MITIGATING RISK AND COSTS BY PROVIDING MULTIPLE REGIONALLY APPROPRIATE SOLUTIONS

ORAL DOSAGE FORMS

Satisfaction drivers that contribute to positive sponsor-CMO relationships
Bottom line, do what you say and when issues arise be transparent. Building trust is the single most important driver.

How your CDMO company can support drug innovators' current and future manufacturing needs? What technologies will support life extension strategies?
Ability to move quickly and support across all our client needs across the value chain- integrated solutions. Providing our services globally also a big plus with the quality/cost value proposition that incorporates our India based sites into client solutions. Our integrated ADC offering from payload/linkers/conjugation/fill finish is probably one of the biggest life cycle extensions, in addition to formulation development services that play into alternate dosage forms leveraging 505b2 pathway.

What are CMO attributes which influence service provider selection by sponsors for both simple and complex oral dose drug product manufacturing?
There are multiple boxes to tick when choosing a manufacturing CMO. Quality, regulatory compliance, safety, geography, risk profile, pricing and service levels are some of the top ones. If all things are equal, then personal history with the CMO, peer recommendation and personal preference play a big factor in a final decision. Again, comes back to confidence and trust..

An overview of the current market dynamics in the oral dose contract manufacturing space. Which oral dosage forms will grow in use over the next five years and which may lose market share? What are the drivers? What is your experience?
Oral solids are here to stay. There is higher level of comfort with patient compliance, transporting and storage, easier to manufacture with lots of CMOs who can offer this service. We are seeing an increase in molecules that have poor solubility, hence technologies like spray drying, soft gel capsules and HME (Hot Melt Extrusion) are becoming more popular.

What are the challenges you are facing and your solutions?
The recent uncertainty created due to Brexit and global Government action on tariffs is impacting our customers' ability to manage unforeseen costs and related country specific risk. Being a truly global CDMO with foot print in every major continent with inbuilt redundancies, Piramal Pharma Solutions is able to help its customers mitigate risk and costs by providing multiple regionally appropriate solutions.

PARENTERAL DOSAGE FORMS

The injectable drug market is expanding in large part because of the rise of biologic drugs, which generally must be administered by injection or infusion. The demand for small molecule parenteral products is also increasing.
Biologic drugs constituted a major portion of the top drugs sold in 2018. The number of innovator companies investing in biologics is also on the rise. Liquid and Lyophilized injections are the main form of delivery for biologics. The other area fuelling the demand for injectable is the growing interest in small molecule oncology drugs. Most of these are administered via the injectable route.

The main challenges that manufactures of parenteral drugs have to face
Depending on location, the acquisition of a highly skilled work force to produce drugs in a sterile environment can be challenging. If a highly skilled work force is not available, the required time and investment to grow from scratch can be substantial. One can never compromise quality and the aseptic/sterile environment is rigorous as evidence by so many critical observations across the industry. PPS biggest selling point from our Lexington facility is our quality record with our last FDA audit earlier in the year yielding zero 483's!

Logistical and technical complexity of filling capacity with small volume programs for multiple drugs
Filling capacity with many small volume programs requires robust support processes and systems to ensure you have short (time duration) turn-around between programs to allow optimization of the filling time windows. Highly sophisticated and robust SCM processes are required to ensure you always have adequate supplies of materials without creating a need to carry large inventories onsite. This could also include agreements with major suppliers to hold "Just in Time" inventory at the supplies warehouses dedicated to your requirements.

How to achieve market and therapeutic success?
With the focus on smaller programs targeting special needs (ex: unmet needs, fast track, etc.), the CDMO has to be nimble and able to quickly change direction depending on the needs of the various customer programs. There is no substitute for having some level of spare capacity when inevitable needs come up on client programs.

Automation and Artificial Intelligence to reduce the risk of error and contamination, and increase both operator and patient safety
Both tools are key in improving overall operational success but require skilled support staff to ensure they operate as designed. When automation fails, it can have significant impact on productivity availability.

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