

## Custom Synthesis Request

Contact Date:

Customer Liaison:

Company:

Contact Person(s):

Phone:

FAX:

Address:

Compound Name:

Quantity Requested:

Desired Delivery Date:

Expected Price Range:

### Product Information

What is the product's application?

If the product is a bulk pharmaceutical, what is the target organ and route of administration?

What future projections, if any, exist for this product?

### Processes Eligible for Immediate Rejection

Could the manufacturing of the requested product involve the production or use of any of the following:

#### Carcinogens

4-Acetylaminofluorene	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4-Aminodiphenyl	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Benzidine	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Bis-Chloromethyl ether	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4-Dimethylaminoazobenzene	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3,3'-Dichlorobenzidine	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Ethyleneimine	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Methyl chloromethyl ether	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Alpha-Naphthylamine	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Beta-Naphthylamine	<input type="checkbox"/> Yes	<input type="checkbox"/> No
N-Nitrosodimehtylamine	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Propiolactone	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Cephalosporin?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Controlled substances?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Crown ethers?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Deoxyrubicin or deoxyrubicin HCl?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Hydrogen cyanide?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Mercury Compounds?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Polymer chemistry?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Pesticides or herbicides?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Penicillin?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Phosgene?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Selenium based compounds?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Is a CAS Number available? If yes, please provide	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Is an MSDS for the product available? If yes, please provide	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Is the compound reportable to TSCA? If yes, please explain below	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Has a PMN been filed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown

**Product Chemical Data**

Are there special handling requirements for this product, or is the product unstable under specific conditions? If yes, please explain below	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
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Is this product or any of its intermediates a known carcinogen or toxin? If yes, please explain below and give any available toxicology information	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
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**Product Synthesis and Specifications**

Is this product to be manufactured under a secrecy agreement?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Is a GMP synthesis required?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Will DMFs or other similar types of documentation be necessary? If yes, please explain below	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Has an in-house synthesis for this product been developed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If so, may we reference it?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Is this synthesis request literature based?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Do specifications exist for raw materials? intermediates?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> No
final product?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If yes, please provide			
Are there any packaging specifications?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

### Custom Synthesis Pre-Quotation Review

#### Processes Requiring Careful Consideration

Could the manufacturing of the requested product involve the production or use of any of the following:

Noxious sulfur based compounds?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Diazo compounds?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Sodium or potassium cyanide?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Generation of strong lachrymators or irritants?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Highly toxic reagents, intermediates, or products?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Known teratogens or mutagens?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Explosive-labeled compounds?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Compounds with strong biological activity?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Benzene?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
1,2-Dibromo-3-chloropropane?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Acrylonitrile?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Ethylene oxide?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Formaldehyde?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Methylenedianiline?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Department: Production

Comments:

Should the formal quotation process be started? Yes No

Prior to the formal quotation, should a separate quote for process development be issued? Yes No

No

Date:

Signature:

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Department: Engineering

Comments:

Should the formal quotation process be started? Yes No

Prior to the formal quotation, should a separate quote for process development be issued? Yes No

Date:

Signature:

In the event of a tie, the unanimous decision of Yes No was reached on \_\_\_\_\_.  
Director of Production Director of Engineering

## Final Quotation Review

Department: EHS Coordinator  
Comments:

- Accept as presented.
- Accept with noted modifications.
- Need to discuss listed concerns.
- Suggest that Regis terminate quotation.

Signature:

Date:

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Department: Production  
Comments:

- Accept as presented.
- Accept with noted modifications.
- Need to discuss listed concerns.
- Suggest that Regis terminate quotation.

Signature:

Date:

Department: Engineering  
Comments:

- Accept as presented.
- Accept with noted modifications.
- Need to discuss listed concerns.
- Suggest that Regis terminate quotation.

Signature:

Date:

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Department: Quality Assurance/Quality Control  
Comments:

- Accept as presented.
- Accept with noted modifications.
- Need to discuss listed concerns.
- Suggest that Regis terminate quotation.

Signature:

Date:

Signature:

Date:

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Department: General Manager  
Comments:

- Accept as presented.
- Accept with noted modifications.
- Need to discuss listed concerns.
- Suggest that Regis terminate quotation.

Signature:

Date:

# Quotation Log Sheet

PROJECT NAME \_\_\_\_\_

COMPANY \_\_\_\_\_

PRE-QUOTATION REVIEW IN: \_\_\_\_\_

DUE BY: \_\_\_\_\_

DATE REVIEWED

PRODUCTION \_\_\_\_\_

ENGINEERING \_\_\_\_\_

FINAL QUOTATION REVIEW IN: \_\_\_\_\_

DUE BY: \_\_\_\_\_

DATE REVIEWED

EHS \_\_\_\_\_

PRODUCTION \_\_\_\_\_

ENGINEERING \_\_\_\_\_

QUALITY CONTROL \_\_\_\_\_

QUALITY ASSURANCE \_\_\_\_\_

GENERAL MANAGER \_\_\_\_\_

COMMENTS:

Compound Cleaning Evaluation Review Sheet

PROJECT NAME \_\_\_\_\_

COMPANY \_\_\_\_\_

<p>EHS Comments:</p> <p>Proposed compound <input type="checkbox"/> may <input type="checkbox"/> may not represent a new "worst case" cleaning scenario. <input type="checkbox"/> No opinion</p> <hr/> <p>Signature _____ Date _____</p>	<p>Quality Control Comments:</p> <p>Proposed compound <input type="checkbox"/> may <input type="checkbox"/> may not represent a new "worst case" cleaning scenario. <input type="checkbox"/> No opinion</p> <hr/> <p>Signature _____ Date _____</p>
<p>Engineering Comments:</p> <p>Proposed compound <input type="checkbox"/> may <input type="checkbox"/> may not represent a new "worst case" cleaning scenario. <input type="checkbox"/> No opinion</p> <hr/> <p>Signature _____ Date _____</p>	<p>Quality Assurance Comments:</p> <p>Proposed compound <input type="checkbox"/> may <input type="checkbox"/> may not represent a new "worst case" cleaning scenario. <input type="checkbox"/> No opinion</p> <hr/> <p>Signature _____ Date _____</p>
<p>Production Comments:</p> <p>Proposed compound <input type="checkbox"/> may <input type="checkbox"/> may not represent a new "worst case" cleaning scenario. <input type="checkbox"/> No opinion</p> <hr/> <p>Signature _____ Date _____</p>	<p>General Manager Comments:</p> <p>Proposed compound <input type="checkbox"/> may <input type="checkbox"/> may not represent a new "worst case" cleaning scenario. <input type="checkbox"/> No opinion</p> <hr/> <p>Signature _____ Date _____</p>

Guidelines for evaluation purposes:

1. Compound is  similar  not similar to a previously manufactured product. If similar, list catalog# \_\_\_\_\_
2. Compound is  highly  slightly soluble in a known solvent.
3. Compound toxicity is known to be  $\geq 3.3$  mg/kg (inv. rats LD<sub>50</sub>)  
 $\geq 14.9$  mg/kg (inv. Mice LD<sub>50</sub>)

Project  accepted or  declined. If accepted, list catalog# \_\_\_\_\_