

## Learn to Avoid Pitfalls when Transferring Box-build Assemblies

Asia in general, and China in particular, continue to attract a great deal of attention from medical device OEMs. Much has been written about the outsourcing of medical device component manufacturing to Asia. OEMs have sourced injection molded parts, printed circuit board assemblies (PCBAs) and various sub-assemblies from Asia for many years. However, the trend to outsource full box-build assembly to Asia is a more recent development. The process may be more complex and the pitfalls greater, but the potential rewards could be greater as well.

This article outlines two common models that have been successfully adopted by U.S. and European medical device OEMs in transferring box-build assembly to Asia.

### High Mix, Low Volume

OEMs that have worked in Asia for some time know that large numbers of Asian contract manufacturers, especially electronics manufacturing services (EMS) providers, run high-volume production plants catering to customers in consumer electronics, home appliances or computer sectors. Typically, sophisticated medical devices do not fall into the high-volume category. In addition, relatively few high-volume Asian EMS providers meet regulatory requirements.

However, an increasing number of specialized contract manufacturers in Asia provide high-mix, low-volume production. COB Technology Pte Ltd, for instance, is a mid-sized EMS contract manufacturer that has provided full box-build assembly services to several global medical OEM customers since 2003 at its 150,000-square-foot Sungei Petani facility in Malaysia. The Singapore-based company is currently setting up additional box-build assembly lines for medical devices at its PCBA plant in Wuxi, China.

With a track record in high-mix, low-volume industries such as avionics, aerospace and medical, plus compliant regulatory certifications, these smaller, specialized contract manufacturers in Asia can be ideal partners for box-build assembly.

### Two Common Models

In Asia, OEMs often follow one of two main types of box build transfer models:

- A phased, conservative rollout
- A rapid rollout (sometimes referred to as the “Big Bang” model).

The phased approach is slow but steady. It would typically take from one to three years to realize the full potential of the cost savings, assuming a transfer of two to three main products with 10-50 hardware/software/language variants in each product line (see Fig. 1). The outsourcing process can be delineated in several steps:

• **Outsourcing of PCBAs and cable assemblies:** The first step involves transferring all electronic and electro-mechanical assemblies either from in-house manufacturing or from an existing local supplier. This typically takes six to nine months from the first article stage to a point at which the supply chain is established for components needed for the assemblies.

• **Outsourcing of sub-assemblies:** During the second step, the OEM can gauge whether the contractor has the mechanical assembly capabilities to move to the next major step of box-build assembly. It also offers an opportunity to test the localization capabilities of the CM. This step typically takes three to six months, including validations.

- **The Outsourcing of box-build assembly:**

“This is the start of a process requiring detailed cross-functional project management,” Lee Kwee Hiong, chief technology officer at COB Technology, explained of the stage. “Significant resources in manpower, time and money need to be committed by both parties. This phase involves the knowledge transfer of the full product-assembly process (currently done in-house) to the contract manufacturer through detailed, in-depth immersion type training. The new production lines or cells are then setup at the contract manufacturer’s site.”

Validations follow, and regulatory filings are updated. This entire step typically takes six to nine months for a single product with variants. The norm is 12 to 18 months for multiple-product group transfers.

• **Localization of box-build materials:** “This is one of the most difficult phases but has one of the biggest cost-savings potentials, provided both OEM and contract manufacturer put in the effort and the commitment to achieve the cost-saving goals”, Lee added.

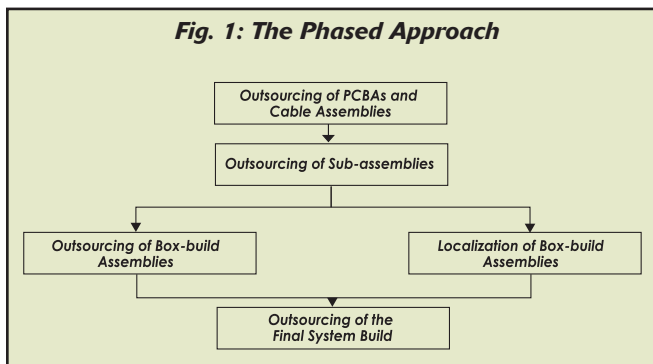
During this step process complexity increases as new Asian vendors of mechanical parts (e.g. plastics and metal) need to be assessed and each piece or part to be localized must



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# Outsourcing in Asia

**Fig. 1: The Phased Approach**



undergo full qualification. An OEM should expect its box-build assembly partner to lead the effort of identifying such vendors and maintaining the relationships. This entire step typically takes one or two years to complete and can start at about the same time as the box-build assembly transfer.

- **Outsourcing the final system build:** This is the final step of the transition whereby system software downloading, system integration, specific end customer customization, and final system level testing are carried out by the Asian contract manufacturer. Manuals and accessories are packed in and a full service contract manufacturer may subsequently take care of all logistics/distribution requirements.

