The ChemWerth Advantage

Your guide to the API world

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The key foundation of ChemWerth's success is our full range of regulatory and compliance services. Our regulatory team manages documentation creation, review and submission while our compliance group manages our factory compliance programs, management and inspections. These are very important things to consider in the current state of the generic market. The Chemwerth motto is "First to quality, fast to market."

The below information was gathered from the FDA's Generic drug forum dated April 3, 2019.

Reported by FDA's LT Lauren E. Woodard, PhD.

"With the publication of Guidance for Industry, ANDA Submissions-Amendments to Abbreviated New Drug Applications under GDUFA, the deficiencies in the drug master files (DMF) may affect the major or minor category of ANDA amendments, which impacts an application's review goal dates."

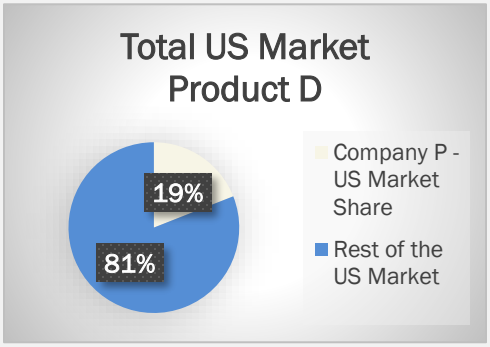
1. *"98% of DMFs being reviewed for the first time are found inadequate and issued a DMF CR letter."*
2. *"Most of these DMFs will receive two or three touches before becoming adequate."*
3. *"Reducing both the total number of review cycles and the time for response from the DMF holder is critical to increasing the chances for a first cycle ANDA approval."*

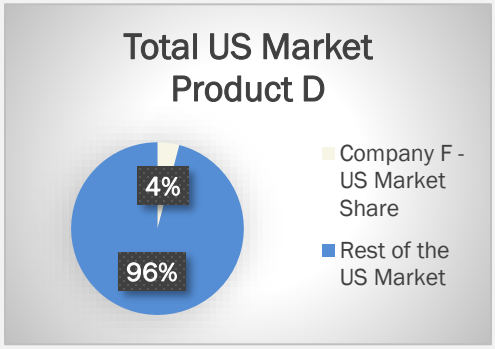
Is $46.5 million in top-line revenue important to you?

Consider the value of being the first ANDA to market. Below is an example of a real world ChemWerth success of being fast to market. **Company P netted $46.5 million more in revenue than Company F in 3 years; $25 million more just from being first to market.**

Company P – Product D	
T-1st Approval	
2014 IMS Data	$7,000,000
2015 IMS Data	$19,000,000
2016 IMS Data	$28,000,000

Company F – Product D	
3rd Approval	
2014 IMS Data	$0
2015 IMS Data	$500,000
2016 IMS Data	$7,000,000





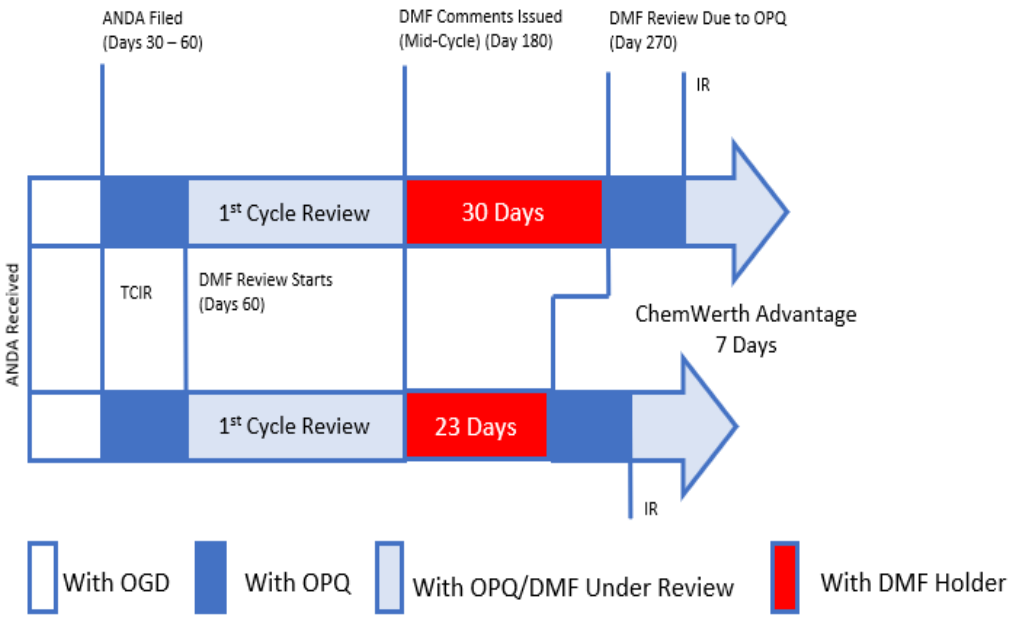
What was the difference? Efficient Cycle Reviews:

