Transforming lives through science, innovation and collaboration

Supporting the delivery of innovative life-changing treatments to patients

CASE STUDY: CELL AND GENE THERAPY SERVICES

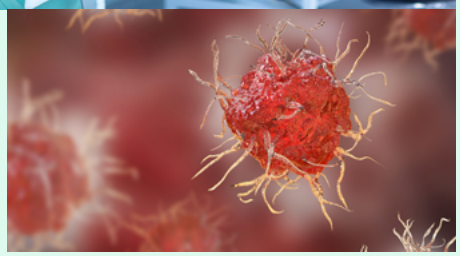
Client profile

An established academic spin-out working in the cell and gene therapy sector, which developed an autologous CAR T-cell therapy candidate to treat cancer patients.

Challenge

In order to progress to clinical trials, the client needed to characterise the materials used in their therapy and prepare a dossier submission. The client did not have the expertise or facilities to do this in-house, so reached out to RSSL.

The candidate therapy comprised around 20 components, including raw, contact and pathway materials, which required an extensive array of instrumentation. While some of the materials had existing pharmacopeia monographs, others – particularly those responsible for the therapeutic efficacy – were more complex and novel. With little regulatory guidance available, the client needed our support to develop appropriate methods.



Our capabilities

We deployed a wide variety of analytical techniques, leveraging the technical capabilities of our microscopy, microbiological and sterility, biomolecular analysis and wet chemistry labs.

By applying their extensive knowledge of biopharmaceutical testing to uncommon materials, our scientists were able to develop methods for even the most challenging materials.

This included developing identity methods for serum-free media – commonly used in cell therapy manufacture – to confirm the species of serum and serum proteins used in cell culture. Our scientists also developed bioassays and identity methods to assess the function of reagents designed to activate cell populations.

Expert problem solving

Given the number and complexity of materials involved, spanning microbiological, chemical and biological analyses, we knew that dedicated project management would be key. This included careful management of the large portfolio of samples and their transport between multiple labs, managing the necessary documentation efficiently and ensuring clear communication with the client.

We also developed our electronic data storage measures to ensure we could help our client meet stringent data retention requirements, which state that cell and gene therapy data must be retained and readily available for 30 years.

Outcome

- 69 testing methods developed over eight months
- Progressed to routine testing
- Client's therapy now in clinical study and we are now working with the client on a second product

Despite the disruption caused by COVID-19, we were able to complete method development for all materials in eight months, resulting in 69 new methods and progressing to routine testing. With the data gathered, we supported the client in their successful submission, and the promising therapy candidate is now in a clinical study. The client hopes to progress to a larger study ahead of submission for regulatory approval and future commercialisation to transform lives for patients.

We continue to work with the client to support their routine testing as they develop another therapy.

And with our data storage methods aligned to the latest industry requirements, we are now in a strong position to support the client with the submission of their next product for clinical trials.

'RSSL had the knowledge and equipment we needed and we always felt in the loop thanks to the ease of communication with the project manager. We are thrilled to now be in clinical trials and look forward to continuing to work with RSSL.'

Client

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