

GRAHAM PARTNERS 2018 ANNUAL IMPACT AWARD NOMINATION FORM

Name of NomineeCompany NomineeJob Position / TitleYears with the company:Thanh TruongMedbio, LLC.Senior Quality Engineer~5 years

Where did the individual make an IMPACT on key business priorities? Please be as specific as possible (e.g. increased sales, improved customer engagement, improved cost position, etc.):

Thanh has demonstrated a strong interest in the regulatory-affairs realm, and coupled with her drive, her attention to detail, and her great intellect, she has been extremely helpful in the improvements we've made to the Quality Management System (QMS) over the past two years.

Because our organization is audited approximately 15 times a year, with new customers being added regularly to the list, it is very important that our QMS be up to date, and able to withstand the rigors of these customer audits. It is imperative to have one or more individuals in our company proficient in the details of FDA and ISO regulations, who can ensure we're in compliance, and Thanh has shown herself to be more than competent in this role.

What actions, qualities or characteristics distinguish this nominee?

Thanh has a level of dedication to Medbio that few exhibit; when she agrees to take on a project, you can count on her getting it completed, and in a way that often exceeds expectations. She is incredibly intelligent and understands even complex subjects quickly, and is able to explain the concepts to others in a way that is meaningful, and her memory for conversations and facts is also exceptional. She is truly a supervisor's dream, and is recognized by all in the company as a standout employee.

Provide a brief description of the specific contribution(s) made by this person and its impact (please utilize specific statistics/supporting quantifiable information if applicable):

Specifically, Medbio upgraded to the 2016 revision of ISO 13485 in 2017, and Thanh was instrumental in developing the initial Gap Analysis and in making many of the necessary modifications to the affected SOPs. She created the procedure for Software Validation through extensive research of FDA guidance and other case studies, and performed training of our staff. The ability to complete our upgrade with minimal audit findings was in large part due to Thanh's support throughout all of 2017, and beyond.

Additionally, she has taken ownership of several improvement projects, such as converting our CAPA system into our ERP, performing the corresponding software validation, and training all of the affected employees. Her help with the software validations and associated risk assessments has also been extremely helpful during our extreme growth period. It is difficult to quantify her contribution, but suffice to say that we would likely not have been able to achieve our ISO upgrade, and handle six customer audits with a total of only one minor finding (in Q1 and Q2 of this year), without the knowledge, efforts, and concern shown by Thanh Truong over the last two years. She is an exceptional employee, and everyone at Medbio regularly verbalizes how important she is to our success.

Your Department / Title Your Telephone Number Email Address
VP – Quality/Regulatory (616) 245-0214 x114 Email Address
JS@medbioinc.com

Sincerely,

Joe Szyperski

PLEASE SUBMIT NOMINATION FORMS, ALONG WITH EMPLOYEE PHOTO, TO JSHERMAN@GRAHAMPARTNERS.NET BY SEPTEMBER 5, 2018*