



Tessella in Action:

Software for Regulated Industries

Companies operating in regulated industries are not free to do whatever they like, how they like. They must conform to the rules of independent regulatory bodies, which normally have the power to impose fines and penalties, and ultimately, to close the business down if their rules are broken.

It is vital that companies develop their software systems strictly in accordance with the appropriate rules and guidelines. The consequences of having a system rejected by the regulator can be economically catastrophic: a pharmaceutical company could find itself unable to market a drug it has spent 10 years and £100,000,000 developing; a train company may find that it is not allowed to operate its trains; or a nuclear plant could be forced to close down, or dramatically reduce its output.

The impact of regulation on software development covers the complete lifecycle, from the specification of the solution's requirements, through analysis and design to implementation and testing.

It is always much more efficient and cost effective to develop the software within the required regulatory documentation and development framework than attempt to retrofit the solution and complete the documentation at a later stage.

The key issues to be considered when

developing software in a regulated environment are as follows:

- The need to understand and meet the regulatory requirements (development life-cycle, documentation, testing, traceability etc.)
- The provision of a robust, secure and managed software development environment
- The requirement for supporting external auditing activities.

In order to produce systems for regulated industries, Tessella needs only to follow its normal working practices; our procedures and documentation sets are more than adequate, and working in a regulated environment is not unusual for us.

- Tessella has experience in developing and supporting regulated systems that are in operational use.
- Tessella's development procedures are scalable to meet customer requirements.



- Tessella has experience of being audited by third parties, including customer representatives.

Tessella has experience of developing solutions for use in a number of regulated environments, such as FDA (Food and Drug Administration), GxP (various industry Good Practice guidelines), Nuclear and the Rail Industry. Central to our ability to develop systems that satisfy the scrutiny of auditors are the high academic standards of our staff, and a very powerful quality management system.

Tessella's Software Development Processes

Tessella has held TickIT accredited certification to BS EN ISO 9001 (formally BS5750) since 1992. Since then we have continually evolved and improved our quality system to allow us to deliver top class software systems to demanding customers in scientific and engineering organizations. Our processes are audited every 6 months by the BSI, and are often inspected by our customers.

The Tessella software development environment provides:

- Procedures to cover the complete software lifecycle
- Simple mapping to the various standard regulatory documentation sets (FDA, GxP etc.)
- Automated Configuration Management
- Automated Issue tracking (web based with customer access)
- Use of automated testing tools and frameworks
- Traceability from requirements through design, implementation and testing

Project execution and management makes use of Tessella's electronic document management and workflow system.

Tessella projects are subject to regular internal audits, covering both technical and project execution aspects.

Many of the projects we carry out are covered by strict non-disclosure agreements. However, the following are a representative selection of projects.

FDA - Pre-market submissions 510(k)

Tessella helped a new company, Remote Diagnostic Technologies Ltd (RDT), to obtain FDA clearance of their new system, Tempus 2000, at the first attempt. Tempus 2000 is a device for remote medical monitoring of patients through satellite communications. It is designed to be used on planes and ships and in any remote location where access to medical facilities is limited. Tessella advised RDT on FDA matters in all stages of this project and were instrumental in the design, development, testing and validation of the system.

Tessella assisted a medical device manufacturer in obtaining FDA clearance for two new devices. Our customer had developed two medical devices that use unique polymer sensing arrays to detect bacterial and fungal infections. When they contacted Tessella the software for the first device had been developed, but was not of sufficient quality for a successful FDA 510(k) pre-market submission. The second device was just starting the specification cycle, and the company wanted to use an approach that would ensure FDA compliance from the start of the project. Tessella initially provided a team to review the software of the first device and identify the work required for a successful FDA submission. We then carried out this work, while at the same time taking over the project management and development of the software for the second device. The result was both devices received FDA 510(k) clearance at first submission after Tessella became involved.

FDA – Clinical Trials

In the ASTIN study, Tessella implemented, validated and ran the system that provided the infrastructure for 'real-time learning'. This system used fax to communicate with some 100 centres world wide, to randomise subjects and collect key follow-up data for a Bayesian adaptive model. The system also monitored and controlled the delivery of drug supplies from Pfizer to the centres. The software validated by Tessella was accepted by the FDA first time. The system was presented at a Bayesian statistics Workshop in Pittsburgh (<http://ftp.isds.duke.edu/WorkingPapers/99-34.pdf>). Tessella is now recognised as being an authority on Bayesian adaptive clinical trials and we are currently validating the design of a new phase 3 clinical trial for a different customer.

Tessella has developed a system to store, manage and analyse data from phase I/II clinical trials for a major pharmaceutical company. Investigators around the world submit data to the database, which is physically located in Tessella's offices, via IVR, fax, PDA or Web, and Tessella makes the data and results of analyses available to the customer's researchers, while keeping the trial double-blinded.

European CE Marking

Tessella helped Alaris Medical Systems to bring a new Infusion Pump to market, satisfying EU regulators. Tessella was invited to review the design of the system's embedded software. We highlighted a number of areas of concern in the design, and subsequently worked with Alaris to redesign and develop this software. The infusion pump is now being marketing throughout Europe.

Environment Protection Agency

Tessella has developed risk assessment modeling software for a major agri-chemicals company. The system models environmental protection and dietary safety. Assessments are used in regulatory submissions for new pesticide and herbicide licences from the EPA.

Nuclear

Tessella worked with Harwell Instruments to produce a nuclear waste assay measurement system for BNFL. The project was designated a safety-related system and was required to conform to IEC-61508 at safety integrity level (SIL) 2.

Rail Industry

Tessella developed an engineering design system for Balfour Beatty Rail to improve the efficiency of designing track alignment for rail renewal projects. This system received approval from Network Rail for use on British mainline railways.

In another project for Balfour Beatty Rail Technologies, Tessella helped to design, develop and install a remote condition monitoring solution for fixed assets, as part of the UK West Coast Mainline Route Modification project. To date it has been installed at multiple sites to monitor the performance and condition of rail switch point machines and trackside redundant power supply nodes. Rail engineers are automatically sent alarms when asset performance drops below thresholds, or is expected to in the near future. A sophisticated interface allows the engineer to drill down for more extensive information on the immediate problem and see the historical performance of the offending asset. In order for this system to be installed on the railway, it had to gain formal safety approval from Network Rail's experts, declaring that it adhered to the rigorous demands of the UK Rail rulebook.

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