Package Insert Conversions Using Topic-Based Writing

Bridging the Gap Between Engineering & Technical Writing

Emily M. DeBusschere

California Polytechnic State University, San Luis Obispo

Dr. David Gillette

Dr. Michael Haungs

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Package Insert Conversions Using Topic Based Writing

Traditional word processing programs, at least for large companies managing controlled documents, are becoming obsolete. The next leap in the field of Technical Writing is employing Content Management Systems (CMSs). According to a Vasont Systems reference guide, content management is the process of organizing and consolidating content such as text and graphics. The organized content can be reused for many publications and tagged using markup languages like XML or HTML (Vasont Systems, n.d.). Each concept or topic created in a CMS can be referenced by multiple publications and allows for global changes. This eliminates the waste of having nearly identical material in different documents where it should be consistent (for example, a legal page or procedure). It also removes the tedious work and hassle of ensuring all instances of reused content are changed when edits are required.

Application/Product

At Cal Poly, through the Liberal Arts & Engineering Studies program, I specialized in Industrial Engineering and Technical Writing. For this senior project, I applied interdisciplinary skills to transfer four of Cepheid's FrameMaker package inserts into an Extensible Markup Language Content Management System (XML CMS) called Vasont *Inspire*. The end objective of this conversion project is to cut down work time, allow for easier peer-review, prevent duplicate or rework, maintain industry standards, and optimize the translation process. By attending trainings, completing tutorials, and seeking counsel from experienced technical writers, I built up a working knowledge of Vasont *Inspire*. Cal Poly's "Learn by Doing" motto was constant reassurance as I made mistakes and troubleshooted errors. This report is a synthesis of the PIC Project: Package Insert Conversions using Topic Based Writing.

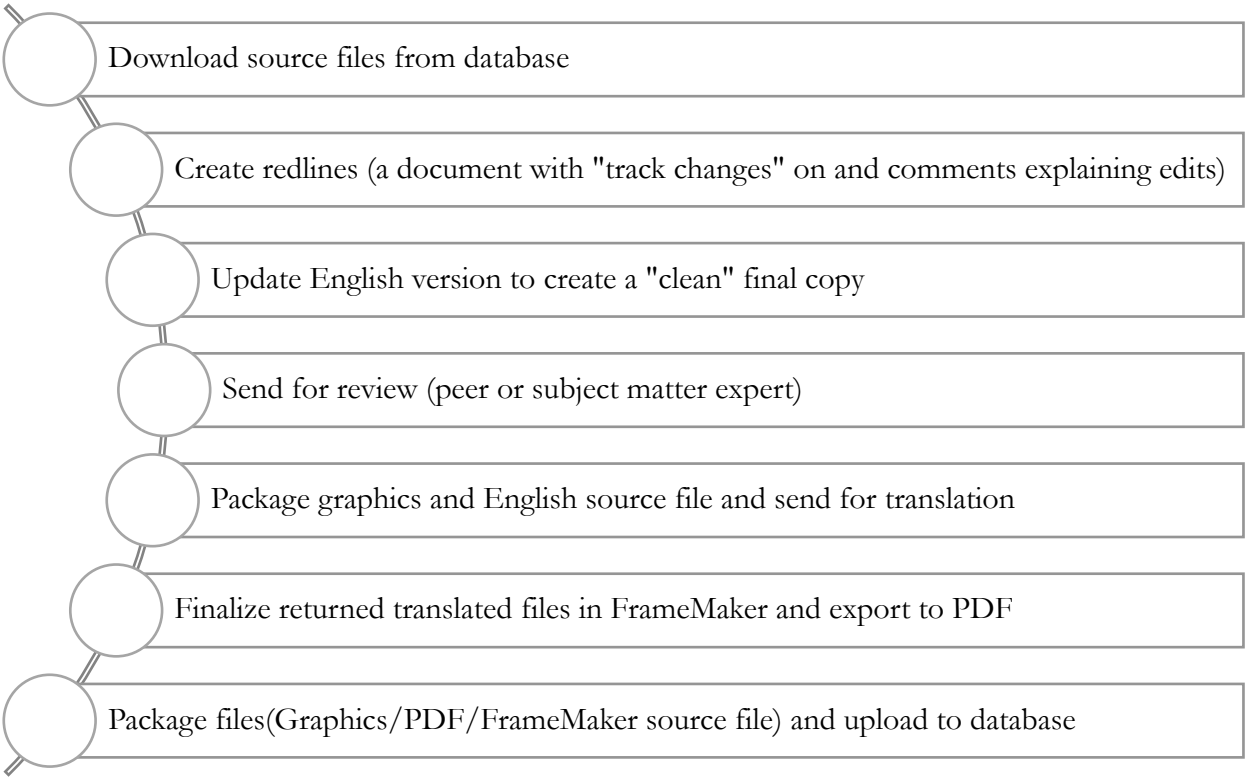
Background: Cepheid & Technical Publications

Cepheid, headquartered in Sunnyvale, CA, has established itself as a global molecular diagnostics company. Their initial claim to fame was their defense role after the 2001 terror attacks; they developed rapid detection units to screen for Anthrax. Cepheid has since returned to the healthcare industry in producing machines and "lab in a bottle" type cartridges that have "multiple clinical applications such as healthcare-associated infections, sexual health, critical infectious disease, virology, and oncology" (Cepheid, 2021). Their technology exists in hospitals around the world and smaller units are deployed in remote areas of developing countries. Rapid results are critical to patient care and Cepheid scientists have worked incredibly hard in order to bring test times down to as low as thirty minutes.

Earl Boggs, Senior Manager of Cepheid Technical Publications, provided a clear and concise description of the department's role: "Technical Publications produces and delivers Cepheid's Product Labeling and end-user instructions in the form of Package Inserts, Operator's Manuals, Service Manuals, Training Materials for Field Applications, Installation Procedures and Handbooks for Distributors. These publications follow style guides and meet FDA regulations and/or CE mark specifications." Because document maintenance of such a wide range of publications becomes progressively more difficult, many companies have turned towards Content Management Systems (CMSs) to organize documents and to simplify and streamline the process.

Design

Adobe FrameMaker is a robust, yet traditional, word processing program. All Cepheid package inserts are created and maintained in FrameMaker. The standard procedure for updating a package insert is summarized in the infographic below.



Identified issues

An analysis of the current process revealed several issues with the current package insert process. It is cumbersome and time-consuming to do even minor updates such as change the revision letter, release date, and copyright year. Furthermore, many sections between different package inserts are nearly identical with only slight grammar and phrase differences. The amount of exports, uploads, and emails it takes to conduct a peer review with a subject matter expert or colleague is problematic and leads to writers dreading the process or forgoing it altogether. Cepheid Technical Publications encountered instances where multiple writers were working on the same publication. This uncoordinated work causes delays, errors, and frustration and often leads to rework. Finally, FrameMaker and other common word processing programs are becoming outdated and further points to a critical need for change in technical publications departments.

Time study

I conducted a preliminary time study by screen recording myself working through the current process. The number of documents in a package insert set is growing since the number of languages necessary is increasing rapidly. I chose to monitor time while working on a package insert that required an English version, redlines, and 9 translated files (11 different FrameMaker documents total).

Task	**Time**
Download documents, create redlines and English final file	1 hour
Update translated files	3 hours
Upload files and archive to shared server	0.5 hours

When all of Cepheid's documentation resides in the CMS, and these standards updates can be made within the CMS, this data will help prove the anticipated improved efficiency of using the new system.

Solution: Content Management System (CMS)

CMSs revolve around reusable content and offer technical writers a way to link one source topic to many different documents. In response to the growing number of documents and subsequent translated files, Cepheid determined a solution that developed into the basis for this senior project: move documents into Vasont *Inspire*. *Inspire* is a web-based Extensible Markup Language (XML) Publishing System and is now Cepheid's CMS. The software uses include content editing and development in XML, real-time collaboration and review, and a more integrated translation process.

Example scenario: Suppose the wording on the legal page on every package insert needs to be changed. Traditionally, it would take a very long time to update all documents in the set (approximately 5 hours for a package insert set with only 11 files, as outlined in the time study). With a CMS, all documents ideally reference shared content, therefore, changing the wording in the original warehouse file (once per language) will change all connected documents automatically.

Project management

I worked with my manager to create an acceptable work timeline for completing the PIC Project. The schedule and scope underwent many adjustments to accommodate roadblocks to progress. Most of the first quarter of senior project was dedicated to planning and preparing for the actual transfer work. This involved determining the number of and which package inserts were to be converted and acquiring the basic skills to work in *Inspire*. The first conversion spanned approximately one month, with the close help of more experienced writers and XML experts. The remaining three conversions averaged approximately one week each to complete.

Implementation

Process & Reproducibility

This section outlines the process of converting an Adobe FrameMaker document into the Vasont *Inspire* CMS. See Figure 1 through Figure 10 in Appendix B for details.

- Export FrameMaker document to a PDF and to a Microsoft Word file for original format reference and content copying
- Create a folder in *Inspire* that will house all subsequent topics
- Create a bookmap from the correct template (package insert, manual, etc.)
- Fill in fields for the front cover (See Appendix A for the quick reference guide: “Setting Up the Front Cover” by Nathaniel Lim (Cepheid Technical Writer)

- Create a new component: concept, topic, or task (these correspond to the different sections in the source document being converted)
- Create a concept called “variables”
    - Items tagged as “phrases” with an ID in this topic will become content references for future use in the document
        - Include the proprietary assay name and common assay name
- Copy/paste content into *Inspire*
- Tags and references
    - Toggle view full tags if not already selected
    - Tag content properly (see common tags below)
    - Add any content references or cross references
- Bringing it all together
    - Open the bookmap
    - Append child
    - Reference concepts, topics, and tasks (numbering of headings and subheadings is automatic based on location in bookmap)
- Publish Custom PDF
- Open in Acrobat and add standard PDF settings

Common tags and things to know	
	Paragraph
   list item 	Ordered (numbered) list with “li” tags for each list item
   list item 	Unordered (bulleted) list with “li” tags for each list item
  <u></u> 	Bold Italic Underline Subscript Superscript
<lines></lines>	Similar to a soft return; good for use in tables when there are two or more lines per cell
<thead></thead>	Table header
Con ref: content reference	Reference a phrase variables folder or the shared variables warehouse for items like assay name, operator manual titles, table of symbols definition
Cross ref: cross reference	Create links within the document; clicking on the text “Figure 1” will take the user to Figure 1, clicking on the text Section 17.2 will take the user to Section 17.2.

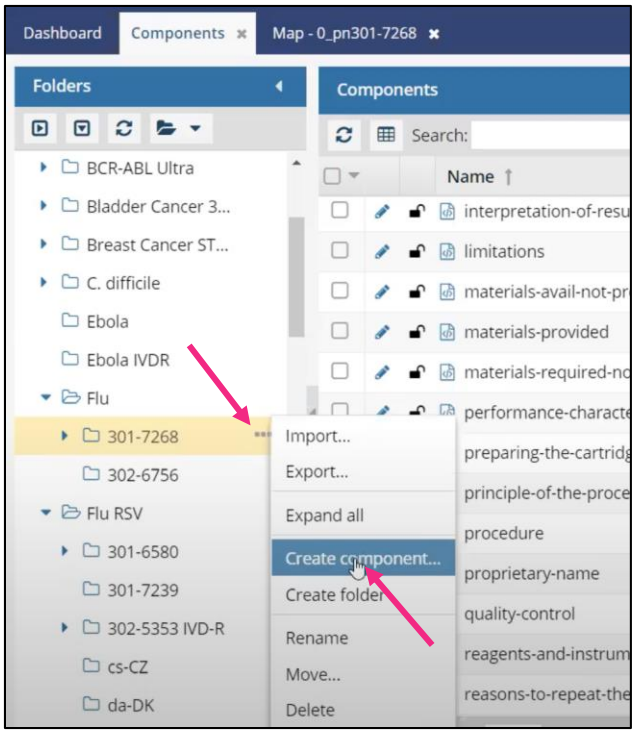
Conversion example using “Overall Results – NS Swab Specimen”

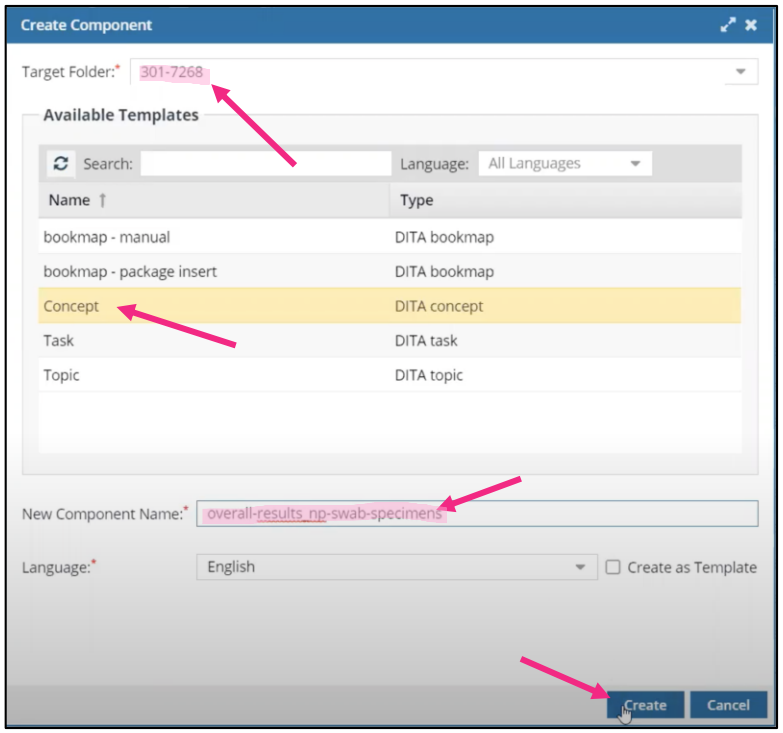
The following ten pages provide a detailed walk-through of moving a section from a FrameMaker document into Vasont *Inspire*. The section “Overall Results – NS Swab Specimen” is a great learning example because it is relatively short compared to other sections, includes content references, cross references, a table, and several different types of tags. It also provides an opportunity to demonstrate the effectiveness of editing a document in the XML editor rather than in the author view to save time.

