DuVal Client Alert

Passing on Tribal Knowledge of FDA Law

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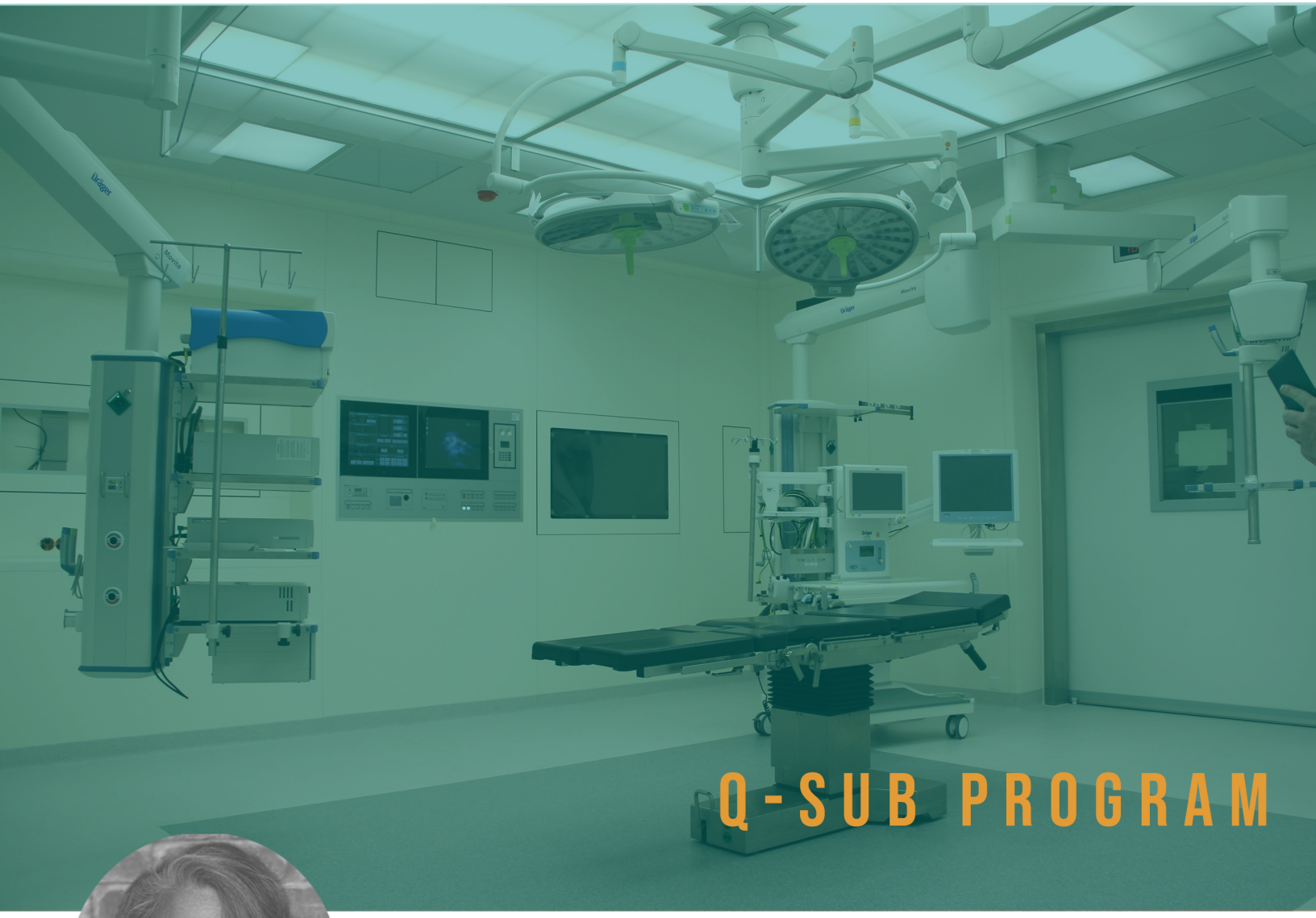
2021 Retrospection Highlight



Lisa Pritchard, BSEEE

Vice President of Regulatory, Quality,Clinical & Engineering

Q-Sub Program

In January 2021, FDA updated its Q-Submission Program that provides for many types of interactions with FDA. For our clients, Pre-Submissions (Pre-Subs) and Submission Issue Requests (SIRs) have been the most popular and useful type of Q- Submissions.

