



## **MountainStar Blood Services: taking control of documentation for 21 CFR Part 11 compliance**

Based at Ogden Regional Medical Center in Ogden, Utah, MountainStar Blood Services is an FDA-licensed blood center that supplies blood products to the Medical Center as well as to 7 local hospitals within the regional hospital network.

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With the network's blood-dependent services, which include emergency surgeries, needing more than 2000 units of blood a month, when MountainStar needed a solution that would enable them to maintain regulatory compliance, they chose Q-Pulse from Gael Ltd.

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With more than 100 000 units of blood and blood products needed by patients annually in Utah, and with more than 20 000 units of those processed at the Center, MountainStar supply an ever-increasing demand for blood products whilst ensuring safe transfusions *'from vein to vein'*.



*'As a small blood center within a hospital, probably the greatest challenge we faced was in finding a program that was user-friendly and within our budget,' says Judy Francis, MountainStar's Technical Supervisor at the Center. 'To find a system that we could configure the way we wanted and that had an impressive customer base was perfect for us.'*

In researching available solutions, MountainStar identified 3 key requirements that had to be met:

- track and monitor controlled documentation including SOPs and quality manuals, with staff able to maintain revisions adequately and to verify what state of completion SOPs and other documents were in
- reduce reliance on paper documents and increase the efficiency of document routing
- compliance with standards and regulations, including 21 CFR Part 11

With the Blood Service currently the only Utah-based blood operation with an interstate FDA license, MountainStar had to make sure that the solution they chose enabled them to comply with strict FDA standards and regulations, including Title 21 CFR Parts 11, 210-211 and 600.

*‘As in every industry, there are so many aspects of blood banking that require control,’ says Judy, ‘and Q-Pulse more than meets our needs, as it allows us to control many of our regulated activities with a single integrated system.’*

*‘Since we were completely relying on paper, controlling our operating procedures always seemed to be problematic. We had trouble controlling the number of manuals – at one time we had 13 in the field – and it was also very hard to maintain revisions adequately and to know what state of completion SOPs and other documents were in.*

*‘Relying on paper also made routing documents really difficult with our previous system. I was only routing documents to 4 people, but with so many documents in the field it still became a huge nightmare, and I finally had to make a chart of where documents were so I could keep track. However, without direct access to the standalone system, departmental staff were unable to get information at the point of need, which restricted the effectiveness of the system and reduced the efficiency of the whole QMS.*

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Judy Francis  
Technical Supervisor  
MountainStar Blood Services

*'With Q-Pulse, controlling our SOPs, forms, etc. it's very easy: we've included all forms, training records and competency tests, as well as pamphlets, donor cards and other documents that we hand out to our donors. In addition, our mobile crews already had laptop computers, so it was easy to make SOPs available to the crews.'*

*'We're now also able to track and monitor all of our documents throughout the document management process, including instantly identifying which documents are being revised, who they've been routed to and who has still to approve. This has allowed us to reduce the time and money that we spend in controlling our documentation.'*

*'And of course the ability to archive documents was a feature we were glad to have – to know that we didn't have to keep hard copies of our previous documents was wonderful, especially when storage space is limited.'*

Q-Pulse can also help blood service providers to comply with FDA 21 CFR Part 11 requirements for electronic records and electronic signatures, with functionality including:

- robust passwords
- intruder lock-out and password expiration
- additional electronic signatures
- full audit trail in creating, editing and deleting records

With detailed audit trail and electronic record management, Q-Pulse gives blood service providers everything they need to put the technical controls of a 21 CFR Part 11 compliant system in place, laying a foundation on which they can build the administrative and procedural controls for compliance with 21 CFR Part 11.

*'We're currently the only Utah-based blood operation with an interstate FDA license, and we use Q-Pulse in dealing with many of the issues that we encounter with the regulator; for example in keeping track of all the documentation and follow-up for non-conformances, training and equipment.'*

*'As we're licensed by the FDA, what we wanted – in a word – was control,' says Judy. 'In meeting the blood needs of 7 hospitals throughout the region 24 hours a day, there's always lots to do with little time to do it in, and it's critical that we can keep up-to-date with everything that our different roles require.'*

*'Now, with Q-Pulse, we can maintain control at the user level, with a central repository that reminds us when we're due to review and update all of the components that make up regulations. For example, we've been able to store all of our supplier qualifications within Q-Pulse, which means that we can make sure they have been reviewed before an inspection.'*

*'Until now, we've focused on the Documents module – right now we're reviewing and updating all of our SOPs – but we're looking forward to having all of the modules up-and-running to their full capacity, especially Training and CA/PA, as well as getting our copy of the new version.'*

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## Conclusion

With FDA oversight of the blood industry increasing significantly, blood service providers are now required to ensure that the collection, testing, processing, storage and distribution of blood are all performed in a robust, quality-assured environment.

And with the penalties for failing to comply with laws and regulations also increasing, ensuring the safety and quality of more than 28 million units of blood and blood products – the amount received by patients last year in the US – is more important than ever.

To comply with strict FDA standards and regulations, including Title 21 CFR Parts 11, 210-211 and 600, as well as AABB standards and CLIA-88 regulations, blood service providers must put systems in place that can help manage their compliance with legal and regulatory requirements.

A compliance management solution that fully integrates key regulatory functions such as Auditing, Document Control and CA/PA Management can help blood service providers to maintain and improve regulatory compliance, as well as to streamline processes and reduce the duplication of effort by enabling the integration of compliance activities and actions.

Q-Pulse can help blood service providers to comply with regulatory requirements including 21 CFR, AABB and CLIA-88, 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 [bloodservices@gaelquality.com](mailto:bloodservices@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.

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