

This page will spotlight issues, address concerns, and elicit questions to answers from OEMs and Suppliers alike — including all members of the Supplier community, not just your current Supplier base. Below, we list some of the issues that have been presented to us in numerous one-on-one conversations. In the next issue, we look forward to your ‘Letters to the Editor’ that will provide more insight into how Suppliers need to prepare themselves to interface with you as a strategic sourcing decisionmaker. If Suppliers are kept ‘in the loop’ with respect to understanding not only current market trends and dynamics, but also your needs and expectations, they will all be better prepared to meet those needs when the call (from you) comes. Add to the list. Share your thoughts.

‘ON THE TABLE’ — FROM OEMS

- Occasionally, we still have ‘quality’ issues relative to the work we receive from our Suppliers (*Editor: Examples?*)
- Suppliers need to escalate their ability to meet GMP’s relative to manufacturing, cleaning, non-sterile packaging, lot control and traceability (*Editor: Are more OEMs looking for Supplier ‘dock-to-stock’ competencies?*)
- We would like to know ‘real-time’ Supplier lead times by capability. (*Editor: What are you being told? What do you want?*)
- Suppliers overstate their capacity and understate their lead time, leading to failure to meet scheduled deadlines.
- Need to know of Suppliers capable and committed to ‘short runs’, ‘quick turnarounds’, particularly for prototype work.
- Want to know of Suppliers who keep themselves on the leading edge of manufacturing technologies.
- Geographical proximity to our plant plays a role in our selection of Suppliers (*Editor: Why is that important? Under what circumstances?*)
- New Supplier processes/technologies.
- We expect Suppliers to assume more responsibility for raw material testing, control, and traceability.
- We have limited sourcing options for raw materials (stock shapes). Would like to know of more materials suppliers.
- Would like to see an on-line RFP/RFQ mechanism for the times when we are interested in sourcing-out short runs and/or prototype work.
- Want to know of Suppliers whose staff possesses design experience and who can provide CAD/CAM support.

‘ON THE TABLE’ — FROM SUPPLIERS

- The medico-legal climate is having an adverse effect on OEM-Supplier relationships. We get “mixed messages” from OEMS regarding our product liability risks relative to products we manufacture for them. What are we supposed to expect? What do we need to do to protect ourselves?
- It appears that OEMs are doing more in-house manufacturing of surgical instruments than in the past. What’s the trend?

‘ON THE TABLE’ — FROM SUPPLIERS (CONTINUED)

- It appears that OEMs are doing more in-house manufacturing of implantable plastics (i.e., bearing surfaces, etc.) than in the past. What’s the trend?
- What is the anticipated impact of the new FDA guidance document relating to sterilization containers?
- We’re concerned about the potential impact of the steel tariff on our ability to access customer specified grades of stainless steel, especially as it relates to the cost of production.
- For OEMs evaluating a potential Supplier’s qualifications — what are their expectations regarding a Supplier’s FDA registration and ISO certification status...regarding a Supplier’s Quality documentation, processes or programs?
- Do they care whether or not a potential Supplier has current medical device (or orthopaedic product) production experience?
- I’m having difficulty identifying key OEM decision-makers. How can I best establish contact with them to ‘get my foot in the door’ to present our products/services?
- I’d like to participate in an on-line RFP/RFQ mechanism.
- Who makes ‘prototype’ vs. ‘production run’ outsourcing decisions at OEM companies?
- What do you see the most likely early applications for the use of shape memory alloys in orthopaedics?
- How do most OEMs prioritize the relative significance of Supplier quality, capacity, lead time, pricing, and service?
- What value-added services are most OEMs looking for? (i.e., engineering support, CAD/CAM integration, finishing, dock-to-stock?)
- What do OEMs consider to be an ideal description of ‘open communication’ with Suppliers? (*Editor: What are some of the historical/existing impediments?*)
- In terms of ‘information-sharing’, are OEMs really opening up to the concept of ‘collaborative communication’ with their Suppliers?
- Some OEMs have informed their Supplier base to expect an arbitrarily reduction in the amount they will pay for services rendered. Is this an example of a ‘collaborative relationship’ between OEM and supplier?