



Client Story: Enabling an Industry Disrupting Biotechnology Company

Enabling ElevateBio's industry disrupting business model

Introduction & Background

Powering transformative cell and gene therapies

Visionary new biotechnology company ElevateBio is solving the challenges of scale and speed to market for the emerging cell and gene therapy (CGT) industry with its next-generation technology platforms, state-of-the-art Basecamp facility, and disruptive business model. ElevateBio BaseCamp provides access to industry-leading scientific expertise, innovative technologies, and scalable manufacturing suites for its partners. ElevateBio were awarded the 2021 ISPE Foya Category Award for Operational Excellence which focused on their cutting-edge technology.

ElevateBio BaseCamp selected Kneat to digitize all its validation processes, resulting in rapid changeover of its manufacturing suites following a 50% cycle-time reduction and a best-in-class quality assurance experience for its partners.



Business Opportunities

Industry leadership through state-of-the-art technology

Since its founding in late 2017, ElevateBio has been committed to a ‘technology first’ business model where state-of-the-art technology is leveraged strategically to advance the entire cell and gene therapy industry and create value for its partners and a competitive edge in the market. Following the completion of its award-winning new facility, ‘Basecamp’, in Waltham, Massachusetts, ElevateBio sought to implement a digital validation solution that enabled that vision.

Commenting on the strategy, Director, Quality Assurance Validation Matt Ostrowski said, “At ElevateBio, we are not trying to be just a biotech company...this is a technology company that provides a seamless, tailored, manufacturing experience. We put in systems that allow us to provide our partners with something different, because we are working with next-generation technologies and a team of experts that have decades of experience in cell and gene therapies. We had the backing of senior leadership to focus on technological advantages and get our work done in a remote environment, quicker and more accurately...that was the big driver, from the beginning.”

ElevateBio’s mission to power the entire cell and gene therapy industry forward means that manufacturing suites at its Basecamp facility are used to develop and produce both its own therapies under development and those of its growing list of partners. As such it is important to have access to a validation solution that meets all business requirements and creates efficiencies in equipment changeover.

“Kneat allowed us to have a digitalized approach to quality and set-up our systems with a right first time approach.”

- Manager, Quality Assurance Validation, Laura Berberian

Manager, Quality Assurance, Laura Berberian explained, “We want to provide the best technology and services for our partners, and we’ve been able to utilize Kneat for this.”

For our partners, the ability to drive competitive advantage by optimizing equipment turnover through digital validation was critically important.

Commenting on the inefficiencies of paper-based and hybrid validation, Berberian stated, "I've been on projects where equipment has been sitting dormant for three years and [the client] wants to bring it back up and you have to go somewhere and request binders or boxes from Iron Mountain and it takes a week for them to show up and then you have to dig through and find it. Then I'm holding this piece of paper, recreating the protocol in Microsoft Word. There's a lot of efficiency lost there, just from the transparency and accessibility."

Solution Requirements & Purchase Decision

Scalability, ease of use, and robust access control

As a technology-driven company, there was no concern about getting buy in from senior leadership to utilize an electronic validation system. At the outset of the project to select the best technology for digital validation, Laura Berberian looked for a 21 CFR Part 11 compliant software solution that satisfied ElevateBio BaseCamp's list of considerations and benefits, including:

- ✓ Integration
- ✓ Ease of use
- ✓ Collaboration
- ✓ Access control
- ✓ Data integrity
- ✓ Efficiency
- ✓ The future
- ✓ Auditability
- ✓ Cost reductions
- ✓ Traceability
- ✓ Innovation

Vendor selection was straightforward. ElevateBio BaseCamp tested different software to evaluate capabilities, usability, and support. It ultimately came down to Kneat and one other provider and ElevateBio selected Kneat.

Matt Ostrowski said, "Kneat is at the top of the line as far as paperless validation, DMS system, document storage, archiving...I saw what it can do, how configurable it was, that it allowed us to implement what we wanted from the beginning versus trying to build a system around something that was already existing...we chose it because it was the most innovative product out there."

