RegulatoryOne

Veeva

Your global authoritative source for regulatory compliance and product information

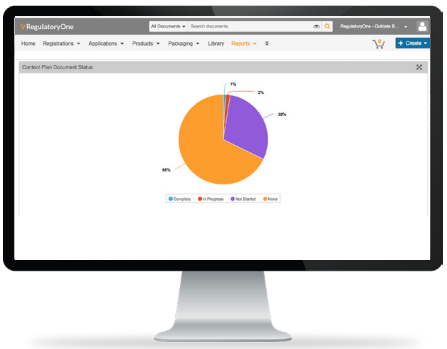
Unifying product registration data, formula compliance, ingredient lists, submission documents and dossiers

Bringing compliant products to market has never been more complex. Compounding an ever-changing regulatory landscape is the fact that most companies still struggle with poor data quality, duplication, and limited visibility into regulatory activities because of disjointed processes. Reducing and managing this complexity is a critical step in satisfying compliance requirements globally and accelerating a product's time to market.

RegulatoryOne provides a global authoritative source for regulatory documents and information. Content and data converge on a single cloud platform to unify registration tracking, correspondence and commitments, submission document management, dossier publishing, and regulatory submissions archiving.

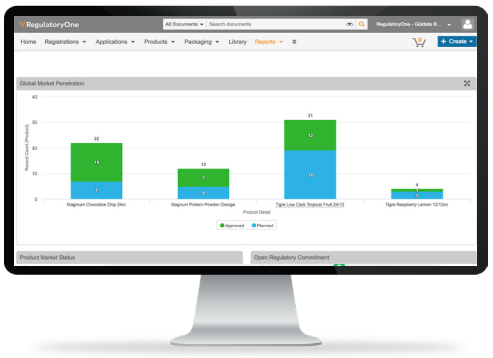
Establishing a single source of truth for regulatory information dramatically increases efficiency. Data and documents are entered just once and are accessible in any context. This approach minimizes discrepancies and uncontrolled copies, ensuring your information is accurate, timely, and easily found. Organizations can respond faster to product and regulatory changes or compliance concerns.

Benefits



- **Velocity to Market:** Today's market forces demand that companies stay agile and responsive to meet customer expectations. From quickly assessing the impact of a proposed product or formulation change, to locating the substantiating and source documentation, and finally coordinating activities on a global, regional and local basis, RegulatoryOne has you covered.
- **Reliable Data Quality:** Create a single source of truth for your product portfolio by capturing timely and accurate information. Information and content is stored once and can be accessed globally. This ensures data integrity as you coordinate product release processes across your stakeholders.
- **Global Coordination & Alignment:** RegulatoryOne seamlessly orchestrates compliance related activities across manufacturing sites, supply chains, outsourced manufacturers and all internal stakeholders. Product information is accurate, timely and accessible throughout the entire product lifecycle.

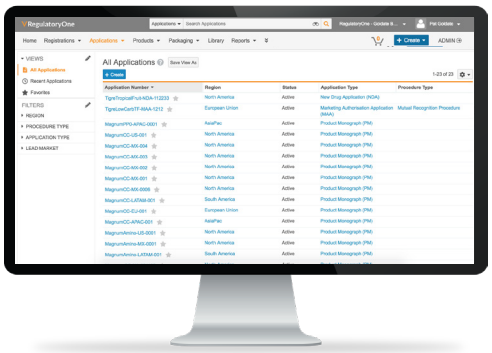
RegulatoryOne Solution Features



RegulatoryOne Registrations

RegulatoryOne's registration capabilities empower your teams to manage product registration information globally with both internal and external partners. Achieve a single, unified view of product data by registration status, by market, by variation – as well as all communication with regulatory bodies.

In RegulatoryOne, companies can manage a complete set of registration information such as approved packaging, formulations, work instructions, standard operating procedures and recommended serving size/ dosage, among other items. As a shared resource for headquarters and affiliates, our registrations capabilities help globalize key processes and improve overall data quality. This solution has a flexible data model that easily maps to various regulatory standards, like IDMP.



RegulatoryOne Formula Insights

RegulatoryOne's Formula Insights capabilities allow you to import relevant regulatory and internal restrictions, providing real-time visibility to your ingredient and formula compliance status. Icons show ingredient status based on country restriction, internal standard, product function, and category, which produces an easy to digest status overview.

Formula Insights also enables more efficient tracking and communication between R&D and Regulatory regarding restricted or banned ingredients by greatly reducing the use of spreadsheets, email communication, and repetitive compliance checks. This streamlined collaboration helps everyone stay ahead of impending restrictions and avoid costly and unnecessary reformulations. And by pairing Formula Insights' pre-launch assessments with RegulatoryOne's impact assessment feature, teams can quickly identify which new restrictions or bans will impact existing formulas.

RegulatoryOne Submissions

RegulatoryOne automates the planning, collection, review and approval of all product related content, including submission-ready documents, content planning and tracking, correspondence, product claims commitments and submission records.

RegulatoryOne's content plans show you expected documents, and you can track submission completeness in real-time without manual updates. Templates and placeholders assist with the creation and collection of required materials, while the application's reporting and approval workflows ensure necessary documents are included and complete. Ultimately, RegulatoryOne's submissions capabilities provide you with full traceability for all your regulatory activities.

RegulatoryOne Ingredient Lists

RegulatoryOne generates cosmetic ingredient lists in descending order, paragraph format INCI nomenclature, in a Microsoft Word editable document. This eliminates the tedious and manual effort of calculations, formatting, approvals, and sharing an ingredient listing. Ingredient list creation is nested within RegulatoryOne's product dossier-related capabilities such as version control, workflow approvals, linked documents, document comparison and auto-matching. Link lists to related documents and materials such as formula cards and artwork to ensure that changes have traceability and are updated accordingly for reformulation or other post-market changes. This RegulatoryOne capability brings efficiency and accuracy to the often manual process of ingredient lists.

About Veeva

Founded in 2007, Veeva NYSE (VEEV), is a leading global provider of industry-specific, cloud-based software solutions for the consumer goods, chemical and life sciences industries. Our applications enable manufacturers to realize the benefits of a modern, cloud-based platform to manage the product journey and bring innovative, high-quality products to market faster without compromising industry-specific functionality, quality or regulatory compliance. Veeva is headquartered in the San Francisco Bay Area, with offices throughout North America, Europe, Asia, and Latin America. Learn more.