

The background of the slide is a dark blue gradient with several bright, glowing blue light streaks and arcs that create a sense of motion and depth. The text is centered and rendered in a clean, white, sans-serif font.

Selection of a Contract Aseptic Fill/Finish Manufacturer

While Avoiding Common Mistakes

By John Dobiecki, Vice President/GM Manufacturing MicroTest Laboratories

“Fill/Finish” is the Last Step of the Injectable Drug Manufacturing Process.

It's Characterized as:

- The Most Critical Step in Drug Manufacturing
- Being Highly Specialized
- A Key Rate Limiting Step in Getting Product to Market or Clinical Trials
- Subject to Extreme Scrutiny by Regulatory Agencies
- Costly

This Presentation Will Provide Some
Guidance About How to Select a Contract
Aseptic Manufacturer.

While the Focus is Primarily on Clinical Trial
Materials, Many of the Key Points Can Also
Apply to Commercial Products.

The Real Basis For This Presentation
Comes From Real World Experiences. Both
as a “Client” and as a “Contractor”

The ABC's of the Selection Process

- A. Request for Proposal
- B. Contractor's Statement of Work
- C. Site Visit
- D. Audit
- E. Selection

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Request For Proposal "RFP"

Minimally the RFP Should *Detail* the Following:

- Description of the Final Drug Product (FDP) and its Intended Use
- Complete Project Scope
- Proposed Manufacturing Sequence
- Listing of "Special" Considerations
- **When** the FDP is Needed
- Testing Requirements
- Shipping Details

The RFP is Where Most Common and Potential Timeline Killing Mistakes are Made

These Include:

- 📊 Overstating Any Process History
- 📊 Understanding of the Products Behavior
- 📊 Underestimating the Time it Takes to Transfer in the Process
- 📊 Not Thinking Through the Volume of Material Needed
- 📊 Realizing the Value of Performing an Engineering Run/Study
- 📊 Container/Closure Considerations

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The Contractor's Statement of Work (SOW)

- Formal Response to the RFP
- Should be Clear and Concise
- Provides a Good Indication as to the Contractor's Understanding of the Project
- Includes the Pricing for the Project

Common Client Mistakes Associated with a Contractor's SOW

- Failure to Notice “Additional Assumptions” Put in by the Contractor
- Misunderstanding the Pricing Model... Firm/Fixed, Time and Materials or a “Blended” Approach

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C. *Site Visit*

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Site Visit

- Performed Once the SOW has Been Reviewed and Deemed Acceptable
- Serves as a Formal Kicking of the Tires
- Provides Information to the Client on the Contractor's Capabilities and Fit

Critical:

If the Client's Lead Contact Person Hasn't Been Identified By the Client Up to This Point Now's the Time to Do It. Likewise, the Contractor Should Have Identified the Contact Person (Project Manager)

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Formal QA Audit

- Needed to Verify the Potential Contractor's Ability to Manufacture Under cGMPs
- The Audit Occurs When the Field Has Been Narrowed Down to Two or Three Candidate Sites
- It May Occur Concurrently With the Site Visit

Basic Audit Check List

- 📁 Company Overview
- 📁 Site Inspection History
- 📁 List of Registrations
- 📁 Key Personnel CVs
- 📁 Site Master Plan, Drug Master File
- 📁 Facility Tour
- 📁 Quality Manual Review
- 📁 Select SOP Review
- 📁 Training Record Review
- 📁 Audit of Select “Other” Documents

Audit *Faux Pas*

- Failure to Provide an Agenda Before the Visit
- Failure to Supply a List of Read Ahead Documents
- Conducting the Audit With Wrong Mix of Personnel
- No Formal Wrap-up/Audit Report
- No Expectation of a Formal Response From the Audited Company (*i.e.* Contractor)

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Selection Process

- Compilation of All Gathered Tangible and Intangible Information
- Level & Quality of Support
- Comfort With Contractor's Personnel

BIGGEST MISTAKE...

- Using Pricing As The Lead Decision Maker
 - Make Sure You Understand the Different Pricing Models and Services Being Offered

A Reputable Contractor Should Be Willing to Freely Discuss Pricing Models and Options

Lastly

Remember...

You Are the Product Expert and Owner!

But

The Contract Manufacturer Is a Process
Expert

*Listening and Working as a Team Will
Assure Project Success.*