ChemWerth's average number of DMF review cycles is less than **1** cycle. For comparison: the industry average is **2.5** cycles. ChemWerth averages a first deficiency response time of **23** days; compare that to the average industry response time of **90** days for a first deficiency response.

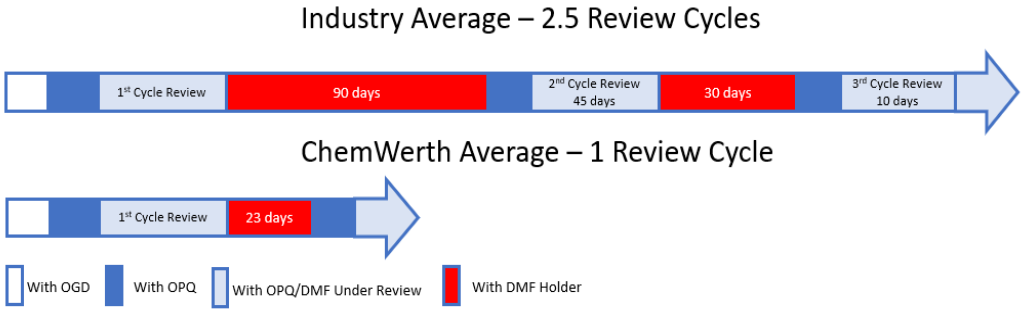
What you don't want:

- You don't want your API provider to submit their first DMF deficiency response in 90 days, then wait for FDA review. Then wait for another deficiency, then wait for that provider to respond, then wait on the FDA again, and so on.
- You don't want to add on 150+ days to your approval time waiting on your API supplier.
- You don't want to lose out on critical market timing because you work with a basic API supply company, *not* a full-service API organization like ChemWerth.

ChemWerth vs. FDA's "Best-Case Scenario"



ChemWerth vs. the competition



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ChemWerth has the ability to get you to market more quickly. We consistently exceed FDA and industry expectations in quality and compliance. **67** days faster for a one-cycle review; **202** days faster on average! That is the **ChemWerth Advantage.**

Locations

1) USA Headquarters:

1764 Litchfield Turnpike, Suite 202, Woodbridge, Connecticut 06525

2) Shanghai, China Regulatory Office & FDA approved laboratory:

20 Floor, BIO Building, No. 1326 YanAn Road (West), Shanghai, 200052, China

3) Hyderabad, India Office:

B-604, 6th Floor
The Platina
Near Radisson Hotel
Gachibowli
Hyderabad 500 032

Contact us at:
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Or call 1-203- 387-7794

"The ChemWerth difference is our commitment to quality and compliance 365 days of the year."

----Peter J. Werth, President and CEO

*Graphics based on data as reported at the Generic Drugs Forum on April 3, 2019 by FDA's LT Lauren E. Woodard, PhD