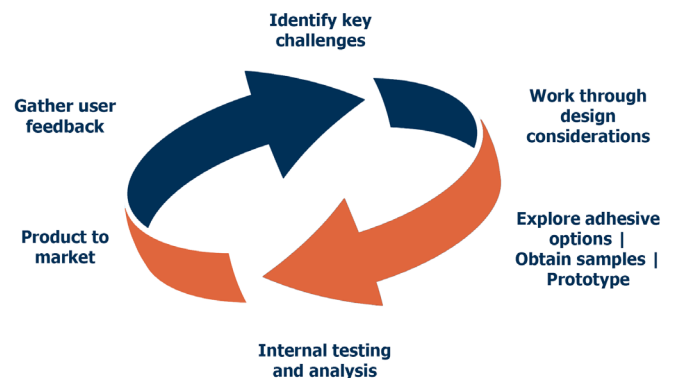


Diagram courtesy of Avery Dennison Medical

This, in turn, helps global brands build designs that reflect a more holistic and informed understanding of material capabilities, production needs, and downstream requirements. A manufacturing partner leverages its relationships with leading material suppliers, such as the pressure-sensitive adhesive (PSA) experts at Avery Dennison Medical, to further optimize device design, production, and performance.

This is the essence of design for manufacturing (DFM). And it can help the client get to market faster, be more cost-effective, and be more responsive to consumer and regulatory needs.

Avoiding Common Manufacturing Problems

Additionally, the manufacturing partner's deeper level of involvement helps avoid common functional problems that can arise during, or stem from, pulse oximeter manufacturing.

- Optical path misalignment — Occurs when optical

components are misaligned during or after their assembly. This can alter the light path between the LED and photodiode, reducing measurement accuracy and increasing signal variability.

- LED/photodiode positional drift — Occurs when small shifts in the position of LEDs or photodiodes during manufacturing affect light transmission and detection, leading to measurement inaccuracy.
- Adhesive “creep,” affecting signal quality — Occurs when a poorly-chosen adhesive slowly flows or shifts when the device is placed under stress. This can affect sensor positioning and degrade device performance.
- Cracking of flexible circuits during lamination — Occurs when excessive stress is applied to the device during assembly, resulting in damage to delicate circuitry.
- Yield loss from multi-material layer tolerance stack-up — Occurs when minor dimensional variations accumulate, causing issues with alignment and assembly quality, and leading to increased scrap.
- Moisture ingress through adhesive layers — Occurs when moisture is allowed to penetrate the device due to inadequate material selection or poor sealing. Moisture can adversely affect electronics, optics, and other delicate components.



Adhesive tape/bandage material used to secure a sensor or flexible circuit

- Skin-contact irritation — Occurs when a poorly-chosen adhesive causes redness, discomfort or other irritation. Manufacturing partners should work with

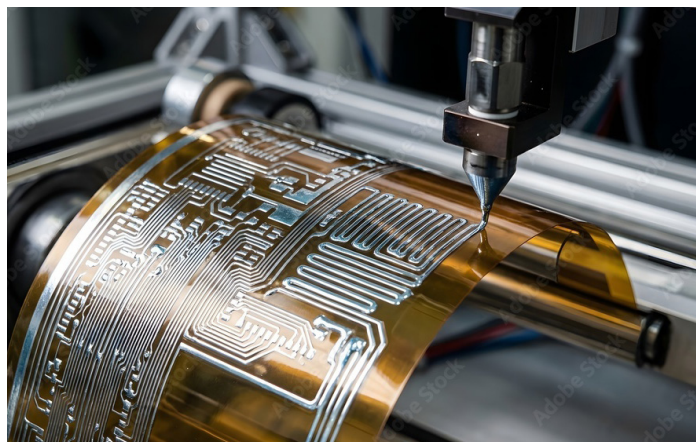
adhesive manufacturers to select formulations that are specifically engineered for skin contact.

What to Consider When Choosing a Design and Manufacturing Partner

The choice of design and manufacturing partner can be a major determinant in whether a device is a success or a failure. How a pulse oximeter brand chooses a manufacturing partner is critical to their business.

Does the Manufacturing Partner have Medical Grade Quality Systems?

The manufacturing of pulse oximeters and other medical-grade wearables requires quality that goes far beyond what's needed for most industries. The manufacturing partner becomes part of the end device's regulatory footprint. Strong quality practices that align with industry requirements help the client avoid product failures, regulatory delays, recalls, costly validation work, and other risks.



Advanced industrial machine precisely prints intricate metallic circuit patterns onto a flexible substrate

A global brand should understand whether the manufacturing partner aligns its operations with quality systems designed specifically for the medical industry. This might include the following practices:

- Documented manufacturing and change management procedures
- Lot traceability for raw materials and finished goods
- Process validation and qualification procedures
- Risk management protocols

- Corrective and preventive action (CAPA) systems
- Calibration and maintenance controls
- Employee training documentation
- Inspection and testing requirements
- Cleanliness and contamination controls
- Supplier qualification and monitoring

A global brand should also evaluate whether the manufacturing partner can support verification, validation, and ongoing change management throughout the device lifecycle: from development, to introduction, to gathering market feedback, to device iteration.

