US ERA ARCHIVE DOCUMENT

MODULE 2. QA PROJECT PLAN TEMPLATE

This module (Athe Template®) provides the framework for the QA Project Plan for your project. The Template contains a brief description of the information to include in each section (provided as a *NOTE* at the beginning of each major section), placeholders targeting specific input in various subsections (set off by << >>), and example text and/or subsection structure to consider in a few of the sections. Example tables, figures, and/or appendices are provided to demonstrate optional ways to present some of the information.

(Note: It=s important to remember that *italicized* information included in each *NOTE* was provided for guidance only and, therefore, needs to be deleted from the finalized QA Project Plan generated from this Template. Likewise, the specific input targeted and set off by << >> should be replaced with the information requested. Any example tables, figures, etc. contained within the Template that are not pertinent to your project should be deleted from the finalized plan.)

The Template follows the same organization structure (that is, the same main section titles and numbers) as the Guidance and the Model QA Project Plan provided, respectively, in Modules 1 and 3. It is recommended that you review the information presented in these other modules prior to and/or in conjunction with the associated section of the Template before completing the Template and writing your QA Project Plan. They provide significantly more detailed information and guidance for developing and documenting your plan. Additional supporting information is also available in the references and links in Module 4, the example standard operating procedures (SOPs) in Module 5, and the guidance on selecting a laboratory in Module 6.

It is not required that you use this Template or follow it exactly. Instead, it is provided as an option and example to document the types of information needed in your QA Project Plan. The closer your QA Project Plan follows the basic structure, the easier it will be for the information to be found during the review and approval process.