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CASE STUDY

As one of the industry leaders offering clinical trial transparency services we are delighted to be working hand-in-hand with some of the world's leading pharmaceutical organisations to help them beat their EMA Policy 0070 submission deadlines.

Our technology enabled and innovative Redaction and Anonymization service - **Redact360** has already delivered 19 successful client submissions and saved clients over £1.4million in revenue by outsourcing their requirements and reducing the need to invest internally in technology or staff.

By redefining the approach to meeting their regulatory commitment, our aim is to help clients reduce their compliance burden and release staff to complete more important life changing work.

> *Congratulations, you now belong to a very special group of people. Not only have you delivered our first redaction package, you have also successfully delivered one of the first EMA policy 70 redaction packages! Big thanks to all of you. We have all learned a lot during the preparation of the proposal package, the consultation and then the final package. FYI, I shared the good news with the Regulatory Department.*
> ***Head of Clinical Disclosure, CSL***

Why Redact360

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We passionately believe we can help our clients save time, money and drive efficiencies. We can protect your resources as our team has the experience and expertise that spans the entire submission process. We're operations people at heart and unlike some other vendors, we only operate in life sciences, so we know the industry inside-out.

And we're incredibly proud to support clients who do life-changing work!

For a **Redact360** demo please visit our website **www.kinapse/redact360**

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CASE STUDY

Below is a sample of some of the outcomes Redact360 has achieved for our clients as they strive to comply with the new regulations.

3 SUCCESSFUL SUBMISSIONS FOR TOP 5 PHARMACEUTICAL CLIENTS

Having successfully partnered with this client for over 7 years on their disclosure requirements, they recognised they lacked the deep experience and the unified approach needed across their team to meet their EMA 00700 regulatory requirements.

OUR SOLUTION INCLUDED

- Completing the redaction of over 900 documents with each package ranging from low to high-complexity documents including structured and un-structured data.
- Over 20 experienced Kinapse senior analysts and reviewers delivered the packages, meeting the tight 8 month deadline agreed, reducing the client's costs and time

DEVISED A UNIFIED FRAMEWORK

- Starting with the smallest package first so that key learnings could be identified and embedded in subsequent batches
- **Redact360** technology platform, complex document redaction was completed first followed by a rigorous manual Quality Control processes
- Created a well-defined redaction and anonymization plan that can be utilized in later submissions.

Based on the successful completion of each submission on time and continuous expert service provided we are delighted to be working with our client on their next 4 subsequent submissions.

LED THE URGENT PREPARATION OF AN EMA POLICY 0070 REDACTION PACKAGE FOR A MID-SIZED GLOBAL PHARMACEUTICAL COMPANY

We recently partnered with a mid-sized global pharmaceutical company, supporting them prepare a100-document package to meet a two month consultation period deadline.

OUR SOLUTION INCLUDED

- Using the automated **Redact360** platform we quickly galvanised a team to provide expert guidance and a high-quality implementation plan based on the agreed checklist to clear the submission package within the desired time-frame.
- This involved preparation for meetings with EMA, CCI justifications, and information in public domain ensuring consistent and measurable quality that would exceed expectations.

The submission was successfully accepted by EMA during the consultation phase with minimal editorial changes in the anonymization report.

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Visit our website at...
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