How Manufacturing Partners Drive DFM Excellence?

Pulse oximeter devices are built on precise, multilayer constructions, flexible circuits, optical components, and PSA optimized for both materials and skin contact. Early DFM involvement by the manufacturing partner helps identify and sidestep potential manufacturing challenges during the design stage of the device. This, in turn, helps the client move quickly from prototype to production and avoid costly late-stage redesigns.

A Manufacturing Partner that Integrates Flexible Circuits at Scale Creates Advantage

Flexible circuits are central to the design and functionality of modern pulse oximeters. A partner that produces and integrates these materials in high volumes while maintaining scale reduces technical risk, improves product performance, and creates a more reliable path



Flexible printed circuit board with tactile switches and adhesive tape

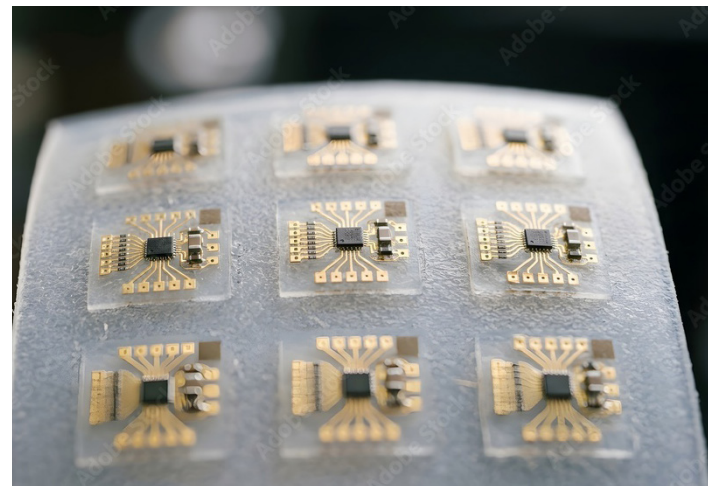
from prototype to large-scale manufacturing.

Global brands should evaluate their manufacturing partners to understand their ability to:

- Precisely align circuits within multilayer assemblies
- Integrate multiple flex circuits in a single device
- Maintain registration accuracy during high-speed production
- Automate placement and lamination processes
- Preserve electrical and mechanical integrity at high volumes

Advantages of Manufacturing Partners with Advanced Inline Quality Control and Monitoring Systems

Given the precise design and construction requirements of pulse oximeters, a manufacturing partner should have robust, automated systems for inline inspection and process control across its production lines.



Flexible printed circuit board components

Such systems monitor components in real time as they move through the various stages of production, detecting even the smallest inconsistencies. This improves device reliability, increases yields and reduces scrap, and aligns with medical regulatory and quality standards.

A pulse oximeter brand should ensure the manufacturing partner has advanced inspection systems that can monitor:

- Flex circuit placement and alignment
- Consistent multilayer assembly alignment
- Optical aperture placement
- LED and photodiode positioning
- Adhesive placement accuracy
- Manufacturing and fabrication dimensional tolerances
- Surface defects or contamination
- Registration between multilayer materials
- Missing or damaged components

Design and Manufacturing Partners with Demonstrated Raw Material Expertise for Wearable Medical Devices Elevate Credibility, Speed to Market, and Performance Excellence

The flexible materials and adhesives that make up pulse oximeter device layers are critical and functional parts of the device. Getting these selections right ensures device performance and accuracy, skin compatibility and patient comfort, device longevity, and durability.

The global brand should understand the design and manufacturing partner’s expertise with materials such as films, foams, circuitry, optical components, and PSAs engineered for skin contact.

A partner with demonstrated expertise, supplemented, where appropriate, by strong relationships with leading material providers understands how these materials interact mechanically, chemically and thermally during manufacturing and end use. Such expertise helps the client avoid a trial-and-error approach to materials selection. This, in turn, accelerates development and market introduction, and ensures device success.

Why Partner with Boyd?

Boyd is a design and manufacturing partner serving the medical industry. It is based in the U.S. and operates globally.

The company partners with customers in a wide range of medical industry segments, providing capabilities and expertise with numerous technology platforms.

Boyd sets itself apart from its competition in numerous ways:

- A strong specialization in medical multilayer wearable systems
- Flexible circuit integration and electronics assembly
- Adhesive system design, including and extending wear formulations
- Scalable manufacturing, including clean room capabilities, packaging and final assembly

Boyd’s Global ISO 13485 Facilities

Beaverton, OR USA
Chatsworth, CA USA
Chonburi, Thailand
Dongguan, China
Grand Rapids, MI USA
Juarez, Mexico
Seattle, WA USA
Singapore
Syke, Germany
Weiler-Simmerberg, Germany
Wuxi, China

Boyd’s global presence, including ISO-certified production sites, helps ensure supply redundancy, regional sourcing, and product launch support virtually anywhere in the world.

