

MAKING EVERYBODY A WINNER!

NOT ALL YOUR CLIENTS NEED OUR HELP. HOWEVER, SOME DO!



THE CLIENTS YOU HAVE THAT NEED OUR HELP ARE HAVING A NEGATIVE IMPACT ON YOUR BUSINESS RIGHT NOW



WHAT ARE SOME OF THE NEGATIVE IMPACTS ON OUR BUSINESS?

The clients you have that need our help are currently:

- 1. A tremendous drain on your project revenue
- 2. Wreaking havoc with your operations team
- 3. Expecting more than can adequately be met
- 4. Undermining Project Management confidence and efficiency
- 5. Undermining operational excellence and increasing the potential for errors
- 6. Increasing your regulatory risk



A TREMENDOUS DRAIN ON YOUR PROJECT REVENUE

- Project Manager contact time is greatly increased
- Project support staff time is increased following up on poor client documentation practices
- Lost time due to client review requirements and responding to multiple client reviewers
- Lost time due to numerous false starts and premature starts
- Increased amount of re-work due to poorly understood expectations and client pressure



WREAKING HAVOC WITH YOUR OPERATIONS TEAM

- Unclear scientific direction can:
 - Waste time at the bench and cause re-work
 - Produce misleading results
 - Create endless feedback loops in method development and/or method validations
- Tremendous client pressure to start projects prematurely can waste time and resources which could have been spent on other client projects



EXPECTING MORE THAN CAN ADEQUATELY BE MET

- The client is always right and the CRO is ALWAYS to blame, and the word spreads like wildfire
 - Our method works, you just don't know how to run it!
 - We don't need long term stability or incurred sample reproducibility!
 - We don't like the results you are giving us. Repeat the assays!
- It is hard to give clients what they want when they don't know what they want!



UNDERMINING PROJECT MANAGEMENT CONFIDENCE AND EFFICIENCY

- The clients who need our help will take a toll on your staff
 - They demoralize staff
 - Wastes the time of very busy, very smart staff who would rather be working with clients who appreciate their efforts
 - When you are always told you are wrong, you may start to believe it
- The clients who need our help will often make their own staff assignments.



UNDERMINING OPERATIONAL EXCELLENCE AND INCREASING THE POTENTIAL FOR ERRORS

- Everyone in operations will come to know the client who needs our help.
- If your staff are not properly protected from this client, if the stress produced by this client are not contained in a healthy way errors will blossom into existence and dominate the project



INCREASING YOUR REGULATORY RISK

- Working with clients who need our help will
 - increase the occurrence of errors made by your wellmeaning staff
 - decrease the likelihood of your staff catching the errors made by this client
 - likely create an environment where the Project Manager makes poor regulatory decisions
- Working with clients who need our help will put your organization at regulatory risk!



WHAT CAN BE DONE WITH THE CLIENT WHO NEEDS STUBBS & HENSEL?

- Charge this client a premium.
- Increase the per sample cost.
- Increase the amount of time upper management spends helping to manage these clients.
- Continue to lose money and demoralize your staff.



TRY A WIN, WIN, WIN SOLUTION

- When you first recognize that you have a client that could use our help, recommend Stubbs & Hensel.
- If they do work with Stubbs & Hensel, we will take on the burden of educating, forming and managing expectations. We will communicate with and guide them. We will form the interface between your Project Manager and their staff.
 - More about this in a moment.....



HOW DO WE APPROACH OUR CLIENT WHO NEEDS YOUR HELP?

- Our assumption is that by this time both you and the client are unhappy with the service they are receiving even when the root cause of the service failure is from the clients inexperience.
- It is easy to approach the client with a genuine desire to help them to be successful
 - Acknowledge service failures and relationship issues
 - Suggest that they consider looking into our services as a way to quickly get things back on track
 - Stubbs & Hensel will extend a discounted rate for such clients



HOW STUBBS & HENSEL HELP YOU AND YOUR CLIENTS

- Planning and execution of bioanalytical studies from late phase discovery through FIH to Development with the client
- Interface directly with your staff
- Assure that you receive critical reagents and documentation
- Assure rapid and accurate information regarding timing of preclinical and clinical sample shipments
- Work with your CRO scientists to establish non-GLP and GLP analytical methods
- Assure that all methods are developed and validated for their intended use and meet pre-established performance criteria
- Review all scope-of-work documents, development and validation plans, and all data generated
- Review IND, NDA, BLA submissions
- Prepare and deliver summary progress reports for these clients who need our help



QUESTIONS?