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# Critical Success Factors in moving from optical design to manufacturing



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## Critical Success Factors in moving from optical design to manufacturing

The ultimate success of bringing life sciences and diagnostic instruments to market lie within the efficiency of the lifecycle workflow. From proof of concept to engineering prototype, and eventual commercial product, there are distinct and critical transitions between each stage.

Of these transitions, design transfer, the movement of a design to production, may be the most important. This is especially true in the development of optoelectronics. Effective design transfer requires a thorough assessment of the product's performance objectives, design documentation, selection of components, and careful definition of production methods. Failure to transfer a design effectively can lead to delays, quality issues, supply chain problems, higher costs and more. Conversely, the rewards of effective design transfer are great: it can lower material and production costs, speed time to market, increase product quality, and generate high levels of customer satisfaction.

The transfer of a product design into a manufacturing environment requires a comprehensive set of processes to coordinate many tasks simultaneously. Proven experience, well-executed procedures, and careful review are the keys to a successful transition. This is especially true when a product design is transferred to an outsource manufacturer.



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## The cost of getting it wrong

The effectiveness of the best-conceived design will be diminished if the design transfer process is not properly planned for and executed. Common problems include:

- Manufacturing at scale was not optimally considered within the design
- Manufacturing processes have not been developed, documented, or validated
- The true scope of the design transfer effort is not understood, with the amount of time and effort being underestimated by the design team, and business managers alike
- Although the design transfer process is well understood by both parties, slow starts and unacceptable delays occur due to the inability to plan the transition of a product design into a controlled manufacturing environment
- The design brings unresolved cost, reliability, or safety issues to the design transfer process
- The workflow of the manufacturing organization is disrupted by postponed materials, procedures, and test fixtures
- Delays occur even after all the documentation is approved, because manufacturing must receive, inspect, and then release parts for production.

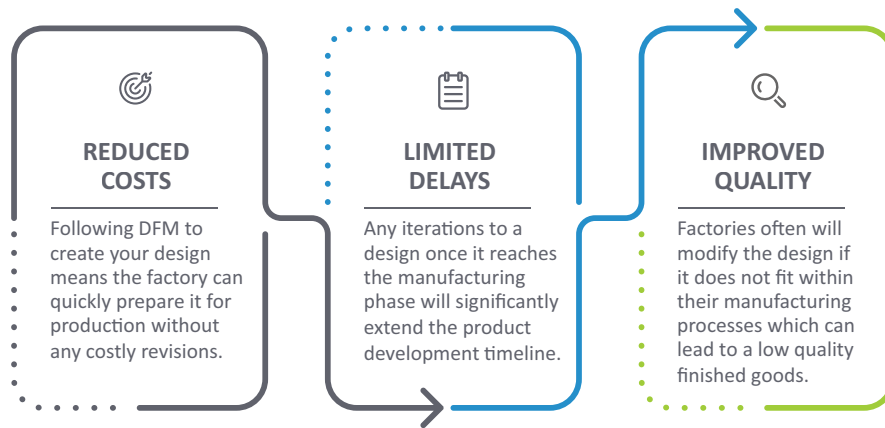
Failure to identify or proactively tackle these challenges inevitably leads to unnecessary project delays, frustration, and misunderstandings between the designer and manufacturer. And while some organizations are concerned that an outsourcing partner may induce even further complications, others have seen the benefit of leaning on an experienced partner who can help address and mitigate these challenges.

To ensure your project isn't plagued by these common pitfalls, it's crucial you look for these key attributes in an outsourcing partner:

- Establish and maintain procedures to ensure that the device design – its components and configuration – is correctly translated into production specifications
- Transfer the product design into production methods and procedures
- Create a production environment that ensures the product complies with regulatory.



