



Tessella: Supporting Life Sciences at every stage

In the highly competitive Life Sciences sector, companies of all sizes need an edge. Biotechnology companies may wish to focus on product design and development and licensing agreements in order to maintain investor confidence; larger pharmaceuticals rely on efficient pipeline management and in-licensing products to deliver a steady stream of new products to market.



Tessella has been a leading independent supplier of software solutions to the pharmaceutical, biotech, medical and agrochemical communities for many years, priding ourselves on understanding our customers' business and technical requirements, and working with them to provide innovative, cost-effective solutions.

Tessella can offer that competitive edge and help world-leading companies improve efficiency in drug discovery, development, risk analysis and portfolio management. Our combination of skills is powerful:

- Automation and robotics
- Drug discovery and development processes
- Image analysis
- Innovative software development
- Mathematical modelling
- Multivariate data visualization
- Regulatory processes
- Risk analysis
- Scientific database development and mining

- Simulation of processes, devices and mechanisms
- Statistical analysis

And has been applied to:

- in silico prediction of molecular properties
- PK/PD modelling
- Lab automation
- High Throughput Technologies
- Sample tracking
- Integrating LIMS
- Database design & development for mass spec, NMR, chromatography & 'omics' data
- Hepatotoxicity studies
- Tablet design and manufacture
- Adaptive Clinical Trials
- Clinical trials simulations and live data management
- Process Analytical Technologies
- Data archiving
- Decision analysis & portfolio management

Workflow and Productivity Enhancement

Productivity, and the pressure to generate more NCEs with the same, or fewer, resources, is a central focus of all pharmaceutical organizations. Organizational productivity improvements can be made by making changes to the business process. Tessella has helped several organizations to implement more efficient processes in clinical trials, and in portfolio management. This has been intimately linked to developing systems which provide the right information to the right people at the right time, enabling them to make better decisions.

Much of the time, organizational productivity improvement is attained by the incremental improvement of individual or departmental productivity. Tessella has extensive experience, across many industries, of implementing systems to help individuals work more efficiently:

- Knowledge management systems to facilitate organizational learning and minimize rework
- Integration of information silos
- Workflow solutions to ensure the efficient movement of information through a defined and controlled process.

The development expertise needed to build such systems is linked to the business analysis skills needed to work with clients to ensure that the underlying process is correct.

Cheminformatics Solutions

Information solutions for chemistry functions must span a wide range of user needs. In the early screening phases, the emphasis is on the efficient handling of large data volumes from HTS systems. Tessella has worked with clients, not only on database systems to handle the data, but also on systems that monitor the process, ensuring the quality of the results obtained.

In the later stages of discovery, the focus moves to a richer set of information on a more restricted set of compounds. The challenges of providing the flexibility to store new data as science moves forward, whilst still providing the sophisticated data searching needed by scientists have been addressed using Tessella's extensive experience in scientific data management.



Laboratory Automation and Robotics

Tessella has a long history of helping our clients automate their laboratories. Whether the goal is high throughput or relieving highly skilled scientists of time consuming, repetitive and error prone manual tasks and manual data processing, we work closely with our clients to analyze laboratory processes and automate them.

High-throughput technologies for screening and experimentation are an essential tool in the discovery process.

Tessella has experience of high throughput technologies from the micro-litre to the litre scale. We have first-hand experience of working with vendors of high throughput robotics. Our projects have ranged from sample logistics and robotic control through to data analysis and quality control.

The full end-to-end process for laboratory functions like synthesis, purification and impurity analysis will often involve moving samples and data between instruments and systems from many different vendors. The gaps in between these systems can be the bottlenecks that limit the performance of the laboratory, and the manual bridges between the systems often involve time-consuming and error-prone reformatting of data.

Tessella has wide experience of integrating multiple systems from different vendors into well-proven automated workflows, increasing throughput and data quality at the same time. Tessella can pick up where the vendors solutions end to coordinate liquid handling, HPLC, Mass Spectrometry and data analysis (to name a few), into a well-managed automated process.

Management and Analysis of Omics Data

With the advent of 'omics' technologies scientists are able to measure tens of thousands of data points in a single experiment, whether they be genes, proteins or metabolites. These technologies bring enormous opportunities for discovery but also problems; how do we safely store such data for future analysis and allow researchers to select specific data for their own analysis?

At the same time, different platforms and new technologies can be brought to bear on a single problem, each with their own data formats and emerging publication standards. At Tessella we have developed data management platforms that can be configured for one or more different experimental platforms, that allow researchers to search for data and files and adds value to results by linking to other bioinformatics databases.

PK/PD Modelling

An understanding of how a drug is absorbed into the human body ('pharmacokinetics' or PK) and how it achieves the target benefit ('pharmacodynamics' or PD) is a critical part of the drug development lifecycle. Building models of these processes allows optimal doses to be selected for clinical trials while avoiding the risk of toxicity, taking patient variability into account. Given the cost and timescale of drug development, in particular the expense of running clinical trials, such predictive capability is key for pharmaceutical drug development companies.

Tessella's expertise has enabled the development of a number of novel non-linear models, with associated solution methods, for systems which cannot be described using standard approaches. We have also developed easy-to-use software tools which allow the rapid solution of the equations for synthetic populations to assess variability in response. This has provided the capability to perform dose optimization and 'what-if' analyses, which were not possible using the industry standard models and tools. Such a capability can also provide the basis for wider modelling of entire clinical trials, improving the probability of success and optimizing trial size to reduce unnecessary costs.