## The Rapid Rollout or 'Big Bang' Model

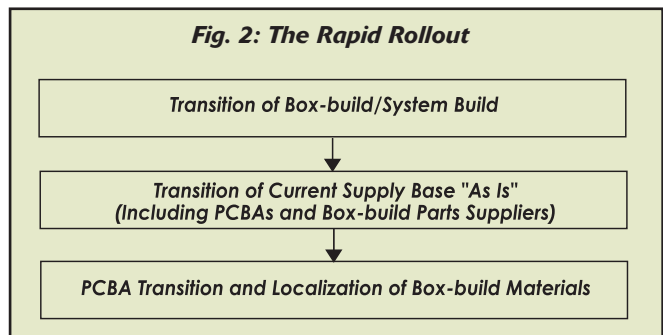
The rapid rollout or "Big Bang" approach can shorten the overall transfer time but requires an allocation of additional project resources. A project time constraint that

requires the OEM to free current assembly lines at its U.S. or European plant for a new product line will often require such an approach; the older, mature product line needs to be transitioned out quickly. This model typically take nine months to two years to realize the full potential of the cost savings. The steps involved are:

- **Transition of box-build/system build:** Given the time constraints (e.g. full transfer within three months), priority is given to getting the assembly lines transferred in full and for all product lines and variants to be transitioned simultaneously. This requires the allocation of significant resources, primarily in man-hours, both from the OEM and from the Asian contract manufacturer. Multiple cross-functional teams are required to train, certify and transfer the various product lines. This critical initial step can typically take three to six months.

- **The current supply base is transferred "as is":** Due to time constraints, the current supply base is transferred intact, and a new supply chain is set up to bring the box-build materials to Asia. Thus, a U.S. supplier would now become an "off-shore" supplier to the Asian manufac-

**Fig. 2: The Rapid Rollout**



## Avoiding Common Pitfalls

When outsourcing to Asia, here is a list of common problems you may encounter:

**The language barrier.** In countries such as India, Singapore, Malaysia and the Philippines virtually everyone at managerial level speaks fluent English as do most workers. However, in China and Taiwan the language barrier can be a significant problem. One solution is to work with a contract manufacturer based in Singapore or Malaysia with facilities in China. These companies almost always appoint good English speakers at managerial levels.

**Communication issues.** Cultural barriers and vast geographical distances can complicate communications. Set aside a

time every week for telephone or video conferences. Develop strong working relationships with key senior executives within the local organization. Personal relationships and trust can go a long way in Asia.

**Documentation.** Ensure that your own documentation, such drawings, is completely up-to-date and that your Asian contract manufacturing partner is working with the same documents.

**Undocumented assembly techniques.** Over the years operators often develop their own techniques to "tweak" a product assembly in order to ensure a perfect result. These techniques are usually undocumented and can take a long time for a new Asian operator to learn.

**Mismatch in production volume runs.**

Do not ask a high volume production house to run the small to medium production volumes that are typical in the medical device industry.

**Existing (box build) supplier issues.** Once the decision has been announced to move box assembly overseas, current vendors may become unsupportive knowing that their business will be lost to an Asian supplier. The transition needs to be carefully managed.

**Quality documentation and reference checks.** Ensure that your Asian contract manufacturer has all relevant quality certifications, such as ISO 13485 and have medical industry experience. Past experience of having implemented box-build transfer projects is essential.

turer, but an Asian vendor becomes a local supplier. This may result in a reversal of the supply chain for certain box-build materials. An OEM sourcing bulky items (such as metal or plastic enclosures) from Asia no longer would need to ship long distances to the U.S. or Europe.

• **Transition of PCBAs and localization of box-build materials:** As there is insufficient time to complete the PCBA transition prior to the box-build/system build transfer, the Asian manufacturer may have to buy PCBAs from existing vendors. This would usually require only a few months before the PCBA transition is completed. As in the phased model, the next step is the localization of box-build materials.

### Knowledgeable Partners

An experienced Asian contract manufacturer should be familiar with both transfer models. OEMs should look for partners with strong project management and communication skills. Ask to have the contract manufacturer describe the detailed implementation of past projects, in particular of medical devices.

Significant cost savings can be made by medical device OEMs sourcing components from Asia. However, outsourcing full box-build assembly to Asia may offer even greater cost reductions.

For companies that are new to Asia, outsourced manufacturing of individual components may be the

best way to start. Excellent advice on how to identify and evaluate potential Asian contract manufacturers can be obtained from embassies, trade missions or consultants that have an intimate knowledge of the region.

For OEMs that have chosen to

explore outsourcing full box-build assembly, success depends not only on the choice of contract manufacturing partner in Asia but on the careful evaluation and selection of the most appropriate box-build transfer model. ♦

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