As a small company, with a limited training department, ease of use was a definite factor highlighted by the validation team, as Ostrowski explained. "Ease of use was important from a training standpoint...we need to be able to provide the training to allow users to get into the system and use it effectively. It needs to be quick, straight to the point. [Kneat] is very similar to a [Microsoft] Windows/Explorer type set up...the idea of folders makes sense to people and gives them the opportunity to learn it fairly quickly. It's kind of what they've seen, and we can provide training much quicker and get them on board quicker."

ElevateBio BaseCamp has a small validation team and, as such, relies on many external vendors and suppliers to deliver support. It was important that the software selected was intuitive, easy to use, and familiar so that all outside stakeholders could easily pick up digitized validation and have the ability to fit with ElevateBio's outlook of a paperless facility. Berberian explained, "It really seemed to me that Kneat was leaning towards being the industry leader. That was important to us here because we want to have people that are familiar with it. We don't want to have super unique software that no-one has seen before, and takes a lot of time, and is cumbersome to use. We want to be able to say, 'We use Kneat' and everyone says, 'I have five people who have used that before.'

"The biggest thing with Kneat was that it was easy to use...Kneat just seemed like it was a faster learning curve, and that people would be able to just jump in and use it...that is the experience that we have had, and we are really happy with our selection."

- Manager, Quality Assurance Validation, Laura Berberian

Implementation & Scaling

Supportive implementation with cost-effective option to scale, anytime

ElevateBio BaseCamp selected Kneat as the preferred solution in early 2020. Before deployment, Laura Berberian workshopped to strategize, harmonize processes, and cement buy in with different validation stakeholders at BaseCamp, such as calibration, metrology, manufacturing, and automation groups.

Questions asked during the workshops included, "does your approach to validation agree with how this other group is going to do it?", "does it agree with the calibration and methodology that you are going to set up?" and "does it agree with how engineering is going to be doing their drawings and their specs?"

During the workshops, the set-up of Kneat Workspaces and folders was agreed upon by all stakeholder groups. Berberian commented, "I think the buy in before implementation was really about the strategy of all our programs and making sure that Kneat satisfied everyone's needs—we made some smart decisions about doing it right from the start... and in that way when we go live, people are excited to use it, and everyone gets what they need out of [Kneat]." Next, ElevateBio BaseCamp and Kneat's Process Engineer worked together on process mapping configuration. They looked at ElevateBio BaseCamp's validation processes together and how to configure and feed them into Kneat. ElevateBio BaseCamp signed off on specifications, got the process mapping document finalized, and then designed all the templates and the folder structure.

Commenting on the configuration and implementation, Ostrowski said, “Our [Kneat] Process Manager at the first implementation was very knowledgeable. She led us towards what she had seen and asked us to tell her about our user requirements and what we wanted to get out of [Kneat]...and then geared it towards what we were trying to put together. She led the conversation which we appreciated and allowed us to move a bit quicker. Everyone being on the same page knowledge-wise was huge.”

Berberian continued, “I think that it was really helpful that the Kneat team has a lot of validation experience. The recommendations they made were helpful and they led the implementation project, which was seamless.” At the point of first implementation ElevateBio BaseCamp had around 50 people who would be using Kneat. The company held multiple End User training sessions so that schedules would not be impacted. Commenting on the onboarding of end users at ElevateBio BaseCamp, Ostrowski said, “Once we did [the training on Kneat], everybody used it and loved it. They saw that it was actually saving them time, especially during the remote workplace. We are 150 people right now, three times the number of users, since [we initially deployed Kneat] in June 2020.”

Commenting on ElevateBio BaseCamp’s relationship with Kneat’s project team and process engineers, Ostrowski stated, “Everyone has been really knowledgeable, really great. [The process engineers] have been answering any time we have a question. There’s always been an email response...the way they respond creates trust that if you are going to get an answer, it’s going to be the right one.”