Example: Converting section “Overall Results – NS Swab Specimen

Step 1: Create a new component

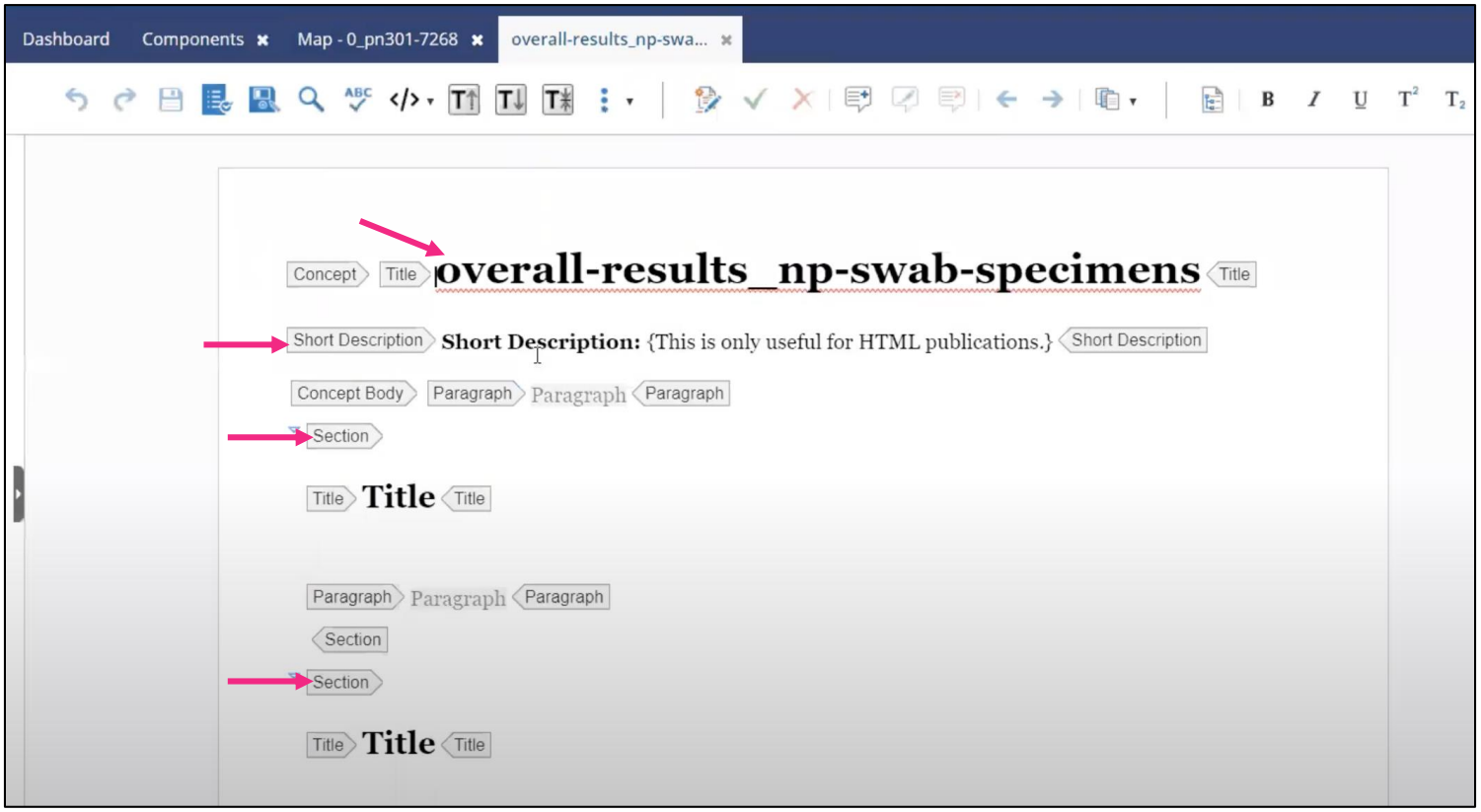
Navigate to the desired folder (301-7268) and click the three dots next to the folder name. Select **Create Component**.
The **Create Component** dialog box appears.
Verify that the target folder is correct. Select **Concept**. Enter new component name (lowercase letters, no spaces). Click **Create**.



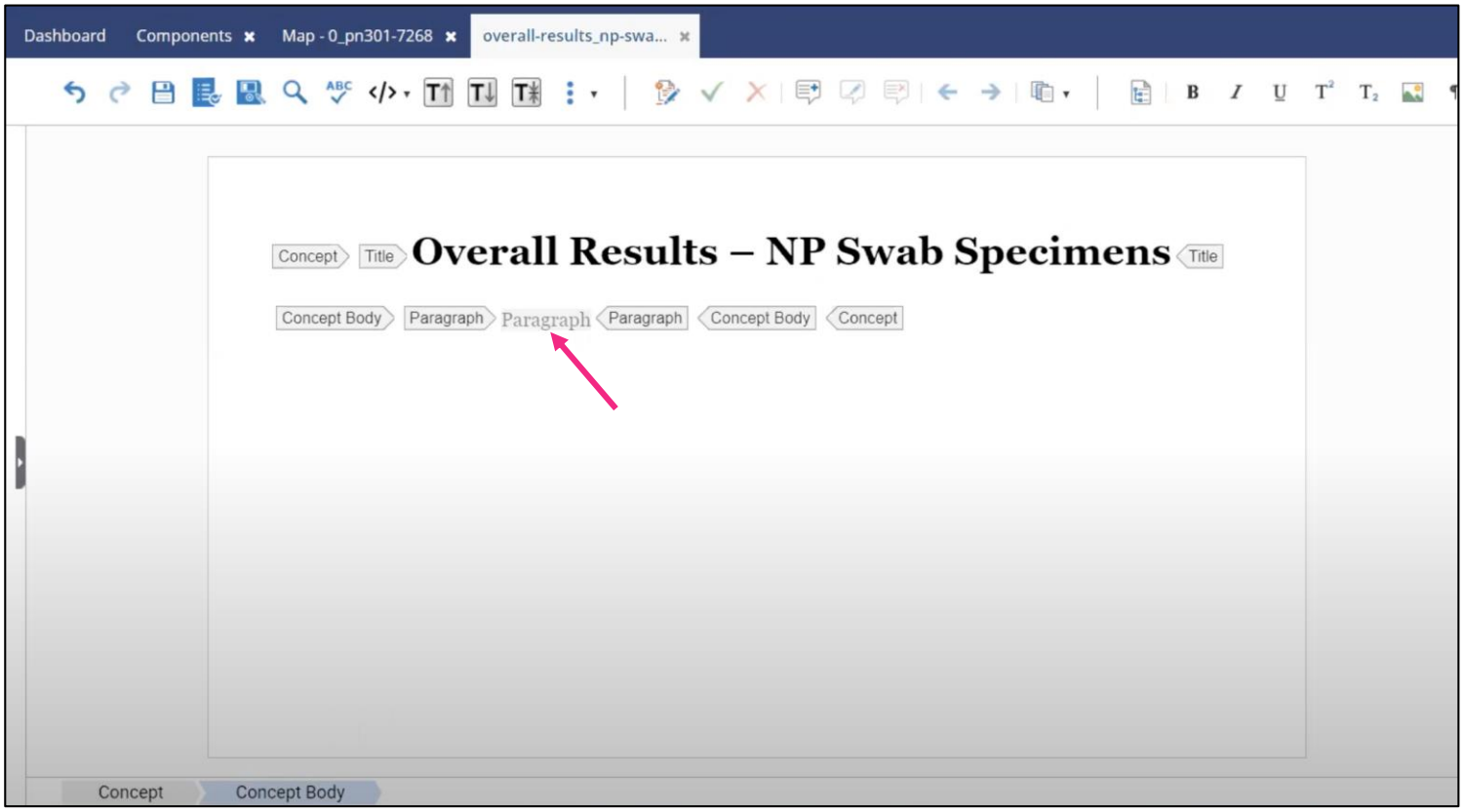


Step 2: Prepare component for content transfer

Open the new component by double-clicking on the name within the folder. The image below shows the default format for a new concept. Fix the title field. Delete the “Short Description” and both of the “Section” elements by clicking on the element tag and hitting the delete button on the keyboard.

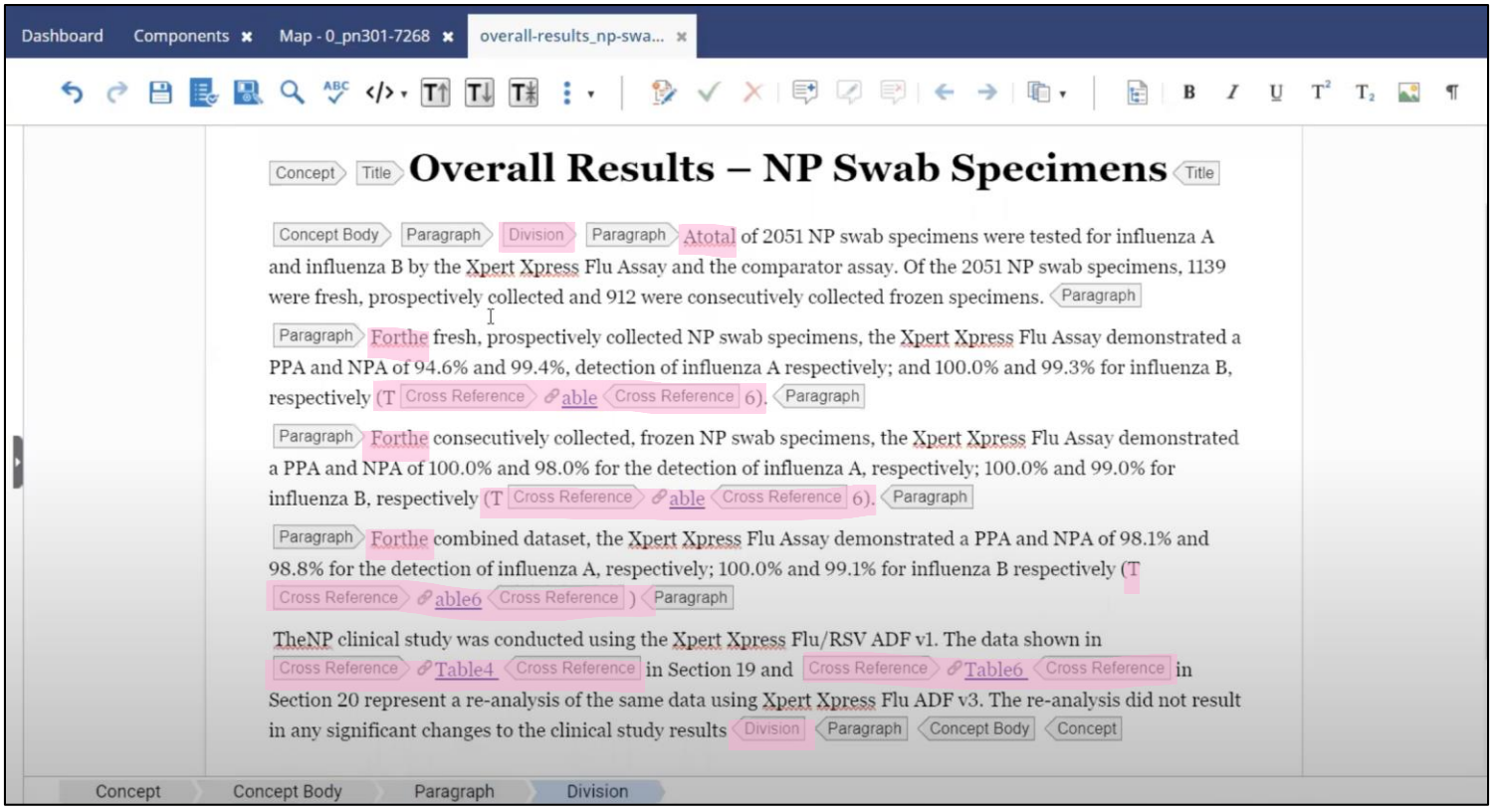


Step 2 information: Resulting concept ready for content

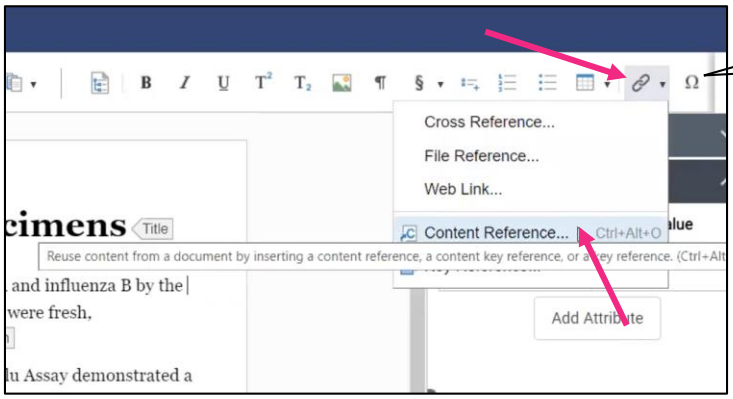


Step 3: Copy text from source file to Inspire concept

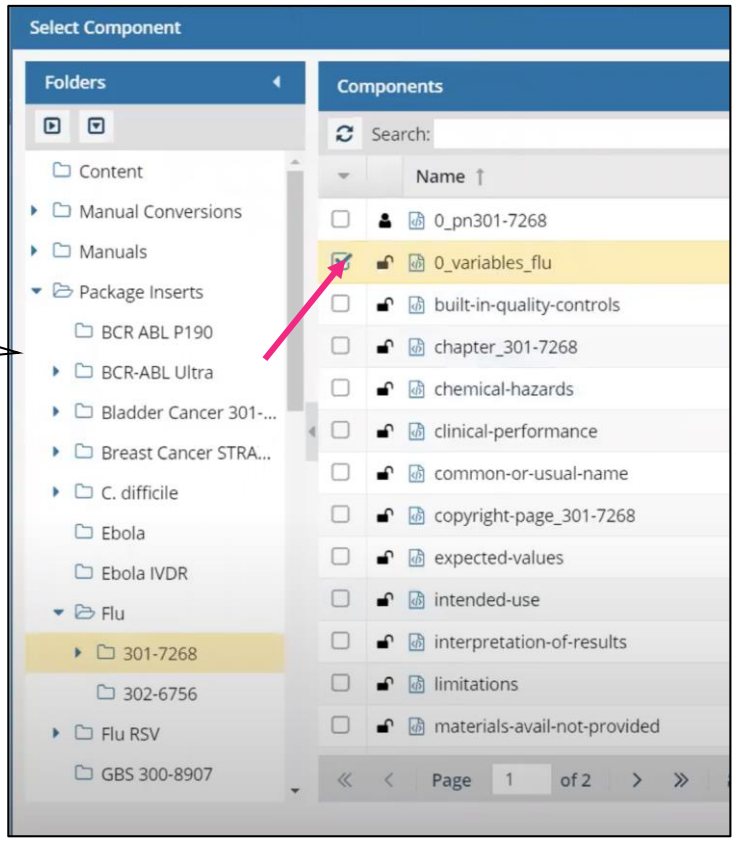
Copy paragraphs from the Word document version of the FrameMaker package insert. Paste the content into the space between the "Paragraph" element tags (shown above). The initial copy-paste is messy and includes errors such as missing spaces between words, retaining old cross references, and unnecessary "Division" tags (highlighted below). Correct the spacing issues and delete unnecessary tags by right clicking on the tag and selecting **Delete Element Tags**.



