



CASE STUDY

Trustpoint's Versatility and Expertise Help Guide Pharmaceutical Companies through Complex ANDA Matter

Generic pharmaceutical company with tight deadlines to review, redact and produce over 400,000 records. They needed a team that had substantive background to review lab notebooks and team members fluent in three languages.

Challenge:

- Review of 600K documents and redaction of 25K documents in rolling productions over 2 months.
- Redactions included thousands of similar but not duplicative spreadsheets requiring extensive redactions.
- 30K foreign language documents
- 1,000 Lab Notebooks

Solution:

- Because of the expedited nature of the review, Trustpoint employed three teams working in tandem.
 - ♦ First Level
 - » Prioritizing review using AI
 - » Building multiple models for responsiveness and hot documents
 - ♦ Redaction Team
 - » Leveraging analytics to automate thousands of redactions.
 - ♦ Foreign Language Fluent Team
- Developed complex workflow to mesh all three teams
- Leveraged technology to drastically reduce the number of redactions required for PDF and Excel documents.
- Built comprehensive timeline from Initial Review of lab notebooks.

Impact:

- Client was able to successfully defend their business by meeting all of their deadlines and leveraging the timelines created from the review of lab notebooks.
- Client was also able to protect their future business because precise work of the redaction team coupled with leveraging technology during the QC process.
- Trustpoint was able to meet every deadline at 38% under budget.
 - ♦ Over \$250,000 under budget
- Reduced redaction count by 29%
 - ♦ Over \$30,000 in saved costs