**Regulatory Guidance – Template Numbering**

Fifth and sixth level subheading numbering should be avoided within a document. Thus, the Artos templates are built with subheadings that do not include the module number within the numbering string. For more information on eCTD numbering please see:

• M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use Guidance for Industry: <https://www.fda.gov/files/drugs/published/M4-Organization-of-the-Common-Technical-Document-for-the-Registration-of-Pharmaceuticals-for-Human-Use-Guidance-for-Industry.pdf>

**Regulatory Guidance informing Module 2.3:**

• Guidance for Industry - M4Q: CTD — Quality

<https://www.fda.gov/media/71581/download>

A discussion of the information and data from 3.2.P.2 of Module 3 should be presented. A tabulated summary of the composition of the formulations used in clinical trials and a presentation of dissolution profiles should be imported directly, where relevant. Note: A separate section 2.3.P should be provided for each dosage form. For example, for a second dosage form, the sections would be labeled 2.3.P [name, dosage form 2].

2. PHARMACEUTICAL DEVELOPMENT [{DRUG PRODUCT NAME}, {DOSAGE FORM}]