

Interpretive Summary Reports

Making sense of your safety data.

Interpreting the multiple final reports issued with a full bioevaluation program can be a daunting task. Individual reports provide good detail into specific safety endpoints but combining all of the data into a cohesive picture can be challenging. If not done correctly, product submission delays or even rejections can result.

WuXi AppTec's technical experts can partner with you to make sense of your safety data – providing you with a single report that will include a summary of all of the biocompatibility data in your entire project, as well as interpretations across the various studies. An overall evaluation of compliance to ISO guidelines can also be provided.

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

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WHAT DOES A SUMMARY REPORT DO?

- Delivers an independent review of your data package.
- Assures adherence to ISO expectations.
- Provides a comprehensive data review to present to stakeholders.
- Saves time and reduces internal workload.

WHAT IS INCLUDED?

- Overviews of all biocompatibility study results.
- Changes made to studies and their impact on ISO compliance.
- Gap identification.
- Conclusions on the overall data interpretation.
- Conclusions on adherence to ISO 10993-1.

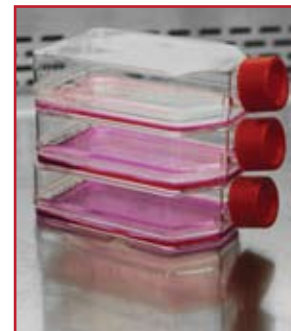
WHAT IS THE PROCESS?

- One-on-one discussion with a technical expert to review scope, product information and regulatory approach.
- Data review and summary.
- Draft report issued.
- Draft report discussion to clarify position.
- Final report issuance.

WHAT DOES IT COST?

Hourly Rate: \$350 per hour / 4-hour minimum

Typical projects take 4-8 hours to complete. Complex projects and those projects requiring significant research may take additional time. During the consultation, an initial estimate of the time required to review the WuXi AppTec data files will be provided. Additional fees for research materials, regulatory standards acquisitions, etc. may be charged if required to complete the summary assessment.



For more information on WuXi AppTec's services please contact:

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