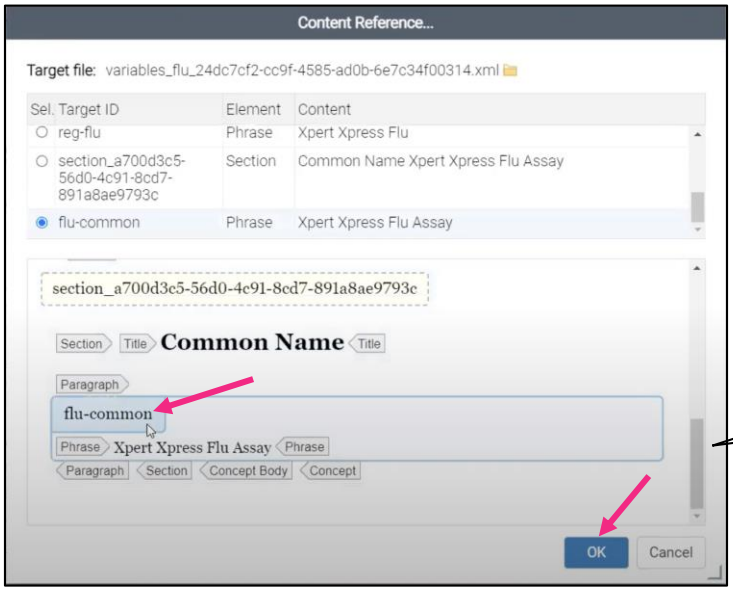
Step 4: Add content reference (conref) for assay name "Xpert Xpress Flu Assay"



Click the link icon and select **Content Reference**.

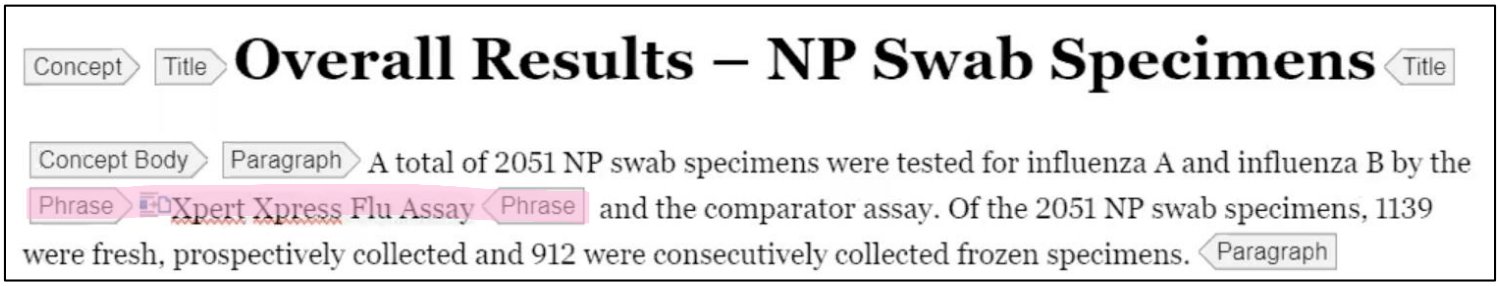


Navigate to the source folder (301-7268). Select the "0_variables_flu" concept.

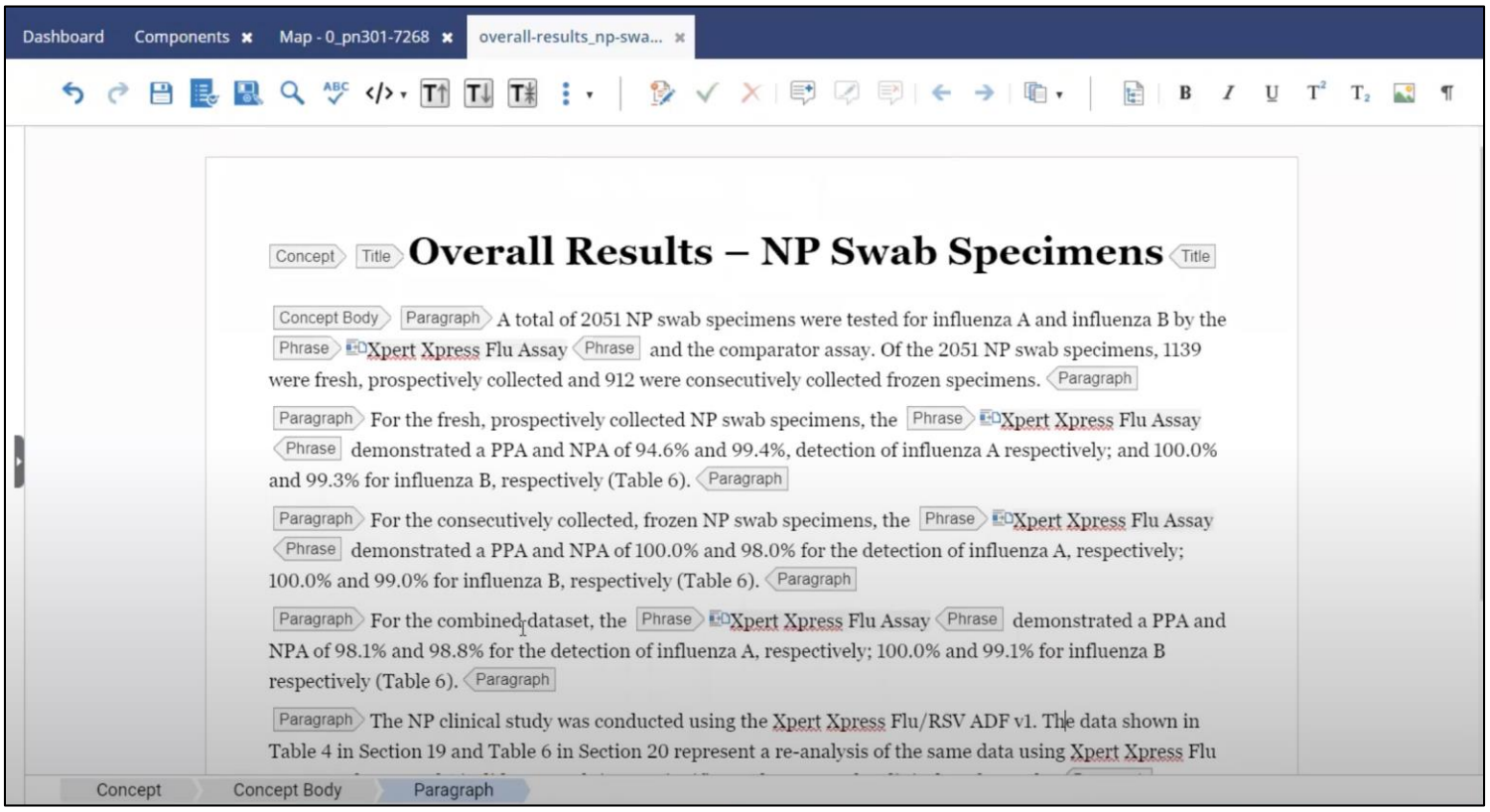


Click the phrase ID "flu-common." Click **OK**.

Step 4 result: Phrase/Conref inserted. Continue replacing all instances of "Xpert Xpress Flu Assay" with the conref. Once it is inserted into a concept once, it is possible to copy-paste the phrase.

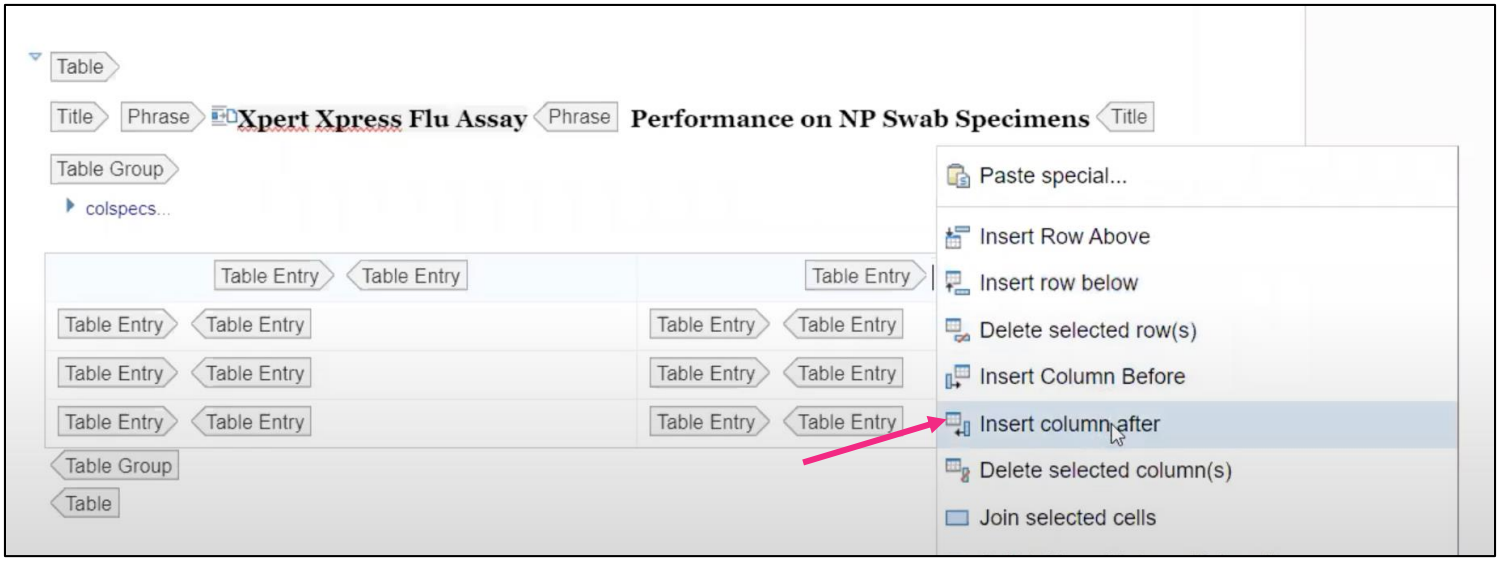


Check point: Current state of Inspire concept (author view)

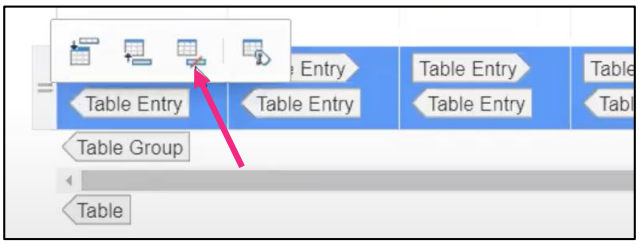


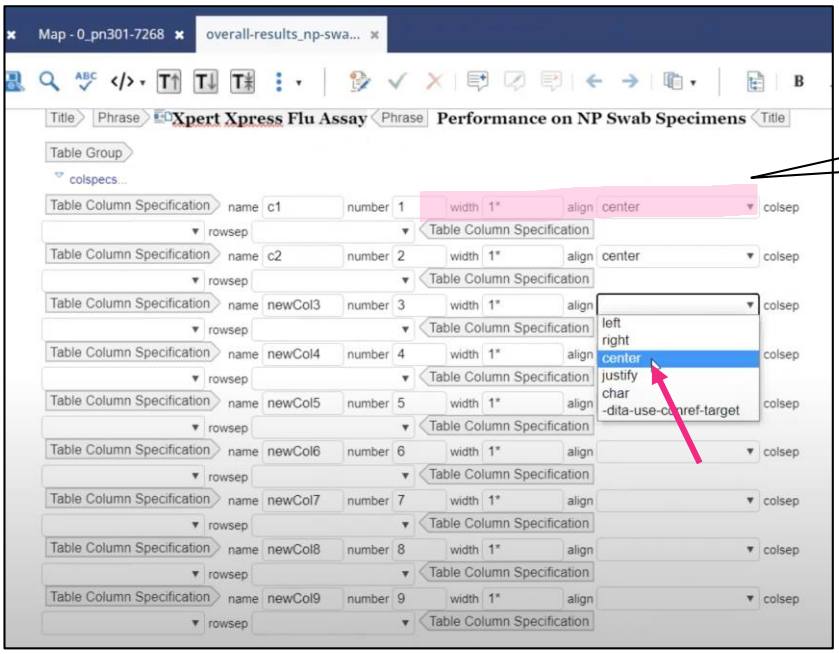
Step 5: Add a table

Click the desired input location. Hit the enter button on the keyboard, type "table," hit the enter button.
Right click in a column and select **Add Column After** until the correct number of columns is created.



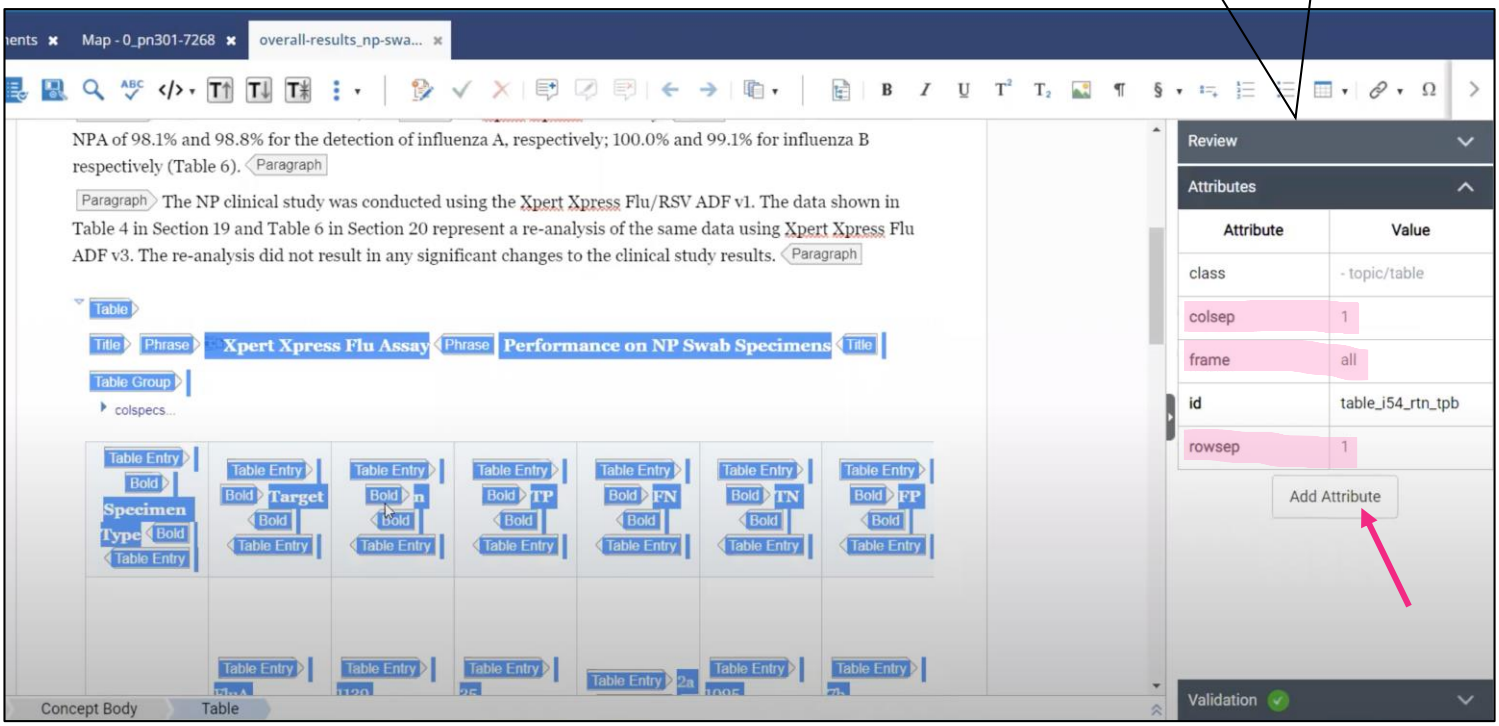
Delete unnecessary tags after pasting content (left)
Delete extra rows by highlighting the row and clicking the "delete row" icon (below).





