Key Areas to Audit When Selecting a Contract Manufacturer

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Selecting a contract manufacturer for mission critical applications can be more challenging than selecting a contract manufacturer in other industries. The regulatory environment associated with these projects is more complex than most commercial products. Traceability and associated documentation requirements are more detailed. Procurement and supply chain management may require specialized knowledge and procedures. Volumes can be low and production builds may only be done a few times a year rather than continuously. Specialized production skills or equipment may be required to support processes required by harsh operating environments. Consequently, the OEM selection team must look beyond production capabilities to determine if the contract manufacturer has the industry-specific processes and expertise to correctly address the requirements associated with each product.

Axiom Electronics, an electronics manufacturing services (EMS) provider who regularly supports rigorous quality requirements. This whitepaper looks at three areas that should be audited carefully in supplier selection:

- Processes to ensure conformance to regulatory requirements
- Material handling considerations
- Expertise in issues related to harsh operating environments

Processes to Ensure Conformance to Regulatory Requirements

Products in industries with stringent regulatory requirements such as medical and defense/aerospace need a more detailed approach. Process changes acceptable in less regulated industries, need customer approval. Inspection criteria, device history recordkeeping and documentation may be more complex.

At Axiom Electronics, each project's requirements are carefully assessed, both at the bidding stage and once the project is awarded. Axiom's new product introduction (NPI) process starts with an initial meeting where a team consisting of manufacturing engineering, program management, quality and supply chain evaluates the scope of work (SOW), notes and assembly drawings to ensure that all information is consistent across the documentation package. For example, if special instructions appear in the SOW, they also need to be noted on the relevant assembly drawings and work instructions. If work instructions are unclear or information is missing from the drawing package, the OEM's team is asked to update the documentation with the required information.

This focus on ensuring all requirements are well understood within the team supporting the project eliminates surprises that could otherwise create defect opportunities or delay the production approval process.

Material Handling Considerations

Mission critical products have very robust material handling requirements. Contract manufacturers should be able to demonstrate receiving, receiving inspection, traceability and material storage practices consistent with relevant industry standards and any customer or flow-down contract provisions.

At Axiom Electronics, material handling and manufacturing processes are evaluated as part of the NPI evaluation. Special consideration is given to:

- Any enhancements needed for material handling, validation and/or traceability requirements

- Traceability requirements at the manufacturing routing and assembly level
- Changes to operator certification requirements and/or processes related to polymeric applications.

The *IPC-1782 - Standard for Manufacturing and Supply Chain Traceability of Electronic Products Based on Risk is* utilized to determine traceability requirements on IPC product classification and failure risk for both material and manufacturing routings. Medical and military/aerospace products often carry IPC Class 3 workmanship requirements.

The standard requires products in its M3 and M4 classification groups to have the following traceability information:

- Internal Part Number
- Product Code
- Product Revision
- Unique Assembly
- Internal Work Order
- Traceability inheritance through sub-assemblies for critical components, with either general exceptions for product groups in M3 or specifically mentioned item exceptions in M4, where it is deemed there is no value traceability of the item(s).
- Actual Bill of Materials
- Use-By/Expiration Date
- Genuine/Counterfeit Screening
- Acceptance for Use
- Hazardous Substance
- Documents (paper or electronic).

The goal behind standards such as IPC-1782 is ensuring a uniform approach to identifying potential failure risks and ensuring material is correctly assessed for damage or modifications in incoming inspection, labelled with all the information needed to indicate proper storage and use requirements, and tracked in ways that minimize the potential for damage through improper storage, prep or handling on the production floor.

Axiom Electronics' incoming inspection procedure incorporates IPC-1782 requirements and has specific requirements for areas of potential risk such as moisture sensitive parts.

Expertise in Issues related to Harsh Operating Environments

Products used in harsh environments where electronics are subject to factors that can accelerate corrosion and weaken solder joints need additional focus. This can include products used in environments requiring sterilization procedures or end user environments that may expose the product to moisture, humidity dust or other extreme conditions. Process control, coating and encapsulation capabilities, and inspection and test processes are all critical elements in ensuring products meet quality requirements. However, an understanding of how harsh environments may impact the hardware is also critical.

Component packaging choices and insufficient spacing between components can lead to both

manufacturability and fitness for environment issues. For example, SMT connectors are less robust than their through-hole counterparts. When a product with an SMT connector mates with a board stack and then is clamped in the system, the stress on the connector can pull the pads off the PCB, particularly in products subject to vibration. For example, if an OEM works with Axiom Electronics in their design process, an Axiom DFX (design for excellence) recommended modification would be to use a through-hole connector. However, when this issue is identified after product qualification, the only mitigation is to apply staking material to the outside of all SMT connectors. If parts are too close together to get staking material around the connector, it increases the amount of staking required. In short, failure to consider environmental stress or maintenance considerations in component package selection and/or spacing requirements can create a cascading series of added costs in the production process.

Working with an EMS provider with expertise in supporting a broad range of mission critical product requirements helps eliminate learning curve, reduces capital equipment cost and may result in better quality solutions than available with a less experienced internal team. This can be particularly beneficial in cases where added required workmanship standards increase operator certification requirements or there are significant in-process inspection requirements. In selecting an appropriate contract manufacturer for products in these industries, evaluate their processes for assessing the scope of work and applicable industry standards, their experience with projects of similar size and scope, and their ability to apply expertise in collaborating in situations where specifications may not be fully developed.

About Axiom Electronics

Axiom Electronics is a leading electronics manufacturing services (EMS) company founded in 1990. Based in Hillsboro, OR, Axiom provides sophisticated manufacturing services to a wide range of OEMs in high reliability sectors such as military/aerospace, instrumentation, medical, communications, test and computer systems.

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