

University of Utah Cell Therapy Facility: streamlining QMS management for 21 CFR Part 1271 compliance

Based at the University of Utah in Salt Lake City, the Cell Therapy Facility is an FDA-registered stem cell processing laboratory that processes human cells, tissues, and cellular and tissue-based products (HCT/PS) for 3 major local hospitals.

Q-Pulse provides tissue establishments like the University of Utah's Cell Therapy Facility with a fully integrated compliance management solution that helps manage regulated activities including Document Control, Auditing, and CA/PA Management, in regulatory environments such as 21 CFR Parts 11 and 1270-1271.

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As an FDA-regulated tissue establishment, the Facility had already implemented controls to prevent the introduction, transmission, and spread of communicable disease. When the Facility needed a solution to maintain and improve the management of quality processes including document control, they chose Q-Pulse from Gael Ltd.

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In ensuring the safety, quality and efficacy of HCT/Ps, the Facility sought to reduce time, effort and cost in meeting the requirements of the FDA's Current Good Tissue Practice (cGTP) by streamlining their document management processes with Q-Pulse.

'We'd looked at other systems prior to selecting Q-Pulse, but none were as good for the price,' says Andrew Havens, the Facility's Quality Assurance Manager. 'We believed Q-Pulse would be a great solution to several process concerns. We primarily sought out Q-Pulse to manage document control, but then we discovered its CA/PA, Asset and Training capabilities and were hooked.'

In selecting a system, the Facility identified 3 key requirements that had to be met:

- the most up to date FDA-required documents, including SOPs, forms and worksheets, must be accessible only to appropriate personnel for review, revision and change control
- deviations and non-conformances must be tracked and managed in line with FDA record-keeping requirements
- compliance with standards and regulations, including 21 CFR Parts 1270-1271

The Facility is regulated by the FDA through the Center for Biologics Evaluation and Research (CBER), which regulates HCT/Ps under Title 21 CFR Parts 1270-1271. The Facility had to make sure that the solution they chose enabled them to comply with strict FDA standards and regulations, including 21 CFR Parts 11, and 1270-1271.

In addition, the Facility's participation in other ventures, such as Investigational New Drug (IND) submissions and Phase I clinical trials, require it to function according to many other sections of 21 CFR, including Parts 210-211 and 820.

“Before Q-Pulse, we managed all of our documents manually,” says Andrew. “Documentation was stored on a shared network drive, and although everything was password protected, it wasn’t secure. In addition, with everything being performed manually, we had no way to formally track document revisions.”

“ We now track and manage deviations and non-conformances automatically through Q-Pulse, making the process simple, organized, streamlined and efficient. This allows us to maintain compliance with 21 CFR Part 1271 record-keeping requirements. ”

Andrew Havens
Quality Assurance Manager
University of Utah Cell Therapy Facility

'We wanted a system that would track, control, secure and automate our regulated documents, including SOPs, regulated forms and worksheets: something simple that would let us track version changes automatically and allow multiple users to interface with a robust change control mechanism.'

'We've now been able to establish a centralized repository for our controlled documents, which has meant that appropriate personnel now have direct access to secure, up-to-date documentation. We've also been able to automate the tracking of version changes, which has enabled us to cut down on the time and effort that we spend at each stage of the change control process.'

'One of Q-Pulse's components we like the most is the messaging functionality, which we've set up to notify relevant personnel of upcoming or required actions for which they're responsible, as well as to automatically escalate overdue actions. This has enabled immediate review by offering point-of-need access to documents from notifications of upcoming or overdue actions.'

'Along with document control, our deviation tracking was also completely manual and cumbersome prior to Q-Pulse. We now track and manage deviations and non-conformances automatically through Q-Pulse, making the process simple, organized, streamlined and efficient. This allows us to maintain compliance with 21 CFR Part 1271 record-keeping requirements.'

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Q-Pulse can help tissue establishments to comply with FDA 21 CFR Parts 1270-1271 requirements for human tissue intended for transplantation, and human cells, tissues, and cellular and tissue-based products (HCT/Ps), including Current Good Tissue Practice (cGTP).

In addition, Q-Pulse can help in achieving compliance with FDA 21 CFR Part 11 requirements for electronic records and electronic signatures. Q-Pulse's detailed audit trail and electronic record management enable tissue establishments to lay a foundation on which they can build the administrative and procedural controls for 21 CFR Part 11 compliance.

'At this point, we're only using Q-Pulse for Document and CA/PA management,' explains Andrew, 'but with equipment an important area of FDA scrutiny, we already have plans to fully implement the Asset module to organise our equipment and its maintenance.'

'In future we will also use Q-Pulse in organising training. Being able to create different training methods and programs in the Training and Competency module, as well as the ability to associate different types of media with each record could help to completely revamp our training program.'

Conclusion

With the FDA oversight of the tissue industry increasing significantly, tissue establishments are required to ensure that the recovery, processing, storage, labeling, packaging, and distribution of tissue all satisfy the requirements of the FDA's Current Good Tissue Practice (cGTP).

Ensuring the safety and quality of human cells, tissues, and cellular and tissue-based products (HCT/Ps) in order to prevent the introduction, transmission, or spread of communicable diseases, and to prevent contamination during manufacturing is more important than ever.

To comply with strict FDA standards and regulations, including Title 21 CFR Parts 11 and 1270-1271, as well as accreditation organization standards, such as FACT and AATB, tissue establishments must put systems in place that can help manage their compliance with legal, regulatory and accreditation requirements.

A compliance management solution that fully integrates key regulatory functions such as Auditing, Document Control and CA/PA Management can help tissue establishments to maintain and improve regulatory compliance.

In addition, by enabling the integration of compliance activities and actions, such solutions can enable establishments to streamline processes and reduce the duplication of effort.

Q-Pulse can help tissue establishments to comply with regulatory requirements including Title 21 CFR Parts 11 and 1270-1271, as well as to identify opportunities for continual improvement, from tracking corrective and preventive actions to measuring the effectiveness of the QMS.

Contact us now at tissueservices@gaelquality.com to find out how Q-Pulse can help you to reduce time and effort, reduce the duplication of effort and reduce resource expenditure.