I-P-DP Transcript

Hi, my name is Laura Moussa and I'm a reviewer on the Animal Bioengineering and Cellular Therapies (ABCT) Team. I am going to demo how to use the Durability Plan Technical Section template in eSubmitter. Before we get started, please note that if you have any broad questions (e.g., what type of submissions are needed for your product), then you can send your inquiries to AskCVM@fda.hhs.gov. That will be routed to the appropriate person within the Center. You can also reach out to our project management team. If you have any issues with eSubmitter itself and require technical help, then you can email CVMeSubmitter@fda.hhs.gov. If you have any questions during the presentation, please put them into the chat box and I will be answering them at the end.

Once you open eSubmitter, to open a new submission, you want to click on the left-hand side of the screen under Menu Options: the button called "Create New Submissions". For traditional products, we have used the "ONADE Submissions" template set. For any product that is designed to go to the ABCT Team, we have our own set of templates. You will need to select the "ONADE Animal Bioengineering and Cellular Therapies Submissions" set of templates. There is a description that shows what types of products are appropriate for these templates. Then you click next, input a descriptive name and a file name, and click "Create".

For the rest of this demonstration, we will be working in the eSubmitter test environment because our ABCT templates are still under development. This means that they will not be available on the eSubmitter on your computers after this demonstration. They should be available on October 1, 2018. To access the template, I'm now switching over to our test environment.

On the first screen, you will need to identify the "Document Type" as an investigational new animal drug (INAD or I). You will need to identify the product category; there are four checkboxes that you can simultaneously click, and usually only one product category will apply [intentionally genetically altered (IGA) animals, cell-based products (including stem cells), gene therapy products, or other; other products could be combination products, new types of products, or anything that doesn't fit into one of the first three categories]. After you've designated the product category, we ask you to describe the product and identify whether or not the animal comes from a food-producing species. If you click "Yes", you will be prompted to tell us whether or not the animal is intended to enter the food supply. If you click "No", the sub-question will go away. The final question will ask "Is this submission for a currently established file or application?". Since this is a technical section, you will click "Yes" and you will be prompted to input your file number.

The next screens are for administrative information. On Screen 2.0, you are requested to input information about who owns the file, whether it's a US institution, and then contact information. On Screen 3.0, you are requested to identify the Responsible Official and choose their role (institution/company representative or regulatory agent) as well as input contact information for that person. On Screen 4.0, you will input information regarding who is putting the information into eSubmitter, including contact information.

On Screen 5.0 "Submission Type Code", you will select "Major Technical Section (P)" as the INAD submission type and "Durability Plan" as the submission classification code. Next you will select the review division; it should be coming into the ABCT Team. The final question is "Is this information intended to amend a submission currently pending and under review by CVM?" The very first time that you submit your durability plan to CVM, you would click "No".

In the case that you receive communication from the Center asking for additional information to be submitted, you would then select “Yes”, and subsequent questions would pop up.

Now we’re into the Durability template. There is an outline of all the screens in the template on the left-hand side. In Screen 1, you are able to select whether you are submitting the durability assessment, the durability plan, or both. What you select here will determine what populates the rest of the template. If you uncheck the assessment, then the associated screens gray out in the outline. Next is a field to input the summary of the information provided in the submission. If you click on the notepad icon, then you can see the maximum number of characters allowed in the field. You are also able to attach a cover letter; you can see by the absence of the blue dot that this is an optional question. It is often helpful for a reviewer to have that though.

On Screen 2, we are asking what type of letter you are seeking from the Center. If you are submitting only the first piece, then you would select “Submitted Information Acceptable; Technical Section Incomplete”. If you are submitting both pieces simultaneously or you are submitting the final piece, then you would select “Technical Section Complete”. The next question is whether or not this is in response to an incomplete letter. If you have previously submitted this information and received an incomplete letter, you would click “Yes” and that will populate some sub questions asking about the incomplete letter. Also, all the subsequent sections will become optional to allow you to answer only the questions that are associated with the incomplete letter comments. If you click “No” and the sub-questions go away and all subsequent screens are required.

In the **Genotypic Assessment section**, Screen A is the Referenced File Node. This node is included in multiple sections, so I’m only going to go over it the first time and then I will skip it in subsequent sections since the same questions and business rules apply in every instance. If you’re using information that’s in another file to support the information in this section, then you will be prompted to input that information here and provide the submission number(s). As you can see in the help text, the submission numbers must begin with a character (V for VMF, I for INAD, N for NADA, or G for General Correspondence) followed by six digits in order to be validated by the system. The next question asks you to provide a summary of the information in the referenced file(s).

In Screen B, we get into the meat of the genotypic assessment questions. We ask that you input a summary of the genotypic assessment information, state the number of generations/cohorts/production lots for which data is provided, as well as the number of animals per generation/cohort/lot. The subsequent questions allow you to attach the file(s) for study report(s), data file(s), and study method SOP(s). For any SOPs, you will be asked for validation information and specifications if that information is available, but these are not required questions.

In the **Phenotypic Assessment section**, Screen A is the Referenced File Node (see above). The second screen asks the same questions as for Genotypic Assessment (see above).

In the **Durability Plan section**, Screen A is the Referenced File Node (see above).

In Screen B, you can input the durability plan title, provide the finished product specifications, and provide the testing method overview and SOP (either as text or as files). You will also provide an overview of the sampling plan, including justification for how the

plan is setup. Finally, we have a catchall additional information question to capture anything else you want to tell us in this section.

Screen C deals with out-of-specification (OOS) results. We ask for a commitment to investigate any OOS results as well as the procedures for the OOS investigation and for the documentation and implementation of the corrective and preventative action (CAPA). The final question is the catchall additional information question.

Screen D deals with the post-approval reporting framework. You will need to provide the plan as a table (preferably as an attachment) with a summary (in the text field). You will also summarize the type of information that you expect will be included in your annual reports and in your periodic drug experience reports. You will also provide information that will be included for the Facility Registration/Drug Listing and in any adverse event reports. The final question is the catchall additional information question.

On Screen E, you will provide a summary of the contingency plan that is put in place in case of catastrophic circumstances (any information that is available at the time of submission) and you can also include any additional information in the final question.

There were no questions during the session.