Biomarkers and Hepatotoxicity

Biomarker discovery will play an increasingly important role in the future of drug discovery and development in a wide variety of applications across the pharmaceutical industry.

For example:

- Developing diagnostic tools for specific diseases
- Monitoring of disease progression
- Measuring the responsiveness of a given subject to a drug treatment
- Revealing toxic effects due to drug-induced hepatic injury earlier on (hepatotoxicity)
- Identifying patients at risk of side effects
- Providing surrogate endpoints for clinical trials
- Stratifying patients for clinical trials and helping elucidate metabolic pathways in normal and pathological states

Tessella has been working on a number of different projects with large pharmaceutical companies in the area of Biomarkers; one involving image handling investigating the suitability of immunohistochemistry for biomarker identification. We are also developing a biomarker database; compiling biomarker information from many different data formats, and then linking the biomarker data up with the discovery data (genomic, proteomic, etc).

Tessella has also implemented a number of systems for the collection and analysis of clinical trials data, including the use of Principal Component Analysis (PCA). One of the challenges has been to develop an effective means of presenting the results of multivariate data analysis to clinicians. Our experience of developing 3D visualization techniques for scientific data provided some useful advances in this area. Tessella's scientific understanding allowed us to work closely with the client to create sophisticated solutions to a very complex problem. Ultimately, the aim is to develop more effective clinical trials which will reduce costs and maximize patient safety.

Portfolio Management

Boards of directors of pharmaceutical companies are coming under increasing scrutiny from investors and the outside world.

Now, more than ever before, there is a need for transparent and auditable decision and portfolio management processes covering:

- In project decisions (eg. multiple indications)
- In-licencing and out-licencing
- Pipeline management (maintenance of a healthy mix of projects at the various stages of discovery and development at all times)
- Optimal resource allocation (eg. financial & human resources)
- Portfolio optimization (maximizing return under the real-world constraints of good pipeline management and finite resources)

The pressure is on to handle these issues with the over-riding aim of maintaining investor confidence. It might not be sufficient to simply choose the combination of projects with the maximum expected return without considering the return as a function of time. Similarly, isolated maximization of individual project returns may not be appropriate.

Traditional approaches often compromise the solution unnecessarily by using processes which obscure or skirt around the real issues rather than revealing them and meeting them head on.

Tessella's aim is to give pharmaceutical companies the tools and support needed to make better-informed portfolio management decisions.

Tailored to the specific current needs of each individual client, we can provide

- Process improvement consultancy
- IT consultancy
- Portfolio review consultancy
- Software to support the process

We build customized solutions using modules from our Portmanto toolkit; this is a suite of portfolio analysis programs that have been developed and used over a number of years.

Please email info@tessella.com to request our capability statement 'Portfolio Management'.

Adaptive Clinical Trials

Adaptive clinical trials are a groundbreaking progression, which attempt to increase the efficiency of clinical trials by breaking out of the confines of conventional experimental design.

Since 1998, Tessella has been working with pharmaceutical clients on adaptive trial designs, including supporting four of the top-ten international pharmaceutical companies. Tessella continues to win new clients in this area, and now have projects underway with two further top pharmas, helping them to run adaptive dose finding studies.

In collaboration with leading statisticians, Tessella has implemented statistical models for phase 1 trials, phase 2 dose finding studies using Bayesian statistics, and phase 2/3 seamless designs. Tessella has supported these models by developing simulation and analysis tools, and by building and running the infrastructure to run the trials. Such infrastructure has included central randomization, electronic data capture, and drug supply management. Tessella has also provided consultancy to pharmaceutical companies to help them adopt adaptive clinical trials and to enhance their own in-house systems so that they can support Adaptive Clinical Trials.

Please email info@tessella.com to request our capability statement 'Adaptive Clinical Trials and Tessella'.

Digital Preservation

Pharmaceutical companies must retain enormous amounts of information over periods long enough to cover many generations of technology; both as a store of corporate knowledge and to satisfy stringent regulatory requirements.

Tessella has been working with public and private sector organizations to develop practical solutions to the challenges posed.

In the public sector, Tessella has worked with the UK, US, Netherlands, Malaysian, and Swiss national archives, on their digital archiving challenges, and now supplies the 'Safety Deposit Box' – a complete solution allowing organizations to benefit from cutting-edge digital archiving innovations.

Please email info@tessella.com to request our capability statements:

'Tessella and Digital Archiving' and

'Tessella SDB – Keeping Knowledge Alive'.

In conclusion

Tessella's exemplary knowledge across the life sciences sector includes genomics, proteomics, toxicology/pharmacology, chemistry and biology.

With a growing presence in the US and European markets, we take great pride in establishing long-term relationships with our customers.

Over two decades of experience working with several of the major pharmaceutical companies and a large number of businesses involved in emergent technologies (such as bioinformatics and pharmacogenomics), means we can understand your business requirements and work with you to provide cutting edge solutions throughout the whole drug discovery and development pipeline.

To find out how Tessella can use its unique blend of scientific, engineering and IT skills to solve your most complex of technical and business problems in a highly cost-effective way, please email info@tessella.com



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Tessella plc 26 The Quadrant, Abingdon Science Park, Abingdon, Oxfordshire OX14 3YS, UK
T: +44 (0)1235 555511 | F: +44 (0)1235 553301 | E: info@tessella.com

Tessella Inc 233 Needham Street, Suite 300, Newton, MA 02464, USA
T: 1 617 454 1220 | F: 1 617 454 1001 | E: info@tessella.com

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