## Benefits of Design Transfer



***Stay on target with costs, time and quality of your product build with Design Transfer***

## How to get design transfer right

A traditional contract manufacturer is most often NOT the answer when it comes to design transfer and manufacturing of smart optoelectronics. For optimal time-to-market with consistent performance and quality, ***working with a partner that possesses deep application area and optical expertise is vital.***

### ***Flexibility***

When at the design transfer stage, it's important to find a partner who can work with you:

- Even when you have the optical technology figured out, or you don't, having a partner with proven expertise brings new perspectives to help you push the boundaries of what you thought was possible
- At every stage, from conception and design, to design transfer and manufacturing, enabling more efficient movement through the workflow
- If you have acquired a technology that's not really ready and need to identify the design changes necessary to make manufacturing at scale, with feasible speed and cost
- When you've tried elsewhere and need a new solution, because your requirements are unique, and demand creative expertise with the flexibility to operate the way you need.



## How to get design transfer right (continued)

### ***A single point of accountability from design transfer through manufacturing***

A hands-off approach in the “design-to-prototype-to-manufacturing” introduces too many variables. These variables can negatively impact the consistency of performance, the quality of the process, and the output. Working with a partner who can provide a single, end-to-end solution from design, to design transfer, to manufacturing means a single point of accountability, with consistent quality and performance.

Production Transfer Project Status Questionnaire	
Questions	Status
1. Project definition / organization	
1.1. Will you own the entire project to the end?	
1.2. Will you be the final decision maker?	
1.3. How do you handle design changes?	
1.4. How do you handle design changes when you are not the design owner?	
1.5. How do you handle design changes when you are not the design owner and you are not the design owner?	
2. Product documentation	
2.1. Design approval	
2.2. Material specification (BOM)	
2.3. Test drawings	
2.4. Test drawings and files	
2.5. Software programs	
2.6. Material and/or module compliance (IPC, etc.)	
2.7. Production process documentation	
2.8. Assembly instructions	
2.9. Test instructions	
2.10. Quality control	
2.11. Final quality	
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### ***A proven design transfer process***

A partner with proven, documented, repeatable process for effectively and efficiently moving designs to manufacturing is critical to mitigating the common challenges, and ensures consistent performance and quality of the optical module.

### ***A focus on quality***

During the design transfer process, quality is a primary requirement, and focus, in establishing consistent, predictable performance of the optoelectronics, manufactured at scale. Having a partner who can provide, or help you develop a quality plan, solid design documentation, product-failure mode and effects analysis, and a product validation plan is key to achieving and ensuring the highest quality.



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## How to get design transfer right (continued)

### *The use of cross-functional design transfer teams*

Working with a partner who encourages a design transfer team that includes representatives from the engineering, manufacturing, materials management, quality, and business development departments from both the designer and the design transfer partner will ensure that all of the product's requirements are met.

### *How does Volpi deliver design transfer and production value?*

As a proven, global, one-stop optoelectronics specialist in Life Sciences and Diagnostics, Volpi has helped many of the world's largest instrument brands, as well as innovative start-ups move from idea to finished product at the highest quality at the best price.

