

Request for contract packaging and / or commercial services proposal template

Company name:

Contact name:

Contact number:

Project overview:

Provide a full summary of the project

Product(s) name:

Product classification:

Cephalosporin

Beta Lactam

Sex Hormone

None of the above

Product strength(s):

e.g. 20mg, 40mg

**Product Safety
Categorisation/OEL:**

Occupational exposure limit

Product substance origin:

Company & location

Business address:

Job title:

Email address:

Current phase:

e.g. pre-clinical, Ph I, Ph II, Ph III

Dosage form:

e.g. tablet, capsule, powder, liquid etc

HBEL (ADE / PDE):

Only required for primary packaging operations in a GMP facility – applicable to UK/EU based CDMOs

Manufacturing required?

Yes

No

Request for contract packaging and / or commercial services proposal template

Manufacturing process:	e.g. Roller compaction, compression	Tech transfer required?	Yes	No
Packaging type:	e.g. bottles, blisters, kit assembly	Serialisation required?	Yes	No
Packaging process:	Primary / secondary	Aggregation required?	Yes	No
Storage conditions:	e.g. room temperature, light sensitivity etc			
Artwork support required?	Yes	No	Artwork requirements:	e.g. improvement of existing wallet etc
Bulk input batch size(s)				
Finished goods batch sizes:	Anticipated batch sizes and volumes required			
Target markets & SKUs	Total number of markets you wish to launch your product into and number of SKUs per market e.g. Europe, USA, Asia etc			
Analytical work required?	Yes	No	Details:	e.g. method transfer
Stability required?	Yes	No	Details:	e.g. study design
Timelines known?	Yes	No	Details:	CDMO selection, kick off meeting
Preferred location(s):			PQ/PV Required?	Yes
				No
			Materials available?	Yes
				No

Request for contract packaging and / or commercial services proposal template

Proposal deadline:	Click to enter date	Details:	Detail urgent requirements
Application type:	N/A MAA NDA CBE30 IMPD/IND	Application submitted:	Yes No N/A
Submission date:	Click or tap to enter a date.	Expected approval date:	Click or tap to enter date
QP declaration required?	Yes No	Audit requirements:	e.g. drug substance / drug product etc
QP cert of bulk required?	Yes No	QP release requirements:	e.g. regulatory release (e.g batch certification, partial / full
CAPEX requirements:			
Forecast:	i.e. bulk forecast for manufacturing and primary packaging and forecast at SKU level for secondary packing		
Misc. information:	Capture additional, relevant information to support your enquiry		

Date of submission: Click or tap to enter a date.