CASE STUDY

DiscGenics® automates their quality processes

Key facts:

Company: DiscGenics

Industry: Biotechnology

Country: United States

Octave products used: Reliance *(ETQ Reliance)*

Key benefits:

- Automated quality processes to eliminate need for additional document control headcount as company scaled
- Streamlined workflows by linking deviations to CAPA, quality records and test validation in one system
- Enabled rapid user adoption with intuitive interface, allowing employees to become productive immediately without extensive training

DiscGenics is a biotechnology company that is developing advanced spinal stem cell therapeutics to treat patients with diseases of the intervertebral disc.

Currently, DiscGenics is developing Injectable Discosphere Cell Therapy (IDCT), which is an offtheshelf injectable therapeutic based on regenerative medicine and progenitor cell science to treat pain associated with degenerative disc disease. DiscGenics is the only company to utilize allogeneic therapeutic progenitor cells derived from intervertebral disc. DiscGenics have a patented technology for isolating cells directly from adult human disc tissue and expanding these cells into their proprietary Discogenic Cells.

DiscGenics was looking for a turn-key solution Quality Management System (QMS) that would support the company through pre-clinical and clinical trials, into commercialization.

The challenge

As a pre-revenue startup company, DiscGenics wanted to do things right the first time around. Many companies use an assortment of point solutions and manual systems to manage various quality management processes which creates redundancies, errors and excess costs. The company first used manual processes, but then realized a need to eliminate the potential head counts within their QMS. Manually managing the company's processes was workable for a few years, but as the company grew and gained more employees, it had to look into what would make the most business sense — continue to use manual processes or start looking into an automated QMS. Manual processes were time consuming, error prone, becoming more difficult to manage as the number of processes and people involved grew. Down the road, ,if the company continued with its manual processes, it would have to hire a document control specialist to handle all of the paperwork.

"The idea was, if we start early and sow the thought that quality is everyone's responsibility, we could reap the benefit of a quality culture where the QMS ran more efficiently and effectively."

Randy Domingo
Head of Quality
DiscGenics

Quality journey

Pre-revenue start-up
Skip the manual processes, do things right the first time

Speed & efficiency
Easy-to-use, get team up and running quickly and minimize manual inputs

Scale as we grow

"Instead of continuing with manual processes, why not organically farm the people within the company who think quality?" stated Randy Domingo, Head of Quality at DiscGenics. "The idea was, if we start early and sow the thought that quality is everyone's responsibility, we could reap the benefit of a quality culture where the QMS ran more efficiently and effectively."

In addition, their existing QMS was proving difficult to manage. Domingo was familiar with enterprise QMS solutions, having used one in the past. He was looking for a similar solution, but geared toward startups. After researching different quality management solutions, DiscGenics chose Reliance because it encompassed more out-of-the-box solutions and was more affordable compared to other vendors.

DiscGenics considered other applications cumbersome and costly, especially when adding additional modules.

Being pre-revenue, it was critical for the company to start off with a more cost-effective solution before making the transition to an enterprise QMS. The fact that Reliance is under the Reliance umbrella of products, made this decision even easier for DiscGenics. While they had looked into other products, trust in the Reliance name ultimately led them to choosing Reliance, along with the option of moving up to Reliance in the future.

Compared to other solutions on the market, Reliance was the clear winner in terms of functionality. Another benefit is that Reliance was the only one to use Amazon servers, which provides the highest level of security and fault recovery.

Filling the gap

Since implementing Reliance, DiscGenics has benefited from ease of use—the company has found that Reliance was easy to adapt to. The company also likes the Reliance dashboard and the ability to see all of the modules that can access, all in one location.

"Reliance is all encompassing," s
ays Domingo.

The processes would be cumbersome to manage if all the tools were in different places. When document control was done manually, there was a lot of time spent to get all the required personnel in the same room — author, reviewer, approver — to review and approve documents. Now with document control, all documents are centralized and the review and approval process is automated. This has also improved productivity, because employees can now remain focused on their jobs rather than spending more time in meetings.

DiscGenics is now planning on growing the team organically and helping them understand quality from a holistic approach so they can relay that message to new employees.

Reaping the benefits

Reliance has cut the paperwork down on processes, because everything is linked. Deviations are linked to Corrective and Preventive Action (CAPA), to Quality Records and to Test Validation, resulting in a seamless process. Currently, users at DiscGenics are now using electronic forms to more easily capture data and quicken process resolutions. Reliance has reduced the number of paper forms, and has sped up the inspection process by enabling the company to enter data directly into the system rather than having to fill out paper forms that are then manually entered into the system.

In addition, many of DiscGenics employees who use the system come from academia background and didn't have any GMP experience. Because of this, the company needed to make sure the system would be aesthetically pleasing to them and user friendly. Reliance even includes instructional pop-ups to educate users on quality.

"Other systems could take a good year to get familiar with," stated Domingo. "We wanted something that users could springboard off of right from the get-go and we found that Reliance solutions would do that."

Looking forward

DiscGenics is building a design control program and plans to start using Document Control for uploading documents into the Document Control system. This will benefit the company in terms of automated workflows, a single point of reference with the centralized database, and the ability to monitor and manage quality measures to improve overall company quality.

Once DiscGenics gets into commercialization, the company plans on looking further into enterprise solutions. Since choosing Reliance, the company knows that as it grows, eventually it can migrate into Reliance as its enterprise solution.

About Octave

Octave is a leader in enterprise software, turning data into decisive action and intelligence into your edge. Our software solves for and simplifies complexity, from the design and build to operations and protection of people, property and assets – for any scope, at any scale. For decades, we've partnered with customers to sharpen performance, elevate efficiency and amplify results. From factory floors to entire cities, our solutions are tuned to scale up what's possible from day one onward.

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