

# Accurate Quoting:

## How Your RFQ Can Lead the Way

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# Request for proposal (RFQ)

# What has been done?

# What needs to be done?

# Accurate Quoting

# Presentation Overview

- How your RFQ can lead the way
- Organizing the RFQ into six key sections
- Address your questions

# How can your RFQ lead the way?

# Thorough RFQ = Thorough Quote

- RFQ and quote initiate the project
- Accurate quote = accurate budget
- Comparing apples to apples
- Better to indicate as TBD than leave out



# Organizing the RFQ into six key sections

# Six Sections of RFQ

1. Basic project information
2. Analytical development
3. Formulation development
4. CTM Manufacturing requirement
5. Stability studies
6. Special handling requirements

# Basic Project Information

- Type of dosage form needed and strengths
- What is the indication
- What are your timelines and deadlines
- Company information and key personnel
- Known physical and chemical characteristics of the API

# Analytical Development

- Are there any methods available for the API
- Adapt existing method or all new development
- Any analytical method outside of the typical HPLC Assay, Dissolution, CU, Moisture, and MLT

# Formulation Development

- Any previous formulation development
- If so, would a tech transfer be sufficient
- If not, a full-scale formulation development including pre-formulation studies
- How many prototype strengths or formulations are to be considered. What is the tentative final strength(s)

# Manufacturing Requirement

## Phase I & II

- How many strengths and how many units
- Any matching placebos and how many units
- What type of packaging and labeling is required

# Stability Studies

- Specify stability study details for CTM: Conduct per ICH guidelines or something else
- Any optional testing or backup storage
- Bulk product stability or just packaged product

# Special Handling Requirements

- Is the API categorized as Potent, Cytotoxic, Controlled Substance
- Indicate if API is light sensitive, hydroscopic, etc.
- Provide MSDS if available



# Summary

- A thorough RFQ can lead the way to a thorough quote and an accurate budget
- Organizing the RFQ in six key sections can help provide critical information
- We are here to help, so contact Metrics Contract Services at
  - Phone: 252.752.3800
  - Toll-free: 1-877-638-7420
  - [metricsinc.com](http://metricsinc.com)

# Questions?