PDP MANUFACTURING AND SUPPLY STRATEGY REVIEW QUESTIONS

There are 13 Manufacturing Strategy Question Subject areas. These questions seek to understand the PDPs' manufacturing approaches and strategies and in particular how they are planning the secure supply of quality products at affordable prices once their products have received regulatory approval.

As you will note the questions are designed with a series of follow on questions that explore the subject area in more detail, these follow on questions will only be asked depending on the answers to the higher level questions.

One hour will be allocated to the telephone questionnaire which might mean that discussion on some of the topics listed will have to be constrained to ensure the overall questionnaire is completed during the call.

Interviewee Information

Name of the PDP
Date:
Names of the person / people interviewed:
Departments:
Emails:

Product	Regulatory Strategy	Phase II	Phase III	Registration	Launch

1. **Organizational design**
    a. Who will manufacture the products that you will market?
    b. Will the manufacturer of your products also be the market authorization holder?
    c. Have you formally developed a manufacturing strategy and has this been endorsed by you and your manufacturing partner's (partners') governance boards?
    d. Who in your PDP is responsible for managing the relationship with the organization that will manufacture and supply your products to market?
    e. Do you anticipate this organizational design will change over time?

2. **Product launch plans**
    a. Is your product a NCE, or an already approved product with a new indication?
        i. If it's a new indication of an existing product, is it available as a generic product?
    b. How many countries do you anticipate will untimely launch your products?
    c. Will your product be supplied on a public tender basis?
    d. Will they also be supplied to the private market?

3. **Understanding Demand**
    a. Who is responsible for modeling the anticipated demand for your products?
    b. Have product demand forecasts been developed?
        i. How have these forecasts been modeled?
        ii. What level of accuracy would you put on these forecasts?
        iii. Has a baseline forecast plus upside and downside forecasts been established?
    c. Do you understand the key drivers that influence demand?
    d. Have you been able to assign demand by pack/strength/country/region etc?
        i. Are you/your partners able to calculate drug product/drug substance demand from these forecasts?
        ii. How far out do the forecasts go post market approval (6mths, 1 year, 5 years, 10 years)?
    e. What time buckets are the forecasts calculated in (yearly/ quarterly / monthly)?

4. **Understanding Capacity**
    a. Do you anticipate that process batch sizes will have to be increased prior to product launch?
    b. Does your manufacturing process require specialized/ dedicated manufacturing equipment?
    c. Have you developed a capacity model showing how capacity will need to increase over time?
    a. Do you have an understanding of how your manufacturing and supplier capacities are aligned with the projected demand for your products?
    d. Do you understand the lead times required to bring new manufacturing capacity on line
    e. Who will pay for increases in capacity?

5. **Additional Manufacturing and Supply Partners**
    b. Have you established any dual/multiple sourcing policies?
    c. Do you intend to roll out supply to local/national manufacturing sites?
        i. If so how will these be selected and managed?
    d. Have you considered if local manufacture is required for market access reasons?
        i. How is this best achieved?
        ii. What will be the decision process to determine at what stage in the manufacturing process local manufacture will be conducted?
        iii. How will the financial impact of this decision be determined?
    e. Do you intend to ensure generic manufacturers get licenses to manufacture and market your products?
        i. If so how will this be managed?
        ii. Will rights be limited to specific countries/markets?

6. **Target Cost of Goods?**
    a. Have you established target cost of goods based on what the customer will pay?
        iii. Were the COGS part of the TPP?
        iv. Are these targets segmented by customer group?
    b. Do you know your current COGs?
        i. If so how was this calculated, what is included in the cost?
    c. Have you projected what the COGs will be at launch and say 5 years post launch?
        ii. How is this related to volume?
    d. Have you identified ways to reduce the COGs?
        i. Process efficiencies?
        ii. Alternative manufacturing processes?
        iii. Lowering cost of raw materials/excipients/packaging components etc?
        iv. Low cost sources of supply?

7. **Manufacturing and Supply contracts?**
    a. What are the key contractual terms you establish with your manufacturing and supply partners?
    b. Do your contracts allow your Pharma partners to make a profit? How is the margin allowed determined?
    c. Do your contracts encourage cost savings and if so how are these savings shared by the parties to the contract?

8. **Quality Compliance**
    a. What will the role of the PDP be in ensuring GMP compliance of supplied product?
        i. What role do you anticipate in the future?
    b. What role does your PDP play in the release of product?
        ii. How will this role change over time?

9. **Manufacturing Process**
    a. What are the key technical challenges to the manufacture of your products?
    b. How robust do you anticipate your manufacturing and analytical processes to be at the time of regulatory submission?
    c. Do you anticipate any significant process robustness and repeatability issues that need to be resolved prior to final approval and launch?
    d. How easy do you anticipate it will be to transfer your process to other manufacturing sites?
        i. What level of technical support do you anticipate tech transfer will require?
        ii. Who will provide this support?
    e. What do you anticipate your PDP's role will be in providing technical support and oversight to the manufacturing process during the products life cycle?
        i. When do you see this role transitioning to others?
    f. What level of technical competence do you anticipate will be required to routinely manufacture your products following successful tech transfer?

10. **Economic Trade Route (How products are bought and sold as it progresses from raw materials to finished product and ultimately use by the patient**
    a. Who buys the raw materials your product is made from?
    b. Who pays for the materials to be converted into finished products?
    c. Who pays for the finished products, if it different to b?
    d. Who pays for the finished product to be distributed to patients?
    e. Who pays for the finished product to be used by patients?
    f. How will this be different for public and private sales?
    g. Who will manage and have oversight to these trade routes?
    h. What do you see as the major risks to these trade routes?

11. **Supply Chain Planning**
    a. What's the anticipated role of your PDP in managing the supply of products to patients?
        i. How will this role change over time?
    b. How will manufacturing and supply partners understand and manage the demand?
    c. How long does it take for raw materials to be converted into finished product?
    d. What lead times are required to manage the production process?
    e. What visibility of stock levels across the supply chain do you anticipate?
    f. Have stock holding levels been established and who manages the supply chain?
    g. Have key performance indicators (KPI's) been established to monitor the manufacture and supply of your products?
    h. How is supply chain security assessed to ensure continuity of supply?

12. **Distribution & Logistics**
    a. Who will manage the logistics and distribution of your products to the end users?
    b. How will this differ for public and private markets?
    c. What role will your PDP have in establishing this capability?
    d. Have you identified logistics and distribution providers who can support this activity?
    e. Will your product require cold chain or controlled condition storage and shipment?
        i. If so how confident are you that suitable storage and transportation conditions can be maintained throughout the logistics and distribution process?
    f. Who will provide oversight to the distribution and logistics processes?
    g. Have you been able to determine the cost of distribution and logistics?

13. **Anything else to consider?**
    c. Is there anything else the PDP considers important in establishing their manufacturing strategy?