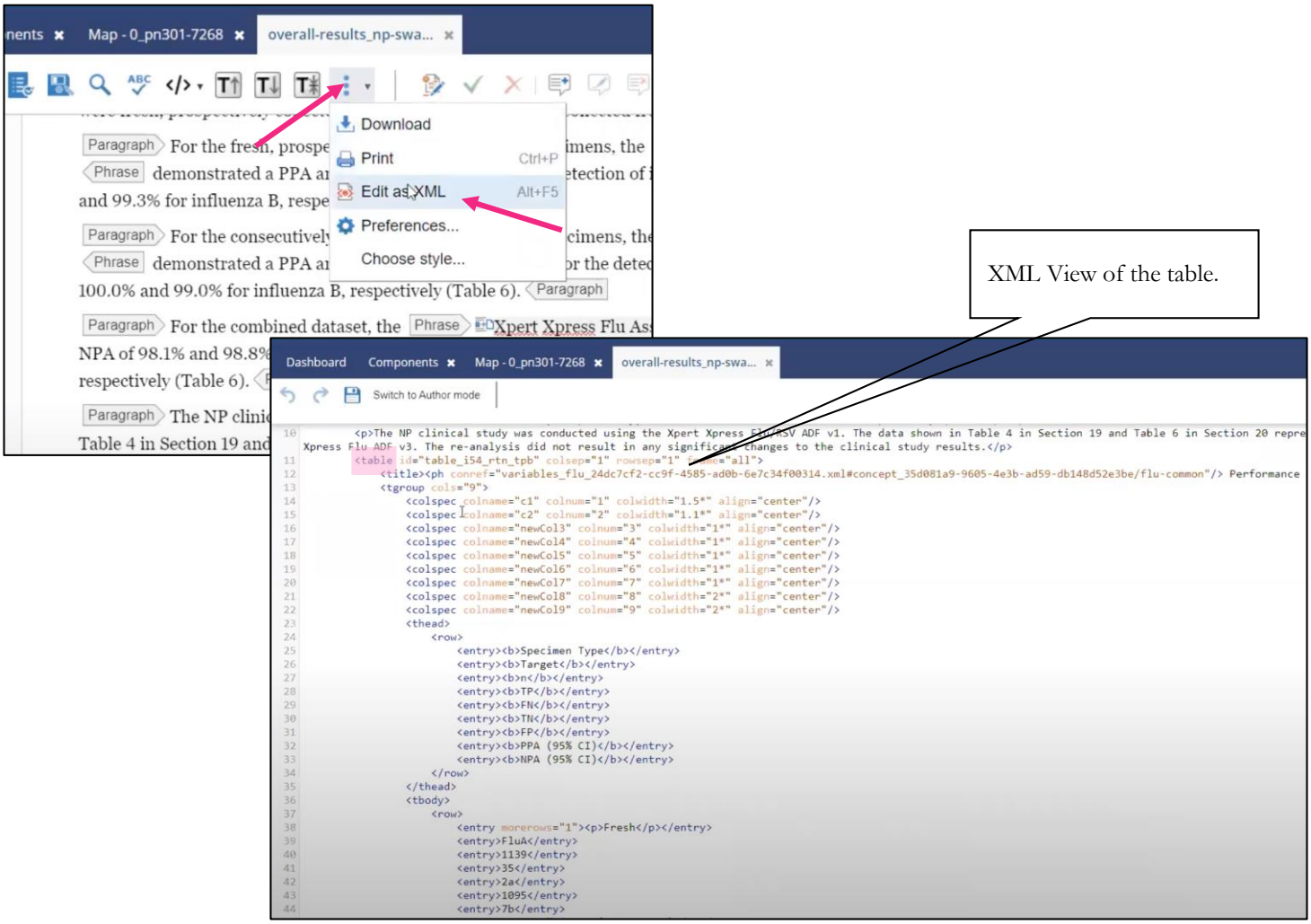
Change cell alignment and column width if necessary.

Select entire table. In the "Attributes" pane…
Click **Add Attribute**.
Add "colsep = 1," "rowsep = 1,"
and "frame = all"



Step 6 (cont.): Table adjustments in XML Editor

Often, it is easier to make changes to table formatting in the XML editor by using a "find and replace" function. The process below is to vertically align all the cell entries in the middle of the cell.



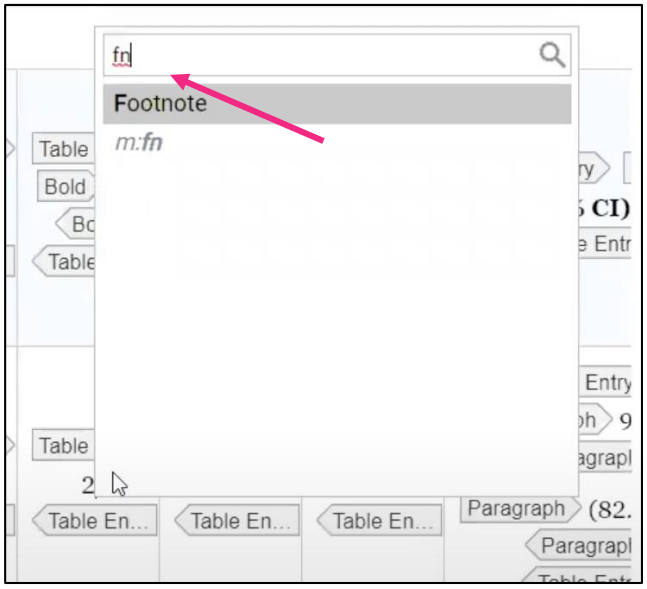
In the XML editor, use the "Find and Replace" function to add the valign attribute to all table entries.

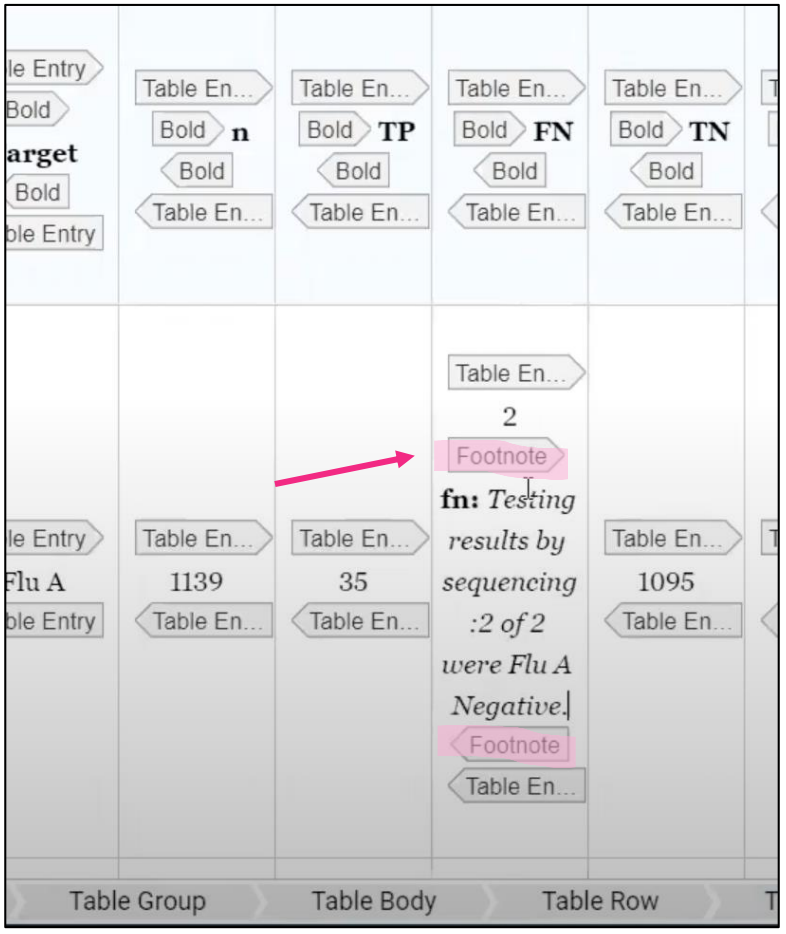
Find: <entry>
Replace with: <entry valign="middle">

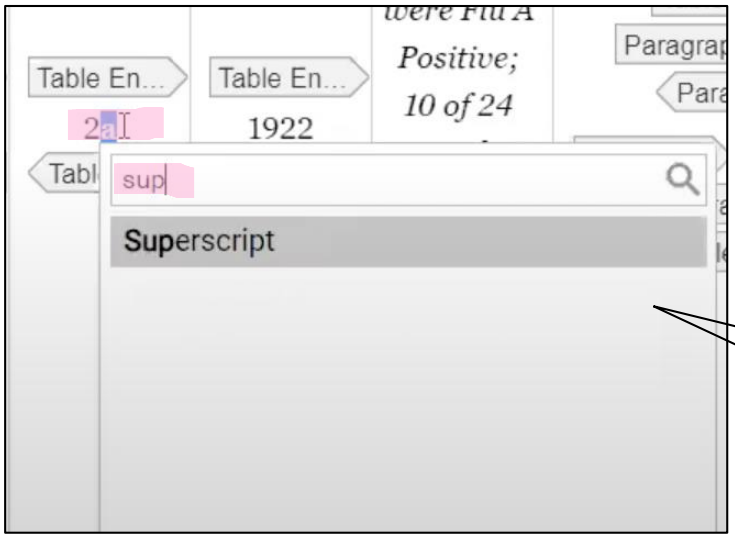
Select **All** to replace all.

Step 7: Add table footnotes

Place cursor in table cell that requires a footnote superscript letter. Hit the enter button on the keyboard. Type "fn" and hit enter. Add the footnote text. In *Inspire,* the footnote text displays within the table, but in the final output, it will appear as a classic list below the table with superscripted letters in the table cells.



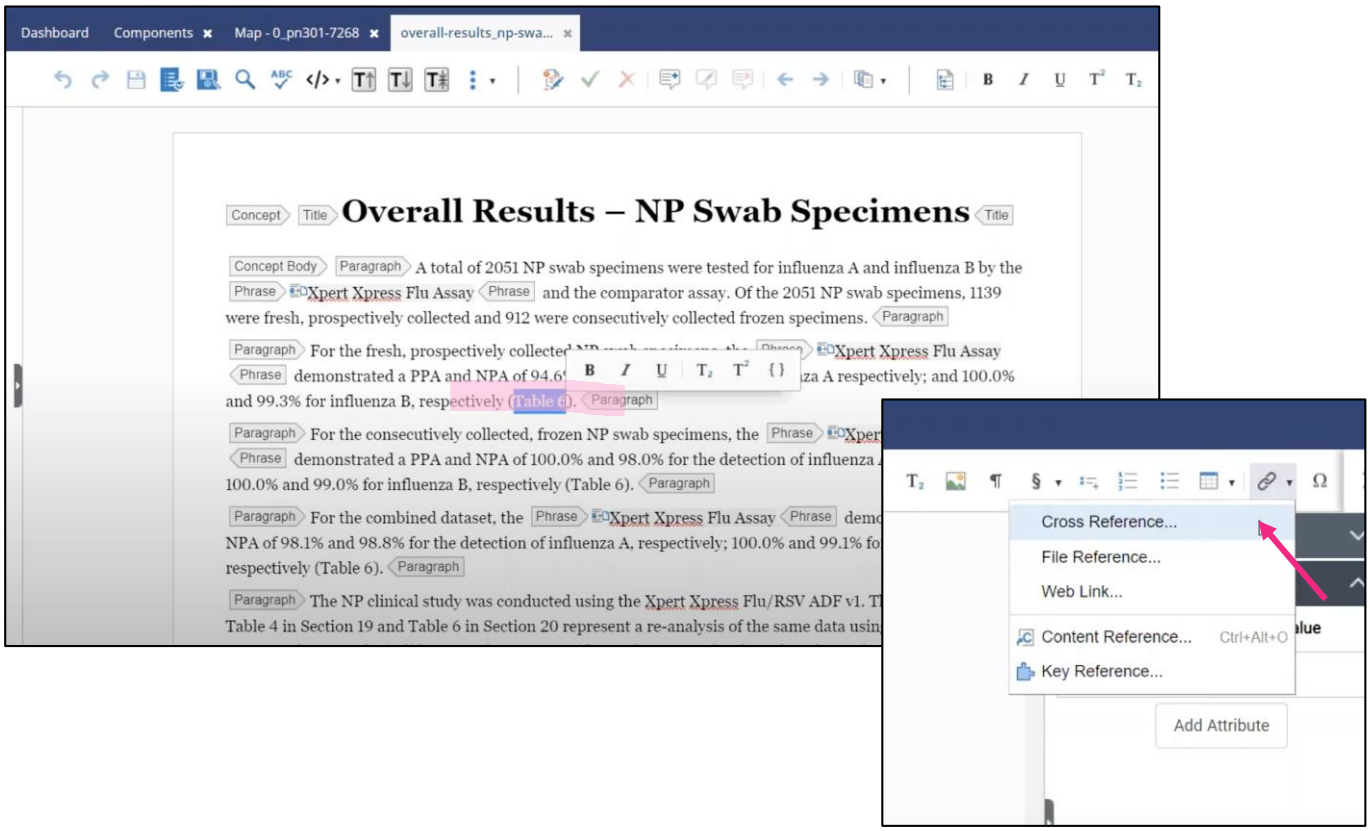


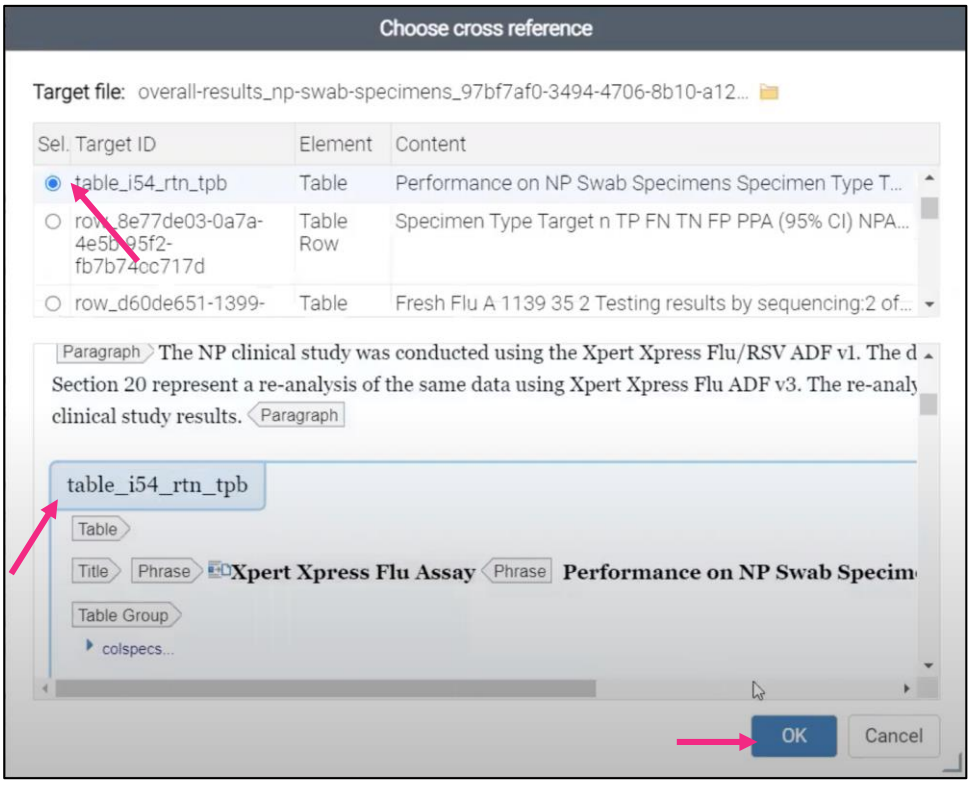


For repeat footnotes (ex. "a" referenced by different cells), manually superscript a letter. Highlight the letter. Hit the enter button. Type "sup" and select **Superscript**.