The Boyd Advantage

For OEMs of pulse oximeters and other medical wearable devices, partnering with Boyd brings numerous advantages.

Global ISO 9001 and ISO 13485-Certified and FDA-Registered Sites

Boyd produces medical device components in controlled environments under ISO 13485:2016 certified quality documentation, inspection, and traceability processes.



Boyd precision converting cleanroom

Robust Quality Management Practices

Boyd's global production sites follow strict process controls. These include ongoing quality monitoring, raw-material inventory control, cleanroom operations, and extensive documentation.

These controls meet customer and regulatory requirements throughout sourcing, fabrication,

assembly, and kitting. The company produces devices and components that support patient and caregiver safety.

DFM Support and Rapid Prototyping

Boyd gets involved early in the customer's design process. Boyd's DFM expertise and ability to quickly create and test prototypes accelerates device development, limits design revisions, and speeds validation readiness. Boyd quickly evaluates proposed designs to optimize manufacturability before full-scale production begins. And with the ability to rapidly produce prototypes and perform functional testing, Boyd moves customers from concept to validated high-volume production faster, with improved yields and greater confidence in long-term device performance.

After a device enters the market, Boyd continues to partner with the customer's design team supporting the analysis of user feedback, identification of key challenges, and opportunities for improvement and device iteration.

Cleanroom Manufacturing Capabilities

Boyd's clean room capabilities include raw material slitting, rotary and flatbed converting, and cosmetic inspection. Independent certification by the National Environmental Balancing Bureau (NEBB) assures that these clean rooms meet the controlled environmental standards required for sensitive medical manufacturing applications.



Cleanroom technician performing precision assembly for medical manufacturing.

Automated, Inline Vision Inspection

Boyd's integrated, automated inline vision inspection systems ensure that complex medical wearable assemblies, such as pulse oximeters, meet strict quality requirements even as production scales. These systems detect even the smallest defects in optical and mechanical components, ensuring device accuracy, durability, and overall quality.



Inline quality inspection system using cameras to monitor consistency and identify subtle streaks and pinholes on a production line

High-Volume Production Capacity

High-volume roll-to-roll processing, pick-and-place automation, assembly, and bagging capabilities are part of Boyd's integrated manufacturing approach. These capabilities support precise component placement, reduced handling variability, cleaner manufacturing environments, and efficient high-volume production.

Combined with rapid prototyping and production in ISO-certified facilities, Boyd's production capabilities help medical device manufacturers accelerate commercialization while maintaining precision, reliability, and scalability.

Materials Expertise and Global Collaborations

Boyd combines decades of experience in engineered materials with strategic collaborations across the global supply chain. These collaborations include providers of medical-grade PSAs, hydrogels, silicones, foams, films, and specialty wearable materials.

This, in turn, accelerates development and improves overall device performance and Boyd's unmatched global footprint enables it to more efficiently source materials and manufacture devices across key geographies.



An example of the value of these collaborations is the company's relationship with Avery Dennison Medical — a leading manufacturer of PSAs for the medical industry.

Through Avery Dennison a leading manufacturer of PSAs for the medical industry, Boyd amplifies its in-house engineering and manufacturing capabilities with additional access to advanced materials technologies and application knowledge. For pulse oximeter devices, this includes leveraging deep expertise in skin-contact PSAs to help ensure wear performance while minimizing patient discomfort.

The Bottom Line: The Choice of Design and Manufacturing Partner is Crucial

With a steady growth forecast over the next several years, the pulse oximeter segment promises a great opportunity for wearables manufacturers. But taking advantage of that opportunity requires design and manufacturing partners that can deliver quality, reliability, and durability, regardless of production scale.

Strong design and manufacturing partners improve customer and patient results with capabilities and expertise that optimize device performance while enhancing quality and reliability.

Notes: ¹MarketsandMarkets, Pulse Oximeter Market Size, Growth, Share & Trends Analysis. June 2025 <https://www.marketsandmarkets.com/Market-Reports/pulse-oximeter-market-68168578.html>

Take the Next Step: Partner with Boyd

Contact Boyd today to see how our capabilities and wearables expertise will accelerate your success in the pulse oximeter device segment.

Ready to start your next project?

Contact Boyd today to discuss your Oximeter Device needs.

BOYD

Boyd is the trusted global innovator of sustainable solutions that make our customers' products better, safer, faster, and more reliable. Our innovative engineered materials advance our customers' technology to maximize performance in the world's most advanced data centers; advance the accuracy of cutting-edge personal healthcare and diagnostic systems; enable performance-critical aircraft and security technologies; enhance reliability and extend range for intelligent mobility applications; and accelerate innovation in next-generation electronics and human machine interface. Core to Boyd's global manufacturing is a deep commitment to protecting the environment with sustainable, scalable, lean, strategically located regional operations that reduce waste and minimize carbon footprint. We empower our employees, develop their potential, and inspire them to do the right things with integrity and accountability to champion our customers' success.

To receive more information, please visit www.boydcorp.com