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PREVIOUS SITUATION

The majority of the work we undertake at eg technology has a medical or biotech focus. That means we are working within regulatory frameworks that require documentation of the design approach and evaluation and traceability of changes when they occur.

About 18 months ago while working on some complex medical projects we were struck by the amount of time required to create and then maintain multiple specifications in MS Word/Excel format. As the design evolves it becomes increasingly difficult and time-consuming to maintain traceability between requirements and then to cross-link these to verification tests.

As an engineering and design consultancy it is important that we fully understand the client's requirements and in most cases a project will commence with an initial specification phase which helps to scope out the development as a whole. Once this specification is written it becomes a living document that evolves over the course of the design lifecycle. We also therefore need to be able to track changes in requirements particularly where the changes will have a significant impact on the scope or timescales of the project.

CLIENT:
eg technology

SECTOR:
Product Design & Engineering
Medical Devices & Biotech

KEY NUMBERS:
Size: <£5m
Number of employees: <50
Location: UK

THE IMPLEMENTATION

We evaluated a number of solutions from different providers. Since we were already an ISO 13485 accredited organization, we were keen to find a tool that fitted well with our established processes rather than one that demanded that we work within a fixed system.

Each project we undertake and each client is different, the ability to customize the project structure and documentation hierarchy on a project by project basis was a key selling point of Visure Requirements. We also wanted a tool that would manage requirements from multiple disciplines including mechanical and electronic design rather than a solution which focused on software development methodologies.

Success with any software tool depends on the people using it properly, but we didn't want anything with too steep a learning curve. It was important that the basic mechanics of requirement entry was no more onerous than working with Word or Excel.

THE RESULT

To date, Visure Requirements has been used on 5 client projects and is now the defacto option when creating specification documents or commencing work for a new client. We have certainly seen benefits in terms of time saving when we needed to produce traceability reports for a product that has been submitted to the FDA for medical device approval.

THE BENEFITS

Visure Requirements fits easily within our existing design processes; the adaptable workflow can be used on smaller and larger projects. Basic specification development and documentation carries little or no overhead when compared to using Word/Excel but offers significant benefits in terms of time, accuracy and rigor as specifications and test plans evolve over the project life-cycle.

The ability to monitor and track the inevitable evolution of a specification during the development process allows us to be more responsive to our customers' needs whilst at the same time maintaining rigorous change control.

Using traceability matrices we can confirm all requirements are covered at the same time having the flexibility to ensure that nothing is gold-plated helps to ensure we deliver projects that meet our client's expectations on time and on budget.

"Visure Requirements removes the administrative overhead of keeping multiple Word/Excel documents up to date, while maintaining a flexible approach which fits with our existing ISO 13485 processes"

David Warwick
Software Group Lead

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ABOUT EG TECHNOLOGY

eg technology is a leading product design, development and engineering consultancy, with skills that encompass industrial design, mechanical and electronics engineering and software development. We work with clients that range from small biotechnology start-ups to industry-leading bluechips. We combine flexible development processes with a thorough understanding of aesthetics, ergonomics and user insight to cost-effectively develop successful products from visualisation to commercialisation.

www.egtechnology.co.uk

ABOUT VISURE SOLUTIONS

Visure Solutions, the Requirements Lifecycle Management Company, is the market leader in Requirements Definition & Management. Through its Requirement Lifecycle Management platform, Visure offers specialized and innovative solutions that enable its customers to develop the highest-quality products, systems and services. Visure's quality, state-of-the-art features and benefits are endorsed by the world's leading organizations. Visure's team has a unique and profound experience in the development and implementation of requirements solutions.

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