

EXTEDOpulse for Agencies

Transform your agency's regulatory information management with EXTEDOpulse.

Regulatory agencies today manage a constant flow of information from the life sciences industry that must be received, validated, assessed, and tracked in line with individual regional standards. At the same time, product data, documents, and correspondence must remain consistent and accessible to multiple stakeholders across the agency.

The EXTEDOpulse Agency solution portfolio supports this entire process end-to-end by bringing all relevant business operations into a single, integrated environment. It receives structured product data, handles large submission packages, validates information against applicable standards, and enables status tracking, data review, and assessment through a user-friendly interface.

By streamlining core agency activities such as submission intake and validation, assessment planning, submission distribution, decision-making, and the management of central product data and documents, EXTEDOpulse for Agencies serves as the single source of truth for all stakeholders involved in the assessment process. Users can access role-based, real-time information, perform detailed searches across products, submissions, and documents, and generate reports that highlight the most important and critical tasks throughout the review lifecycle.

A unified workspace for agencies and applicants

EXTEDOpulse provides a secure, easy-to-use applicant portal that enables agencies to offer fast and reliable ways for applicants to submit individual submissions. Applicants can track the status of their requests, download documents provided by the agency, and communicate with the authority via integrated correspondence management. The EXTEDOpulse portal also provides access to approved controlled vocabulary and product data, giving applicants a user-friendly interface while ensuring data quality and reuse. Agencies retain full control over the level of information shared, supporting



Benefits

- **Faster processing** – from weeks to days or hours.
- **More transparency** – real-time case status and dossier access.
- **Higher accuracy** – validation reduces errors and rework.
- **Greater efficiency** – automation frees up staff time.
- **Better collaboration** – smoother exchange between users and agencies.
- **Higher user satisfaction** – a simpler process builds trust and adoption.

secure collaboration without compromising governance.

Clear, transparent and role-based working

At its core, the EXTEDOpulse Agency solution provides a clear, concise, and straightforward user interface for data collection, data maintenance, and data compliance. Beyond compliance with submission standards, it also strongly supports project management and maintenance activities by offering milestones and task functionalities. This helps agencies structure their assessment workflows, monitor progress and ensure that every step is transparently documented.

Agency Master Data Management

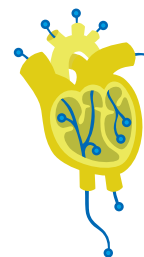
EXTEDOpulse Master Data Management is at the core of the agency solution, acting as an information lake for regulatory master data. It brings together controlled vocabulary, product master data management, and product lifecycle management in a single, unified environment. Serving as the agency's single source of truth for product-related information, it includes comprehensive versioning to ensure all changes are fully traceable over time.



Submission Management Hub

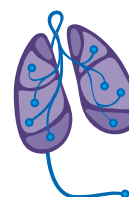
The EXTEDOpulse Agency Submission Management Hub brings submission validation, management, and reviewing together in a single, cohesive module. Submission validation supports medicinal electronic submissions in line with global eCTD and non-eCTD criteria, with the ability to define and implement dedicated validation rules for new regions to ensure local requirements are met.

The Hub allows health authorities to easily access submissions and documents, manage submission lifecycles, and maintain clear links between regulatory activities and submission sequences. Advanced search across structured data and document content enables rapid access to relevant information, while collaborative assessment features support joint review across teams and departments. End-to-end submission automation from initial receipt to final decision ensures submissions flow seamlessly through scientific assessment, review, and approval stages. Automation features include the automatic storage of submission deep links for archived cases, reducing manual effort, strengthening links between documents and submissions, and improving overall review efficiency.



Registration Management Hub

The EXTEDOpulse Agency Registration Management Hub combines regulatory procedure management with applicant interactions, anchored in Master Data Management. Regulatory procedure management supports case management, submission downloads, template-based planning, clock stop management, and case assessment when used with the Submission Management Hub. Integrated correspondence management captures all communications linked to the relevant regulatory and data context.



Document And Content Management Hub

The EXTEDOpulse Agency Document and Content Management Hub provides document-centric capabilities tailored to regulatory requirements and seamlessly extends your EXTEDOpulse solution. It offers a flexible user interface, lifecycle and workflow control, and comprehensive metadata management. Agencies can configure folder structures and dynamic dimensions, link documents to master data, and maintain dashboards for document activity visibility. In addition, documents are linked directly to the relevant case within the Regulatory Procedure Management, ensuring full traceability across regulatory processes. Advanced search, reporting, tagging, and collaborative authoring simplify document handling, while electronic signature support ensures compliance.

Automation, installation scenarios and compliance

EXTEDOpulse offers flexible automation capabilities that streamline agency workflows and reduce manual effort. These features ensure seamless handling of submissions, documents, and assessment tasks, strengthening links between related data and improving overall review efficiency.

To accommodate different IT strategies and regulatory environments, EXTEDOpulse offers flexible installation options, including in-house or hosted deployments to meet varying infrastructure, security, and operational needs.

The solution is designed to support compliance with FDA 21 CFR Part 11 and EU GMP Annex 11 and is accompanied by validation documentation aligned with GAMP 5 guidelines. Together, these technical and regulatory capabilities make EXTEDOpulse for Agencies a comprehensive, future-ready solution offering that unifies master data, submissions, registrations, and documents in a single, controlled environment.

Ready to Transform Your Agency?

By combining all core agency functions into one integrated solution, EXTEDOpulse for Agencies enables faster, better-informed decision-making and more efficient regulatory operations. Its clear interface, robust compliance foundations, automation capabilities, and full portfolio coverage provide agencies with a sustainable solution for digital regulatory management.

To learn more or schedule a tailored demonstration – contact EXTEDO at info@extedo.com

or visit

www.extedo.com.

Our team is ready to help your agency streamline submission validation, improve data quality, and strengthen regulatory workflows.



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