An Industry Perspective

COMPLETENESS ASSESSMENT: FRIEND OR FOE?

Ed Vanderbeck, Senior Vice President of Sales
A full-service global developer of Active Pharmaceutical Ingredients.

- Established 1982 - 30+ years
- Headquarters - Woodbridge, CT
- Regulatory Office and Analytical Lab - Shanghai, China
- Sales Offices - Hyderabad, India and Freiburg, Germany

- Three C’s of Compliance
- 37 FDA Inspections since 2010 - all passed, 10 with zero 483s
- Our Focus: One World. One Quality.
Industry Trend - One World. One Quality.

1. Global Industry

2. EU Directive 62

3. Overseas FDA Inspection Notice

4. International Market. Local Inspection.

5. Completeness Assessment
Pre-Completeness Assessment

Time to Market

DMF Quality  Review Efficiency

Inconsistent GMP and DMF Quality
GDUFA Implementation - Completeness Assessment

Consistent GMP and DMF Quality Achieved
How to Speed DMF Approval

1. Submit in eCTD format

2. Submit at least 6 months prior to ANDA submission

3. Pay DMF fee and pass Completeness Assessment

4. Submit High Quality DMF to avoid deficiencies during full scientific review

5. Comply with GDUFA Self-ID and Facility Fee Requirements
Low Quality DMF Impacts

Fail Completeness Assessment
Delay in DMF becoming adequate
ANDA Refused-to-Receive
Delay in ANDA approval

Market Share Loss

High Quality DMF Impacts

Pass Completeness Assessment
Available for Reference
ANDA accepted to file w/o delay
Faster ANDA approval

Market Share Advantage
Average Time for Completeness Assessment to be Finalized

<table>
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<th>ANDA</th>
<th>FTF</th>
<th>Expedited</th>
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<td><strong>Average Months</strong></td>
<td>6.2</td>
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<td><strong># of DMFs</strong></td>
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<td>1</td>
<td>1</td>
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<td><strong>Shortest</strong></td>
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Completeness Assessment (Current Month & Cumulative View)
CA Disadvantages

1. Increase in API Cost.

2. More upfront work prior to DMF filing.

3. Incompleteness responses delay ANDA filing.

4. The market does not reward API suppliers for higher quality.
CA Advantages - Better Quality Industry

1. Weeds out bad factories or fly by nights.

2. Buffer time between DMF & ANDA submission.

3. Generic manufacturers have higher confidence DMF will not delay approval.

4. GDUFA fees assure 3Cs!

5. “Available for Reference” is good for business.

An Opportunity to Stand Out
What Does It Accomplish?

1. Increases Industry Integrity.

2. Decrease Hollow DMFs.

3. GDUFA Fees assure The Three Cs.

4. Leverage GDUFA improvements as competitive advantage.

The Main Goal: Factories prepared for inspection 365 days of the year.
ChemWerth Strategy on Global Quality

1. New products developed to cover global markets.

2. Design submission strategy with factory BEFORE product development.

3. Design product with CQAs meeting the designed markets.

4. Submit DMF, COS, CMC, etc. as designed strategy.
Wrap Up Summary

1. Increase FDA Work Force.

2. Higher Quality API Facilities.

3. Faster DMF Approval = ANDA Approval = Faster to Market.