

## Request for contract development and / or manufacturing proposal template

<b>Company name:</b>		<b>Business address:</b>	
<b>Contact name:</b>		<b>Job title:</b>	
<b>Contact number:</b>		<b>Email address:</b>	
<b>Project overview:</b>	Provide a full summary of the project		
<b>Product(s) name:</b>		<b>Current phase:</b>	e.g. pre-clinical, Ph I, Ph II, Ph III
<b>Product classification:</b>	Select an item: Cephalosporin Beta Lactam Sex Hormone None of the above	<b>Dosage form:</b>	e.g. tablet, capsule, powder, liquid etc
<b>Product strength(s):</b>	e.g. 20mg, 40mg	<b>Tablet/capsule fill weight:</b>	
<b>Product Safety Categorisation/OEL:</b>	Occupational exposure limit	<b>HBEL (ADE / PDE):</b>	<i>Only required for operations in a GMP facility – applicable to UK/EU based CDMOs</i>
<b>Drug substance origin:</b>	Company & location	<b>Excipient origin:</b>	Company & location / to be procured

<b>Manufacturing process:</b>	e.g. Roller compaction, compression	<b>Tech transfer required?</b>	Select an item: Yes No
<b>Batch size(s):</b>	e.g. 50kg, 100kg	<b>Packaging type:</b>	e.g. bottles, blisters, kit assembly
<b>Storage conditions:</b>	e.g. room temperature, light sensitivity etc		
<b>Total number clinical batches:</b>	Total volumes required e.g. 500kg, 1000kg		
<b>Analytical work required?</b>	Select an item: Yes No	<b>Details</b>	e.g. method development / validation
<b>Stability required?</b>	Select an item: Yes No	<b>Details</b>	e.g. study design
<b>Timelines known?</b>	Select an item: Yes No	<b>Details</b>	CDMO selection, GMP batch timelines
<b>Proposal deadline:</b>	Click or tap to enter date	<b>Details</b>	Detail urgent requirements

<b>Will API development and / or manufacturing be required?</b>	Select an item:  Yes  No
<b>Will clinical packaging, labelling and / or distribution be required?</b>	Select an item:  Yes  No
<b>CAPEX requirements:</b>	
<b>Audit requirements:</b>	e.g. drug substance / drug product / other?
<b>Misc. information:</b>	Capture additional, relevant information to support your enquiry