Ostrowski continued, “We got our first protocols approved in Kneat. A lot of our wrapper documents, facilities, and engineering documents became official Kneat documents after implementation. I think that everybody loved that. In the hybrid work environment, [Kneat] was very key in helping us to get things reviewed and approved timely without the use of binders and piles of paper.

“The configurability of Kneat is huge...if we want to onboard a new client, it’s a 15-minute meeting between us, and we set it up how we want. We update our process mapping document, and we move on—and that has been really great.”

- Manager, Quality Assurance Validation, Laura Berberian

“Kneat kind of grew with the company. The configurability was huge...allowing us to get bigger and how we wanted to configure it to our standards, our SOPs, our behaviors. The scalability of Kneat, from what I see in other computer systems, it’s much better, because you don’t have to buy a million licenses. You can just buy what you need, as you start out, and it could grow with your company versus having to put huge money in at the beginning...from a budget standpoint the scalability is a huge benefit.”



Results & Customer Experience

Quick and easy review and approval, audit and partner friendly

Following deployment of Kneat, ElevateBio BaseCamp has seen a range of efficiencies including a 50% reduction in review cycle-time, enabling rapid equipment changeover of its manufacturing suites, and a best-in-class quality assurance experience for its partners.

The key efficiencies realized by leveraging Kneat's technology at ElevateBio BaseCamp include:

- **50% reduction in review cycle-time:** The ability to conduct simultaneous reviews and have fewer physical handoffs results in a significant reduction in review cycle-time.
- **Full transparency:** Over validation and quality documentation, aiding project management.
- **Capability:** Timelines that would not have been achievable on paper, are now achievable due to the ability of multiple stakeholders to review, comment, address comments, and approve at the same time, on the same platform.
- **Efficiency:** Kneat has shortened the overall validation schedule enabling the team to commit to tighter deadlines and accelerate speed to market.
- **Improved GDP:** Execution is more focused on content, going paperless has resulted in less 'paper-based' errors and legibility issues.
- **Productivity:** Reduction in time spent to reconcile comments, resulting in less meetings.
- **Auditability:** The ability to view audit trails and see whether people are signing off in a timely manner, or when they executed it.
- **Remote accessibility:** The ability to access, manage, and maintain validation processes, while working remotely.
- **No physical storage:** There is no longer a need to store documents and maintain a huge archive, saving a significant amount of time and money. Documents are instantly available to all stakeholders to view.

Commenting on Kneat's approval and audit functionality, Berberian stated: "The approvals process is relatively simple and easy to customize." Ostrowski continued, "And when we have an audit...the fact that we have all the documentation available [in Kneat] is huge."

Kneat's ability to offer the set-up of Workspaces for both ElevateBio BaseCamp and its partners has helped the validation team to better manage partner relations, efficiently and seamlessly. Berberian explained, "We set up Workspaces for our partners as it captures their technology transfer work including engineering runs, aseptic process simulation, etc., and in that way it is all in one space."

Berberian continued, "We obviously have access control and it allows for instantaneous feedback and transparency on both sides, which I think our partners really appreciate."

Ostrowski added, "The biggest thing is Display Workspaces and the security involved there. We utilize that just between partners. You can only see the Workspaces that you have access to."

Reflecting on the differences between paper-based and digital validation processes, Ostrowski added, "My whole career has been in paper up until now—it creates a lot of unnecessary errors. Some people are just better at documenting than others. Kneat removes the variability. It forces you to be better at documenting."

Talking about the future potential for further efficiencies with Kneat, Berberian stated, "Now that we are continuing to replicate the same thing, we should begin to see more of those time-saving improvements. Before, most of our time saving was focused on downstream efficiencies, like review and approval. Now we are getting to the point where some of our time savings are seen on the front end, with Doc Gen and execution."



Kneat

Talk to Us

Find out how Kneat can make your validation easier, faster, and smarter.
Start your validation revolution by speaking to our experts.

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