



RADPHARM
SCIENTIFIC

Tel +612 6251 6533, Fax +61262533325, info@radpharm.com.au www.radpharm.com.au

A division of Global Medical Solutions Australia Pty Limited

**CONTRACT MANUFACTURE
QUESTIONNAIRE**

To enable us to accurately assess our ability to manufacture your product, it would be appreciated if you could complete this questionnaire as precisely as possible. Thank you.

Orders will only be accepted on receipt of a completed and signed copy of this form.

General:

Name of company:

ABN No. (if registered in Australia):.....

Manufacturing Licence No: (If applicable).....

Does the Company have a formal Quality Management System? Yes No

If yes please state type of system. (eg. ISO 9000 or other)_____

Address/contact details:.....

.....

Contact name:

Contact email

Product Details:

Name and Type of product: (eg. Human Medicine, Veterinarian, Biotech)

Is the product registered /listed with a Regulatory Agency

Yes. No N/A

If yes state Name of Agency..... Approval Date: ___/___/___.

Expected annual volume (no. of units or bulk volume):

Number of batches per year and preferred batch size:

Stage of development: Product Development Pilot Batch
 Clinical Trial Stability Batch
 Commercial Sale Final product

Dosage Form: _____ Route of Administration: _____

Visual Identification: _____

Type of Container/Closure (Please provide details including drawings and dimensions if available)

Pack Size (fill volume /vial): _____

Sterility: (Is the product or any of its components supplied sterile?) Yes No

Type of Sterilisation: Aseptic fill Terminal sterilisation Gamma Irradiation Other.....

Shelf life/expiry:

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Formulation:

Manufacturing instructions available: Yes No
 If yes, attach information.

Is process validated (including autoclave or lyophilisation cycles if applicable) Yes No

MSDS/Safety Data Sheet available: Yes No

In-Process/filled product QC tests to be performed/organised by Radpharm Scientific:

QC Test Required	Acceptance Limits	Test Validated – Yes/No

List raw materials required (ie. API, excipients):

Material	Description (eg. powder, solution)	Supplier	Tests to be Performed by Radpharm	Acceptance Limits

Packaging:

Product packaging requirements (eg. labels, cartons, trays, etc):

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Artwork available for printed packaging: Yes No

GMP Agreement

Have you worked with GMP agreement in the past? Yes No

Do you have a GMP Agreement template? Yes No

Other Requirements or Comments

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Project Manager or Director

Name: _____

Signature: _____ Date: ___/___/___

Quality Assurance Manager or Director

Name: _____

Signature: _____ Date: ___/___/___

Regulatory Manager or Director

Name: _____

Signature: _____ Date: ___/___/___

After completion of Radpharm Contract Manufacture Questionnaire please fax to : 02 6253 3325