

Veraciti™ Sets New Quality Benchmarks at Integra LifeSciences



Kallik enabled us to move from a process that was impossible to measure to one that was fully transparent. This enabled us to focus and address inefficiencies in areas of the business that were true bottlenecks, rather than risk assigning valuable resources to projects that might have limited impact.



David Dreibelbis,
Senior Marketing Operations
Manager, Integra Life Sciences,
Plainsboro, NJ

Surgical and medical instrument manufacturing leader Integra LifeSciences, a world leader in medical technology, is dedicated to limiting uncertainty for surgeons so they can concentrate on providing the best patient care. The New Jersey, US-based firm offers innovative solutions in orthopedic extremity surgery, neurosurgery, spine surgery, and reconstructive and general surgery. Kallik's Veraciti solution has embedded clarity and control into Integra's artwork approval process — enabling the organization to streamline manufacturing operations, reducing time to market for new product launches.

Challenges

Like many other successful life sciences businesses, Integra LifeSciences was experiencing business growth pains that meant it had outgrown its legacy paper-based labeling and artwork based processes. As a result, it needed a completely new approach to cope with ever-increasing volumes of regulatory and product-driven changes.

“We wanted to implement a single organization-wide solution that would bring new levels of robustness into the artwork approval process,” notes the company's Senior Marketing Operations Manager, David Dreibelbis.

“We had 20 different processes in place across the organization, making artwork and label management extremely challenging. We knew there was a knock-on effect on product launches, but with zero visibility, we couldn't measure the impact, and so were unable to take corrective action.”

How Kallik Helped

Integra's brief was for a solution that would deliver greater transparency, enhanced compliance, plus deliver to internal stakeholders tools for improved oversight and governance, with an ultimate objective of being able to eliminate uncertainty and simplify all touchpoints in the lifecycle process. Operating a paper-based approval mechanism was also masking true process bottlenecks across Integra's label and artwork management processes, while with an expanding product portfolio, and an ever-increasing volume of compliance requirements, Integra needed to achieve new levels of scale and consistency to meet its quality objectives.



Veraciti's artwork approval process represents one of the most mature and complete quality processes across the entire Integra organization. It is now the quality benchmark against which all other processes are measured.



Integra Vice President -
Quality, Integra Life Sciences, Plainsboro, NJ

Kallik's Veraciti solution was able to meet all Integra's requirements with its tailored artwork approval and asset approval lifecycle workflows. As Dreibelbis confirms, "Initially we were looking for an artwork approval tool with the capability of workflow management. We considered a number of established vendors, but Veraciti's simple-to-use approval tools, plus the artwork creation functionality it offered, made it a clear choice for us.

"Veraciti's artwork approval workflow satisfies all our compliance requirements," he continues. "Because everything is in one place, retrieval of documents and artwork assets is a simple process for any stakeholder to access. This process now sets an unparalleled standard not seen before in our organization; the reports and audits available are first class."

This was just the tip of the iceberg. Veraciti's modular structure has made it both simple and effective to adopt additional functionality, such as Veraciti's Automated Artwork Generator. Many manual repetitive tasks that previously consumed valuable resources have, as a direct result, been completely eradicated from internal Integra workflows.

Results

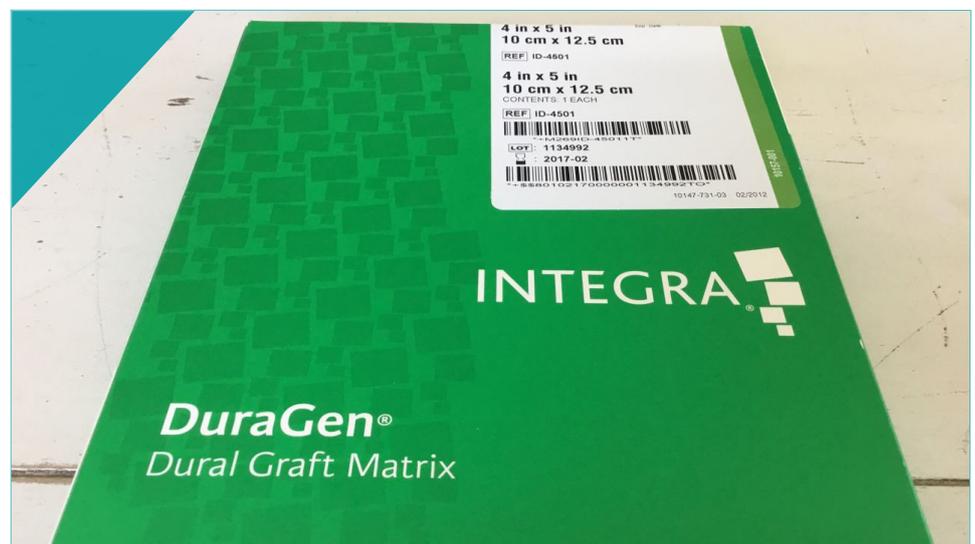
Since implementation more than 5 years ago, Integra reports it has not had a single issue with compliance. "We are delighted with our 100% success rate that Kallik helps us to deliver," Dreibelbis enthuses.

Reduced time to market and increased productivity are two other significant outcomes, while as it's now benefiting from fully task-driven, accountable processes, Integra's throughput yield has improved significantly, yet without the need for any additional resources.

Veraciti has also been pivotal in simplifying transition of labeling content during periods of business acquisition. The flexibility to import and export data through multiple sources makes the solution agile enough to cope with meeting the individual requirements of multiple geographic regions whilst ensuring global levels of consistency.

For Dreibelbis, "Deploying the Kallik solution has been transformational for Integra, and has been a great decision. What began with labeling has moved onto marketing materials and the launch of an online catalogue.

"Each of our commercial organizations has benefited hugely due to the simplicity of Kallik's artwork approval workflow," he goes on. "Real-time Business Intelligence (BI) reports give



80% improvement
in speed to market with
10 weeks
taken out of the process

senior business stakeholders full visibility of product launches, while our QA team has peace of mind from being able to generate compliance reports at the touch of a button. We are now planning full roll-out of Veraciti across our entire organization.”

Business benefits at a glance

- 100% compliance reporting success rate over a period of 5 years
- Collapse of 20 individual siloed labeling & artwork processes down to one
- One single, enterprise-wide Integra LifeSciences process for all artwork creation and approval processes
- Delivery of consistency and alignment across labeling, marketing and on- line catalogue resources
- Full visibility of product launches
- Real-time BI reporting
- Improved processes via the Kallik solution held up as the quality benchmark for the rest of the organization to achieve.



About Kallik

Kallik delivers trust in the label, process and brand for highly regulated industries including medical devices, life sciences, chemicals and cosmetics. By connecting workflow and approval with dynamic content management, artwork assembly and analytics, Kallik's cloud-based solutions bring integrity, traceability and transparency to global labeling processes.