

case study



“Randstad proved to be a valuable business partner in meeting our mandated timelines for regulatory compliance. They worked quickly to onboard an expert safety team that kept us on track through the process.”

–Drug Safety Officer

pharmacovigilance literature reporting

Randstad has been working with this global, diversified healthcare company for over five years and initially partnered with the client to augment its direct hire business. In 2005 the company centralized its global pharmacovigilance activities and engaged Randstad to implement project solutions to assist in maintaining regulatory compliance during the centralization process.

The challenge

The client was faced with the challenge of processing a backlog of abstracts for their biopharmaceutical solution delivery and oncology products. The initial backlog estimation was 2,000 abstracts of which the client estimated 1,000 cases to be reportable.

The solution

The Randstad solution involved the development of an on-site team to manage and support safety database entry and case assessment. The Randstad team was comprised of three Safety Physicians, nine Safety Review Nurses, seven Safety Data Coordinators, three Safety Associates, and administrative support staff. These individuals strategically complied with the request to review, enter, and process all cases within the established timeframe.

As the project progressed, the scope increased from 2,000 cases to 6,000 cases. Randstad successfully supported the client's backlog literature team and expanded personnel to include seven Product Safety Associates who specialized in processing medical device cases. In addition, a safety call center was created within 24-hours to field a high volume of incoming calls.

Overall, Randstad leveraged the client's existing resources to effectively complete the project according to the outlined plan. As a result, the client's time and resources were permitted to focus on other key activities, allowing for “across the board” maintenance of regulatory compliance.

The results

- Processed more than three times the original project case load within mandated timelines while maintaining regulatory compliance.
- Standardized recruitment and on-boarding processes and reduced time-to-hire by 12 weeks.
- Randstad continues to support the client as a preferred supplier and is accountable for a vast majority of the global pharmacovigilance hires including the Senior Director of Global Pharmacovigilance.
- The client has further involved Randstad on medical review projects via an outsourced solution model.