Pre-Subs can be very helpful to de-risk an IDE or commercialization (e.g., 510(k), De Novo, or PMA) submission. We have found these to be most valuable for obtaining feedback on proposed testing (bench or animal) or clinical study designs. We have seen an increase in the FDA suggestions for use of the Pre-Sub program. Unfortunately, this has also resulted in an increase in the amount of time that it can take to be granted a meeting (70-75 days for most groups within FDA). This should be planned for within the development timeline and strategic decision of whether to engage in a Pre-Sub or how often. Pre-Subs currently are not associated with any user fee. As a result, if they are well done, and ask provocative questions without giving FDA a blank check upon which to write down their wish list (which invariably is much longer than you would want or should be necessary), these can be very helpful in a US commercialization strategy. ***A key challenge that we have seen with this program over the past year is the increase in time to hold the meeting, and undisclosed prohibitions on accepting them within some divisions (e.g., OHT-7) due to excessive continued workload demands due to COVID-19.*** We are hopeful that 2022 will gradually return to a sense of normalcy with this program. Note that at this time, all meetings continue to be held remotely with no visibility to a return to in person meetings in the FDA White Oak facility. Details of how to be successful with this program are discussed in detail in our three-part Client Alert series Navigating the Strange Pre-Sub Experience.

Submission Issue Requests (SIRs) are the other popular Q-Submission type. ***SIRs provide an opportunity for obtaining feedback related to requests for additional information that may be received during a submission review.*** The content of these submissions is very similar to the Pre-Sub but is focused

on the additional information requests and the proposed response strategy. Our experience has indicated that if an SIR is submitted within 60 calendar days of receipt of the AI request, FDA has been faithful about scheduling the SIR meeting within 21 days of receipt of the request. If the SIR is received more than 60 days after the request, then the standard scheduling of about 70 – 75 days applies. This should provide a strong motivation to, whenever possible, get the SIR submitted within the first 60 days.

For 510(k) submissions, the strategy for the timing of an SIR request should also consider whether a Least Burdensome Flag (LB Flag) may need to be submitted. The LB Flag is an opportunity for an informal appeal. The deadline for submission of an LB Flag is 60 calendar days after the additional information letter is issued. The LB Flag also requires that you have tried to resolve the issue with FDA before submission. This is often done through the SIR. If an LB Flag may be needed, the SIR should be submitted no later than about 20 – 30 days after receipt of the additional information request to allow time for the SIR to be held, and if necessary, the LB Flag prepared and submitted within the 60-day window. At the present time, the LB Flag is only available for 510(k) submissions, so this is not a factor for IDEs, De Novos or PMAs. ***We urge FDA to consider expanding the LB Flag program to encompass other submission types, and to allow a larger window within which to submit them (such as any time within the review process).***

DuVal & Associates
Drug, Device and Food Law

DuVal & Associates is a boutique law firm located in Minneapolis, Minnesota that specializes in FDA regulations for products at all stages of the product life cycle. Our clientele includes companies that market and manufacture medical devices, pharmaceuticals, biologics, nutritional supplements and foods. Our clients range in size from Global Fortune 500 companies to small start-ups. As one of the only dedicated FDA regulatory law firms in the United States, our mission and absolute focus is providing our clients appropriately aggressive, yet compliant, guidance on any FDA related matter. We pride ourselves not only on our collective legal and business acumen, but also on being responsive to our client's needs and efficient with their resources. DuVal & Associates understands the corporate interaction between departments like regulatory affairs, marketing, sales, legal, quality, and clinical, etc. As former industry managers in the drug and device spaces, we have been in your shoes. Our firm has extensive experience with government bodies. We understand what it takes to develop and commercialize a product and bring it successfully to the market and manage its life cycle. Impractical or bad advice can result in delays or not allow for optimal results; while practical, timely advice can help companies succeed.

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