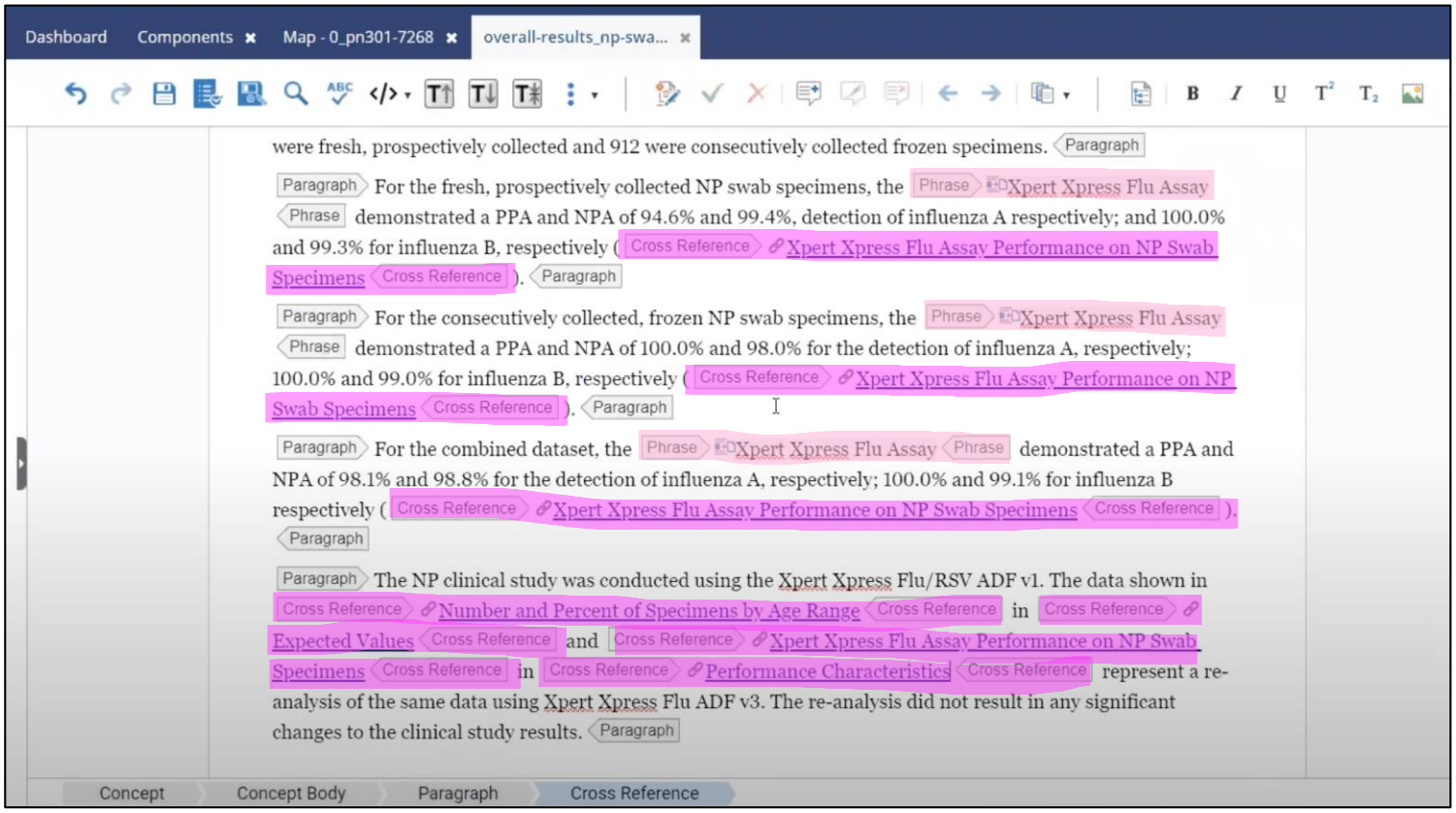
Step 8: Add cross references

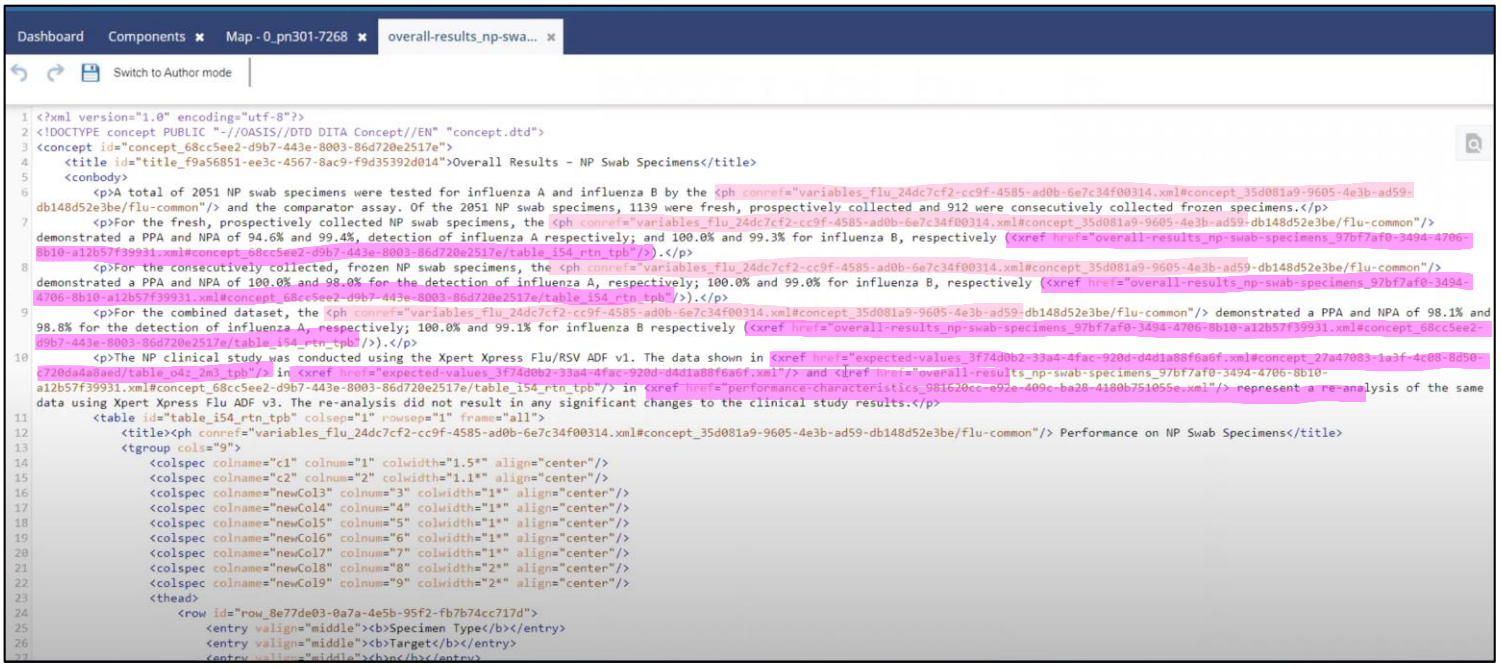
This is very similar to adding a conref (Step 4). Delete the text "Table 6." Click the link icon and select **Cross Reference**. Navigate to the target folder and select the correct table. Click **OK**. It will display the table title, but the final output will say "Table 6." Repeat the same process for creating cross references for the sections and other tables.





Check point: Current state in Author and XML View
Cross references (magenta) and content references (pink) highlighted.

