



# Contract Manufacturing Questionnaire **sypharma**

---

*Please complete the following questionnaire to ensure Sypharma can easily assess the ability to manufacture your product. Once completed return questionnaire and all relevant documentation and fax Attention: QA Manager on (03) 9706 4914 or download form on [www.sypharma.com.au](http://www.sypharma.com.au)*

## **Company Details:**

**Company Name:** \_\_\_\_\_

ABN Number: \_\_\_\_\_

Manufacturing Licence Number: \_\_\_\_\_

Company Address: \_\_\_\_\_

**Contact Name:** \_\_\_\_\_

**Contact Details:** \_\_\_\_\_

## **Product Details:**

**Name of Product:** \_\_\_\_\_

Type of Product (Human, Veterinarian or Biotech): \_\_\_\_\_

Is Product Registered with a Regulatory Agency? **YES / NO**

If so which Regulatory Agency? \_\_\_\_\_

Shelf life/Expiry of Product: \_\_\_\_\_

Pack Size/ Fill to Levels: \_\_\_\_\_

Dosage Form (Liquid, Powder, Suspension): \_\_\_\_\_

Type of Container/Packaging: \_\_\_\_\_

Is Product or any part of Product Sterile? \_\_\_\_\_

Type of Sterilisation (eg: Aseptic/Terminal Sterilisation): \_\_\_\_\_

Number of Batches per Year Required: \_\_\_\_\_

Preferred Batch Sizes: \_\_\_\_\_

Annual Volume: \_\_\_\_\_



# Contract Manufacturing Questionnaire

## Developmental Update:

- |                     |                          |                 |                          |
|---------------------|--------------------------|-----------------|--------------------------|
| Product Development | <input type="checkbox"/> | Pilot Batch     | <input type="checkbox"/> |
| Clinical Trial      | <input type="checkbox"/> | Stability Batch | <input type="checkbox"/> |
| Commercial Sale     | <input type="checkbox"/> | Final Product   | <input type="checkbox"/> |

## Product Formulation:

*Please provide a sample of the documentation being asked for in product formulation section.*

- |   |     |                          |    |                          |
|---|-----|--------------------------|----|--------------------------|
| Are manufacturing instructions available?       | YES | <input type="checkbox"/> | NO | <input type="checkbox"/> |
| Is Production Process validated?                | YES | <input type="checkbox"/> | NO | <input type="checkbox"/> |
| MSDS/Safety Data Sheets available?              | YES | <input type="checkbox"/> | NO | <input type="checkbox"/> |
| Are analytical methods available and validated? | YES | <input type="checkbox"/> | NO | <input type="checkbox"/> |
| Is stability monitoring necessary?              | YES | <input type="checkbox"/> | NO | <input type="checkbox"/> |

## Raw Materials:

Materials	Description (eg: Solution, Ointment or Powder)	Supplier	Testing to be performed by Sypharma	Acceptance Limit



# Contract Manufacturing Questionnaire *sypharma*

---

## Packaging Requirements:

Product Packaging Specifications: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Outline of artwork for Labelling and Packaging: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## General Comments:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## Disclaimer:

If, on the basis of your responses to the above questionnaire that Sypharma feels that they can satisfy your needs would you be prepared to enter into a Privacy Agreement in the first instance and then followed by a Technical Agreement? **YES**  **NO**

### *Managing Director*

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

### *Quality Assurance Manager*

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_