Dot Compliance Regulatory Affairs Solution

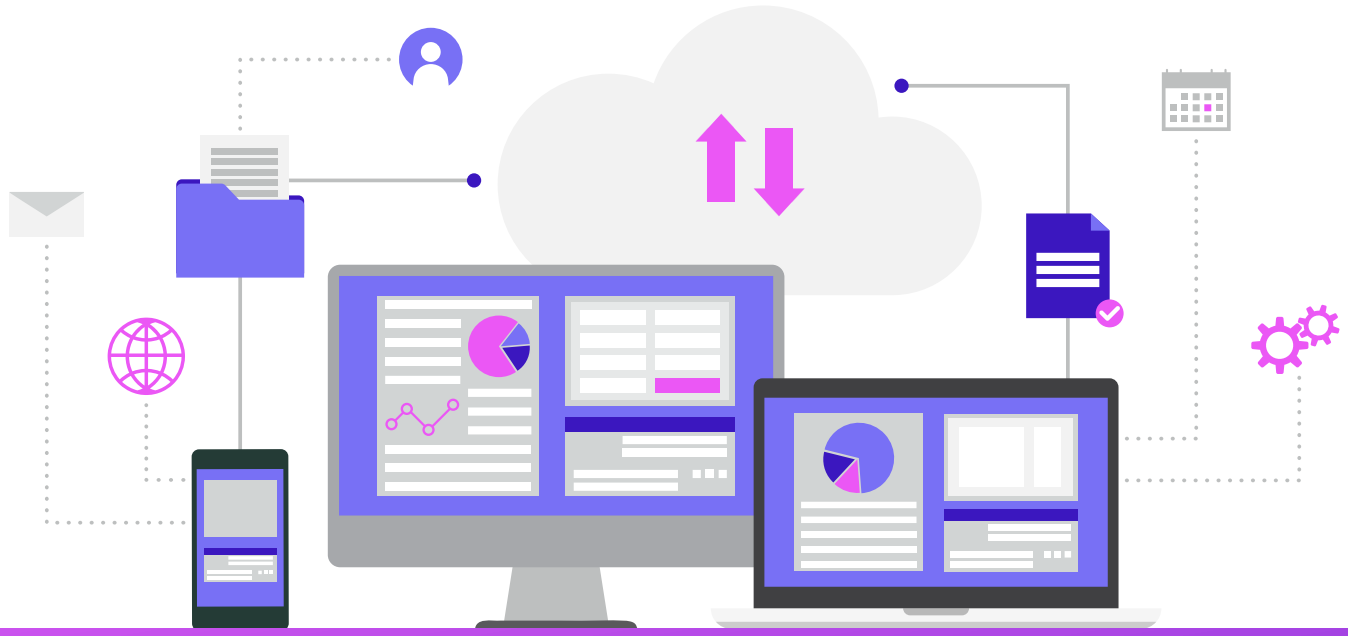
Regulatory compliance is an integral part of an integrated electronic quality management (eQMS). Dot Compliance's eQMS offers a regulatory affairs solution designed to streamline regulatory and quality processes that simplify submissions, accelerate time to market, and ensure compliance of all global regulations and laws - including standards such as GxP, ISO, and ICH requirements. This allows organizations to respond faster to changing regulations and helps coordinate regulatory efforts between the organization, partners and regulatory authorities.

Dot Compliance Regulatory Affairs key benefits include:

Increased visibility
Manage global registration of products, product variation, and registration renewals.

Improved Coordination
Track commitments and required submissions through correspondence with authorities.

Global Alignment
Monitor regulatory history, approval conditions and commitments for all countries, and product quality.



User Requirements Support

Application Support	System Support
Plan, manage and track the status of regulatory submissions and related activities.	Manage regeneration renewal process.
Health Authority Interactions: Centralized Procedure (CP), Decentralized Procedure (DCP), Mutual Recognition Procedure (MRP) and National registrations.	Manage dossier files and binders associated with submission in a flexible or predefined structure.
Data input by affiliates, partners, and all departments within the organization.	Management and link variation to applicable change management processes within the eQMS.
Designation of approvers for various registration procedures.	Checklist for submission / registration preparation.
Streamline submission planning through approval by automating regulatory process steps.	

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