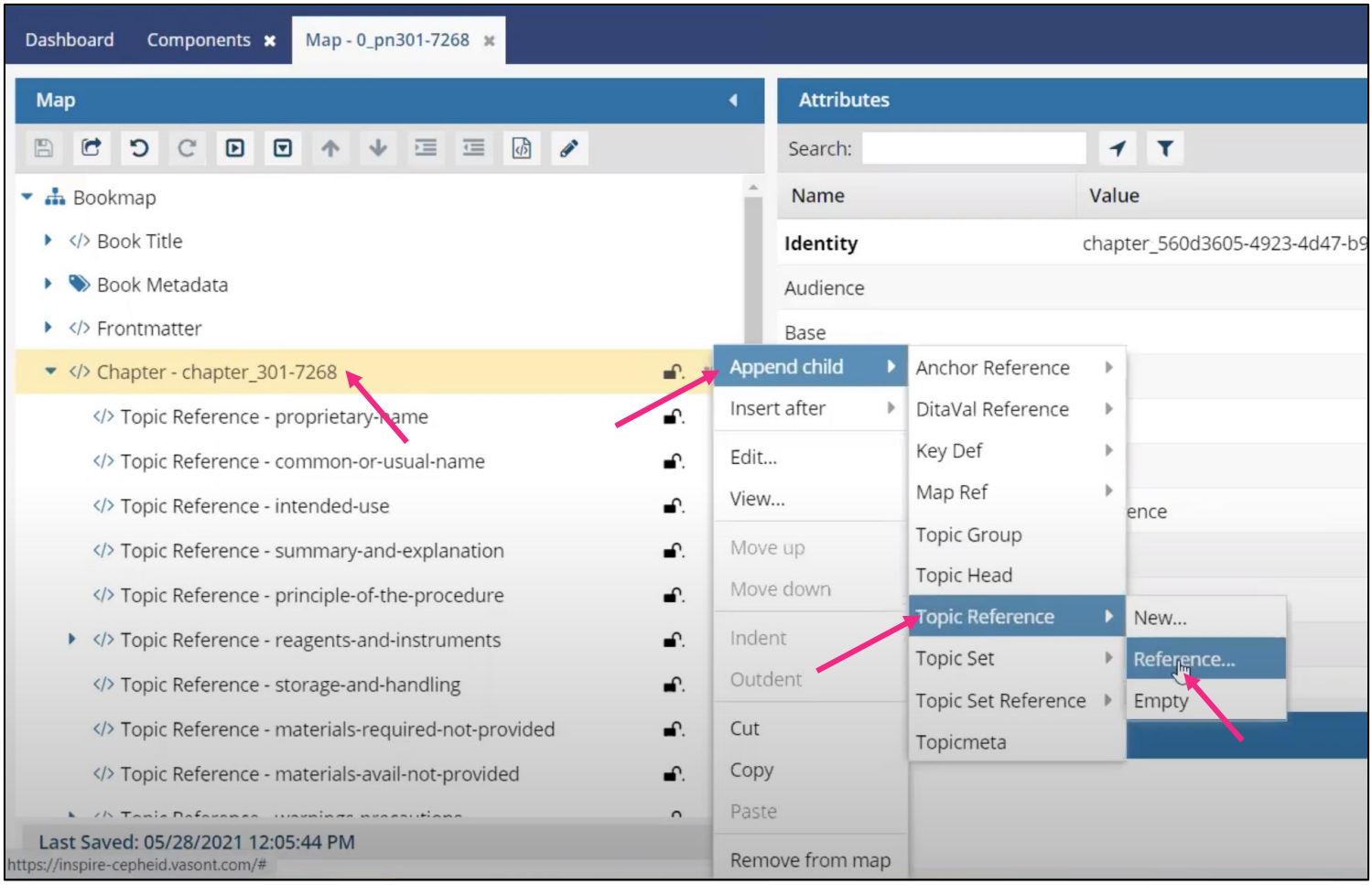


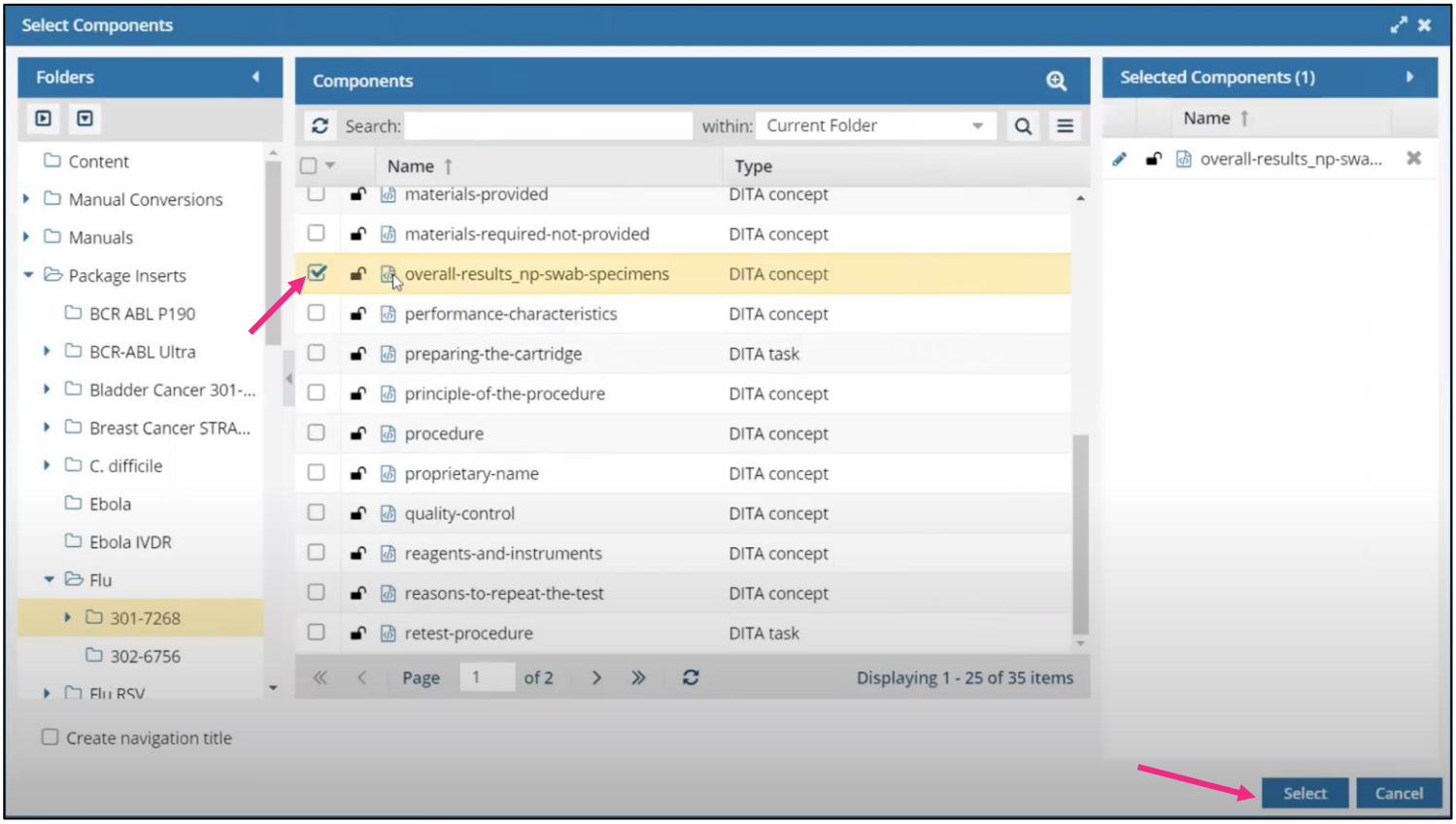



```
<?xml version="1.0" encoding="utf-8"?>
<!DOCTYPE concept PUBLIC "-//OASIS//DTD DITA Concept//EN" "concept.dtd">
<concept id="concept_68cc5ee2-d9b7-443e-8003-86d720e2517e">
    <title id="title_f9a56851-ee3c-4567-8ac9-f9d35392d014">Overall Results - NP Swab Specimens</title>
    <conbody>
        <p>A total of 2051 NP swab specimens were tested for influenza A and influenza B by the <ph conref="variables_flu_24dc7cf2-cc9f-4585-ad0b-6e7c34f00314.xml#concept_35d081a9-9605-4e3b-ad59-db148d52e3be/flu-common"/> and the comparator assay. Of the 2051 NP swab specimens, 1139 were fresh, prospectively collected and 912 were consecutively collected frozen specimens.</p>
        <p>For the fresh, prospectively collected NP swab specimens, the <ph conref="variables_flu_24dc7cf2-cc9f-4585-ad0b-6e7c34f00314.xml#concept_35d081a9-9605-4e3b-ad59-db148d52e3be/flu-common"/> demonstrated a PPA and NPA of 94.6% and 99.4%, detection of influenza A respectively; and 100.0% and 99.3% for influenza B, respectively (<xref href="overall-results_np-swab-specimens_97bf7af0-3494-4706-8b10-a12b57f39931.xml#concept_68cc5ee2-d9b7-443e-8003-86d720e2517e/table_i54_rtn_tpb"/>).</p>
        <p>For the consecutively collected, frozen NP swab specimens, the <ph conref="variables_flu_24dc7cf2-cc9f-4585-ad0b-6e7c34f00314.xml#concept_35d081a9-9605-4e3b-ad59-db148d52e3be/flu-common"/> demonstrated a PPA and NPA of 100.0% and 98.0% for the detection of influenza A, respectively; 100.0% and 99.0% for influenza B, respectively (<xref href="overall-results_np-swab-specimens_97bf7af0-3494-4706-8b10-a12b57f39931.xml#concept_68cc5ee2-d9b7-443e-8003-86d720e2517e/table_i54_rtn_tpb"/>).</p>
        <p>For the combined dataset, the <ph conref="variables_flu_24dc7cf2-cc9f-4585-ad0b-6e7c34f00314.xml#concept_35d081a9-9605-4e3b-ad59-db148d52e3be/flu-common"/> demonstrated a PPA and NPA of 98.1% and 98.8% for the detection of influenza A, respectively; 100.0% and 99.1% for influenza B respectively (<xref href="overall-results_np-swab-specimens_97bf7af0-3494-4706-8b10-a12b57f39931.xml#concept_68cc5ee2-d9b7-443e-8003-86d720e2517e/table_i54_rtn_tpb"/>).</p>
        <p>The NP clinical study was conducted using the Xpert Xpress Flu/RSV ADF v1. The data shown in <xref href="expected-values_3f74d0b2-33a4-4fac-920d-d4d1a88f6a6f.xml#concept_27a47083-1a3f-4c08-8d50-c720da4a8aed/table_o4z_2m3_tpb"/> in <xref href="expected-values_3f74d0b2-33a4-4fac-920d-d4d1a88f6a6f.xml"/> and <xref href="overall-results_np-swab-specimens_97bf7af0-3494-4706-8b10-a12b57f39931.xml#concept_68cc5ee2-d9b7-443e-8003-86d720e2517e/table_i54_rtn_tpb"/> in <xref href="performance-characteristics_981620cc-e92e-409c-ba28-4180b751055e.xml"/> represent a re-analysis of the same data using Xpert Xpress Flu ADF v3. The re-analysis did not result in any significant changes to the clinical study results.</p>
        <table id="table_i54_rtn_tpb" colsep="1" rowsep="1" frame="all">
            <title><ph conref="variables_flu_24dc7cf2-cc9f-4585-ad0b-6e7c34f00314.xml#concept_35d081a9-9605-4e3b-ad59-db148d52e3be/flu-common"/> Performance on NP Swab Specimens</title>
            <tgroup cols="9">
                <colspec colname="c1" colnum="1" colwidth="1.5*" align="center"/>
                <colspec colname="c2" colnum="2" colwidth="1.1*" align="center"/>
                <colspec colname="newCol3" colnum="3" colwidth="1*" align="center"/>
                <colspec colname="newCol4" colnum="4" colwidth="1*" align="center"/>
                <colspec colname="newCol5" colnum="5" colwidth="1*" align="center"/>
                <colspec colname="newCol6" colnum="6" colwidth="1*" align="center"/>
                <colspec colname="newCol7" colnum="7" colwidth="1*" align="center"/>
                <colspec colname="newCol8" colnum="8" colwidth="2*" align="center"/>
                <colspec colname="newCol9" colnum="9" colwidth="2*" align="center"/>
                <thead>
                    <row id="row_8e77de03-0a7a-4e5b-95f2-fb7b74cc717d">
                        <entry valign="middle"><b>Specimen Type</b></entry>
                        <entry valign="middle"><b>Target</b></entry>
                        <entry valign="middle"><b>nc</b></entry>
```

Step 9: Add concept to the bookmap

Open the bookmap for this publication. Click the three dots next to the chapter. Click **Append child**, then **Topic Reference**, followed by **Reference**. Navigate to the recently completed concept ("overall-results_np-swab-specimen). Check the box next to the concept and click **Select**. Now, the conversion of this section of the package insert is complete.





Analysis/Verification

Document comparisons

The verification process to ensure that all the original content from the FrameMaker document has been transferred into the new *Inspire* output is a series of document compares using Adobe Acrobat and Microsoft Word. The programs highlight differences between the document versions and identify discrepancies. The conversion work must be periodically verified and reviewed since these are controlled documents approved by the FDA (Food and Drug Administration).

Evaluation

Earl Boggs, Senior Manager of Cepheid Technical Publications, evaluated the quality of the completed senior project work. This section summarizes his evaluation, and his full review is available in Appendix C. Boggs provided a rating for each specific requirement set for the PIC Project and his feedback from a manager's perspective will guide future work.

The objectives of this project that Earl Boggs evaluated are as follows:

- Gather information and develop a reasonable scope for the Package Insert Conversion (PIC) Project
- Acquire a basic working knowledge of Vasont *Inspire* with help from experienced writers
- Conversion of 4 US-IVD package inserts
- Application of Technical Communication Concentration: Work completed in Technical Publications to an acceptable standard with attention to detail
- Application of Industrial Engineering-Project Management Concentration: Plan and adhere to a project schedule and form a "project team" of mentors, instructors, and reviewers

Boggs rated each objective on a 1-5 scale (5 being highest level of satisfaction). The average satisfaction rating was 4.6, which demonstrates Boggs' appreciation and approval of the project deliverables for his department. Working with an external stakeholder for this senior project

proved challenging as the timelines, expectations, and procedures did not always match up with the Cal Poly quarter system. I am proud that Boggs' level of satisfaction was high and that this project will enter customer hands in the coming months.

In his review, Boggs mentioned an area for improvement that I also recognize and discuss in the Related Work section. It involves using tags more effectively and exploring new applications of advanced tagging. Standardizing which tags are used to create the desired result will greatly speed up the conversion process and maximize usability of documents for Technical Writers and, subsequently, customers. Boggs also included two future work comments. His notes do not pertain to the evaluation of the Cal Poly senior project, rather they refer to my future role at Cepheid in Technical Publications.

Interdisciplinary Connections

Industrial Engineering (IE) emerged as a field dedicated to work studies, standardization, and production lines. A modern attitude exists: Industrial Engineers aim to establish and maintain harmony between economy, environment, and society (Darwish & van Dyk, 2016). As field of study and as an industry, IE has developed into a utilization of process improvement, efficiency maximization tactics, and project management – all while considering the human component. In their article, "Women in Industrial Engineering: Stereotypes, Persistence, and Perspectives," Brawner et al., present that IE degrees draw more women than most other engineering majors in the United States. The researchers came to a consensus that statistically more women chose IE "for a myriad of social factors including: warmth, flexibility, a sense it is more feminine, and career opportunities" (Brawner, Camacho, Lord, Long, & Ohland, 2012).

Dr. Donella Meadows, a well-respected role model in Industrial Engineering, dedicated her professional life to practical applications of systems analysis to all areas of society and global events. She was an environmental scientist and professor at Dartmouth College…and a "systems thinker." One of her books, *Thinking in Systems,* gives a practical overview of system structure, system behavior, and system leverage points for change management.

Key words of Industrial Engineering wisdom from *Thinking in Systems*:

Quote	Commentary
"Get the beat of the system" (Meadows, 2008)	Before you go poking around and adjusting things, watch how the system behaves. Watch it work, learn its history, talk to people in all points of the process. The root cause of any problem may not be what it immediately appears to be.
"Stay humble - stay a learner" (Meadows, 2008)	Be prepared for surprises and recognize that small steps and a willingness to change course are critical for system optimization. This lends itself well to a comparison to Cal Poly's "Learn by Doing" message. Learning from mistakes is much better than being frozen by a fear of failure.
"Don't erode the goal of goodness" (Meadows, 2008)	Keep standards high and absolute. Work with honesty and integrity; never compromise ethics for short-term results.

Dr. Meadows' career remains an example of cross-disciplinary work and this discussion is a transition into Technical Writing. In C. P. Snow's pivotal essay, "The Two Cultures and The Scientific Revolution," he discusses the divide he encountered between professional scientists and professional writers throughout his career (Snow, 1961). He emphasizes that one group is not intellectually superior to another, rather they stopped communicating and began seeing each other as opposites. C. P. Snow's evaluation clearly notes a need for people to bridge the gap and reunite society.

The role of technical writers has expanded greatly in the last several decades. In a 1964 publication, Dolores Landerman recommends a technical writing career to students who have an affinity to both Science and English. She states that "technical writers ordinarily are concerned with communicating information concerning […] scientific discovery or engineering accomplishment." Furthermore, "subject matter may range from extremely complex material […] to simple instructions" (Landerman, 1964). The Society for Technical Communication offers a fresh and inclusive definition: "technical communicators research and create information about technical processes or products directed to a targeted audience through various forms of media" (The Society for Technical Communication, 2017).

The shift from communicating information to creating information speaks to C. P. Snow and Dr. Donella Meadows' vision of a unified and collaborative approach to technological progress. The responsibilities, channels of communication, and mediums may have changed, but the goal of technical writing remains as translating something complicated into something usable and accessible.

Concentration connection

The interdisciplinary skills I learned at Cal Poly, through the wide range of classes I was able to take, are evident in the process and deliverables of this senior project. I directly used my Technical Communication concentration in that this project was completed as a Technical Writer for a publications department handling medical diagnostic package inserts. Also, utilization of a CMS was part of a greater initiative to move towards the technical communication industry standard.

While the application of liberal arts concentration is more apparent in the context of this project work, the knowledge and experience the Industrial Engineering concentration gave me proved critical to the PIC Project's success. My studies at Cal Poly prepared me for learning a new, technical program and employing project management techniques. Finally, a more grand-scheme concept, the PIC Project is a pursuit of efficiency, improvement, and system development. This new documentation process will be a superior way to manage documents after writers overcome the learning curve and departments move towards widespread implementation.

Related Work

There were several noteworthy challenges I encountered during the two quarters on this project, that could not be addressed due to time constraints, that present excellent opportunities for future projects. First, there should be more consideration given to references. At present, they are inputted at the end of each publication and indicated with superscripts throughout the document. If an additional reference is added, then all the superscripts must be changed individually. A resolution may be linking sources in a similar way footnotes are marked in tables, but this requires more attention and testing.

Second, images pose problems – different documents often have varying size and quality requirements (even if they are the same images). A possible workaround involves creating and maintaining multiple copies of a graphic, but this negates the CMS tenet of single-sourcing pieces of content and is not a sustainable solution.

Finally, "key references," a tag in XML and HTML, is becoming increasingly important. Cepheid has not attempted to utilize this tag yet. Key references theoretically allow for even more widespread reuse of topics and could partially solve the references dilemma. For example, the Flu

package insert shares a significant amount of content with the Flu/RSV package insert. A key reference (instead of a content reference, as used widely in this senior project) could be used for the test name. So, it would be possible to use the same existing *Inspire* topic and have the program automatically change specific variables depending on which bookmap is referencing the topic. These, among other issues, are areas of discussion and debate for technical writers that require more support and research.

Future Work

Cepheid Technical Publications still has much work and analysis to do on standard procedures using the CMS. They will need Standard Operating Procedures (SOPs), formal writing guides, and a major research project to identify reusable content between documents. As mentioned previously, there are sections of the package inserts that vary only slightly from document to document. There will be a large project in the future to reconcile the minor inconsistencies and take full advantage of the benefits a CMS offers.

As stated in the Related Work section, there are places where CMSs are under-utilized because writers have not yet determined how best to implement the features to serve their needs. I hope that more college courses will begin exploring topic-based writing and Content Management Systems. More broadly, this is in no way the last conversion technical documents and writing will see: the technology constantly develops and improves.

Conclusion

Content Management Systems are the future of technical writing and will, no doubt, see even more widespread use and new applications in the near future. This report aimed to provide an in-depth summary of my senior project design process and implementation as well as comment on future work in the field. In the two quarters allotted for senior project, I delivered four converted package inserts. The PIC Project allowed me to demonstrate my learned interdisciplinary skills and present an example of senior project work in collaboration with a company. The Liberal Arts & Engineering Studies major enabled me to flourish as a student and I am well-prepared for industry work. With great support from professors, advisors at Cal Poly, and the LAES program, I was able to tailor a degree to personal interests and complete this senior project to a high standard.

