

CASE STUDY

SOP Review For A Clinical Stage Biopharmaceutical Company

BACKGROUND

Since the release of ICH (E6) R2 in 2017, clinical research companies have been taking active measures to ensure compliance with its new guidance which, “encourages implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording, and reporting while continuing to ensure human subject protection and reliability of trial results.”

In 2018, a clinical-stage biopharmaceutical company requested that WCG Avoca perform a thorough review of its policies, procedures, work instructions, forms, and templates against the expectations outlined in ICH E6 (R2) and other relevant industry-leading practices.

Because the company was a Member of the Avoca Quality Consortium (AQC), Avoca’s project team leveraged AQC leading practices, where applicable.

SOLUTION

WCG Avoca reviewed the company's existing quality approaches as outlined in their quality documents and conducted a Needs Assessment and Gap Analysis to identify any missing elements.

The project was completed over a nine-week period from the date access to the company's SOPs was given and the date the readout session was done.

Based on discussions with the client, the scope of work outlined below was executed by WCG Avoca.

The introduction of ICH E6 (R2) has led companies to review regulatory gaps and operating procedures to ensure compliance with current regulations.

DOCUMENT GAP ANALYSIS

- A project plan was developed to outline the scope of work, which included an outline of the planned approach to meet the project's objectives within the agreed-upon timeline.
- Over 250 relevant internal documents and SOPs were reviewed to assess the needs, requirements, challenges, and gaps.
- A Gap Analysis was conducted to identify the delta between the company's current state and ICH E6 (R2) guidance, as well as industry-leading practices within the Avoca Quality Consortium.
- Gaps were cataloged in an Excel document (indicating risk level from low to high) along with details of ICH E6 (R2) gaps. Other identified gaps within the SOP or related documents were cataloged as well (e.g., leading practice gaps).

DOCUMENT NEEDS ASSESSMENT & GAP ANALYSIS READOUT

- Avoca conducted a two-hour teleconference with the company's key stakeholders to review the gaps identified in the reviewed documents and to determine how to proceed.
- Two Avoca SMEs presented the Document Needs Assessment and Gap Analysis readout.
- Because the company was a Member of the Avoca Quality Consortium (AQC), the client was shown which AQC tools to use to close the gaps identified.

PROJECT COMMUNICATION

- Based on the above scope of work, biweekly check-in meetings were held to provide status updates on document review and to evaluate alignment of the company's needs with Avoca support.

FINAL DELIVERABLES

- A copy of the slide deck used in the Document Needs Assessment and Gap Analysis.
- An SOP tracker which identified the key gaps and recommendations for each document reviewed.

RESULTS

- Avoca SMEs reviewed 272 documents (policies, SOPs, work instructions, forms, and templates).
- Of the documents reviewed, 51 (18.75%) were found to be non-compliant with ICH E6 (R2).
- Of the 51 documents containing ICH E6 (R2) gaps,
 - 15 contained high-risk findings (29.41%)
 - 22 contained medium-risk findings (43.14%)
 - 14 contained low-risk findings (27.47%)
- Additionally, 118 of the 272 documents reviewed were given suggestions for improvement in accordance with ICH (E6) R2 and industry-leading practices.
- Based on the Document Needs Assessment and Gap Analysis, the company learned the delta between the current state of the reviewed documents and the guidance outlined in ICH E6 (R2).

CONCLUSION

The company recognized the gaps and understood the action required to ensure compliance with ICH (E6) R2. They proceeded to address the regulatory gaps to ensure all operating procedures were compliant with current regulations.

To inquire about SOP consulting support for your organization, contact Dawn.Auerbach@theavocagroup.com.