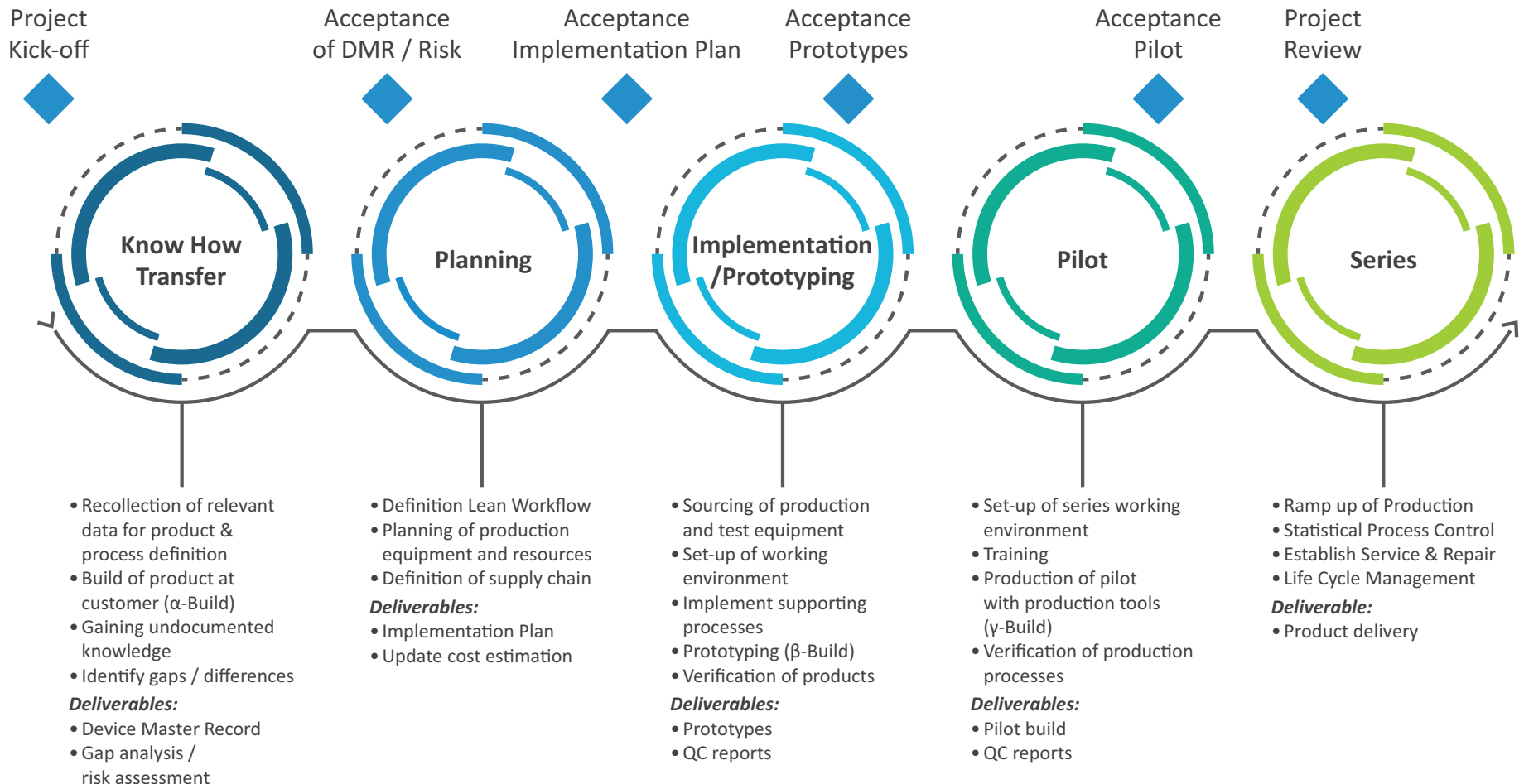
Our in-house design team, combined with our design transfer and manufacturing capabilities, offers an ideal partnership, whether you've designed the instrument yourself or acquired it. Effective and efficient production are enabled by our:

- Deep expertise in bespoke optoelectronics design and manufacturing
- Flexibility to take a design project at any stage (just design, prototype, etc.) and transfer that successfully into production
- Use of cross-functional teams to ensure all of the product and business metrics are met
- Relentless focus on quality (ISO 13485 certified)
- Proven, repeatable design transfer process.



## The Volpi Design Transfer Process

Volpi has a proven process for the effective and efficient transfer of optoelectronic module designer at any phase to production.





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## Life Sciences Applications Focus



qPCR



Digital PCR



Automated Fluorescence  
Microscopy



Cell Imaging

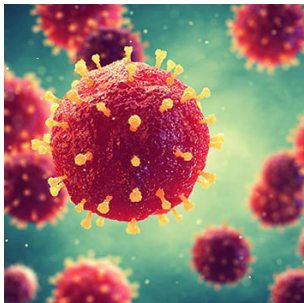


Genetic Barcoding



Next Generation  
Sequencing

## Clinical Laboratory and Point of Care IVD Applications Focus



Clinical Chemistry



Immunochemistry



Molecular Diagnostics



Microbiology

## About Volpi

We improve patient's lives through light-created insights. Volpi helps healthcare professionals make more informed treatment decisions by delivering innovative optoelectronic solutions that enhance the performance of the diagnostic instruments used to research and diagnose disease. With offices in the US and Switzerland, and clients around the globe, Volpi works with the world's best-known and most respected Life Sciences and Diagnostics instrument manufacturers.

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