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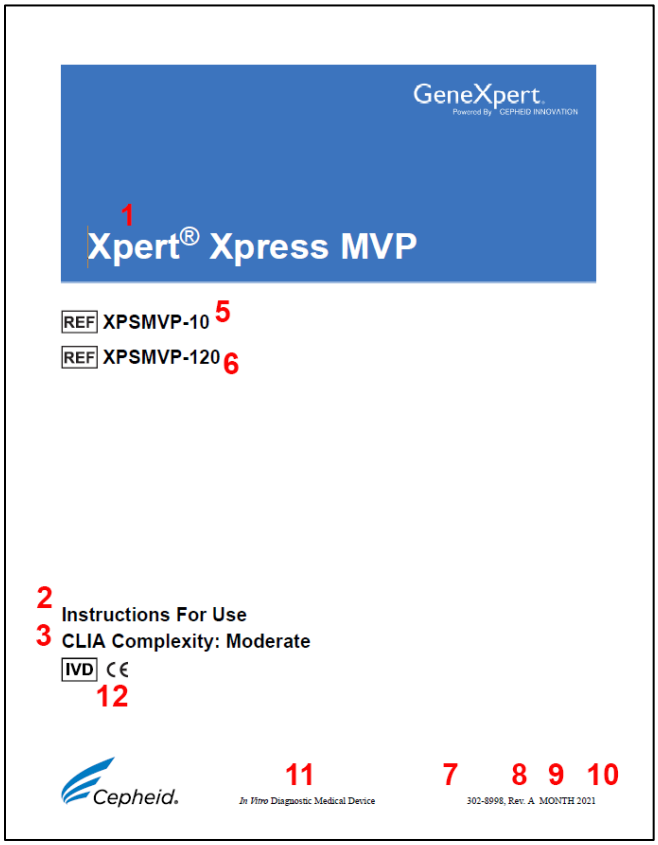
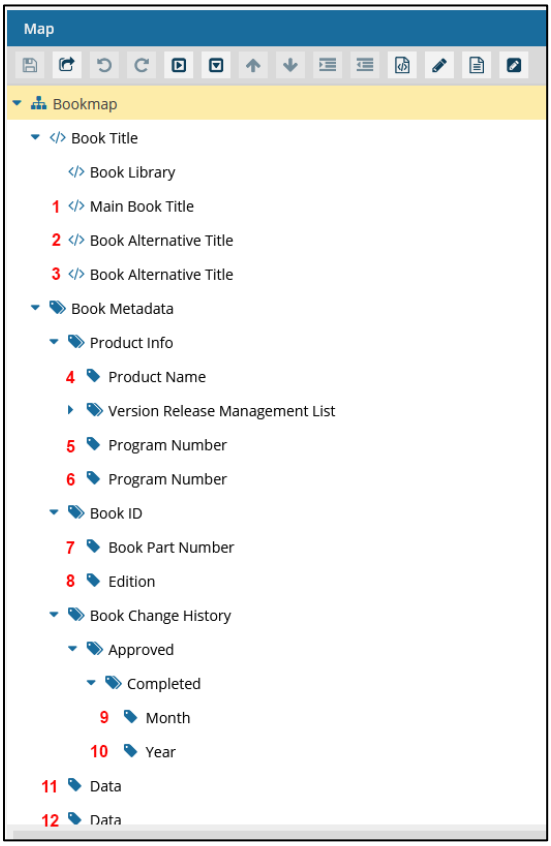
Appendix A: Setting Up the Front Cover

Nathaniel Lim's quick reference guide for setting up the front cover of a package insert in *Inspire*. (Lim)

No.	Bookmap Label	Publishing Label	Example
1	Main Book Title	Document Title	<tm tmtype="reg">Xpert</tm> Xpress MVP
2	Book Alternative Title	Instructions for Use	Instructions for Use
3	Book Alternative Title	Extra Text	CLIA Complexity: Moderate
4	Product Name	<leave empty>	
5	Program Number	Catalog Number	XPSMVP-10
6	Program Number	Catalog Number	XPSMVP-120
7	Book Part Number	Part Number	302-8998
8	Edition	Revision	Rev. A
9	Month	Month	April
10	Year	Year	2021
11	Data	Footer Text	<ph>In Vitro Diagnostic Medical Device</ph>
12	Data	Icon	Ivd_ce





Appendix B: Vasont *Inspire* Tour

Figure 1: An example of a folder with components

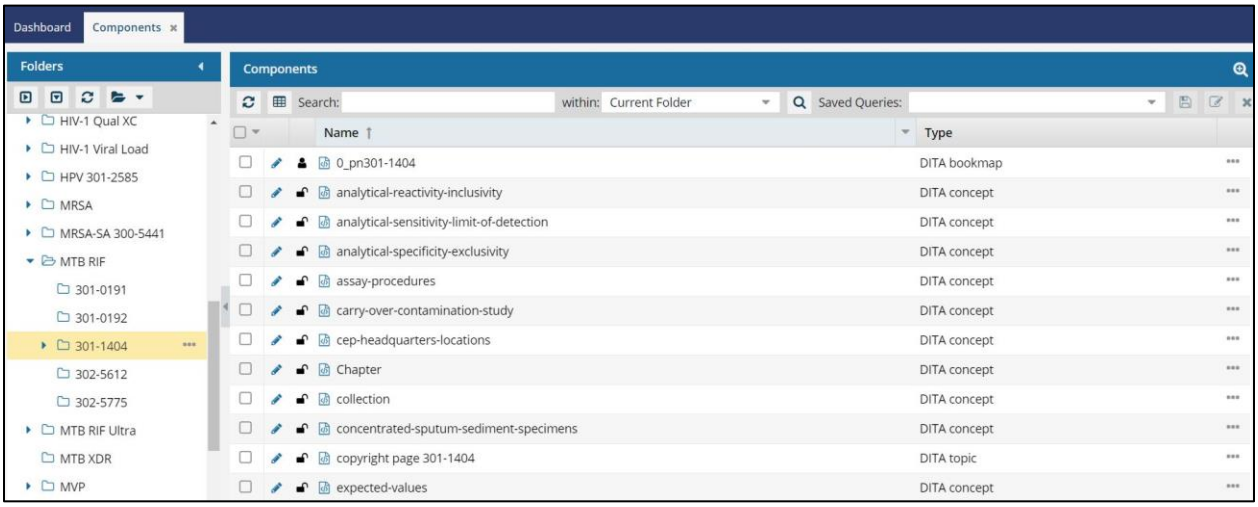


Figure 2: Example of a bookmap with referenced topics

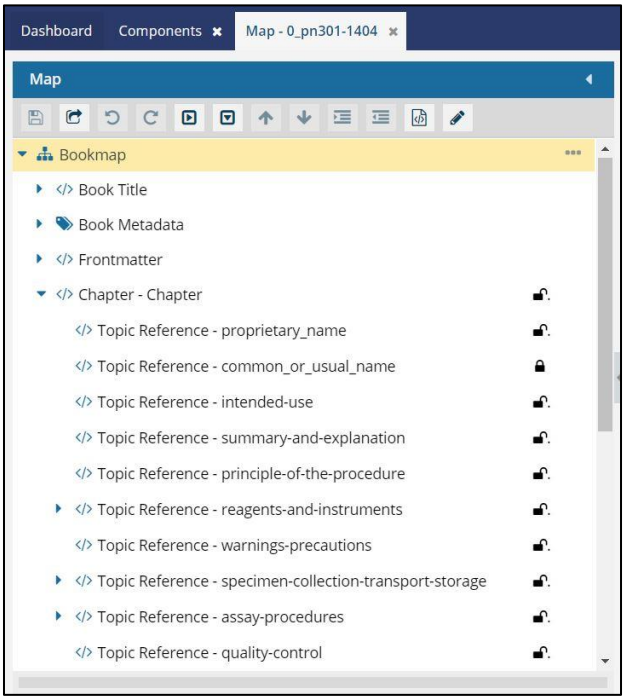


Figure 3: Creating a new component

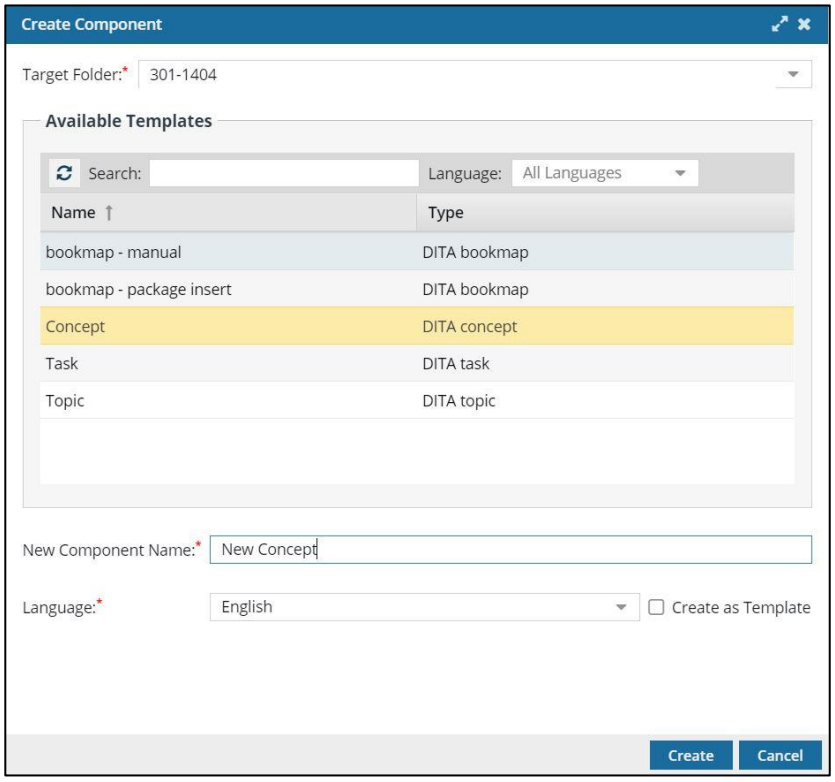


Figure 4: Example of a section with full tags (paragraph, phrase/conref, italic, cross reference)

