CM Selection Guidance

key tech

Background

An advantage of working with Key Tech is that we do not perform production manufacturing in house, and therefore, we can help clients find a CM that is the best fit for their product. While selection is ultimately their choice and the CM is their vendor, Key Tech has experience aiding in the selection process. At the end of the product development process Key Tech ramps off the project as the CM ramps up, but there is usually substantial overlap between Key Tech and CM project schedules to maximize quality and optimize knowledge transfer. This document reflects our recommendations for CM selection.

Typical Selection Process

1. Generate a complete list of CMs in a preferred geographical area. Roughly rank them based off of their website and our background knowledge.
2. Set up introductory calls interviewing the top five to ten
3. Based on results of introductory calls, visit the the top three to five
4. Seek reference's feedback and recommendations on the top three
5. Request a rough quote from the top three with an explicit and complete bid package as basis. This package would ideally include a presentation that introduces the product, the assembly process rough outline with time estimate, the checkout process rough outline with time estimate, other important peripheral information such as packaging and shipping needs and maintenance/ repair needs if applicable, assumptions and expectations, and planned timeline. It would ideally also include solid models and electrical design files of the current design (likely Alpha design, as this is the best time to engage the CM) and one or more Bill(s) of Materials (BOM).
6. Select a CM and work together to define their role in the remainder of development
7. Proceed with development, asking for DFx feedback from CM at set intervals (especially Design for Assembly feedback)
8. Engage the CM for preproduction and production

Selection Worksheet

The pillars of CM selection are the primary decision points.

		Desirable Criteria
Pillars	**Total Cost**	Production cost + NRE + time cost + markup is minimized and fair
	Schedule	Devices can be built on the schedule required
	Bilateral business fit	Opportunity is significant to CM but not overtaxing, both parties are in sync on scaling of product
	Location	Location is convenient for design transfer, support, and target sales markets
	Competency	CM is confidently able to accomplish the production tasks and provide a reasonable level of technical support
	Quality of Work	Production quality and yield are suitable for the device and they have a mature quality management system
	Peer Feedback	Trusted peers have used the CM and continue to use them on similar complexity products

Other factors are secondary decision points that may feed into the pillars.
They also provide a list of things to look for or questions to ask to determine competency.

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		Desirable Criteria
Experience	Work on similar complexity devices	CM has worked on products with similar challenges and sensitivities (e.g. electromechanical, pneumatic, fluidic, high-reliability)
	Work on similar scale	CM is accustomed to builds the size of the product
	Years in business	Have been in business for long enough to have established facilities, experience in the industry, and a list of references

		Desirable Criteria
Capabilities	Pilot production	There exist facilities to run pilot builds and vet the manufacturing process, may or may not be a separate NPI/Pilot line
	Required capabilities for device production	Have all key equipment and experience to work with device components
	Subcomponent production	Able to manufacture critical circuit boards, cable assemblies, or mechanical parts in-house to maintain quality and reduce supply chain risks
	Scalability	Have the space, equipment, and labor to scale to the desired production quantity
	Sourcing	Can proactively manage component sourcing and supply chain
	Upcoming capabilities, ability to add more	Are willing to add capabilities and equipment if necessary

		Desirable Criteria
Corporate	Corporate history	Extended corporate history with consistent leadership
	Likelihood of going out of business or changing focus	Have a healthy pipeline and are unlikely to go out of business or change focus
	Meets IT audit qualifications	Meet appropriate IT requirements if storing proprietary information

		Desirable Criteria
Location	Sufficient for operations	Are easy to access for design transfer visits, audits, support
	Sufficient for fulfillment	Are suitably located to fulfill product and perform RMA services
	Tax credits	Location is somehow tax advantaged
	Environmental robustness	Limited exposure to natural disasters or geopolitical events

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		Desirable Criteria
Value Adds	Electronic sustaining engineering	Provide sustaining engineering services to manage basic part obsolescence, bugfixes, and DFM adjustments or design improvements
	Mechanical sustaining engineering	Provide sustaining engineering services to manage basic part obsolescence and bugfixes or design improvements
	Fulfillment	Provide device fulfillment directly or can easily get completed devices to fulfillment location
	RMA and repair	Have logistical infrastructure to manage RMAs and repairs as needed
	Failure analysis	Have equipment and experience to perform failure analysis (electrical, mechanical, etc.) if necessary

		Desirable Criteria
Transfer to Mfg.	Clear roadmap	Are able to present a clear roadmap to production manufacturing that meets Key Tech and client needs
	Able to offer DFM	Are willing and able to provide high quality DFM feedback at the Alpha and Beta stages
	Engineering change process	Have a well-defined and controlled engineering change process
	Document ownership	Are amenable to the document/design ownership arrangement preferred by the client

		Desirable Criteria
Process Engineering	Material inspection	Have a “cage” to receive and inspect materials before they are introduced to the mfg line
	Travelers	Have traveler documents that track the progression of a device, these travelers are electronic or easily accessible to the client
	Work instructions	Produce high quality work instructions for assembling the device and performing substeps
	Defect handling	Have a means of tracking production defects and efforts in place to drive to “zero defects”
	Test engineering	Dedicated test engineers are available to define tests and conduct them during manufacturing
	Checkouts	Are used to and willing to run necessary checkouts on hardware, including burn in
	Process FMEAs	Are able to produce a process FMEA for medical device production, or at least comfortable providing detailed review of one created by lead product developer
	Statistical process controls	Can employ statistical process controls where appropriate
	Process validation	Can validate processes where necessary

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		Desirable Criteria
Facility	Busyness	Production floor is sufficiently busy with other projects to indicate CM has history of success
	Tidiness	Production floor and especially assembly cells are tidy and organized
	Assembly Cells	A specific final assembly cell can be setup for the device
	Manner of employees	Employees are professional and show ownership of their tasks
	Environmental control	Facility is temperature and humidity controlled or at least humidity monitored
	Process flow	Production floor has good flow, work in process is well organized and safely stored
	ESD control	ESD control measures are visible when handling or around electronics

		Desirable Criteria
Personnel	Dedicated project manager or engineer	CM provides a dedicated point of contact, usually a manufacturing engineer who sticks with the product
	Ability to escalate	Communication channels exist to escalate problems
	Temps or full time	Assembly technicians are full time employees and not temporary hires
	General experience of techs	Technicians are trained to IPC or other industry standard, have years of experience

NOTES

The above is an exhaustive list and some criteria don't apply to a CM producing a consumable or small device. They may not all apply to a non-medical device.

For more information about the appropriate document structure and system definition, please reach out to us at TalkToUs@keytechinc.com