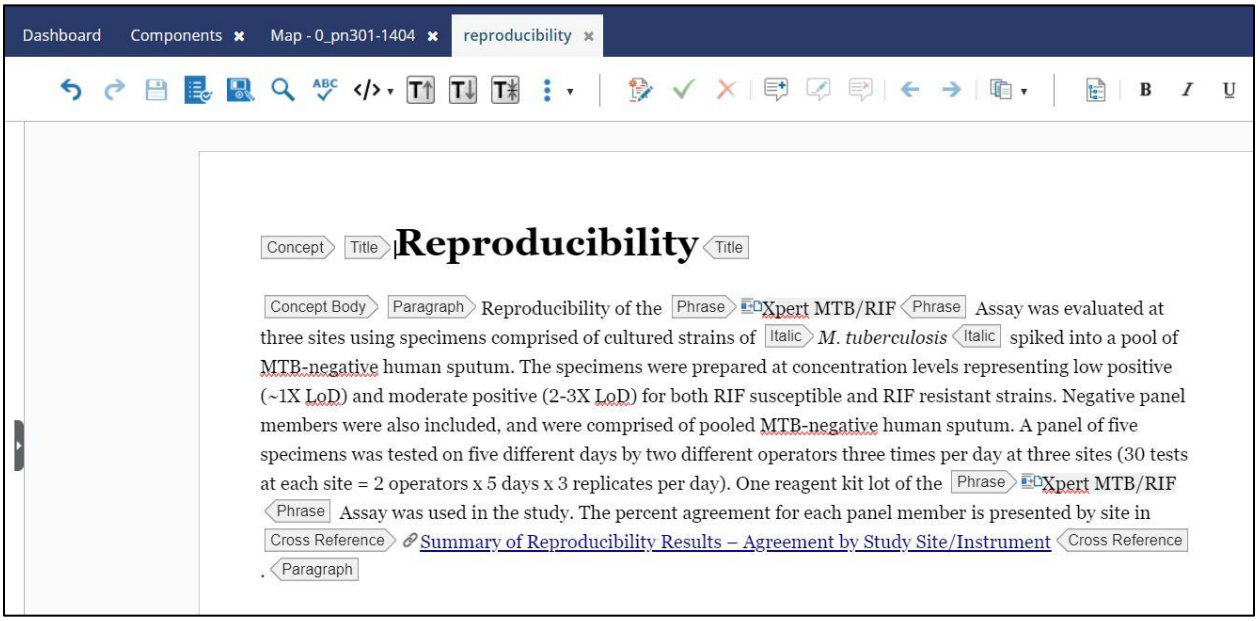


Figure 5: Figure set-up and attributes

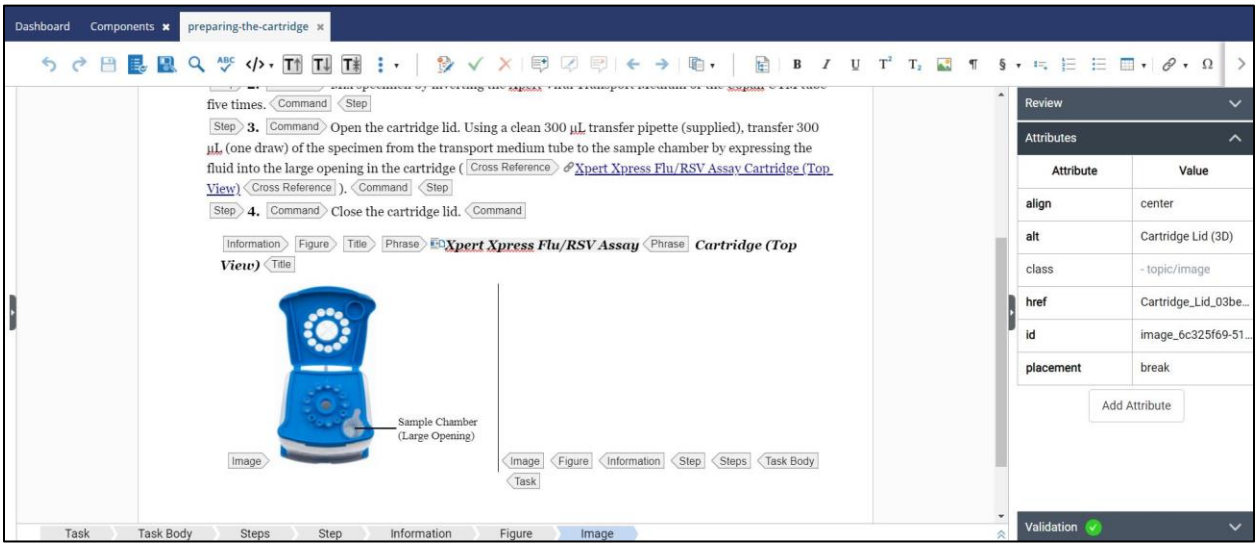


Figure 6: Table view in author mode with full tags

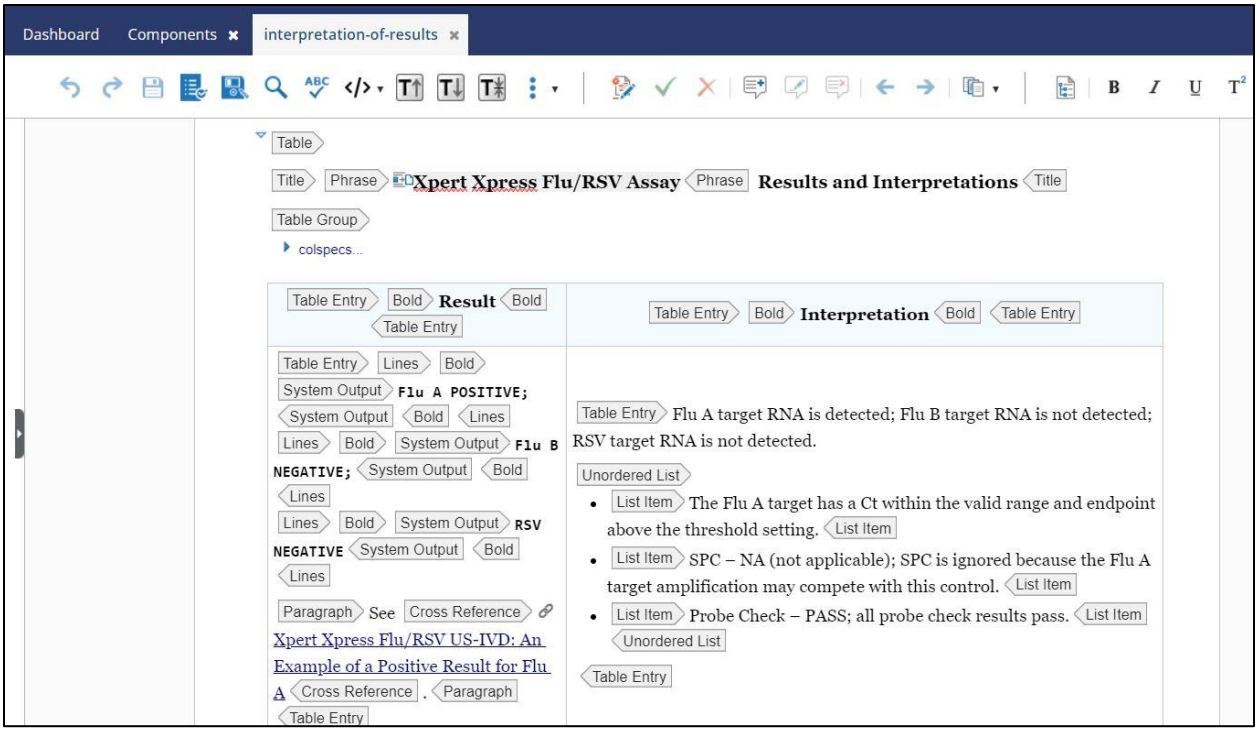


Figure 7: Table view in author mode with attributes

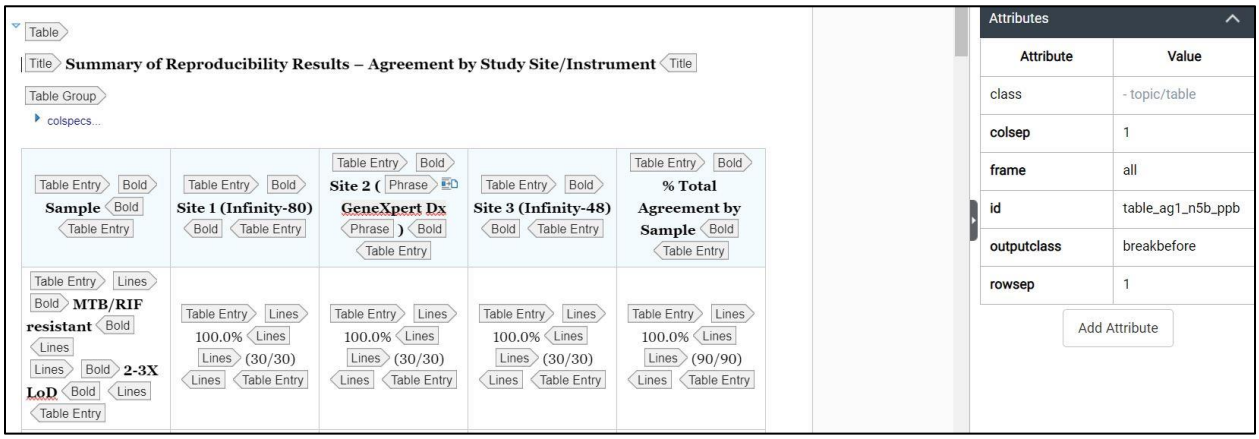


Figure 8: Table view in XML editor. Here I was adding [valign="middle"] to quickly format the cells so that the content was centered in the cell

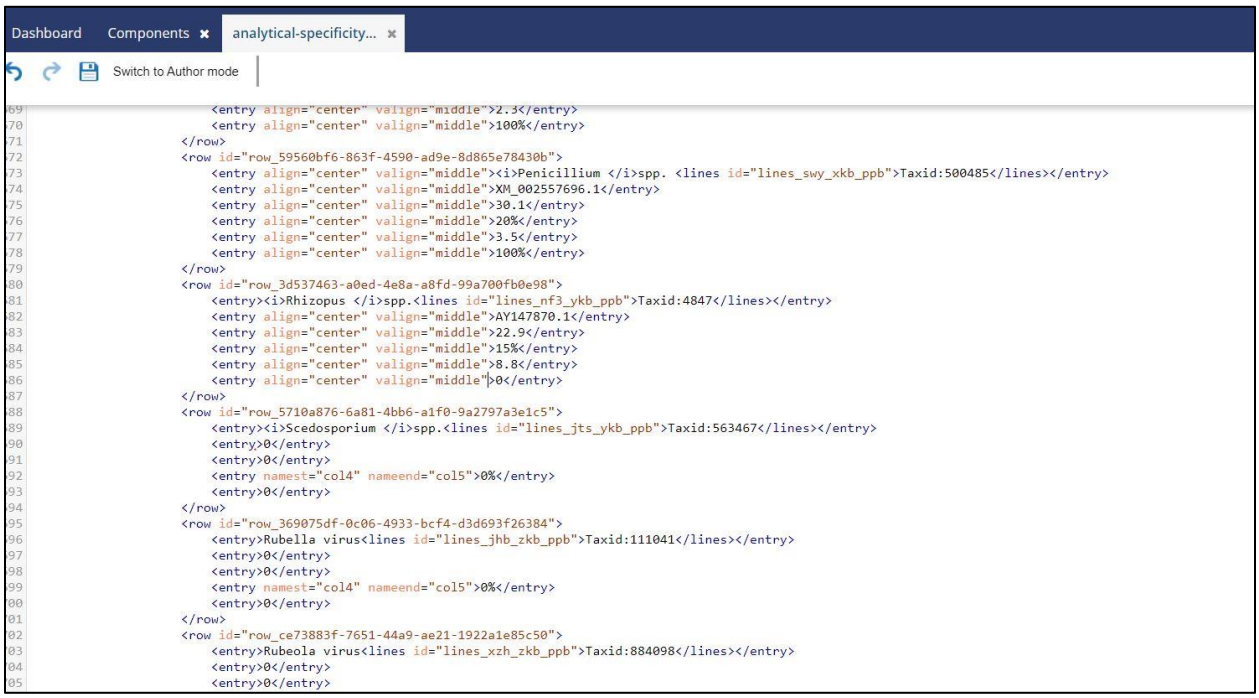


Figure 9: Building the bookmap by referencing topics

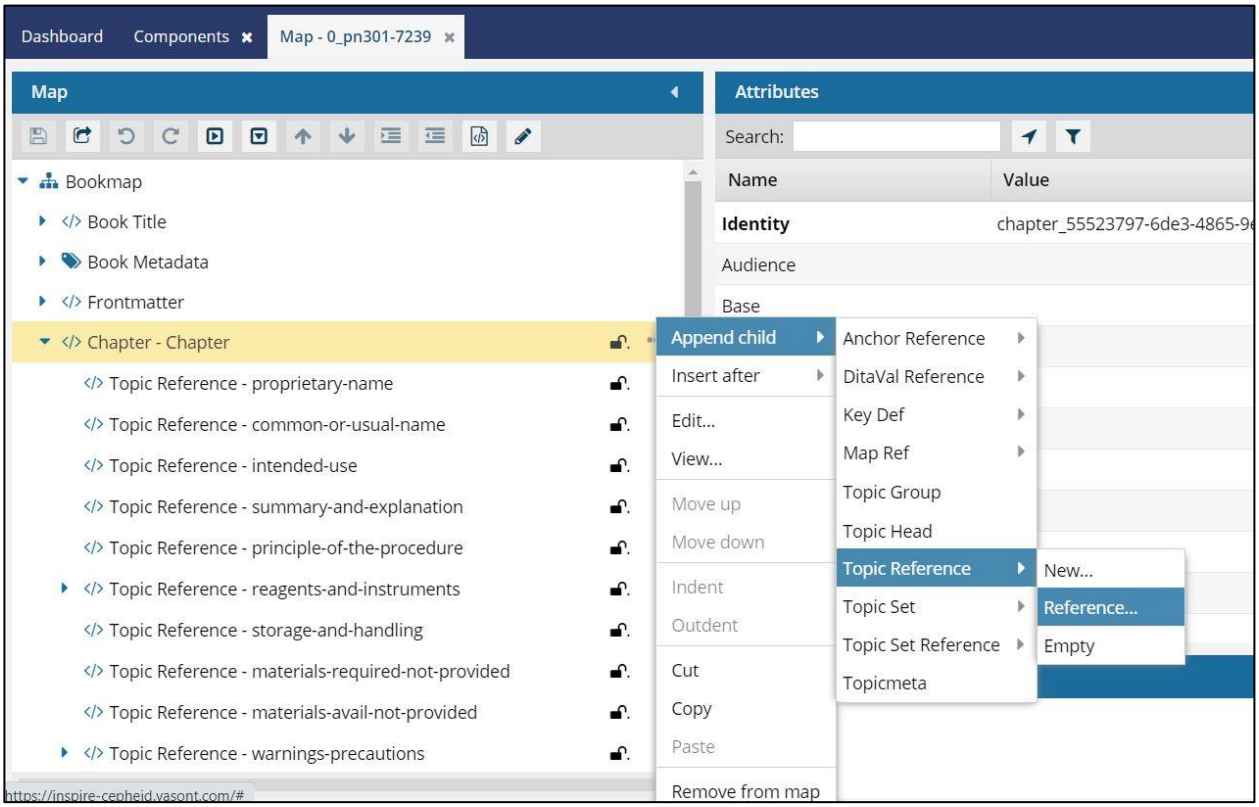
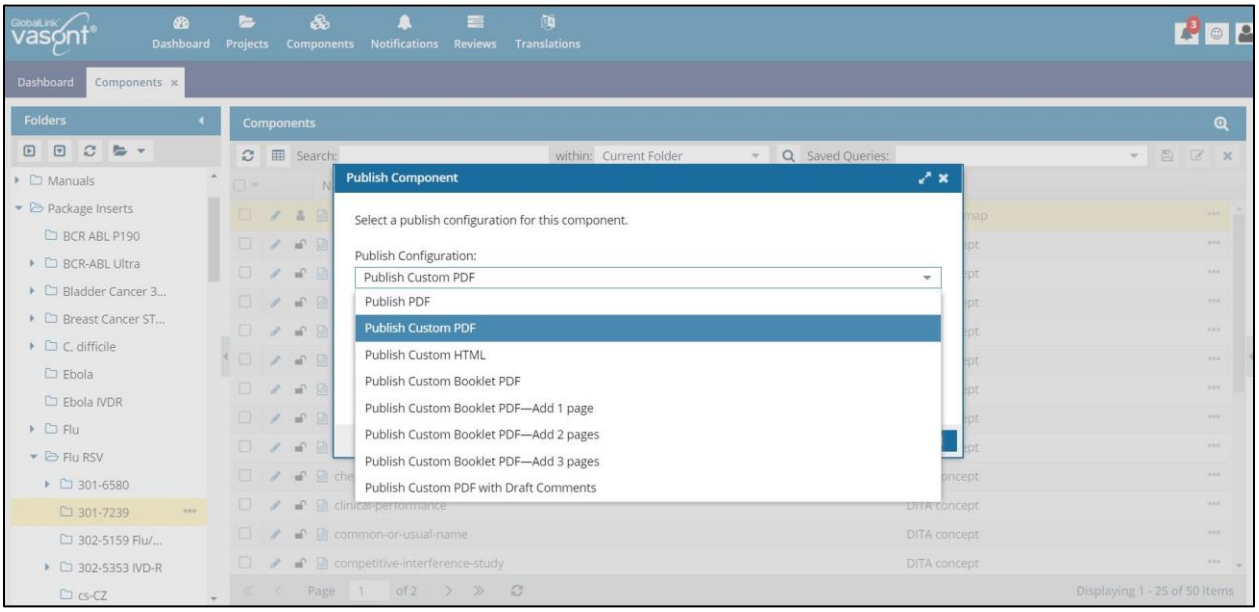


Figure 10: Publishing a custom PDF



Appendix C: Certification of Project Completion for Cepheid

June 2021

To whom it may concern,

This document serves as an official confirmation that Emily DeBusschere, student at California Polytechnic State University, San Luis Obispo, completed her senior project for Cepheid in June 2021.

Task	Level of Satisfaction (1-5 scale, five being highest)	Comments (if none, "N/A")
Gather information and develop a reasonable scope for the Package Insert Conversion (PIC) Project	4	Emily and I spent quite a lot of time discussing the project and the scope. Emily then mapped out what she needed to do to complete the project.
Acquire a basic working knowledge of Vasont *Inspire* with help from experienced writers	5	Emily spent many hours reviewing training videos that we had previously recorded about how to accomplish various tasks in Vasont. After that, she then started to execute on her plan and to put her first package insert into Vasont Inspire. She spent time with various people on our team when she ran into issues or needed to know more specifically how to accomplish something.
Conversion of 4 US-IVD package inserts	5	As of last weekend, Emily had completed all four package inserts that she committed to. A couple of them were longer and more complicated than most.
Application of Technical Communication Concentration: Work completed in Technical Publications to an acceptable standard with attention to detail	5	I have inspected 2 of the 4 package inserts that Emily completed. I only found minor issues with the package inserts. I believe Emily spent a lot of time doing her own reviews prior to sending them to me which resulted in a very high level of quality.
Application of Industrial Engineering-Project Management Concentration: Plan and adhere to a project schedule and form a "project team" of mentors, instructors, and reviewers	4	Emily put together a detailed plan for completing her senior project which included spending time with others on the team (mentors/instructors) and reviewers including me. I have found that Emily is great at planning and executing her plans both for this project and in other areas where she has been working on my team.

Areas for Improvement	Anticipated Future Work
Explore new tags or improve application of tagging in Vasont Inspire to increase efficiency and usability of documents.	Continue with package insert conversions from FrameMaker to Vasont Inspire
	Inclusion on new product development core teams representing technical publications

Kind Regards,

Earl E. Boggs

Earl Boggs
Senior Manager, Cepheid Technical Publications